

## BOOK REVIEW

A NATION OF GUINEA PIGS. By Marshall S. Shapo. New York: The Free Press, 1979. Pp. xvi, 300.

*Reviewed by Barry R. Furrow\**

Scientific progress has brought us many rewards: new energy sources, more effective medical care, and a greater understanding of ourselves and our physical environment. Simultaneously, scientific progress has created new risks arising from, for example, toxic substances, side-effects of drug products, and unforeseen effects of seemingly harmless substances (from freon to coffee). Modern science has expanded the language of "risk" to include whole new categories of previously unsuspected hazards: carcinogenesis (the induction of runaway growth of the cells of some part of the body); mutagenesis (modification of the body's genetic material); and teratogenesis (alteration of the development of a fetus in utero).<sup>1</sup> Desiring the benefits of science, we must develop principles for regulating scientific activities that create risks and institutional approaches to handle the complex issues modern science and technology create.

Marshall S. Shapo,<sup>2</sup> in *A Nation of Guinea Pigs*, attempts to satisfy the first need. Shapo presents four case studies of technologies at the interface of law and science: birth control pills; DES (diethylstilbesterol); taconite dumping in Lake Superior by Reserve Mining; and recombinant DNA research. These case studies represent a "manifestation of a general social problem":<sup>3</sup> risks that have an "unknowable and insidious character,"<sup>4</sup> are "manmade in origin,"<sup>5</sup> and present unexpected hazards that confound our expectations of the safety of modern technology. These hazards represent the larger class of products and activi-

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1. For a general discussion, see W. LOWRANCE, OF ACCEPTABLE RISK 24-29 (1976). See also Ames, *Identifying Environmental Chemicals Causing Mutations and Cancer*, 204 SCI. 587 (1979).

2. Frederic P. Vose Professor of Law, Northwestern University School of Law.

3. M. SHAPO, A NATION OF GUINEA PIGS xii (1979).

4. *Id.* xv.

5. *Id.*

ties whose long-term effects are uncertain. Members of the general public, who are exposed to the risks of these products and activities, are, in effect, subjects or guinea pigs; hence, the title of the book.

## I. SHAPO'S THESIS

### A. *Risks and the Scientific Enterprise.*

Having defined the problem as controlling scientific progress, Shapo turns first to the nature of science on the assumption that we must understand science to govern it. He draws heavily on Jerome Ravetz's work<sup>6</sup> in elaborating on the nature of science and its complexities. Science is concerned with artifacts that represent a reality one cannot view directly. Scientific inquiry has a substantial craft component: the use of judgment and experience in recording, measuring, and evaluating data, to avoid what Ravetz has termed "pitfalls."<sup>7</sup> Pitfalls are traps for the unwary. For example, a pitfall can be a concealed error in data, an equipment malfunction, or an ambiguity or false deduction undermining an argument's reasoning. Scientific "truths," tentative in their initial contours and subject to continual reassessment, are therefore considerably more evanescent than lawyers or lay people realize.

Shapo points out that the complexity and uncertainty of most scientific judgments suggest caution in evaluating apparently definitive scientific conclusions. The legal system therefore needs a sophisticated method to translate the scientific dialect, and when such translation fails, the adoption of a risk-averse stance toward the particular hazard.<sup>8</sup> Given the complexity of modern science, a primary problem is "the case in which scientists and technological innovators are themselves quite uncertain about the long-term consequences of their activities. Yet even in their uncertainty, they are prone to make technical statements that are impenetrable to the layman."<sup>9</sup>

Novelty is the hallmark of science. New specialties now exist that were unrecognized fifty years ago.<sup>10</sup> This proliferation of "new" sciences (*e.g.*, recombinant DNA) poses a dilemma for the policy maker: science is both a creator of risks and the sole means of measuring and evaluating those risks.

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6. J. RAVETZ, *SCIENTIFIC KNOWLEDGE AND ITS SOCIAL PROBLEMS* (1971).

7. *Id.* 95-97.

8. M. SHAPO, *supra* note 3, at 14.

9. *Id.*

10. *Id.* 8.

