

# The Law-Science Interface in Public Policy Decisionmaking

HAROLD P. GREEN\*

## I. INTRODUCTION

I have written, spoken, and taught extensively on the interface between law and science for the past thirty-five years. During this period I have been an invited participant or speaker at many conferences that were primarily gatherings of scientists, engineers, and the like. In 1975 I was one of the five nonscientists<sup>1</sup> invited to participate in the Asilomar International Conference on Recombinant Molecules of DNA.<sup>2</sup> On the first evening of the Conference while walking to the dining hall, I was joined by a prominent young molecular biologist, and we exchanged introductions. Noting that my name badge said only "George Washington University," he asked about my affiliation with the university. When I identified myself as a law professor, his shock was evident. "What are *you* doing here?" he asked. The only appropriately modest answer I could give was that I had been invited. It was obvious that my new friend's perception of lawyers was that we were concerned solely with litigation, and he could not conceive that litigation was in any way relevant to the subject matter of the Conference. The essence of this experience has been repeated many times before and since.

Unfortunately, the legal profession, including that part of it in academia, has likewise had difficulty in understanding law professors who are involved with science. Not uncommonly, when I meet lawyers or law teachers who ask what I teach, they are baffled when I mention that my academic specialty is the law-science relationship. To move the conversation along, they typically opine that I must be interested in how computers and other new technologies can facilitate the work of lawyers and courts; or that I must be into intellectual property and patents; or that my ambit is medical malpractice; or that I must teach Evidence and am particularly interested in scientific expert witnesses; or perhaps that I am one of the odd academic ducks who seek to enrich the education of law students by "teaching them about science." In fact, none of these is an accurate description. The study of the law-science relationship, as I define it, seeks to determine how the various processes of law—primarily judicial and legislative—respond to changes brought about by scientific advances. It is this aspect of the interface between law and science that forms the basis of this Article.

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\* Professor of Law, George Washington University National Law Center. A.B. 1942, J.D. 1948, University of Chicago.

1. Interestingly, all five were lawyers.

2. Asilomar is regarded as an historic event in the annals of science. In 1974 the leading researchers in recombinant DNA called for a moratorium on further research because of their concerns about possibly unacceptable hazards. The call for the moratorium was generally accepted throughout the world. The 1975 Asilomar Conference brought together the world's leading recombinant DNA researchers to discuss the hazards and to consider what should be done about the moratorium.

## II. A REVIEW OF RECENT LITERATURE

Although the 1989-90 edition of the *Directory of Law Teachers* lists more than one hundred law teachers who report that they teach in the Law and Science field, which is defined to include "Technology Assessment" and "Jurimetrics,"<sup>3</sup> legal academics and other scholars struggle to understand and explain the justification for the involvement of law schools in this field. Following is a discussion of some recent scholarship addressing this issue.

Steven Goldberg has emerged in recent years as a leading scholar in the law-science field. His general approach is to look at the relationship from the perspective of science. His starting point is to inquire how "various legal doctrines apply to [science]" just as we look at how various legal doctrines apply to corporations.<sup>4</sup> That law schools offer courses on law and science suggests to him that science is sufficiently distinctive, unlike screwdrivers, for example, to warrant "specialized treatment."<sup>5</sup> The catalogue of what is distinctive about science "becomes a list of the central dogmas of law and science."<sup>6</sup>

Before proceeding to develop this catalogue, Goldberg attempts to define "law" and "science" for this purpose. He defines "law" as "focus[ing] on public ordering of private institutions" and "science" as "the pursuit of testable knowledge about the natural world."<sup>7</sup> He then goes out of his way (significantly in light of his further position as discussed below) to note that the latter definition includes "financial support for research as well as regulation of that research."<sup>8</sup>

Goldberg also posits four central dogmas of science. These are:

\* *Community*, meaning that there is generally a consensus or near consensus among scientists on scientific judgments, making it rational in many cases for nonscientists to rely on the scientific community's views in forming their own scientific judgments;<sup>9</sup>

\* *Progress*, meaning that science has a forward momentum, and that it is the goal of every scientist to move science forward;<sup>10</sup>

\* *Empiricism*, meaning that science believes that scientific theories can be tested;<sup>11</sup> and

\* *Externalities*, meaning that scientific activity often generates effects on a wide variety of interests far beyond the ambit of the researcher.<sup>12</sup>

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3. THE AALS DIRECTORY OF LAW TEACHERS 1989-90, at 1005. To the best of my knowledge, no one has undertaken a canvass of the kinds and content of the courses they teach. Eighteen teachers say they have taught in the field for more than ten years. *Id.* at 1006.

4. Goldberg, *The Central Dogmas of Law and Science*, 36 J. LEGAL EDUC. 371, 371 (1986).

5. *Id.*

6. *Id.*

7. *Id.* at 372.

8. *Id.* Presumably Goldberg intends "funding" to mean government funding and "regulation" to mean government regulation of government-funded research. One might ask whether government-funded research is ever really "regulated," or whether what passes for regulation is merely a condition of the funding.

9. *Id.* at 372-75.

10. *Id.* at 377.

11. *Id.* at 377-79.

12. *Id.* at 379-80.

In a subsequent article<sup>13</sup> Goldberg seeks a "framework for understanding what happens when legal controls are applied to science."<sup>14</sup> He finds that the fundamental difference between the disciplines is that science emphasizes progress while law emphasizes process, that is, "the peaceful resolution of human disputes."<sup>15</sup> The tensions between law and science, Goldberg argues, increase as scientific research advances from basic research to its technological applications. This may be a self-evident proposition, particularly since Goldberg seems (although this is not entirely clear) to equate law's "treatment of science" with "regulation."<sup>16</sup> After all, scientific research usually does not have much direct potential for causing injury by itself. One can visualize, of course, that research in a laboratory can result in an explosion or the release of toxic agents into the environment, but good laboratory practices generally obviate any need for external regulation.<sup>17</sup> Although this premise may not be particularly revealing, what is interesting is the way in which Goldberg constructs his argument.

Goldberg's bottom line is that analysis of the law's treatment of basic research—even when mission-oriented—exposes a "remarkable degree of deference to the scientific community."<sup>18</sup> This conclusion is based solely on the outcomes of four federal court cases. In three of these cases the courts refused to grant relief to applicants for federal grants whose applications had been rejected by the funding agencies;<sup>19</sup> in the fourth case the court rejected out of hand a suit brought *pro se* by a member of the public for a writ of mandamus to compel the funding of research on whether a particular substance could cure cancer.<sup>20</sup> Goldberg contrasts this "judicial abdication" with the manner in which the courts review denials of disability claims by the Social Security Administration; in those cases the courts grant relief about half the time.<sup>21</sup> Goldberg finds judicial abstinence in the research funding area to be an indication that science is one of the few areas in American life where something reflecting a consensus exists as to what is, and what is not, good work.<sup>22</sup> He ignores a much more compelling rationale: that social security is an entitlement program giving claimants the right to compensation if they meet certain crite-

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13. Goldberg, *The Reluctant Embrace: Law and Science in America*, 75 GEO. L.J. 1341 (1987).

14. *Id.* at 1342.

15. *Id.* at 1342, 1345. It would be more accurate to define law as "the optimal resolution of human disputes," which, of course, would include "peaceful resolution." Goldberg would undoubtedly agree, in any event, that law does not emphasize the objectively correct resolution of human disputes. See *infra* text accompanying note 123.

16. *Id.* at 1352.

17. There are, of course, some kinds of research that may be subject to government restrictions, such as research on human subjects. It is not clear whether Goldberg defines "regulation" to include government restrictions imposed contractually as a condition of a contract or grant. This Article rejects such a definition.

18. Goldberg, *supra* note 13, at 1352. Although Goldberg seems to equate technology with "commercially important products," *id.* at 1364, the fact is that the law may intervene even at the research stage when the research involves experiments or other actions that may be perceived as dangerous.

19. *Id.* at 1355-58. See *Kletschka v. Driver*, 411 F.2d 436 (2d Cir. 1969); *Grassetti v. Weinberger*, 408 F. Supp. 142 (N.D. Cal. 1976); *Apter v. Richardson*, 361 F. Supp. 1070 (N.D. Ill. 1973), *rev'd*, 510 F.2d 351 (7th Cir. 1975).

20. Goldberg, *supra* note 13 at 1358-59. See *Mannoff v. HEW*, 456 F. Supp. 1120 (S.D.N.Y. 1978), *aff'd mem.*, 595 F.2d 1208 (2d Cir.), *cert. denied*, 442 U.S. 913 (1979).

21. Goldberg, *supra* note 13, at 1360-61.

22. *Id.* at 1361.

ria; but no scientist is entitled to a research grant except in the nonarbitrary, noncapricious, nondiscriminatory discretion of the granting agency.

On the other hand, Goldberg argues, when research evolves into technology, legal control takes over "with a vengeance."<sup>23</sup> This gives rise to a "regulatory gap" between research and application with "enormous practical consequences."<sup>24</sup> He sees the possibility of narrowing the gap in two ways: law and regulators could move into the basic science area; or scientists could move into the task of steering science along the lines of social realities.<sup>25</sup> His preference seems to be the latter possibility, and he speaks of the emergence of a new profession, the "science counselor," who would work to help shape science to meet regulatory constraints.<sup>26</sup>

Another commentator, Robert Merges, takes a narrower view of the relationship.<sup>27</sup> After a cursory, and not completely accurate, review of the history of "law and science" courses in law school curricula, he criticizes Goldberg's tendency to discuss legal issues only from the perspective of the scientist.<sup>28</sup> This, says Merges, "still leaves technical issues in the hands of scientists" and "seems to run the risk of further enshrining the priesthood of science, thereby reinforcing the amateur status of legal actors."<sup>29</sup> Accordingly, he argues that Law and Science courses should expose students to "basic scientific sources and institutions" and to "technical material sufficient to familiarize students with scientific methods."<sup>30</sup>

The Merges view reflects a sentiment frequently articulated by scientists who find lawyers involved in their affairs.<sup>31</sup> As Merges puts it, "The need to educate amateurs to understand and manage legal disputes having a scientific dimension is at the heart of the problem that the academic field of Law and Science must address."<sup>32</sup> A leading scientist who expresses this view is Maxine Singer.<sup>33</sup> Dr. Singer can claim some familiarity with the law and its ways since her husband is a prominent lawyer. In fact, she was a doctoral candidate in

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23. 23. *Id.* at 1364.

24. *Id.* at 1368. The gap may not be as substantial as Goldberg argues. The legal system has developed an interest in some fruits of scientific research short of technology. For example, the restrictions on recombinant DNA activities were directed primarily against research-type experiments and not against products flowing from the science.

25. *Id.* at 1379.

26. *Id.* at 1380. Goldberg acknowledges that the science counselor would become a competitor of the lawyer.

27. Merges, *The Nature and Necessity of Law and Science*, 38 J. LEGAL EDUC. 315 (1988).

28. "The goal seems not so much to instruct students about legal issues as to educate them about the divergence between how scientists and lawyers approach problems." *Id.* at 325.

29. *Id.*

30. *Id.* at 326-27.

