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INTRODUCTION

Just as laws may create entitlements to the use of information, they may also be written to distribute information and to encourage information production. This Article discusses the ways in which law affects the generation and distribution of information related to chemical exposure and toxicity.[1] It describes the economic impact of recently enacted right-to-know laws[2] and proposes that better and

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1. Petroleum byproducts and derivatives, synthetic organic chemicals, and inorganic chemicals, including asbestos and heavy metals, are the categories of substances that pose the greatest risks to health through occupational and environmental exposures. *See* Schroeder, *A Decade of Change in Regulating the Chemical Industry,* 46 LAW & CONTEMP. PROBS. 1, 4-9 (Summer 1983). The manufacturing sector of the economy is the source of the bulk of the chemicals introduced into the workplace, the environment, and consumer products. For example, OSHA has determined that the manufacturing sector employs almost one third of the nation's workers, but accounts for one half of chemically related occupational disease. 48 Fed. Reg. 53,285 (1983). The industries within the manufacturing sector that are of the greatest concern are petroleum firms and chemical producers. The term "chemical" will be used generically in this Article to indicate both the products and wastes of these industries.

2. Federal law requiring dissemination of toxicity data for chemicals used in industry is contained primarily in two sources: (1) the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), 42 U.S.C. § 1101 (Supp. IV 1986), which was enacted as Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA); and (2) the OSHA Hazard Communication Standard, 29 C.F.R. § 1910.1200 (1987). The EPA is currently completing regulations mandated by SARA. 52 Fed. Reg. 38,344 (1987) (to be codified at 40 C.F.R. § 370); *see also* M. KRIZ, CHEMICALS AND THE COMMUNITY: NEW LAW, NEW RESPONSIBILITIES (1987).

Earlier federal environmental and consumer protection statutes contain a variety of more limited disclosure requirements. The EPA was directed by the Resources Conservation Recovery Act, 42 U.S.C. § 6901 (1982), to establish a hazardous waste management system which includes a manifest system. In addition, pesticides must be labeled with their active ingredients and a registration number, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 (1982). Products regulated pursuant to the Federal Food, Drug, and Cosmetic Act must be labeled with their ingredients. 21 U.S.C. § 301 (1982). The Consumer Product Safety Act, 15 U.S.C. § 2051 (1982), authorizes the Consumer Product Safety Commission (CPSC) to promulgate labeling requirements. Labeling of hazardous materials in transit has been required by the U.S. Department of Transportation pursuant to the Hazardous Materials Transportation Act of 1974, 49 U.S.C. app. § 1801 (1982).

Right-to-know laws adopt a more aggressive approach to the use of information than the earlier statutes. They reach a broader segment of the population and require disclosure of all

more abundant data could be produced if the law paid greater attention to basic economic principles that influence research and information systems.

Toxicity information is necessary for intelligent private choices, as well as for the protection of public health. Yet the manufacturers and industrial users of commercial chemicals have little incentive to produce and distribute data about chemicals' adverse side effects and, indeed, even the identity of these chemicals. Because generic product trade names have been substituted in the public domain for more specific and informative chemical names,[3] it has been difficult for those who use chemicals, or for third parties, to undertake the task of data collection. As a result, the nature and extent of human exposure to chemicals have been masked.

The relative invisibility of chemicals hampers the market's ability to screen chemicals for toxicity and has hindered the development of chemical information services. The lack of data has also handicapped the scientific study of the health and environmental effects of industrial chemicals; and it has profoundly affected the law's attempt to deter and to compensate for chemical harms.[4]

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known health effects of a chemical, an advance on the ingredient labeling approach that evolved in the 1970s.

This Article uses the term "right-to-know law" to include the rules contained in the OSHA Hazard Communication Standard. The two names may be read as having distinct conceptual roots and very different implications which are not explored in this Article. *See generally* Baram, *The Right to Know and the Duty to Disclose Hazard Information,* 74 AM. J. PUB. HEALTH 385 (1984); Note, *A Duty to Warn, A Right to Know:* Odgers v. Ortho Pharmaceutical Corporation, 1986 DET. C. L. REV. 163; Note, *Occupational Health Risks and the Worker's Right to Know,* 90 YALE L.J. 1792 (1981) (making efficiency and normative arguments for the worker's right to know).