Shapo also discusses the dynamics of modern science and its mode of investigation. Modern science is specialized and capital intensive, requiring large sums to start up and continue research, either from the government or from private enterprise. Because private enterprise must recoup in sales the costs of research and development, there is a tendency toward less extensive experimentation and quicker marketing of goods than when such functions are governmentally funded. It is when scientific progress is greatest that these pressures most affect entrepreneurs and thus compel strict scrutiny of their evaluations of risk. Scientific research takes substantial time; often years are necessary to complete a project. The legal system's structuring of incentives can seriously affect the production of scientific data. Rules directly regulating the conduct of science must therefore be sensitive to possible negative effects in curtailing or deterring research.<sup>11</sup>

The initial difficulty for the regulators of science is their dependence on the scientists who work in a highly specialized and technical area. As Shapo acknowledges, "in the trenches of research, operational decisions of considerable magnitude must fall on the bench scientist."<sup>12</sup> An additional difficulty is the divergent incentives that can motivate a scientist. Incentives to take shortcuts counterbalance the scientist's concern for reputation and for continued funding. Restrictions on research entail time and expense, and priority of discovery is essential to enhance one's career.

Shapo points out the growth in the number of practitioners of science and the proliferation of its research product. Currently thirty thousand scientific journals are published, and over three hundred journals exist that print only abstracts of current articles.<sup>13</sup> Shapo comments: "Legislation designed to control potentially hazardous experimentation or the marketing of products that may pose a threat to human life should respond to the difficulties of unearthing as well as assessing information that may signal danger to the expert but is not within the ken of ordinary citizens."<sup>14</sup>

Regulators must understand the sociology of science, therefore, to evaluate effectively the likelihood of honest assessment by scientists of the hazards of a line of research, a product, or a process. Scientists in contemporary practice may be organized according to the orthodoxy of a particular institution. Dangers of conformity, which can stifle honest assessment, can be counterbalanced by the effects of monitored scien-

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11. *Id.* 6.

12. *Id.* 238.

13. *Id.* 7.

14. *Id.* 7.

tific journals that subject articles to stringent selection and editing. Big Science may, however, lead to a High Priesthood, in which leaders control the direction of the field.<sup>15</sup>

Shapo's discussion of the scientific enterprise is a useful introduction for a reader ignorant of the dynamics of science. Unfortunately, it is useful to understanding only chapter eight, which discusses the recombinant DNA controversy. Shapo fails to discuss in an introductory manner the nature of scientific evidence in assessing the hazards of various substances; the range of tests that are available for testing human reactions to drugs, airborne agents, and other environmental agents; and means by which a court or agency can better understand the nature of the risks and the evidence it must consider.<sup>16</sup>

### B. *The Nature of Experimentation.*

The book's title, *A Nation of Guinea Pigs*, is drawn from Shapo's broad definition of experimentation. Shapo stretches the term "experiment" to encompass a spectrum ranging from traditional medical experiments to the mass-marketing of products. He defines "experimentation" as "an attempt to solve problems in a fresh and novel way, using the subjects of the attempt as a means to gather information . . . widespread distribution [of products] in fact involves a continuous process of experimentation."<sup>17</sup> Concerned about unknown risks, Shapo worries about the "external consequences of scientific progress which may not be known until after the introduction of a new product or process, sometimes months or years later."<sup>18</sup> The law's task is to limit such adverse consequences, in part by providing incentives to scientific professionals "to identify possibilities as well as probabilities that [such consequences] will happen."<sup>19</sup> His concern is to define attitudes toward risk in concrete situations.<sup>20</sup>

Shapo's notion of market experimentation is not original,<sup>21</sup> but he

15. *Id.* 11.

16. See W. LOWRANCE, *supra* note 1, for a general orientation to the problem of scientific evidence and risk.

17. M. SHAPO, *supra* note 3, at 30.

18. *Id.* 12.

19. *Id.*

20. *Id.* 26-27.