31. The author has frequently encountered this sentiment when he has spoken before scientific groups on such matters as benefit-risk assessment or the nuclear power licensing process and has expressed views that the audience found unsettling. A not atypical reaction is a question such as "Would you please tell us exactly what education you have had in physics, chemistry, biology, mathematics, etc?" There is usually a sense of satisfaction and triumph when the author's response is, "For your purposes, essentially zero."

32. *Id.* at 324-25.

33. Singer, *Genetics and the Law: A Scientist's View*, 3 YALE L. & POL'Y REV. 315 (1985).

biochemistry at Yale at the same time her husband studied law there, and she was very much involved with the law school community.<sup>34</sup>

Dr. Singer believes that most lawyers and judges "are incapable of dealing adequately with technical issues" because during their secondary school education they "decided not to learn any more science."<sup>35</sup> This scientific ignorance is dangerous because when choices are made at the societal level, even a single well-placed individual "can manipulate scientific ignorance and consequent fears into support for irrational, almost primitive myths."<sup>36</sup> Her example of this is the havoc wreaked by the Soviet agronomist, T. D. Lysenko, in the 1930s when he successfully established as official Soviet policy his opinion that "classical genetics was all wrong."<sup>37</sup> But Lysenko was not ignorant of science; he was a scientist, albeit, as Dr. Singer notes, "admittedly poorly educated,"<sup>38</sup> and an ideologue to boot.<sup>39</sup>

Dr. Singer attempts to demonstrate that lawyers are not "up to the task" of "societal evaluation" of "biology's potential for both good and evil" by quoting a passage from the "background" section of Judge Sirica's opinion in *Foundation on Economic Trends v. Heckler*:<sup>40</sup>

A little over a decade ago scientists developed the capability of modifying genetic material in the laboratory. Through a process of splitting and recombining a subcellular unit known as DNA, laboratory scientists could begin to control the natural processes of organism reproduction and growth. The product of this process of altering natural hereditary material is generally known by the name "recombinant DNA." The use of this process has been limited to small organisms, usually bacteria.<sup>41</sup>

Dr. Singer does not criticize the substance of Judge Sirica's effort. Instead, almost *ad hominem*, she asks: "Did the judge's training and knowledge provide a reasonable basis for writing this paragraph?"<sup>42</sup> Could the lawyers before the court understand this paragraph? Well enough to know whether it is accurate and precise in nature?<sup>43</sup>

Dr. Singer offers a concrete suggestion for "beginning to bridge the gap between law and science" as a step towards the "real goal, the scientific education of the entire citizenry." She suggests including in the Law School Admissions Test "a set of questions concerning science."<sup>44</sup> At the same time, she ex-

34. *Id.* at 315.

35. *Id.* at 319.

36. *Id.* at 320.

37. *Id.* at 320-23.

38. *Id.* at 320.

39. *Id.* at 323. Lawyers generally are not ideologues, but one of their functions is to attempt to articulate science in a manner that supports their client's position.

40. 587 F. Supp. 753 (D.D.C. 1984), *aff'd in part and vacated in part*, 756 F.2d 143 (D.C. Cir. 1985).

41. *Id.* at 755.

42. She does not discuss the likelihood, or the implications of the likelihood, that the passage may have come from, or may have paraphrased, evidence or a portion of a party's brief.

43. Why are these questions relevant, let alone important, since the quoted material has no conceivable operative significance? Dr. Singer's point could have been made more succinctly and cogently by quoting the following passage from Judge Bazelon's article *Risk and Responsibility; Risk Regulation: A Problem for Democracy in the Technological Age*, 205 Sci. 277, 278 (1979): "[J]udges have little or no training to understand and resolve problems on the frontiers of nuclear physics, toxicology, hydrology, and a myriad of other specialties."

44. Singer, *supra* note 33, at 334. This would presumably induce prelaw students to study science.

presses doubt that this proposal will win favor because "the absence on [LSAT's] of substantive questions of any kind, let alone scientific ones" makes it appear that "knowledge is irrelevant to the selection of candidates for law school."<sup>45</sup>

The final example of recent scholarship is an editorial by Daniel Koshland, Jr., in *Science*.<sup>46</sup> In Dr. Koshland's view, "law has become so complicated that there is almost always a technical flaw or a distant precedent that can allow any decision." As a consequence, we are fast becoming "a nation of men and not laws," so that there is not enough predictability to patent an invention, create a new industry, or make a new chemical.<sup>47</sup> His main complaint seems to be that regulatory agencies are more often than not overruled on the basis of "minor legal technicalities" that are themselves often overruled after seemingly interminable delays. Koshland's proposed solution is hardly one to make the law less complicated. He calls for the judge or jury that overrules an agency or commission to prepare a "judicial impact statement" to "demonstrate appropriate expertise in the field and awareness of the consequences of the judgment."<sup>48</sup>

The recent law-science literature reviewed above reflects a rather narrow focus of interest. At best, it begins with detail and makes some movement in the direction of the peripheries. The approach spelled out in the remainder of this Article is quite the opposite because it begins with an analysis of the central roles of law and science in society and works inwards toward greater detail. It reflects in a very rough manner the way I have conducted my Law, Science, and Technology Seminar since it was first offered in 1965.<sup>49</sup>

### III. THE PROBLEM OF SOCIAL CONTROL

A good place to begin is to ask, as Goldberg and Merges do, what there is about science that warrants the special attention of the law and lawyers. In the remainder of this Article I will try to demonstrate that law schools should offer courses in the law-science relationship in order to expose students to the process of public-policy decisionmaking directed towards enabling society to enjoy the maximum benefits of science and technology without being forced to bear unacceptable risks and other costs.<sup>50</sup> Courses in the law-science relationship also ex-

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45. *Id.* at 334-35. Dr. Singer's comment about the irrelevancy of knowledge speaks for itself. One wonders, however, recalling the apparent deficiencies in Lysenko's science education, whether a little scientific education of putative lawyers would turn out to be a dangerous thing.

46. Koshland, *Judicial Impact Statements*, 239 *Sci.* 1225 (1988).

47. *Id.* at 1225.

48. *Id.* One might ask, demonstrate to whom?

49. The seminar was originally styled "Science and the Legal Process," but the name was changed several years ago. Initially I relied on my own mimeographed (prephotocopying!) materials, which examined issues such as the use of radar to control highway speeding, blood grouping tests to establish nonpaternity, fluoridation of public water supplies to prevent dental caries, and the use of radiation-producing technology. Later, as societal concerns changed, I reduced the attention given to radiation and spent time on biotechnology. Since publication of the Areen, King, Capron, and Goldberg case book, I have abandoned my own materials and have used materials in that book as points of departure for discussion of the basic issues. See J. AREEN, P. KING, S. GOLDBERG & A. CAPRON, *LAW, SCIENCE AND MEDICINE* (1984).

50. In many respects, my seminar concentrates on the role of the law and lawyers in cost-benefit and risk-benefit assessment. Risk is, of course, a component of cost.

plore the action of law in a dynamic process that involves very high stakes for the future of American society and perhaps mankind itself. The primary focus of such courses should be on the way law (as a body of rules, as a process for decisionmaking, and as a discipline) reacts and responds to new challenges resulting from scientific advances.<sup>51</sup> This approach is consistent with the views expressed by Professor Milton Wessell, former Director of the Center for the Study of Law, Science and Technology at Arizona State University's College of Law.<sup>52</sup> He finds that "the need for our legal system to deal more satisfactorily with the rapidity of change resulting from technological impact" is an "important unifying theme."<sup>53</sup> He defines "law, science and technology" to mean "the discipline that deals with how our legal system can and must adjust to accommodate the problems created by the ever more urgent and ubiquitous impact of technology on society."<sup>54</sup> Under this definition, two major functions are involved: (1) "Technology assessment," which includes the timely identification of concerns so that remedial action can be taken before irreversibility sets in; and (2) modification of legal practices and institutions to deal more satisfactorily with the concerns unearthed by technology assessment.<sup>55</sup> Significantly, most lawyers who have written on the subjects have concentrated their attention on the ways that the legal system should be altered to accommodate the ways of science, and virtually no attention has been given to the alternative of helping scientists adapt to the legal system.

Scientists seem to have a clearer view of the need for law to interact with science than do lawyers, although their points are not always sharply focused. The tremendous potential impact of this relationship was recognized as early as the mid-1930s, when the question of the capability of societal institutions to regulate new technology was raised by the Natural Resources Committee, created by President Franklin D. Roosevelt to consider the significance and deployment of the country's natural resources in overcoming the depression. Interestingly, at that time, science was considered a natural resource and a Science Committee was created by the parent body to explore more fully the role of science as a natural resource. The Science Committee in turn established a Technology Subcommittee. This Subcommittee's 1937 Report<sup>56</sup> is, in several respects, a remarkable document that should be closely read by students of public policy for science and technology.

The Technology Subcommittee, cognizant of the fact that it was performing its function at roughly the end of the first third of the twentieth century,

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51. Students in my seminar are told at the outset that they will learn nothing substantive during the semester, except, perhaps, for a few incidental pieces of trivia. However, they are also told that they will have an opportunity to look at the law in action in a way that they have not had the opportunity to look at it in their prior law school experience and, moreover, that the arena is of the most critical importance to society. Judging by the course evaluations, students seem quite pleased with the experience, which, incidentally, is almost 100% socratic.

52. Wessell, *What Is "Law, Science and Technology" Anyway?*, 29 JURIMETRICS J. 259 (1989).

53. *Id.* at 260.

54. *Id.*

55. *Id.* at 261.

56. TECHNOLOGY SUBCOMM., UNITED STATES NATURAL RESOURCES COMM., TECHNOLOGICAL TRENDS AND NATIONAL POLICY (1937) [hereinafter TECHNOLOGY SUBCOMM. REP.].

undertook to evaluate the "unparalleled" technological advances<sup>57</sup> that had occurred during that period and their consequences to society. The Subcommittee also undertook to peer into the future in order to predict the course of technological progress during the coming second third of the century. This latter endeavor was wildly short of the mark,<sup>58</sup> not even hinting at nuclear energy, radar, computers, or the jet engine, all of which were in existence only a few years later. In fact, the Report suggested that civil aviation had largely run its course and that future developments would lie mainly in safety and comfort rather than speed.<sup>59</sup>

The Report also discussed society's ability to take timely action necessary to bring rapidly emerging technologies under effective social control. It concluded that there was no cause for concern because "from the early origins of an invention to its social effects the time interval averages about 30 years."<sup>60</sup> The experience of the past half-century demonstrates, however, that this time interval has shrunk dramatically and that the social effects of new technologies may be almost instantaneous. Exacerbating this problem is the fact that many presently emerging technologies will bring with them destructive social effects dramatically greater than those previously experienced.<sup>61</sup>

Twenty years after the publication of the Technology Subcommittee Report, scientists began discussing the competence of their disciplines to play a leadership role in coping with the fruits of scientific and technological growth. In a report published in 1957<sup>62</sup> a Committee of the American Association for the Advancement of Science (AAAS) catalogued some of the increased uses of scientific knowledge that "generated new hazards of unprecedented magnitude."<sup>63</sup> This report was not concerned with any relevance that these developments had to law; quite the opposite, it was a plea to scientists, *qua* scientists, to become more involved in the political process, a development that was already well under way. Beginning towards the end of World War II, scientists who were involved in the development of the atomic bomb embarked upon a major political effort to bring the enormous destructive capabilities of atomic weapons under effective control.<sup>64</sup>

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57. *Id.* at 3. The members of the Science Committee were Frank Lillie, E.B. Wilson, J.C. Merriam, E.C. Elliott, C.H. Judd, W.D. Cocking, William F. Ogburn, H.A. Millis, and Carter Goodrich. The Technology Subcommittee consisted of Ogburn as Chair, Merriam, and Elliott. *Id.* at iv.