3. Familiar consumer products such as Windex, Fantastic, and Drano are examples of chemical mixtures whose ingredients are unknown to their users. Commercial users of chemicals also rely on trade names. The lack of more specific information abut these products can lead to their misuse and hinder medical treatment of persons injured by exposure. *See infra* notes 40-41, 49.

4. There is an extensive literature on proposals for use of market incentives to reduce pollution. The lack of adequate toxicity data has been a recurring theme; but for the most part, commentators have accepted the current lack of data as a part of the regulatory landscape and worked around it. Two important exceptions are Schroeder & Shapiro, *Responses to Occupational Disease: The Role of Markets, Regulation, and Information,* 72 GEO. L.J. 1231 (1984) (identifying lack of information as a key element in the failure to protect workers from occupational disease), and Latin, *Environmental Deregulation and Consumer Decisionmaking Under Uncertainty,* 6 HARV. ENVTL. L. REV. 187 (1982) (emphasizing that sound environmental decisionmaking requires extensive data not produced by an unregulated market) [hereinafter Latin, *Environmental Uncertainty*]. *See also* Portney, *Toxic Substance Policy and the Protection of Human Health,* in CURRENT ISSUES IN U.S. ENVIRONMENTAL POLICY 105 (1978) (proposing limited measures to cope with disincentives to information production).

The main focus of scholarly discussion has been whether and how to apply market incentives, as opposed to "command and control" technology-based standards, to the control of pollution. *See, e.g.,* Latin, *Ideal Versus Real Regulatory Efficiency: Implementation of Uniform Standards and "Fine-Tuning" Regulatory Reforms,* 37 STAN. L. REV. 1267 (1985); Ackerman & Stewart, *Reforming Environmental Law,* 37 STAN. L. REV. 1333 (1985) (commenting on Latin); Stewart, *Economics, Environment, and the Limits of Legal Control,* 9 HARV. ENVTL. L. REV. 1 (1985);

Attempts to remedy the problem have, for the most part, consisted of complex statutory schemes which empower administrative agencies to control various forms of pollution. A central challenge for regulators has been to strike an appropriate balance between the costs and benefits of regulation. As risk assessment has assumed a more central role in chemical regulation, uncertainty about chemicals' actual health effects has become a dominant theme in the debate over whether, as a society, we are spending too much or too little on pollution control.[5] Some of this uncertainty results from the slow evolution of toxicology and the complexity of toxicology's findings; additionally, of course, some uncertainty is inherent in the characteristics of chemical commerce and consumption. However, not all of the uncertainty is so intractable; improved production and dissemination of toxicological data would go far to alleviate this problem. In a system such as ours, which has increasingly relied upon health effects data to legitimize controls, information strategies should be a central concern.

The 1980s have seen the emergence of right-to-know laws and the Hazard Communication Standard of the Occupational Safety and Health Administration (OSHA). These laws trace their jurisprudential roots to the doctrine of informed consent and utilize the economic principles incorporated in consumer protection regulation. They attempt to make better use of existing data by requiring its distribution to chemical purchasers and workers, to local government officials, and, under some circumstances, to the general public. This new availability of data should facilitate market mechanisms for differentiating among the toxicity levels of different chemicals. But while right-to-know laws are an important advance in regulation, their accomplishments are likely to be limited, since they cover only a small proportion of the relevant universe of chemicals in use. Moreover, the legal context in which they operate often works at cross purposes with information dynamics.

The analysis presented here suggests that the law can move beyond

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Stewart, *Regulation, Innovation, and Administrative Law: A Conceptual Framework*, 69 CALIF. L. REV. 1256 (1981) [hereinafter Stewart, *Regulation, Innovation, and Administrative Law*].