21. He echoes the concerns of earlier reformers about the flood of advertising of potentially dangerous products. For example, in A. KALLET & F. SHLINK, *100,000,000 GUINEA PIGS* (1933), Kallet and Shlink graphically describe market experimentation in an era bereft of a Federal Trade Commission and a Food and Drug Administration:

In the magazines, in the newspapers, over the radio, a terrific verbal barrage has been laid down on a hundred million Americans, first, to set in motion a host of fears about their health, their stomachs, their bowels, their teeth, their throats, their looks; second, to

tries to give the notion a philosophical underpinning by emphasizing individual inviolability, with the corollary that "one who proposes to impinge on the physical or psychological intactness of another must justify his act."<sup>22</sup> This burden of justification on the actor who would cross a person's boundary is required even if a strong argument can be made for the social utility of the act.<sup>23</sup>

Shapo acknowledges that a new technology over the long run can have a net benefit, even though it generates risks. Considerations of utility are appropriate so long as the victims consent to the risks to which they are exposed.<sup>24</sup> Consent must be focused, however, specifically on the hazards particular to the experiment. The degree of consent required may vary according to available information, comprehension, and external pressures.<sup>25</sup> "And sometimes consent will not be enough by itself to achieve a solution. It may be necessary to require review by both experts and nonexperts, rationalized decisions on the record, and the advance provision of compensation for those injured in experiments."<sup>26</sup>

"Experimentation" is a loaded term to a lawyer. The history of abuse and subsequent regulation of experimentation gives the term perjorative content.<sup>27</sup> By using the word to cover such a wide spectrum of activities, Shapo dulls our ability to make necessary distinctions between activities for regulatory purposes. He paints with a broad brush to justify a broad risk-averse regulatory stance, and by doing so obfuscates rather than clarifies.

### C. *Risk-aversion as an Emerging Regulatory Stance.*

Shapo sees risk-aversion to "uncertain long-term risks"<sup>28</sup> as a general trend in contemporary American culture and public policy. His

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persuade them that only by eating, drinking, gargling, brushing, or smearing with Smith's Whole Vitamin Breakfast Food, Jones' Yeast Cubes, Blue Giant Apples, Prussian Salts, Listroboris Mouthwash, Grandpa's Wonder toothpaste, and a thousand and one other foods, drinks, gargles, and pastes, can they either postpone the onset of disease, of social ostracism, of business failure, or recover from ailments, physical or social, already contracted.

*Id.* 3.

22. M. SHAPO, *supra* note 3, at 43.

23. Shapo seems to draw upon Nozick's notion of personal inviolability by using the metaphor of a boundary around each individual. The development of this idea is found in R. NOZICK, *ANARCHY, STATE, AND UTOPIA* (1974).

24. M. SHAPO, *supra* note 3, at 44.

25. *Id.* 46.

26. *Id.*

27. See AD HOC ADVISORY PANEL, FINAL REPORT OF THE TUSKEGEE SYPHILIS STUDY (1973). See generally J. KATZ, *EXPERIMENTATION WITH HUMAN BEINGS* (1972); M. PAPPWORTH, *HUMAN GUINEA PIGS: EXPERIMENTATION ON MAN* (1968).

28. *Id.* 257.

survey of the modern regulatory terrain leads him to conclude that a consensus has developed among the American people concerning cumulative unseen and uncertain long-term dangers. He writes: "[T]he view has developed that those who market new goods or create external consequences from processes that are novel or not thoroughly tested owe the community a scientific affirmation of safety at particular levels of use, or at least an abundance of warnings and opportunities to make a choice."<sup>29</sup> Shapo seems to draw this conclusion primarily from the actions of the Food and Drug Administration, operating under the regulatory umbrella of the Delaney Amendment.<sup>30</sup> The central chapter of the book, chapter five, is entitled, "The Delaney Amendment: Rough-Hewn Regulation." References to the Delaney Amendment, as illustrative of a public policy statement based on consensus, permeate the rest of the book.<sup>31</sup> The Delaney Amendment's uncompromising approach, says Shapo, "may provide as much refinement as we wish to afford when it is we who are the guinea pigs."<sup>32</sup> Society is thus risk-averse, and our regulatory superstructure tends to mirror society's consensus. Shapo writes:

How much risk we willingly accept is related to general norms of social acceptability. But over the last half century we have grown somewhat less philosophical about accepting artificially created, avertable dangers, especially when information about them is or readily could be available to those in a position to avoid them.<sup>33</sup>

Shapo believes we look for protection, first, in improved disclosure of risks to those affected by new drugs, products, or experiments, and second, in direct governmental intervention, either by the setting of standards or by the prohibition of hazards. Disclosure of hazards is central to Shapo's thesis. Producers of consumer goods are not likely to disclose hazards. Therefore, we have created a regulatory apparatus, *i.e.*, the Consumer Product Safety Commission, the Food and Drug Administration, and the Federal Trade Commission, which furthers consumer protection.

These regulatory agencies not only fill a void of market failure resulting from information shortcomings; they also compensate for the limitations of private tort litigation for harm suffered. The risk of paying damages in a tort case can create a powerful incentive for an industry to improve its practices. The products of many new technologies, however, such as industrial chemicals, pose causation problems that

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29. *Id.* xv.

30. 21 U.S.C. § 348(c)(3)(A) (1970).

31. *See, e.g.*, M. SHAPO, *supra* note 3, at 164, 188-90, 215, 250.

32. *Id.* 162.

33. *Id.* 50.

tort litigation is ill-equipped to handle.<sup>34</sup> As Shapo observes, "Thus there is a strong thrust toward regulation of things and processes which blend uncertainty and untraceability, for liability rules will not serve to vindicate personal interests nor achieve deterrent effects."<sup>35</sup> Compensation, therefore, provides only a secondary remedy; primary reliance should be placed on regulation that limits exposure to hazards in advance.<sup>36</sup> Legislation provides a "truly public form of choice"<sup>37</sup> when the market for a product or a service does not function properly.

Shapo makes a strong case for a risk-averse regulatory stance that places the burden of producing evidence on the proponent of a line of research or technological application. When long-term benefits are balanced by long-term risks, and both are speculative, he concludes that the burden of producing evidence concerning risks and benefits should "rest principally on those who propose to act."<sup>38</sup>

The themes developed in the book are thus (1) a new category of risks, generating (2) a risk-averse posture by the government to protect us from (3) treatment as guinea pigs in experiments performed without our consent. Given these premises, Shapo's purpose is to structure an answer to the question of "what approach government should take to the creation of risks whose potential for damage is uncertain,"<sup>39</sup> a problem "of defining attitudes toward risk in concrete situations."<sup>40</sup> His ultimate goal is to articulate more precisely the foundations "of a more general theory of legal control of scientific endeavor and its consequences."<sup>41</sup>

## II. A CRITIQUE

Shapo proposes no innovative expansion of public regulation of risky activities and products; instead he elaborates on well-established government roles, usually in an attempt to justify prior actions. He seeks to breed caution among regulators, particularly in the regulation of drugs and toxic chemicals. His analysis is subject to criticism on several grounds.

First, the use of examples of drug regulation to derive a basic principle of risk-aversion as representative of social consensus makes too

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34. *Id.* 55-56.

35. *Id.*

36. *Id.* 257.

37. *Id.* 251.

38. *Id.* 244.

39. *Id.* 26.

40. *Id.* 27.

41. *Id.* xii.

large a jump. The food and drug laws were enacted in response to a great proliferation of patent medicines and the mass marketing of drugs; and the Delaney Amendment in particular arose in response to emerging conceptions of the link between cancer and food additives.<sup>42</sup> The social context was special. In addition the Delaney Amendment has been invoked only rarely and circumvented on occasion.<sup>43</sup> One cannot therefore derive a consensus about risk-aversion from the Delaney Amendment.