58. It is tempting to speculate on the reasons. Certainly, the Subcommittee could not have predicted the war or the military technologies that would be so quickly developed, nor could it have predicted that after the war the federal government would make a massive commitment to the financial support of science and technology.

59. This observation was not included in the Report itself, but rather in an annexed study of transportation technology prepared by Harold A. Osgood, an iron company executive. Osgood seemingly accepted the conclusion based on his quotation of an unnamed aviation executive. TECHNOLOGY SUBCOMM. REP., *supra* note 56, at 200.

60. *Id.* at ix.

61. These social effects may be destructive not only in their potential to cause physical injury, but also in their impact on moral and spiritual values and the very nature of humanity.

62. *Report of the AAAS Interim Committee on the Social Aspects of Science*, 13 BULL. ATOM. SCIENTISTS 81 (1957).

63. These hazards include "the dangers to life from widely disseminated radiation; the burden of man-made chemicals, fumes, and smog of unknown biological effect which we now absorb; large scale deterioration of our natural resources; and the potential of totally destructive war." *Id.* at 85.

64. See A. SMITH, *A PERIL AND A HOPE* (1965), for a description of the early involvement of the atomic scientists in politics.



Writing in 1965, Ralph Lapp, one of the atomic scientists involved in this effort, took an approach rather different from that of the AAAS committee. Lapp was concerned about the future of mankind because the time lag between science and technology was constantly decreasing, thus raising the possibility that "[b]y the time the necessity for the control of the technology becomes apparent the problem may be too advanced for adequate solution."<sup>65</sup> His worry was not that scientists would not have influence, but rather that the professional policymakers' scientific illiteracy would lead them to abdicate the making of decisions to the scientists. Two years later, Nobel Laureate Dr. Glenn T. Seaborg, then Chairman of the Atomic Energy Commission, spoke in the same vein when he noted that "man's ability at technological innovation has far outstripped his ability at social innovation."<sup>66</sup>

Although the concerns of Lapp and Seaborg are not expressly addressed to the role of the law in coping with the impact of science on technology, it is obvious that social control over technology must come about through the making of law by courts and legislatures. Another commentator, one of the pre-eminent technologists, was less reticent. Speaking at the Philadelphia Bar Association's Law Day observance in 1964, Admiral Hyman Rickover, the "father of the nuclear navy," discussed the "potential for injury to society" created by the pressures exerted by technologists on individuals to alter their lives. Admiral Rickover said that it was "almost as if technology were an irrepressible force of nature to which we must meekly submit" and called upon the legal profession to protect society from the onslaughts of technology "as a special civic responsibility."<sup>67</sup>

Lawyers trained in Anglo-American jurisprudence understand that our legal system aspires to reconcile the desire for stability with the necessity for change. Although science per se usually does not directly inspire a need for change in the law, it breeds technology, which frequently does. Indeed, it has been stated that science is "disruptive of the juridical order."<sup>68</sup>

It is remarkable that the legal profession has not raised or responded to the question of how society can best bring about timely and effective control over new technologies. A quarter of a century after the question was first raised by scientists and engineers, legal scholars still have contributed very little to its answer. It is difficult to believe, for example, that the 1968 American Assembly Report, *Law in a Changing Society*,<sup>69</sup> neither considered nor mentioned the role of law in the context of the scientific and technological revolution. Lawyers, it would appear, are not uncomfortable with being viewed, and viewing themselves, as litigators, judges, scriveners, and counselors, who eschew any significant role in broader issues of public policy decisionmaking that are not directly related to the law.

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65. R LAPP, *THE NEW PRIESTHOOD* 30 (1965).

66. Address before the Industrial Research—100 Award Banquet, New York, AEC Press Release S-36-67 (Sept. 19, 1967).

67. Rickover's address was printed at 110 CONG. REC. S10,478-81 (1964).

68. See DeJouvenal, *The Political Consequences of the Rise of Science*, 19 BULL. ATOM. SCIENTISTS 2 (1966); Mesthene, *Can Only Scientists Make Government Science Policy?*, 145 SCI. 237 (1964).

69. *Report of the American Assembly on Law and the Changing Society*, 54 A.B.A.J. 450 (1968).

## IV. THE LEGAL ENVIRONMENT

To understand the law-science interface, it is necessary to look at the way law responds to the stimuli of scientific developments—indeed, to look generally at the way law is made and changed in our society.

Science, like all human activity, takes place within a societal environment that provides incentives, deterrents, or neutrality with respect to the particular activity. The institutions of government are the primary sources of these influences and are vehicles for expressing law. In a developed society it is primarily the law that creates the societal environment in which scientific activity takes place.

It is possible to offer some generalizations about the societal environment for science in the United States. The Anglo-American political-economic-legal system has always placed a high premium on individual freedom. People, and the entities they create, have the freedom to pursue their individual interests so long as they do not improperly impinge upon the interests of others. Those who want to engage in scientific research may presumptively do so, just as those who want to play chess, throw a ball, or make and sell clothing, for example, may engage in those activities. There is no law that explicitly authorizes these activities; none is necessary because our legal system, in the absence of some specific incentive or deterrent, is neutral and gives people the freedom to act as they wish.

But American law has never been strictly neutral with respect to science. Congress has established patent and copyright systems to promote the progress of science as it is explicitly authorized to do under the Constitution.<sup>70</sup> It is clear, therefore, that the law views science with at least some degree of benevolence. Moreover, although there is no solid support for the proposition, the first amendment appears to protect at least some aspects of scientific activity.<sup>71</sup> But although the Constitution may extend to science a certain protected status, it does not shield science from government regulation and restriction to the extent that scientific activity may be injurious to health, life, safety, public order, and other legally protected interests. On the other hand, our society's benevolent attitude towards science is reflected in the fact that since World War II, the federal government has provided very substantial funding for scientific education and research.

Viewed as a purely intellectual activity, science rarely will have a sufficient impact on society to warrant restriction or regulation. In this respect, an analogy can be drawn to the speech-action dichotomy under the first amendment. That is, the first amendment protects pure speech, but this protection does not necessarily extend to actions that are outgrowths of that speech.<sup>72</sup> Similarly,

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70. U.S. CONST. art. I, § 8.

71. See Delgado & Millen, *God, Galileo and Government: Toward Constitutional Protection for Scientific Inquiry*, 53 WASH. L. REV. 349 (1978); Goldberg, *The Constitutional Status of American Science*, 1979 UNIV. ILL. L.F. 1; Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203 (1977).

72. See, e.g., *Cox v. Louisiana*, 379 U.S. 559, 563-64 (1965). See generally J. NOWAK, R. ROTUNDA & J.N. YOUNG, CONSTITUTIONAL LAW §§ 16.37-16.40 (3d ed. 1986) (discussion of fighting words doctrine).

purely intellectual aspects of scientific research might be protected, but physical results that flow from these endeavors might be subject to regulation. It is only when science, as a purely intellectual pursuit, leads to experimentation or technology that such impacts can be perceived.<sup>73</sup>

It is not common in our political system to establish statutory rules to deal with hypothetical or future problems. Premature regulation may force a new technology to develop along lines that may prove unwise or less than optimal in the light of actual experience.<sup>74</sup> There are also practical, political considerations militating against such regulation. Legislators are usually busy enough attempting to cope with immediate pressing problems, leaving little time or incentive to expend their efforts and political capital dealing with issues that may never materialize.

Accordingly, when science or its consequences have an impact on legally protected interests, it is likely, in the earlier stages of the impact, that courts will be called upon to extend common law rules, or perhaps even statutory rules, that evolved in quite different contexts.<sup>75</sup> When the automobile came into being, for example, the initial reaction of the courts was to apply the rules of the road applicable to horse-drawn vehicles.<sup>76</sup> Thus, the response of the courts to problems bred by new technology is a trial-and-error process, often slow and uncertain in developing rules for the effective control of new developments in the public interest. As a consequence, unacceptable injuries may result, prompting legislatures to preempt the decisionmaking process by intervening to enact positive rules. The fact that unacceptable injury may result in the interim is a price we pay for a society that places so high a value on individual initiative and freedom. Of course, it would be preferable for the legislatures to step in at an earlier point; however, there is no button that can be pushed to ensure action, let alone wise action, by legislators.

In short, it is unusual for legislatures to act on a substantive matter until the demonstrable need for action is widely recognized and pressed. Even then, legislation may not follow. A good example is the issue of recombinant DNA. In response to considerable clamor for Congress to enact regulatory legislation, several bills were introduced, and hearings were held, but in the end even the sponsors of the bills backed off in the face of a near consensus by the scientific community that legislation was not necessary.<sup>77</sup> This does not mean that the

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73. It can be argued that science, even as a purely intellectual activity, has the potential for being transformed into activity that may involve harm and, therefore, warrants restriction or regulation.

74. The Atomic Energy Act of 1954, 42 U.S.C. §§ 2011-2281 (1982), is an exception to the proposition that legislators usually avoid enacting statutes to deal with hypothetical or future problems, and the present plight of nuclear power may, indeed, be a consequence of the adoption of a detailed regulatory blueprint before there was anything to regulate. See Green, *Lessons of Three Mile Island for the Institutional Management and Regulation of Nuclear Power*, 365 ANNALS N.Y. ACAD. SCI. 311 (1981).

75. See *infra* note 77 and accompanying text. Although it may ultimately be necessary to establish a regulatory structure explicitly directed towards recombinant DNA technology, lawmakers to date have concentrated on extending an amalgam of pre-existing environmental and health statutes to the new technology.

76. See, e.g., *Wright v. Crane*, 142 Mich. 508, 510, 106 N.W. 71, 71-72 (1905): "There is no doubt that owners of automobiles have the same rights . . . that the drivers of horses have."

77. See Perpich, *Genetic Engineering and Related Biotechnologies: Scientific Progress and Public Policy*, and Schmitt, *Biotechnology and the Lawmakers*, in *BIOTECHNOLOGY IN SOCIETY: PRIVATE INITIATIVES AND PUBLIC OVERSIGHT* 65, 87 (J. Perpich ed. 1986).

issue will not be revisited in the future, but new legislation will probably be considered only if something happens to suggest strongly that the hazards are greater than previously believed. This example also demonstrates the principle that by the time scientific developments ripen into technology, powerful vested interests<sup>78</sup> will have developed. Groups representing these interests will argue cogently, because they generally control the relevant data, that legislation is unnecessary or premature.