5. *See, e.g., In re* "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740, 777-82 (E.D.N.Y. 1984) (discussing "[t]he distinction between avoidance of risk through regulation and compensation for injuries after the fact"); Crandall & Lave, *Introduction and Summary*, in THE SCIENTIFIC BASIS OF HEALTH AND SAFETY REGULATION 3-5 (1981); Samuels, *The Uncertainty Factor*, in MANAGEMENT OF ASSESSED RISK FOR CARCINOGENS 269 (W. Nicholson ed. 1981) [hereinafter MANAGEMENT OF ASSESSED RISK]; Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277 (1985); Latin, *Environmental Uncertainty, supra* note 4; Schwartz, *Product Liability, Corporate Structure, and Bankruptcy: Toxic Substances and the Remote Risk Relationship*, 14 J. LEG. STUD. 689 (1985); Shavell, *Uncertainty Over Causation and the Determination of Civil Liability*, 28 J. L. & ECON. 587 (1985).

disclosure provisions to become more fundamentally attuned to the nature of the informational problem that underlies the regulatory cost-benefit dilemma. If we think of information in a more explicitly economic framework, new options for the production and use of data begin to appear, including the intriguing possibility of a more robust private market for toxicology. The legal system can be structured to respond more fully to the possibilities of research and development in this area.

Several developments support taking a fresh look at the problem. Toxicology, computer science, and information management science have matured considerably in the past two decades.[6] We can now produce more information about toxicity and manage the data much more effectively than we could in the early 1970s, when the environmental regulatory scheme was first established. New environmental technologies and service professions have evolved, and the short history of environmental regulation has provided experience with a variety of legal rules and systems. These conditions pave the way for a more focused information strategy for toxics regulation.[7]

Basic work in the economics of information provides us with some tools with which to analyze the nature and behavior of data related to chemicals.[8] Economists have produced an extensive literature on the role of information in the market, examining the ways in which asymmetries of information affect market structure and product quality. They have also described market responses to these asymmetries, including information pooling, advertising, and the development of third-party providers of information. This Article draws on this work to describe the ways in which toxicity and exposure data are used,

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6. *See, e.g.*, H. PAGELS, THE DREAMS OF REASON — THE COMPUTER AND THE RISE OF THE SCIENCES OF COMPLEXITY (1988); Langevoort, *Information Technology and the Structure of Securities Regulation*, 98 HARV. L. REV. 747 (1985) (elaborating on the impact and opportunities of computer technology in securities regulation).

7. *See* 1 M. PORAT, THE INFORMATION ECONOMY: DEFINITION AND MANAGEMENT 8 (1977):

> As information technologies "invade" various sectors of the economy, old arrangements may come into conflict with the new. Applications of the new technologies may raise either economic issues or value conflicts that previously lay dormant. The seeds of tomorrow's opportunities and difficulties are sown today. And therein lies the presumption that information policy should adopt a prospective look at future applications of information technology.

8. *See* Joskow & Noll, *Regulation in Theory and Practice: An Overview*, in STUDIES IN PUBLIC REGULATION 1 (G. Fromm ed. 1981); R. BARTLETT & U. APTE, INFORMATION, UNCERTAINTY AND REGULATION IN ATTACKING REGULATORY PROBLEMS — AN AGENDA FOR RESEARCH IN THE 1980'S 19-39 (1981); F. THOMPSON & L. JONES, REGULATORY POLICY AND PRACTICES: REGULATING BETTER AND REGULATING BEST 67-84 (1982); THE REGULATION GAME: HOW BRITISH AND WEST GERMAN COMPANIES BARGAIN WITH GOVERNMENT 12-13 (A. Peacock ed. 1984); Simon, *Rational Decision Making in Business Organizations*, 69 AM. ECON. REV. 493 (1979).

both in the market and in the legal system, and to explore ways in which the law could concern itself with information in order to encourage optimal investments in chemical safety.

Part I describes the multiple uses of toxicity and exposure data. The information can have value to many agents in the economy, in the sciences, and in the law, since its production and distribution reduce a variety of costs to individuals, firms, and government. This is data that saves lives and reduces liability by making possible the prevention and treatment of disease related to chemical exposure.