Second, the basis for this putative consensus is less clear than Shapo indicates. An individual's decision whether to assume a risk presupposes that first he measures the risk (i.e., that he has some awareness of its probability and its likely severity if it materializes), and that next he makes a judgment about the acceptability of the risk. Yet perception of risk is more difficult than it once was because the nature of risky activities has changed. The risks are now less easily visualized and understood, they transcend neighborhood or community boundaries, and they threaten damage of greater magnitude, often taking years to manifest themselves. As a result, it is arguably incorrect to assume, as Shapo seems to, that all risk-generating activities engender a uniform stand of risk-aversion among the populace. For example, when the nature of the harm that may materialize from a risk-generating activity is easy to perceive, as with cancer from radiation or lung damage from air pollution, individuals may be understandably highly risk-averse.<sup>44</sup>

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42. See R. MERRILL & P. HUTT, *FOOD AND DRUG LAW: CASES AND MATERIALS* 2-7 (1980). On the Delaney clause, see Blank, *The Delaney Clause: Technical Naïveté and Scientific Advocacy in the Formulation of Public Health Policies*, 62 CALIF. L. REV. 1084 (1974).

43. See Merrill, *Book Review, Regulation of Toxic Chemicals*, 58 TEX. L. REV. 463, 474-76 (1980).

44. Moreover, individuals can be highly risk-averse to the chance of large losses, even though the probability of occurrence is slight, and are often willing to pay inordinate sums of money to eliminate such risks. "The fact is, most people are willing to pay excessive amounts of money to get rid of vagueness. Perhaps this is because they don't know how to cope with it rationally or purposively or perhaps the explanation is more purely emotion, the specific reasons are immaterial." I. RAIFFA, *DECISION ANALYSIS: INTRODUCTORY LECTURES ON CHOICES UNDER UNCERTAINTY* 159 (1970).

The reasons for such risk-averse behavior are unclear. They include historical explanations, see generally W. ROWE, *AN ANATOMY OF RISK* 263-64 (1977) (past accidents have sensitized us to the hazards of activities previously thought safe), and biological explanations, see Mole, *Accepting Risks for Other People*, 69 PROC. OF THE ROYAL SOC'Y OF MED. 15 (1976) (there may be an evolutionary advantage to special concern about catastrophic accidents). Studies of insurance reveal that a protective action that reduces the probability of a harm from one percent to zero is valued more highly than an action reducing the probability of the same harm from two percent to one percent. This result reflects a pseudocertainty hypothesis, whereby individuals seek security against risk, even if in fact the source of security is only the apparent elimination of the risk. See Tversky & Kahneman, *The Framing of Decision and the Psychology of Choice*, 211 SCI. 453 (1981).



The recombinant DNA controversy, however, which Shapo cites as one case study supporting his general analysis of public policy trends, provides an example of inappropriately minimal risk-averse behavior. Thus, even though the usual risk assessment experiments were not complete, or even underway, the National Institute of Health regulations allowed most recombinant DNA research to proceed.<sup>45</sup> These regulations are now being dismantled, although they are only a few years old.<sup>46</sup> Rather than focusing on the possible harm that might result from recombinant DNA research, those who proposed and evaluated further recombinant DNA research considered instead only the possibility of a research accident, concluding that "the chance of an accident . . . remains vanishingly small."<sup>47</sup> As a result, the regulators of recombinant DNA research tended to adopt only a minimally risk-averse stance.

The real problem with assessment of new risk-generating activities seems to be that dangers are being ignored by the risk-assessors because the dangers are difficult to perceive, as in the recombinant DNA case.<sup>48</sup> We tend to underestimate the likelihood of events that are hard to conceive, outside our normal experience even if conceivable, or lacking in memorability even if conceivable and within our experience.<sup>49</sup> In evaluating the hazards of complex systems, we generally tend to underestimate the probabilities of failure. Current psychological theory views man as a creature of bounded rationality with "limited computational ability and possessing limited information and limited imagination, seeking to survive in a world rich in complexity."<sup>50</sup> The need is for a mechanism to compensate for cognitive shortcomings and unrecognized or understated hazards. Instead, Shapo offers vague prescriptions for regulators to heed. Risk-aversion does not cut cleanly across the spectrum of scientific and technological activities. A method is

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Whatever the cause, inordinate risk-aversion to catastrophic results is indeed often part of the mental frame of individuals. See Epstein, *A Taste for Privacy: Evolution and the Emergence of a Naturalistic Ethic*, 9 J. L. STUD. 665 (1980).