Admiral Rickover accurately described this process when he pointed out that after first attempting to confuse the issue by arguing as if a law of science were at issue, the vested interests supporting the status quo continue as follows:

If this argument fails, the need for the proposed law is then categorically denied. Warnings of scientists are rejected as "unproven" or "exaggerated." Later . . . the argument shifts to an attack on the legitimacy of any kind of protective legislation. Such violation would violate basic liberties, it is claimed; it would establish government tyranny and subvert free democratic institutions. If all this is futile and legislation is imminent, there will be urgent demands that it be postponed until "more research" can be undertaken to establish the appositeness of the proposed law.<sup>79</sup>

The development of the vested interests makes the process of imposing effective social controls very difficult. As a consequence, social controls are usually imposed only after (too often long after) substantial injury has been sustained by the public.

There is, of course, an interplay between the legislature and the judiciary. Not infrequently, the legislature acts to replace a common-law legal principle with a direct statutory principle. It is, however, the function of the courts to apply the statutory language in particular cases, and in so doing, the courts are faced with the task of interpreting the language. The important point is that it is always within the power of the legislature to amend the statute to correct what it regards as an erroneous interpretation or application of the statute. On the other hand, legislators not infrequently find themselves unable to agree on statutory language, and implicitly resolve the stalemate by enacting a deliberately ambiguous statute and bucking the issue to the judiciary.<sup>80</sup>

A key role has also been played by administrative regulatory agencies established by the legislatures to promulgate rules and regulations in order to implement, by making more specific, the relatively general provisions of organic statutes. Such agencies often enforce the statutes and the rules and regulations. They perform a function that in earlier, simpler times would have been performed by the legislature itself, but which the legislatures, recognizing the increasing complexity of modern life, have now opted to assign to expert, or at least specialized, government entities. Principles of separation of powers and judicial supremacy have brought functions of the agencies under judicial re-

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78. The phrase "vested interests" is not used invidiously. It embraces the consumers who enjoy the benefits of the technology as well as the economic and political interests that may profit from the application of the technology.

79. *A Humanistic Technology*, Address by Vice Admiral Hyman Rickover, Granada Guildhall Lectures of the British Association for the Advancement of Science (Oct. 27, 1965).

80. *See American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 543 (1981) (Rehnquist, J., dissenting).

view.<sup>81</sup> More important, but less recognized, is the fact that the agencies are creatures of the legislature, and they only have authority to perform the functions delegated to them by statute. Deviations from policies acceptable to the legislature are always immediately correctable by legislative enactments and, indeed, by less formal mechanisms such as hostile hearings, political pressures, and cuts in appropriations. Of course, even those agencies structured to be independent of the executive branch<sup>82</sup> are subject to its influence through both the budgetary process and the power to appoint and reappoint administrative agency members or heads. Moreover, agency decisions are always subject to legislative review and revision, as are judicial decisions concerning agency actions. These considerations point towards the reality that decisionmaking by regulatory agencies and the courts, where public policy issues are involved, is to some extent a part of the political process.

Regulatory agencies may aspire, and are expected, to reach decisions on scientific and technical issues that will be regarded as "correct" by scientific consensus. There are, however, political realities that frequently tend to weigh against this goal. First, the outcome of any decision is necessarily shaped by the statutory mandate under which the agency operates, and the statutory language may require an "incorrect" decision. For example, a statute may focus solely on the elimination of risk and not allow for the balancing of risk against benefit, thereby producing a result that is enormously and disproportionately costly to society<sup>83</sup> or widely condemned by scientific consensus.<sup>84</sup> Second, the agenda and policy attitudes of agency heads are inevitably shaped to some extent by the executive who appoints them. This is due to the fact that the executive chooses her nominees with regard for their likely willingness to implement the executive's own policy goals. Third, the agency's decisions are necessarily constrained by political realities, such as the political and public relations costs of antagonizing key players in the executive and legislative branches, concerns about the possibility of being criticized or overruled by the legislature, and the personal interest of the agency heads in their own political careers.

As Goldberg noted,<sup>85</sup> a major distinction between law and science is that the law emphasizes process, while science emphasizes progress. In a sense, the scientist's vision of progress is also closely related to truth. Obviously, science does not seek progress at any cost; its interest is in letting science go forward in the march to progress unless and until it reliably appears that a particular forward step involves genuine, unacceptable costs. Along with Maxine Singer<sup>86</sup> and *The New York Times*,<sup>87</sup> science deplors the influence not only of the scien-

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81. See, e.g., *Crowell v. Benson*, 285 U.S. 22 (1932).

82. For example, by the establishment of agencies with multiple heads serving fixed staggered terms.

83. A good example of this is the Delaney clause of the Food and Drug Act, which bars the use of any chemical food additive that is known to cause cancer in animals. 21 U.S.C. § 348(c)(3)(A) (1984). See *infra* note 134.

84. See Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 MICH. L. REV. 171 (1978).

85. See *supra* notes 7-8 and accompanying text.

86. See *supra* notes 35-39 and accompanying text.

87. See *infra* notes 102-10 and accompanying text.

tific charlatans but also of lawyers and judges who are scientific know-nothings. The law, on the other hand, is more concerned with the optimal resolution of disputes than it is with achieving "correct" decisions that accord with objective truth. Although the law aspires to decide issues correctly, it is also concerned with reaching decisions that will be acceptable to the public. The legal process gives each party the maximum opportunity to make its case as strongly as it can in an adversary context, with the decision to be made by an objective fact finder who has no previous special knowledge of the facts in the case. The underlying premise is that such a decision will be more acceptable to the public than one based on scientific pronouncements *ex cathedra*. This is, of course, the judicial analog to a democracy's legislative process. Few would accept the proposition that laws emerging from the legislative process are based on objectively true premises, but we prefer these decisions to those emanating *ex cathedra* from a dictator, however benign, benevolent, and omniscient.

## V. CONTEXTS IN WHICH THE INTERFACE ARISES

The formulation and implementation of public policy decisions relating to science require the participation and, hopefully, the collaboration of scientists and lawyers.<sup>88</sup> The remainder of this Article will explore the manner in which law and science, and their respective dogmas, meet in several decisionmaking contexts. We will first consider the law-science interface in the context of litigation involving scientific issues. Second, we will explore the relationship in the context of prospective rulemaking by legislatures or regulatory agencies. Finally, we will consider the respective roles of law and science in decisions relating to public funding of scientific research and development.

### A. Litigation

An instructive example of the tensions between law and science is found in a straightforward case, *Wells v. Ortho Pharmaceutical Corp.*,<sup>89</sup> decided in 1985 by Judge Shoob of the United States District Court for the Northern District of Georgia. The plaintiff, Katie Wells, was born in 1981 with a number of serious birth defects.<sup>90</sup> Her parents sued individually and on her behalf, alleging that the birth defects were caused by a vaginal spermicide product, Ortho-Gynol Contraceptive Jelly, which had been on the market for about thirty years and had been used by millions of women.<sup>91</sup> The product was manufactured by the defendant and had been used by the plaintiff's mother for several months both prior to and after conception until she became aware that she was pregnant.<sup>92</sup>

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88. See generally LAW AND SCIENCE IN COLLABORATION (J. Nyhart & M. Carrow eds. 1983); SCIENCE AND LAW: AN ESSENTIAL ALLIANCE (W. Thomas ed. 1983); SCIENTISTS IN THE LEGAL SYSTEM: TOLERATED MEDDLERS OR ESSENTIAL CONTRIBUTORS? (W. Thomas ed. 1974).

89. 615 F. Supp. 262 (N.D. Ga. 1985).

90. *Id.* at 267-68.

91. *Id.* at 268.

92. *Id.* at 269.

In a two-week bench trial, each side presented a battery of expert witnesses whose testimony Judge Shoob found to be "in direct conflict."<sup>93</sup> Under these circumstances, he defined his task as follows:

[N]ot to presume the expertise to resolve, once and for all, the dispute within the scientific community about the safety of spermicides. Rather the Court's function was to render a legal decision, not a medical one. That is, the Court's duty was to weigh carefully the evidence that *these* parties presented to *this* court in the trial of *this* case and to determine with reference to the facts of the case at hand whether plaintiffs had satisfied their burden of proving that they were entitled to the relief sought.<sup>94</sup>

He emphasized that the plaintiffs' burden was not to produce "an unassailable scientific study which proves that spermicides have caused birth defects . . . but rather to show from *all* the evidence presented, to a reasonable degree of medical certainty that the spermicide caused some or all of *Katie Wells'* birth defects."<sup>95</sup>

Judge Shoob then devoted the bulk of his lengthy opinion to a detailed summary of the testimony of each witness and his views as to the credibility each should be given. His ultimate finding of fact was:

Plaintiffs presented competent evidence that the Product had proximately caused Katie Wells' birth defects, and this evidence generally was credible. Defendant offered evidence that the Product was not the proximate cause of these defects, yet this evidence often lacked credibility because it reflected bias or inconsistency. Accordingly, the Court found to a reasonable degree of medical certainty that the Product had proximately caused the birth defects of Katie Wells' left shoulder and arm and right hand.<sup>96</sup>

The judge awarded damages of about \$5.1 million.<sup>97</sup>

On appeal, the Eleventh Circuit affirmed the decision, but reduced the damages by about \$400,000.<sup>98</sup> The Court of Appeals considered and rejected Ortho's contention that "epidemiological studies should be relied on to provide the essential data to formulate an opinion on causation."<sup>99</sup> The court noted, however, that in addition to evidence based on personal medical examinations of the child and medical and scientific studies relative to causation, the plaintiffs' experts presented several epidemiological studies indicating an association between spermicide use and deleterious effects on the fetus.<sup>100</sup> Since the studies presented by both sides were inconclusive on the issue of whether the product had caused the birth defects, the trial court "was thus forced to make credibility determinations 'to decide the victor.'"<sup>101</sup>

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93. *Id.* at 266.

94. *Id.*

95. *Id.*

96. *Id.* at 294.

97. *Id.* at 296-98.

98. *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 747-48 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986).

99. *Id.* at 744. The court defined "epidemiology" as "the field of science dealing with the relationships of the various factors which determine the frequencies and distributions of certain conditions and diseases in human populations." *Id.* Cf. the *New York Times'* definition, *infra* text accompanying note 106.

100. 788 F.2d at 744.