Part II addresses the market's failure to produce toxicity and exposure data. It identifies the reasons for the lack of data and discusses the effects of this problem on the market for chemicals. Part III describes the effect the law has had on information production. It suggests that tort liability, administrative exposure standards, and reporting requirements do not correct the market failure and may, in fact, aggravate it. Direct government investment in data production has been the most effective response, but this effort has not been substantial enough to cope with the numbers of chemicals that merit study.

Part IV describes right-to-know laws. It suggests that, since the permutations of the many chemicals in use and the types and combinations of human exposures cannot be screened adequately by a central agency, polycentric decisionmaking is a logical development in toxics control. Part V proposes to expand and improve data production with funding and planning modeled upon the Superfund and national contingency plan approach, now used for hazardous waste cleanup. Linking public research costs to their private economic origins and opening up the possibilities for independent research could encourage cost avoidance by the producers of chemical products. Part VI suggests that toxicity data collection and management should be conducted according to principles that will foster an accessible national data system, one which would be a resource analogous to a utility or common carrier service.

The Article concludes, in Part VII, with some observations on the functions of information in toxics control and the confusion that prevails in the existing statutory scheme.

I. The Uses of Toxicity and Exposure Data

Worldwide production of organic chemicals rose from 7 million metric tons in 1950 to about 250 million metric tons in 1985.[9] Many

9. UNEP, *Chemicals in International Trade,* 17 Envtl. Poly. & L. 66 (1987). Production

of today's chemicals did not exist a decade or two ago, but are now pervasive in the environment.[10] In the United States, chemicals are handled in every sector of the economy and in every home.[11] They are discharged into the environment in every medium,[12] and chemical ac-

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of synthetic organic chemicals in the United States rose from 1.3 billion pounds in 1940 to 320 billion pounds in 1978. R. NADER, R. BROWNSTEIN & J. RICHARD, WHO'S POISONING AMERICA 5 (1981). A presidential panel reported a 581% increase in production of synthetic organic chemical products between 1949 and 1969. Production of raw materials and intermediates rose 1150% in the same period. Panel on Chemicals and Health, President's Science Advisory Committee, CHEMICALS AND HEALTH 78 (1973) [hereinafter CHEMICALS AND HEALTH]. The panel calculated that the total amount of manufactured consumer organic chemicals was 500 lbs. per capita. *Id.* at 27. Figures quoted by F.D. Hoerger, of the Dow Chemical Company, are somewhat different: an increase in U.S. production of synthetic organic chemicals from 4 billion pounds in 1940 to 228 billion pounds in 1979. Hoerger, *Indicators of Exposure Trends,* in BANBURY REPORT 9: QUANTIFICATION OF OCCUPATIONAL CANCER 435, 438 (1981) [hereinafter BANBURY REPORT 9]. *See also* Schroeder, *supra* note 1. However, aggregate production figures may sometimes be misleading because chemicals do not all have the same health impacts. Nor does the number of chemicals indicate the extent of human exposure. Seventy percent of all chemicals in production in the United States have annual production volumes of less than 100,000 pounds. Hoerger, *supra,* at 440.

10. Figures vary on the number of chemicals now in use. In 1983, OSHA estimated that as many as 575,000 chemical products might be in use, with hundreds of new ones introduced annually. 48 Fed. Reg. 53,323 (1983). Pursuant to the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 (1982), the EPA reports that nearly 66,000 commercial chemical substances have been identified by manufacturers or importers since 1975. *See* U.S. ENVTL. PROTECTION AGENCY, TOXIC SUBSTANCES CONTROL ACT (TSCA): REPORT TO CONGRESS FOR FISCAL YEAR 1986, at 4 (1987) [hereinafter TSCA 1986 REPORT]; OFFICE OF TOXIC SUBSTANCES, U.S. ENVTL. PROTECTION AGENCY, THE LAYMAN'S GUIDE TO THE TOXIC SUBSTANCES CONTROL ACT 6 (1987) (EPA 560/1-87-011) [hereinafter LAYMAN'S GUIDE]. The National Research Council has estimated that there are 65,725 substances currently in use that are of possible toxicological concern. NATIONAL RESEARCH COUNCIL, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES (1984) [hereinafter TOXICITY TESTING].