45. See Letters from Philip Bereano to Dr. Donald Fredrickson (October 8, 1979, and December 18, 1979), reprinted in 5 NATIONAL INSTITUTES OF HEALTH, PUBLIC HEALTH SERVICE, U.S. DEPT. OF HEW, RECOMBINANT DNA RESEARCH: DOCUMENTS RELATING TO NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES, JANUARY 1979-JANUARY 1980 346-47, 532 (1980).

46. See Sun, *NIH Plan Relaxes Recombinant DNA Rules*, 213 SCI. 1482 (1981).

47. Holliday, *Should Genetic Engineers Be Contained?*, 73 NEW SCIENTIST 399, 401 (1977).

48. Tversky & Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 SCI. 1124, 1128 (1974).

49. *Id.*; Slovic, Fishoff & Lichtenstein, *Cognitive Processes and Societal Risk Taking*, in COGNITION AND SOCIAL BEHAVIOR 165 (J. Carroll & J. Payne eds. 1976).

50. Simon, *The Behavioral and Social Sciences*, 209 SCI. 72 (1980).

needed to generate and assess information that is useful in determining the need for a risk-neutral or risk-averse stance toward particular hazards.

Third, the supposed principle Shapo has extracted from his cases may have been based in large part on a "perception of the possibilities of public policy," in the words of Aaron Wildavsky.<sup>51</sup> We have come to expect more from regulation; we expect it to deal both with newly emerging hazards and with familiar ones that we are no longer willing to tolerate. Basing a principle of risk-aversion on such a perception is dangerous because the perception of the capabilities of public regulation can change. Indeed, it may be changing in light of the Reagan administration's actions and the new conventional wisdom that social regulation—actions affecting health, safety, and the environment—must yield to economic regulation and economic growth. Also, in some cases consumer perceptions of risk may not lead, through lobbying, constituency pressure, or direct petition, to direct agency regulation. Rather, agencies such as the Consumer Product Safety Commission may act in advance of individual or social perceptions of risk and thereby shape those perceptions.<sup>52</sup>

Even if we accept the notion that American society is now risk-averse, we still need a sophisticated understanding of the strengths and weaknesses of alternative regulatory approaches, whether public or private, to various hazards. Shapo provides a list of general principles, useful in summarizing a consensus regarding the general goals to be sought in regulation. Such a list, however, in the words of another reviewer, can "only facilitate judgments at the margin, the sort reflected in exhortations to legislators and regulators to heed the lessons of experience and improve their procedures."<sup>53</sup>

Shapo offers little assistance in designing regulatory responses to new chemical hazards or to emerging areas of scientific research. He has not placed his case studies, which are intended to justify a risk-averse regulatory posture, in the larger context of government regulation. Drug regulation, the source of most of his examples, represents a distinct category of hazards to which Congress has assigned a highly risk-averse position. But the larger context is that of uncertainty, including uncertainty about the allocation of burdens. Lawyers know that allocation of the burden of proof and persuasion is often dispositive of outcome. Drug regulation is a paradigm for a restrictive model in which proponents of a technology must produce data in support of

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51. Wildavsky, *Richer is Safer*, 60 PUB. INTEREST 23, 32 (1980).