101. *Id.* at 745 (citing *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1535 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984)). Also quoting *Ferebee*, the Court stated that a "cause-effect relationship need not be clearly

The scientific community responded to this case with great vigor. The usually cautious *New York Times* dealt with the case in an emotional editorial entitled *Federal Judges vs. Science*.<sup>102</sup> The editorial referred to an assertion by the *New England Journal of Medicine* that the courts would no longer be bound by reasonable standards of scientific proof and went on to spell out the reasons why it regarded the decision in *Wells* as grossly erroneous. According to the *Times*, there was "no serious difference among experts" as to the safety of the product because "after reviewing some 20 epidemiological studies, an expert committee advised the Food and Drug Administration in 1983 that the preponderance of available evidence 'indicates no association' between spermicides and birth defects."<sup>103</sup> The editorial complained that Judge Shoob, trying the case without a jury, rejected the written evidence of the scientific literature and focused on the oral testimony presented, paying "close attention to each expert's demeanor and tone."<sup>104</sup> He chose to believe the plaintiff's main witnesses, three pharmacologists and an expert in birth defects, "none of whom had any expertise in epidemiology,"<sup>105</sup> which the *Times* characterized as "the science of determining the causes of disease."<sup>106</sup> According to the *Times*, "science's finest achievement is finding methods to raise objective evidence above the merely anecdotal,"<sup>107</sup> but Judge Shoob was not moved by the preponderance of the scientific evidence, nor was the Court of Appeals, which "espoused the fiction that there had been a battle of experts, even though no scientist would consider pharmacologists expert in a matter of epidemiology."<sup>108</sup> According to the *Times*, the Eleventh Circuit rejected scientific standards of evidence when it upheld Judge Shoob's decision because there was "sufficient evidence of causation in the legal sense in this particular case, and that . . . finding is not clearly erroneous."<sup>109</sup> The *Times* labelled Judge Shoob's and the Court of Appeals' position an "intellectual embarrassment" that could have profound practical consequences in driving spermicides off the market and further narrowing contraceptive choice for women.<sup>110</sup>

More recently, Carl Djerassi, a Stanford chemist who synthesized the first oral contraceptive, described the finding of causation in the *Wells* case as "a possibility inconsistent with current epidemiological evidence" and asserted that fear of litigation and unavailability of insurance have eliminated most competition in development of new contraceptives.<sup>111</sup>

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established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists." *Id.*

102. N.Y. Times, Dec. 27, 1986, at 22, col. 1.

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.* (quoting *Wells*, 788 F.2d at 745).

110. The *Times* editorial pointed out that Ortho's profit on the spermicide product was only \$3 million per year. *Id.*

111. Djerassi, *The Future of Birth Control*, Wash. Post, Sept. 10, 1989, at C1, col. 1.



*Wells* is an excellent vehicle for discussing a number of important issues relating to the respective roles of law and science in American society, the law-science interface, and the role of expertise in public policy decisionmaking for science and technology.

### 1. *The Role of Science*

Scientists play a crucial role in formulating society's safety standards and resolving disputes over whether a particular agent caused injury to a plaintiff. It is essential to bear in mind, however, that there is a substantial difference between the skills and data necessary to make determinations concerning safety and those required to make determinations concerning the cause of a particular malady. For example, epidemiologists are capable of making judgments where data are available, as they were in *Wells*, about the correlation between a vaginal spermicide and birth defects. Even if every single use of the spermicide could be documented, without a single birth defect in the case of a child born to a user of the product, it does not follow that a birth defect will *never* be caused. This is another way of stating that a negative cannot be proved. It does follow, however, if the sample is large enough, that scientists and regulators could validly conclude that the product is safe. It also follows that the manufacturer of the product should not be liable for negligence because it had no reason to believe the product could cause birth defects. But in *Wells*, according to Judge Shoob's findings, there was credible evidence that showed *some* causal link between the product and birth defects,<sup>112</sup> and the manufacturer was held liable in negligence for not labeling the product to warn users that an increased risk of birth defects might result from use of the product.<sup>113</sup>

### 2. *The Role of Law*

The legal system has no competence to determine the abstract issue of whether spermicides in general or particular spermicides cause birth defects or other injuries.<sup>114</sup> The system does, however, have the duty to decide, in accordance with established legal procedures and on the basis of all the evidence presented by the parties, whether use of the spermicide caused injury in the particular case before the court. Whereas science can duck issues of this kind by asserting that the evidence is inconclusive, a court does not have this luxury. When a lawsuit is filed, the case must be decided in a binary manner: liability or no liability. Moreover, in the Anglo-American legal system, responsibility for managing the case rests with the judge, who probably has no scientific competence; and responsibility for actually deciding the issue of causation rests with a

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112. 615 F. Supp. at 292. The defendant's epidemiologist witness testified that epidemiological studies had shown clearly that spermicides do not cause birth defects. *Id.* at 285. Nevertheless, on cross-examination, the witness conceded that "a small increase [in birth defects] cannot be ruled out." *Id.* at 286.

113. *Id.* at 292-94.

114. Law is, however, competent to assist in formulating processes for making such determinations.

jury of lay persons.<sup>115</sup> This does not mean that the court's decision is objectively valid. It cannot be flatly asserted that the Ortho-Gynol spermicide in fact caused Katie Wells' birth defects. The only certainty is that in this particular case, at this particular time, and before this particular judge, the evidence presented by these particular witnesses with the help of these particular attorneys led Judge Shoob to conclude that the plaintiffs had made a sufficient showing of causation to warrant his finding liability rather than no liability. Accordingly, it cannot be stated that the case was correctly decided in accordance with objective fact, but it probably was decided in the optimal manner from the societal standpoint.

Both the court and scientists had legitimate roles to play relating to the safety of Ortho-Gynol. One function of scientists was to advise the Food and Drug Administration for regulatory purposes as to the product's safety; another function was to provide testimony on behalf of the plaintiff or the defendant as to whether a causal relationship existed between the product and the specific injury. The function of the court was to determine whether Ortho Pharmaceutical Corp. should be liable for Katie Wells' birth defects. This illustrates a fundamental principle that should be applicable to any risk or benefit-cost assessment; that is, it is essential that the purpose of the assessment be specified and understood. The criticisms of the treatment of scientific expertise in *Wells* would have much greater cogency and validity in a case directly involving the question of whether the product was safe rather than a question of whether a particular injury was caused by the product.

### 3. *The Validity of the Decision*

Aside from the above considerations, the *Wells* decision and the reaction to it raise other questions relating to public comprehension of what courts are about. It is difficult to believe that very many unbiased lawyers would regard the opinions and decisions by Judge Shoob and the Court of Appeals as unreasonable. Accordingly, it is also difficult to understand the emotion and the zeal for attacking the legal system generated by the decision, particularly in view of the factual underpinnings set forth in the opinions.

The *New York Times* editorial characterized the courts' decisions in the Ortho-Gynol case as an "intellectual embarrassment." Its principal complaint seems to have been that the trial court ignored the accepted scientific wisdom (emanating from epidemiology) in favor of the testimony of "three pharmacologists and an expert in birth defects, none of whom had any expertise in epidemiology."<sup>116</sup> The *Times*' obsession with epidemiology is puzzling, indeed almost an intellectual embarrassment itself. Epidemiologists would probably be startled to learn that their discipline is "the science of determining the causes of disease."<sup>117</sup> And while it may be true that "no scientist would consider pharmacol-

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115. One who possessed relevant scientific knowledge would almost certainly be excluded from the jury. Of course, when a case is tried without a jury, as in *Wells*, the findings on causation are made by the judge.

116. *N.Y. Times*, Dec. 27, 1986, at 22, col. 1.

117. *Id.* Random House defines "epidemiology" to mean "the branch of medicine dealing with epidemic diseases." *RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE* 479 (1966) [hereinafter *RANDOM HOUSE*].

ogists expert in a matter of epidemiology," scientists would probably be surprised to learn that pharmacologists are not expert in "the science dealing with . . . the effects of drugs,"<sup>118</sup> which, after all, was the issue in the case.

In fact, the defendant called seven expert witnesses, only one of whom was an epidemiologist, and that witness testified that "a small increase [in birth defects] cannot be ruled out" as a result of spermicide use.<sup>119</sup> The defendant's other experts were a biochemist; a physician certified in emergency medicine who had been involved in some epidemiological studies of birth defects; an obstetrician-gynecologist employed by the defendant's corporate parent; a "professor of pediatrics, radiology, and anatomy" (whom the court characterized as the defendant's primary witness); a pharmacist; and a regulatory specialist employed by Ortho who had a bachelor's degree in biology.<sup>120</sup> Judge Shoob's opinion makes no reference to any documentary evidence presented by the defendant that purported to be a definitive epidemiological study generally accepted by the scientific community as establishing that spermicides are not a cause of birth defects.

The plaintiff called four expert witnesses on the causation issue: a pharmacologist; a physician-pharmacologist; a general surgeon; and a physician "certified in pediatrics, chemical genetics, and biochemical and metabolic genetics" whose research area was the "study of the effects of drugs and environmental agents on developing fetuses."<sup>121</sup> The plaintiff presented, through direct testimony and cross-examination, evidence in epidemiological studies of some link between vaginal spermicides and birth defects.

Since the evidence presented by the two sets of experts was directly contradictory, the case necessarily hinged on how much weight the judge attached to the particular items of evidence before him. He found the plaintiffs' expert testimony "generally to be competent, credible, and directed to the specific circumstances of the case," while the defendant's testimony "often indicated bias or inconsistency."<sup>122</sup> If one assumes that the judge accurately and fairly characterized the testimony of the experts, his conclusion about these matters seems to be sound and reasonable, although not necessarily correct.

In short, the decision in *Wells* cannot be fairly characterized as wrong or as right on the issue of causation. The issue had to be decided one way or the other. Some epidemiological studies suggested a causal link between use of spermicides and birth defects; others were sufficiently persuasive that the Food and Drug Administration decided no warning label was necessary.<sup>123</sup> The judge weighed the conflicting evidence and decided that the plaintiffs should prevail. This does not mean that the spermicide caused the birth defects as a matter of

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118. Random House defines "pharmacology" as "the science dealing with the preparation, uses, and especially the effects of drugs." RANDOM HOUSE, *supra* note 117, at 1079.

119. 615 F. Supp. at 286.

120. *Id.* at 279-88.

121. *Id.* at 269-76.

122. *Id.* at 267.

123. The fact that no warning label was deemed necessary by the FDA does not necessarily mean that the FDA regarded the product as totally without risk in some cases.

objective truth, but only that this particular dispute was resolved in this manner in accordance with the usual legal dispute resolution processes.

#### 4. *The Consequences of the Decision*

Merely because the case was decided in a legally proper manner does not mean that the decision was sound or desirable from the standpoint of public policy. However, this was not a matter that should have been of great concern to Judge Shoob. The impact of the substantial liability imposed on the drug manufacturer, compounded by the liability imposed on the manufacturer of the Dalkon Shield intrauterine contraceptive device,<sup>124</sup> has apparently operated as a serious deterrent to contraceptive research by the pharmaceutical industry.<sup>125</sup> The industry and the majority of the scientific community seemingly regard this as a public policy tragedy unjustified by what they consider to be the small risks of these products.

This is not the first, nor will it be the last, occasion on which a judicial decision has been widely condemned as producing tragic social consequences. But there are ways to correct the situation short of turning the legal system upside down to mollify those who are complaining. The fix is, of course, political and legislative. It is within the power of state legislatures and the Congress to create new legal rules to prevent similar disasters. Dollar caps could be placed on liability. Standards for determining the culpability of drug manufacturers could be tightened through statutes that would protect manufacturers of specified products from liability for punitive damages unless it is established by "clear and convincing evidence that the harm suffered was the result of the reckless disregard of the manufacturer or product seller for the safety of product users."<sup>126</sup> Indeed, to satisfy the *New York Times*, the legislature could even specify that heavier, perhaps decisive, weight should be given the testimony of epidemiologists as to the cause of particular ills.<sup>127</sup>

To one concerned about the public policy consequences of the *Wells* decision, the inaction of legislative bodies to negate these consequences is at least as blameworthy as the asserted deficiencies of the judicial process. But the resolution of conflict is even more subjective and uncertain in the legislative setting. First, unlike a court, which must decide a matter properly before it one way or the other, legislatures are free simply to ignore whatever they choose. Moreover, legislators are expected to act as politicians rather than as objective, impartial arbiters. Important legislation is typically the product of political compromise

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124. A number of courts, state and federal, have upheld verdicts against A.H. Robins Co., manufacturer of the Dalkon Shield. *See, e.g.*, *Craig v. A.H. Robins Co.*, 790 F.2d 1 (1st Cir. 1986); *Worsham v. A.H. Robins Co.*, 734 F.2d 676 (11th Cir. 1984); *Hilliard v. A.H. Robins Co.*, 148 Cal. App. 3d 374, 196 Cal. Rptr. 117 (1983); *A.H. Robins Co. v. Ford*, 468 So. 2d 318 (Fla. Dist. Ct. App. 1985); *Tetuan v. A.H. Robins Co.*, 241 Kan. 441, 738 P.2d 1210 (1987).

125. *See* Djerassi, *supra* note 111; *Birth Control Industry Is Being Transformed*, *N.Y. Times*, Feb. 22, 1989, at D1, col. 4; *Drug Firms Halting Contraceptive Study*, *Chicago Tribune*, Jan. 8, 1989, at C1, col. 2.

126. S. 100, 99th Cong., 2d Sess. § 12(a)(1), 131 CONG. REC. S221 (daily ed. Jan. 3, 1985).

127. These possibilities are merely illustrative. Legislatures have available to them a wide variety of measures that would protect the pharmaceutical industry against the consequences of such judicial outcomes.

and, necessarily, cannot be expected to reflect an objectively correct disposition of an issue.<sup>128</sup>

Thus, neither the courts nor the legislatures acting alone or in concert can be expected to intervene at an appropriate time to bring a technology's evolution under social controls that will reflect a "correct" and scientifically objective balancing of its costs and benefits. Of course, a problem exists in defining what is correct and scientifically objective given that there is rarely unanimity among scientists on any particular subject. However, as Goldberg points out, a near consensus generally exists among scientists on scientific judgments, making it rational for policymakers to rely upon the views of the scientific community.<sup>129</sup> Nevertheless, even if Goldberg is correct, a more vexing problem remains: who qualifies as a "scientist" for purposes of establishing the existence of a consensus? This is a genuine problem, as is evident from the *New York Times*' view that only epidemiologists are, and pharmacologists are not, "experts in birth defects."<sup>130</sup>

### B. *The Rulemaking Process*

It is instructive and useful to contrast litigation such as *Wells*, which focuses on the question of whether liability should be imposed on a defendant as a consequence of injury allegedly caused by him in the past, with the process of making prospective rules prohibiting or regulating particular products or activities. In the latter procedure the focus is not on whether liability should be imposed, but on whether a particular product or activity involves risk such that it should be subject to restrictions in order to protect the public from injury.

The rulemaking process is essentially legislative. Indeed, although we tend to think of safety rulemaking as a function performed by administrative regulatory agencies, the legislature may, and frequently does, make the determinations itself.<sup>131</sup> Even where the determination is made by an administrative agency, however, the agency is exercising a portion of the legislature's power delegated to it by the legislature, using the basic standards for decisionmaking spelled out in the organic statutes. Indeed, one of the difficulties with understanding "safety" in a regulatory context is that different statutes define the concept differently.<sup>132</sup>

128. Paradoxically, despite the concept of legislative supremacy in a democratic society, we accept the premise that legislatures act subjectively, arbitrarily, or perhaps even irrationally, and our society expects a greater degree of "correctness" from the courts, much of whose business consists of deciding cases in accordance with the statutory output of the legislatures, and almost all of whose decisions are subject to legislative rejection or revision.

129. Goldberg, *supra* note 4, at 372-73.

130. See *supra* notes 102-10 and accompanying text.

131. See Green, *The Role of Law in Determining Acceptability of Risk*, 363 ANNALS N.Y. ACAD. SCI. 1, 3-4 (1981).

132. For example, the 1958 Chemical Food Additives Amendments to the Food, Drug and Cosmetics Act, particularly in the light of their legislative history, seem to call for reasonable certainty that no harm will result from the proposed use of an additive. On the other hand, the Consumer Product Safety Act seeks to protect against "unreasonable risk of injury," as does the Toxic Substances Control Act. The Occupational Safety and Health Act requires standards that assure "to the extent feasible" that "no employee will suffer material impairment of health or functional capacity." Green, *supra* note 131, at 6-10.

Neither the legislature nor the agency is constrained in rulemaking, in the way a court is in litigation, to consider only the evidence introduced by contending adversary parties. Each is free on its own initiative to search out the data it believes to be relevant. Nor is it constrained to engage in the kind of careful assessment and weighing of evidence that is the responsibility of a court. The rulemaking process, whether by the legislature or by a regulatory agency, is largely political.<sup>133</sup> Nevertheless, we as citizens hope and expect that the function will be performed with a degree of objectivity in assessing evidence that is sometimes inconsistent or conflicting.

Rulemaking in the arena of public health and safety is based on experience, prediction, or a mix of both. Where there has been experience with a product or an activity for a sufficiently long time, a body of data may exist, permitting a judgment as to the correlation, if any, between the product or activity and certain safety consequences. This judgment can be the basis for a regulatory determination of whether the product or activity is safe enough to be permitted without restriction, whether it should be permitted subject to regulation, or whether it should be curtailed or prohibited. Although, as noted above, epidemiological studies tell us nothing certain about the cause of a specific illness or injury affecting a specific individual, they can inform us of the probability that such an illness or injury may result from the product or the activity. However, the epidemiological inputs cannot be exclusively controlling. The fact that no such correlation is shown by existing data does not necessarily mean that new data resulting from future experience will not show a correlation. Conversely, the fact that a correlation is shown does not necessarily mean that the product or activity is unsafe. Whether it is adequately safe is a function of how adverse its consequences may be and the balance between the risks and benefits (taking into account the costs and risks of alternative means of achieving like benefits).<sup>134</sup>

Scientists' predictions may also enter into safety determinations. When the scientific community was reaching a judgment forty years ago about the safety and efficacy of artificially fluoridating drinking water to minimize dental caries in children,<sup>135</sup> the Public Health Service's unequivocal determination that it was safe was based on the fact that the morbidity and mortality rates were no higher in areas of the country with naturally fluoridated drinking water than in

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133. See *supra* text accompanying notes 84-85.

134. See *infra* text accompanying notes 164-70. The validity of this proposition is subject to possible statutory language that defines the manner in which safety determinations are to be made. For example, the Delaney clause in the Food, Drug and Cosmetics Act, 21 U.S.C. § 348(c)(3)(A) (1984), defines as unsafe any chemical shown to cause cancer in humans or animals. In recent years the Food and Drug Administration has interpreted this provision more flexibly by reading into it a *de minimis* principle. 52 Fed. Reg. 49,572 (1987). The courts, however, have tended to be more rigid. See, e.g., *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988).

135. See Wollan, *Controlling the Potential Hazards of Government-Sponsored Technology*, 36 GEO. WASH. L. REV. 1105, 1125 (1968). The Surgeon General of the United States announced the Public Health Service's "unqualified endorsement" of fluoridation to the extent of one part per million in April 1951. F. McCLURE, *WATER FLUORIDATION: THE SEARCH AND THE VICTORY* 249-55 (1970).

areas with extremely low fluoridation levels.<sup>136</sup> These epidemiological conclusions were supplemented with the predictive judgment that drinking water laced with artificially supplied fluoride would be essentially identical to drinking water in which fluoride occurred naturally<sup>137</sup> (that is, that there were no environmental factors associated with the presence or absence of naturally occurring fluoride that might make a significant difference in morbidity or mortality rates).

The conclusion that fluoridation of drinking supplies was safe appears in retrospect not to have been unreasonable. On the other hand, even if this conclusion is one hundred percent valid, it does not mean that drinking fluoridated water may not result in injury to some individuals. In this context, the safety determination means only that the risk of injury is so minimal and the anticipated benefit so substantial that the measure is, like vaccination against a contagious disease, justifiable. Nor does this conclusion mean that four decades of epidemiological data are enough to provide assurance that the risk is in fact so minimal.<sup>138</sup>

The prediction of scientists is an even more important factor when it is necessary to make safety judgments about a technology when there has been little, if any, prior experience on which to rely. Nuclear power technology is a good example. Usually, a major new technology is introduced over an extended period of time on an incremental basis in which experience with each step provides confidence for going forward with the next step. Each step is taken in response to market forces, which include a reckoning of the costs of potential liability incident to the technology's hazards, and regulation is not imposed until experience demonstrates that there are safety concerns requiring regulation to supplement market constraints. As indicated in the discussion of *Wells*,<sup>139</sup> when there is a threat of substantial liability, and insurance is unavailable or extremely expensive, private enterprise may be highly reluctant to undertake socially useful technological development.

The case of nuclear power technology, however, was highly unusual. Conceived in secrecy during World War II, its promise was such that as a consequence of various social and political influences, a national policy commitment was made to bring the technology to fruition as quickly as feasible through government support.<sup>140</sup> Although the initial policy was one of government monopoly,<sup>141</sup> the Atomic Energy Act of 1954<sup>142</sup> opened the technology to private

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136. C. RHYNE & E. MULLIM, JR., FLUORIDATION OF MUNICIPAL WATER SUPPLY; A REVIEW OF THE SCIENTIFIC AND LEGAL ASPECTS 8-13 (1952).

137. Testimony of Dr. Bruce Forsyth, Hearings before the House Select Committee to Investigate Chemicals in Food and Cosmetics, House of Representatives, 82d Congress, 2d Sess. 1635-37 (1952).

138. There are some recent indications that the predictive judgments may have been somewhat off target. See, e.g., Marshall, *The Fluoride Debate: One More Time*, 247 Sci. 276 (1990).

139. See *supra* notes 124-25 and accompanying text.

140. This commitment was implicit in the original Atomic Energy Act of 1946, ch. 724, 60 Stat. 755 (current version at 42 U.S.C.A. §§ 2011-2296 (West 1973 & Supp. 1989)). It directed the new Atomic Energy Commission to assure "adequate scientific and technical accomplishment" and "the broadest possible exploitation of the technology." 60 Stat. 755, 756.