52. See generally Okrent, *Comment on Societal Risk*, 208 SCI. 372 (1980).

53. Merrill, *supra* note 84, at 473.

safety before a product can be marketed. Insufficiency of data leads to agency disapproval of the drug.<sup>54</sup> This assignment of the burden of uncertainty represents an extreme stance in government regulation, not a prevalent and expanding one. Toxic-substances regulation, for example, is not based on this model, but rather on a compromise position of premarket notification.<sup>55</sup> Regulation of occupational hazards in the workplace, in accordance with the Supreme Court's decision in *Industrial Union Department, AFL-CIO v. American Petroleum Institute*,<sup>56</sup> places the burden of proof on the Occupational Health and Safety Administration to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to benzene presents a significant risk of material health impairment.<sup>57</sup> The National Environmental Protection Act imposes on the Environmental Protection Agency heavy burdens of production of evidence concerning environmental hazards.<sup>58</sup> The complexity of the burdens assigned to various agencies regulating a spectrum of activities suggests that Shapo sweeps too broadly and imprecisely in his statements about public policy.<sup>59</sup> Advocating a risk-averse position, without a more detailed discussion of the problem of burdens of proof, relative institutional capacities, and distinctions among classes of hazards, is like arguing against sin—such a position is fine but it lacks specificity as a guide to action. Shapo mentions a few legal mechanisms in passing, such as the proposed Science Court<sup>60</sup> and the expanding common law of public nuisance,<sup>61</sup> but few other significant alternatives are found in the book.

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54. Section 355(d) of the Food, Drug and Cosmetics Act provides that the Secretary can refuse to approve any new drug if industry fails to submit adequate safety tests. 21 U.S.C. § 355(d) (1976).

55. See 15 U.S.C. §§ 2601-2629 (1976). For a description of the compromise, see TOXIC TORTS: TORT ACTIONS FOR CANCER AND LUNG DISEASE DUE TO ENVIRONMENTAL POLLUTION 330, 333-35 (P. Rhemgold, N. Landau & M. Canavan eds. 1977).

56. 448 U.S. 607 (1980).

57. *Id.* at 653.

58. The National Environmental Protection Act (NEPA), 42 U.S.C. §§ 4321-4347 (1976), requires a cost-benefit analysis, according to the courts interpreting the statute. See *Calvert Cliff's Coordinating Comm. v. Atomic Energy Comm.*, 449 F.2d 1109 (D.C. Cir. 1971). NEPA thus imposes a heavy burden of study and documentation. See 42 U.S.C.A. § 4332(2)(A)-(C), (E) (1976).

59. For a particularly lucid presentation of the regulatory burdens of uncertainty and a spectrum of the requirements for cost-benefit analysis, see Rodgers, *Benefits, Costs, and Risks: Oversight of Health and Environmental Decisionmaking*, 4 HARV. ENV'T'L L. REV. 191 (1980). For a detailed study of a particular technology, nuclear power, see the carefully argued position in Yelkin, *High Technology and the Courts: Nuclear Power and the Need for Institutional Reform*, 94 HARV. L. REV. 489 (1981).

60. M. SHAPO, *supra* note 3, at 257.

61. *Id.* 259.

## III. CONCLUSION

*A Nation of Guinea Pigs* contains useful descriptions of the genesis and history of several significant regulatory problems. Unfortunately, Marshall Shapo fails to develop sufficiently several notions in the book, allowing himself to be sidetracked by a world of hazards for which the drug is the exemplar and the Food and Drug Administration is the paradigm regulator. His discussion of the scientific enterprise, in one of the most interesting chapters in the book, uses material from various nonlegal sources to outline for the nonscientist some of the forces that affect scientific work and the dynamics of the discovery process. He recognizes correctly that a lawyer must understand the characteristics of modern science because lawyers confront the results of science in attempting to understand the risks and implications of research and in evaluating the opinions of technical experts in areas ranging from environmental law to malpractice litigation. Knowing how scientists think and work is essential for lawyers. Such knowledge enables them to evaluate scientific hazards accurately, even through the filter of scientific tests and opinion. From a lawyer's viewpoint, the increasing interaction between law and science suggests that the study of science should be an essential task for lawyers and regulators in the future.<sup>62</sup> An elaboration of chapters one and eight would have provided a useful monograph on the regulation of science, leaving the remainder of the book (except chapter seven) to discuss lessons to be learned from food and drug regulation. Given Shapo's failure to weave together the separate threads he raises into a coherent theory of legal control of scientific endeavor, one must conclude that *A Nation of Guinea Pigs* does not achieve its stated goal.

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62. See Graff, Book Review, 93 HARV. L. REV. 282, 287-88 (1979). See also Markey, *Science and Law—Toward a Happier Marriage*, 59 J. PAT. OFF. SOC. 343 (1977).