141. See Green, *Nuclear Technology and the Fabric of Government*, 33 GEO. WASH. L. REV. 121, 124-25 (1964).

investment and exploitation. Recognizing that this technology involved substantial risks to the health and safety of the public,<sup>143</sup> the Act included a detailed scheme and structure for stringent regulation of the industry, even though it was not yet in existence. On the other hand, the Act called for rapid development of the technology, and as matters worked out in practice, the regulation was as benign as it was stringent.<sup>144</sup> Moreover, since private enterprise balked at investing in a technology that could give rise to enormous liability,<sup>145</sup> the 1957 Price-Anderson Act amendments created a scheme for government indemnity and a cap on liability that in effect insulated the industry from public liability in the event of an accident.<sup>146</sup> Accordingly, because there was virtually no experience with nuclear power plants and because the deterrent effect of the liability mechanism had been eliminated, protection of the health and safety of the public against a catastrophic accident rested entirely with the predictive safety judgments of knowledgeable nuclear power experts—nuclear scientists and engineers.<sup>147</sup>

Risk is generally considered to be the product of the probability of an event times the magnitude of the adverse consequences that may result.<sup>148</sup> When one seeks to measure the risk of a low probability-high consequence occurrence such as a catastrophic accident in a nuclear power plant, the multiplication will yield a very small number if either of the multiplicands is a very small number. Even though by definition of the problem, the adverse consequences are high, a very large number, the overall risk will turn out to be small if the probability of the occurrence is determined to be very low. This probability can easily be manipulated downwards simply by being optimistic about the efficacy of safety devices. Throughout the history of nuclear regulation, the probability of a catastrophic accident has been characterized by verbal formulations such as “extremely remote,” “exceedingly remote contingency,” “low probability,” “remote possibility,” and “highly improbable event.”<sup>149</sup> This kind of characterization has provided a rationale for ignoring worst-case scenarios.<sup>150</sup>

Although the safety of nuclear power has been an extremely controversial issue for the past two decades, the controversy has for the most part pitted knowledgeable scientists and engineers against opponents with substantially in-

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142. Atomic Energy Act of 1954, ch. 1073, 68 Stat. 919 (1954) (current version at 42 U.S.C.A. §§ 2011-2296 (West 1973 & Supp. 1989)).

143. The 1954 Act referred explicitly to protection of the health and safety of the public more than 20 times. *See id.*

144. Green, *Safety Determinations in Nuclear Power Licensing: A Critical View*, 43 NOTRE DAME LAWYER 633, 643-47 (1968).

145. Green, *Nuclear Power: Risk, Liability, and Indemnity*, 71 MICH. L. REV. 479, 481-87 (1973).

146. *Id.* at 487-91.

147. *Id.* at 491-98. Although it is true that there had been virtually no experience with land-based, stationary nuclear power plants, there had been considerable experience with naval nuclear propulsion systems.

148. *See, e.g.*, W. LOWRANCE, OF ACCEPTABLE RISK: SCIENCE AND THE DETERMINATION OF SAFETY 75-101 (1976).

149. These euphemistic phrases and others like them are found in a 1966 report of the Joint Committee on Atomic Energy on legislation to amend the Price-Anderson Act. H.R. REP. NO. 2043, 89th Cong., 2d Sess. (1966).

150. For an official description of this policy and its subsequent revision after the Three Mile Island accident, see U.S. Nuclear Regulatory Commission Statement of Interim Policy, Annex to Appendix D, 36 Fed. Reg. 22,851 (1971) (to be codified at 10 C.F.R. § 50) (withdrawn Nuc. Reg. Rep. (CCH) ¶ 1059 (June 13, 1980)).



ferior knowledge and technical resources. During the past decade the introduction of new nuclear power facilities has been brought to a standstill without any legislative prohibitions or deterrents, but rather by harrassment, agitation, and litigation spawned by opposition groups whose efforts have made nuclear power "too hot to handle" in the political arena. A strong case can be made that this is another example of a Lysenko-type paralysis that deprives society of a vitally needed energy source that the knowledgeable scientific expert consensus holds to be not only optimal, but also quite safe, at least relative to the hazards of other energy sources.<sup>151</sup>

This raises a fundamental question: can the experts be trusted? Clearly, they are the only ones who can be trusted to design and oversee the construction and operation of nuclear power facilities to ensure their adequate safety. They are also the only ones who can be trusted when they tell us that a facility meets all regulatory requirements and that the possibility of a major accident that will affect the public is very remote. They also have something useful to say about the potential consequences of such an accident, although they rarely discuss it because the exceedingly low probability of the accident makes it irrelevant to them. Similarly, they can contribute to a discussion of the risk-benefit balance, subject to the caveat that they have no particular knowledge of what benefits the public wants and what risk the public is willing to assume to achieve those benefits.<sup>152</sup> On the other hand, they cannot be credited with either omniscience or infallibility. For the political and legal systems to place blind faith in the experts would require us to believe that they have considered all that is relevant, constructed defenses against all possibilities, and taken into account the vagaries of both nature and human behavior. In short, it would be necessary for the public to repeal the most important of all laws: Murphy's Law.<sup>153</sup>

It is also significant that scientific judgment about the safety of nuclear power is not consistent with some important institutional indicators. Insurance underwriters, who are the real professionals in risk assessment, apparently regard the risks of nuclear power technology as sufficiently real that they are willing to provide only a small fraction of the liability coverage required by the nuclear industry. Moreover, the nuclear industry itself apparently regards the risks as sufficiently real that it has been unwilling to construct and operate nuclear power facilities without the continuing protection of the Price-Anderson

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151. See U.S. Congress, Office of Technology Assessment, *Nuclear Power in an Age of Uncertainty* (1976). In these respects, the situation resembles that in the contraceptive area, where it has been argued that verdicts against manufacturers of vaginal contraceptives operate to reduce drastically the birth control options available to women.

152. Green, *The Risk-Benefit Calculus in Nuclear Power Licensing*, in *NUCLEAR POWER AND THE PUBLIC* (H. Foreman ed. 1970).

153. Charles Perrow argues convincingly that serious accidents are inevitable in high technologies such as nuclear power. C. PERROW, *NORMAL ACCIDENTS* (1984). In the introduction to his book, he offers this warning: The new risks have produced a new breed of shamans, called risk assessors. As with the shamans and physicians of old, it might be more dangerous to go to them for advice than to suffer unattended. In our last chapter we will examine the dangers of this new alchemy where body counting replaces social and cultural values and excludes us from participating in decisions that a few have decided the many cannot do without. The issue is not risk, but power.

*Id.* at 12.

Act. This latter point is particularly significant because the dollar amount of nuclear accident coverage provided is many times greater than the maximum liability coverage ever previously offered for a single accident not involving atomic energy.<sup>154</sup> An important question to be pondered is whether there may not be some activities that are so dangerous that they ought not to be permitted even if the probability of an accident is virtually zero.

It is also important to recognize that although the question of whether particular products or activities meet statutory and regulatory safety standards is a question of law, the question of what constitutes adequate safety is one for the legislature to resolve in the crucible of the political process. The legal profession's concern with process should not be limited to litigation procedures, but should extend as well to the manner in which law is made by legislatures. This brings us back to the role of scientific expertise. As with respect to other issues, such as civil liberties, economic and tax policy, and the fitness of nominees to serve on the Supreme Court, the legislative process should consider the views of all segments of the public, expert or know-nothing, rational or irrational. Error is inevitable in free debate, as Justice Brennan pointed out,<sup>155</sup> but it can be tolerated, even where the issue is one of science. Nevertheless, if error results, it can be more easily tolerated if its effect is to retard progress rather than to result in injury to the public. After all, to retard progress is only to postpone the enjoyment of benefits not previously available.

### C. *Public Funding of Scientific Research and Development*

Decisionmaking on safety issues involving government-sponsored projects is an important special case. When confronted with this question in my seminar, students almost invariably assert their belief that government-sponsored development and introduction of a technology involves less risk to the public health and safety than if the technology were to be developed and introduced by private enterprise. This reaction flows from the students' beliefs that private profit motivation is antithetical to safety and that the lobbying power of private enterprise will forestall effective regulation. One of the major themes of the seminar involves the exploration of this question.

Prior to World War II, there was relatively little federal support of scientific research and development. Since then, however, a major proportion of all research and development done in the United States has been conducted with government sponsorship and funding. The scientific establishment has become so dependent upon federal funding that there has been a tendency to call government decisions not to fund particular projects "prohibition" or "suppression" of research or technology.<sup>156</sup>

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154. See Green, *supra* note 145, at 483-84.

155. *New York Times Co. v. Sullivan*, 376 U.S. 254, 271 (1964).

156. See e.g., Dyson, *Death of a Project*, 149 Sci. 141 (1965), characterizing the government's decision not to expend additional funds on Project Orion (which sought to develop a system for propelling spacecraft by the detonation of small hydrogen bombs that would be thrown out by the craft) as the suppression of technology. *Id.* at 144.

Much of the government support is committed to basic research or to applied research that does not directly involve major technological advance. It should be noted, however, that such research increases the pool of scientific knowledge, provides building blocks for future technological development, and therefore serves to accelerate the general advance of technology. Some government support is, on the other hand, committed specifically to new technological advances. Examples of such support over the past several decades are nuclear power, weather modification, the supersonic transport, AIDS and cancer research, and the artificial heart.<sup>157</sup> In each of these cases the justifications for government support have been that development of the technology was in the public interest and that the marketplace would not produce sufficient private investment to yield adequate technological development on the requisite time scale.

Unlike private investment, government support is not motivated by signals from the market; indeed, government investment is made in defiance of these signals. Therefore, the cost of potential liability arising from the hazards involved in the technology does not operate as a deterrent to the government to the same extent as it does in the private sector. Moreover, unlike the case of the private sector, where government regulation often takes over after the fledgling technology passes the test of the marketplace, technological development by the government is not subject to government regulation. Since there are no economic or regulatory constraints on potentially hazardous developments, the only constraint is the government's self-restraint.

Although, hopefully, the political process does not permit the government to make its decisions irresponsibly or recklessly, we must acknowledge that the bureaucracy and its contractors have powerful vested interests in going forward. The inevitable tilt, therefore, is towards overstating benefits and understating risks. This tilt is accompanied by sincere professions of belief that progress should not be deterred by speculative and hypothetical risks, that the risks will turn out not to be too great, and that those risks can probably be minimized by technological fixes. Then comes the ultimate promise: If it turns out that the risks are unacceptably high, we will abandon the whole thing. It is unlikely, however, that a government bureaucracy will find it politically feasible to abandon its promotion of a useful civilian technology after strong vested interests in both its use and its enjoyment have come into existence.<sup>158</sup> After all, the process of assessing benefits and risks is sufficiently soft and subjective to enable good faith continuation of the project on the basis of a finding that the benefits exceed even the confirmed risks.

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157. Of course, the development of military technology is an extremely important area of government funding, but for obvious reasons it is excluded from the scope of this Article.

158. In *Power Reactor Dev. Co. v. International Union of Electrical, Radio and Machine Workers*, 367 U.S. 396 (1961), the Supreme Court interpreted the Atomic Energy Act as permitting the AEC to defer a definitive safety finding until after the commission issued a construction permit and received the application to operate the nuclear power plant. *Id.* at 406. Justice Douglas was highly skeptical that this would adequately protect the public. He said: "[W]hen millions have been invested, the momentum is on the side of the applicant, not on the side of the public. The momentum is not only generated by the desire to salvage an investment. No agency wants to be the architect of a 'white elephant.'" *Id.* at 417.

Bringing government-sponsored research and development projects that may involve hazard under effective control is a particularly challenging puzzle. On the one hand, it appears that once a project gathers momentum, it will be very difficult, perhaps impossible, to turn it off. On the other hand, a society that does not proceed with a project merely because it involves risks of an unknown, but possibly substantial, degree would never make technological progress. To complicate the problem further, an objective risk-benefit assessment performed at the outset of the project would almost invariably result in a conclusion that the benefits clearly outweigh the risks. This is because the potential benefits are usually obvious and relatively imminent, while the risks are speculative, hypothetical, relatively remote, and, in any event, possibly manageable and acceptable. From the scientists' standpoint, the assessment would always lead to the conclusion that the project should go on at least until we know more about the risks.

One possible answer to this dilemma may be for government to get out of the business of supporting science and technology, so that market forces and regulatory structures could operate. This would mean, however, that our society would be deprived of the earlier enjoyment of technological benefits. On the other hand, there is no political or ethical imperative that the government must procure technological benefits, even a cure or therapy for cancer, for its public in the same manner that it procures police and fire protection. The problem is easier to define than to answer, particularly since there are international dimensions that must be taken into account.

## VI. DICHOTOMIES IN THE LAW-SCIENCE INTERFACE

In considering the law-science relationship in the public policy context, we encounter a number of fundamental dichotomies that are at the heart of the tensions between law and science.

The first dichotomy involves the conflict between progress and process. When Koshland complains that a technical flaw, distant precedent, or minor legal technicality frequently delays scientific or technical advance,<sup>159</sup> he is saying in essence that it is the lawyers' process that causes the delay. This implicitly raises the dichotomy of the respective roles of experts and generalists in public policy decisionmaking for science and technology, an issue that is raised more explicitly by Dr. Singer.<sup>160</sup> This in turn leads to the question of whether issues of science and technology are so unique and important that they should be resolved in some kind of extraordinary forum rather than in the manner in which other major societal issues are decided.<sup>161</sup>

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159. Koshland, *supra* note 46.

160. *See supra* notes 33-45 and accompanying text.

161. During the 1970s Dr. Arthur Kantrowitz proposed the establishment of a "science court." Kantrowitz, *Controlling Technology Democratically*, 63 AM. SCIENTIST 505 (1975). The underlying premise is that the decisionmaking process can and should separate the scientific (*i.e.*, facts) from the nonscientific (*i.e.*, values). The science court (in which lawyers would play no, or at best a minimal, role) would determine the scientific facts, and its decision would then be turned over to the more conventional decisionmaking institutions for application of value and political judgments. *Id.* at 506-08. Proponents of the concept have never dealt with the difficult question of how constitutional due process requirements could be met.

A second dichotomy centers upon the role of government in procuring scientific and technological advance. Scientists, perhaps because of their economic dependence on federal support,<sup>162</sup> tend to regard government funding of science as mandated by the welfare clause of the Constitution.<sup>163</sup> Serious questions arise as to how multitudinous beneficial research projects should be prioritized in light of limited available funds. Scientists tend to favor technological, rather than social, fixes for social problems. For example, when fluoridation of public water supplies was under consideration as a fix for dental caries in children, there is no record that any serious thought was given to legislation mandating periodic visits to the dentist, or restricting the manufacture and sale of candy and chewing gum. Similarly, scientists, who play the de facto key role in the process of prioritization among competing scientific projects, seem to have a predisposition for high-technology projects rather than low-technology public health measures. Finally, very little thought has been given to the alternative of government stimulation or subsidization of regulated private enterprise to perform this procurement function.

Another dichotomy involves the issue of quantitative versus qualitative assessments of risks and benefits. Scientists have a clear preference for, indeed an insistence upon, quantification. As Dr. Philip Handler noted when he was president of the National Academy of Sciences, in government safety regulation decisions "an attempt is required to state both the costs and benefits in quantitative form,"<sup>164</sup> even though difficulties stem "from the seemingly incommensurable nature of these risks and benefits, which may even accrue to different populations."<sup>165</sup> Nevertheless, Dr. Handler concedes that in most regulatory situations "knowledge of risks is rather imperfect and knowledge of benefits is likely to be decidedly less satisfactory."<sup>166</sup>

The legal profession is no stranger to risk-benefit assessment. In the law of torts, for example, where conduct creating an "unreasonable risk of harm" to others may give rise to liability, "unreasonable" is defined in terms of the risks outweighing the benefits ("what the law regards as the utility of the act or the particular manner in which it is done"). The risk is measured by the social value the law attaches to the interests imperiled, the probability that injury will result, the magnitude of the likely injury, and the number of persons who may be injured. "Utility" is a function of the social value the law attaches to the interest to be advanced or protected by the conduct, the probability that the interest will be advanced or protected, and the availability of less dangerous alternatives to advance or protect the interest.<sup>167</sup> All of this is done without any quantification. Indeed, in one case Judge Learned Hand constructed an algebraic formula to be applied to ascertain liability and then proceeded to give

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162. See *supra* note 58 and accompanying text.

163. See Green, *Law and Genetic Control: Public Policy Questions*, 265 ANNALS N.Y. ACAD. SCI. 170, 176-77 (1976) for the author's colloquy on this point with Dr. Bernard Davis.

164. Handler, *A Rebuttal: A Need for a Sufficient Scientific Base for Government Regulation*, 43 GEO. WASH. L. REV. 808, 809 (1975).

165. *Id.*

166. *Id.* at 808.

167. RESTATEMENT (SECOND) OF TORTS §§ 291-96 (1965).

content to the algebraic terms in a purely nonquantitative analysis that included consideration of custom in the industry.<sup>168</sup>

Of course, Dr. Handler's remarks about quantification were made in the context of regulatory decisions, not torts cases, but it is not clear that quantification is really a *sine qua non* of regulatory risk-benefit assessments.<sup>169</sup> Indeed, from the standpoint of public acceptance of regulatory decisions, it is probably preferable for the agency to communicate its conclusions about risk in words rather than numbers. For example, the public would undoubtedly be more comfortable if it is told that the probability of a serious accident is "exceedingly remote" than if it is told it is "10<sup>-6</sup>" (one in a million).<sup>170</sup> In any event, there would appear to be no harm in a regulatory agency's use of quantitative risk-benefit assessment if it so chooses, as long as the results are not presented to the public as being anything more than an educated "guesstimate."

This leads directly to another dichotomy: probability versus magnitude of consequences. It has been observed that the general public tends to give much more weight to the magnitude of the consequences of an accident than to its probability. Thus the risk of an enormous catastrophe in the highly remote possibility of a severe nuclear accident causes greater public apprehension than the mining and use of coal for energy, even though scientific consensus regards the risk-benefit ratio as much more favorable for nuclear power.<sup>171</sup>

Finally, there is the dichotomy of experience versus prediction. The common expressions about experience ("experience is the best teacher," "there is no substitute for experience") reflect a deep-seated predisposition. Our economic, political, and legal systems are all constructed to resist sudden, dramatic change, but to accommodate incremental change. Since World War II, science

168. *United States v. Carroll Towing Co.*, 189 F.2d 169 (2d Cir. 1947). Seven years earlier, in a case involving an automobile accident, Judge Hand had defined the degree of care required of the defendant as "the resultant of three factors: the likelihood that his conduct will injure others, taken with the seriousness of the injury if it happens, and balanced against the interest which he must sacrifice to avoid the risk." *Conway v. O'Brien*, 111 F.2d 611, 612 (2d Cir. 1940), *rev'd*, 312 U.S. 492 (1941). He stated that none of the three factors was practically susceptible to quantitative estimate, and that the latter two were not even theoretically susceptible. Accordingly, since a solution always involves some "choice between incommensurables" the choice is assigned to the jury "because their decision is thought most likely to accord with commonly accepted standards, real or fancied." *Id.*

Interestingly, Judge Hand applied similar principles in a rather different context. In *United States v. Dennis*, 183 F.2d 201 (2d Cir. 1950), *aff'd*, 341 U.S. 494 (1951), he wrote for the Second Circuit in affirming the conviction of the "first string" leadership of the Communist Party that applying the "clear and present danger" test requires "a comparison between interests which are to be appraised *qualitatively*" *Id.* (emphasis added). The appraisal that was necessary was to determine whether the "gravity of the evil" that might be produced by the Communist Party, "discounted by its improbability," justifies the invasion of free speech necessary to avoid the danger. *Id.* at 212.

169. *See Aqua Slide 'N' Dive v. Consumer Prod. Safety Comm.*, 569 F.2d 831, 840 (5th Cir. 1978) ("elaborate cost-benefit analysis" not necessary to conclude that unreasonable risk exists); H.R. REP. NO. 94-1341, 94th Cong., 2d Sess. 14 (1976), part of the legislative history of the Toxic Substances Control Act, which asserts that the cost-benefit assessment required under that statute does not require a "formal benefit-cost analysis under which a monetary value is assigned to the risks . . . and to the cost to society."

170. Dr. Handler acknowledges that "to establish that untoward incidents will not occur with a frequency greater than 10<sup>-6</sup> is a monumental task." Green, *The Risk-Benefit Calculus in Safety Determinations*, 43 GEO. WASH. L. REV. 791, 796 (1975).

171. Slovic, Fischhoff & Lichtenstein, *Facts and Fears: Understanding Perceived Risk*, in *SOCIETAL RISK ASSESSMENT: HOW SAFE IS SAFE ENOUGH?* 181 (R. Schwing & W. Albers, Jr. eds. 1980); Slovic, Fischhoff & Lichtenstein, *Characterizing Perceived Risk*, in *PERILOUS PROGRESS: MANAGING THE HAZARDS OF TECHNOLOGY* 91 (R. Kates, C. Hohenemser & J. Kasperson eds. 1985).

and technology, however, have in effect been leap-frogging experience with successive revelations and developments occurring before there has been an opportunity to absorb previous ones.

## VII. CONCLUSION

Lawyers should have a profound interest not only in what the law is but in how the law is made. This proposition applies not only to those lawyers who have a client interest in the subject matter of the law, but also to the legal profession as a whole in its role as architects of public policy. This is particularly true with respect to the scientific revolution of the past five decades and the technological consequences it has spawned. The stakes are very high in view of the potential of science for both good and evil.

There is a substantial gulf between the scientific and legal disciplines. Although this gulf has been characterized by some in terms of antagonism, there is no reason to conclude that the interface involves real antipathy on either side. The scientific community has been reluctant to become involved with lawyers, but this seems to be a function of its perception that lawyers are merely meddlers with little capacity to be of assistance to science in its efforts to improve the store of knowledge and the human condition. There has also been a fundamental lack of communication between the disciplines, largely because of the legal profession's failure to recognize the weighty public policy issues requiring its attention.

The law school world has, of course, been aware of the migration of scientists and engineers into law school. Many of these migrants have been motivated by an interest in public policy for science issues and have sensed that the law is where the public policy action takes place. It is questionable whether law schools have delivered on these expectations.

In any event, the challenge is not to make scientists literate in law, to make lawyers literate in science, or to create a new breed of lawyer-scientist or scientist-lawyer. Rather, it is to teach the lawyer and the scientist, each doing her thing, to achieve common goals.