11. The average household uses a wide variety of hazardous substances, often as ingredients of such products as toilet bowl cleaners, fabric softeners, spot removers, bleach, disinfectants, polishes, and paint removers. M. GREENBERG & R. ANDERSON, HAZARDOUS WASTE SITES 4 (1984).

EPA's five-year Total Exposure Assessment Methodology (TEAM) study of personal exposures has identified consumer products in the home as a potentially greater source of toxic exposure to volatile chemicals than outdoor sources. *EPA Air Toxics Study Turns Up Surprises,* COMMUNITY RIGHT-TO-KNOW NEWS, Sept. 22, 1987, at 7-8. EPA has suggested that "[i]t seems probable that consumer products (paints, cleaners, propellants, plastics, cosmetics, etc.) and building materials (adhesives, fixers, resins, insulation, etc.) comprise the major source categories of exposure." *Id.* Davis, Bridbord & Schneiderman report, in *Estimating Cancer Causes: Problems in Methodology, Production, and Trends,* in BANBURY REPORT 9, *supra* note 9, at 285, 296, report that it is difficult for epidemiologists to identify control groups that have had no exposure.

12. Estimates of annual discharges into the environment are staggeringly high, but imprecise. The Office of Technology Assessment (OTA) recently found that, of 184 million metric tons of air pollution emitted in the United States in 1984, between 4.5 and 24.7 million metric tons may have been hazardous chemicals, although no national data are available. Water quality data for conventional and toxic pollutants do not indicate what is being discharged, only what industries are permitted to discharge. Earlier OTA research determined that between 255 to 275 million metric tons of hazardous waste are generated annually — about one ton per citizen. OFFICE OF TECHNOLOGICAL ASSESSMENT, SERIOUS REDUCTION OF HAZARDOUS WASTE 152 (1986). *See also* CONGRESSIONAL QUARTERLY, ENVIRONMENT AND HEALTH (1981); *infra* note 214, concerning the new national inventory of toxic discharges being compiled by the EPA pursuant to the EPCRA.

cidents or "sudden uncontrolled releases" have become commonplace.[13] As production has burgeoned, new chemical measurement technologies have revealed the presence of small amounts of toxic and potentially toxic substances throughout the environment and population.[14] For example, numerous suspected carcinogens are found in urban air and drinking water.[15] In addition, chemical exposures have been linked to numerous diseases besides cancer.[16]

Two characteristics of many chemical-related diseases shape the basic informational issues in toxicity regulation. First, it appears that many diseases may be caused by more than one kind of exposure; relatively few marker or signature symptoms have been identified to connect particular diseases with particular chemicals. Moreover, people vary in their susceptibility and their exposure history, although most people are now exposed to a variety of chemicals. Second, when low-level exposures cause a disease, the effect is often not apparent for

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13. *See* R. Abrams, Toxic Chemical Accidents in New York State: The Risk of Another Bhopal 2, A-5 to A-6 (1986) (unpublished report by N.Y. Attorney General citing an average of five reported accidents in that state each week from January 1983 through November 1985, many involving large companies); T. WHITESIDE, THE PENDULUM AND THE TOXIC CLOUD — THE COURSE OF DIOXIN CONTAMINATION (1979).

14. *E.g., Damaged Wildlife Shows Pollution Still Plagues Great Lakes,* N.Y. Times, July 12, 1988, at C4, col. 1.

15. David P. Rall, Director of the National Institute for Environmental Health Sciences, reported in 1979 that "it appears probable that the United States population is exposed to low concentrations of many different carcinogens, and that the summation of many low-level chemical insults yields the current 16-percent death rate from cancer." Rall, *Validity of Extrapolation of Results of Animal Studies to Man,* in PUBLIC CONTROL OF ENVIRONMENTAL HEALTH HAZARDS 85, 91 (E. Hammond & I. Selikoff eds. 1979). *But see* Peto, *Distorting the Epidemiology of Cancer: The Need for a More Balanced Overview,* 284 NATURE 297 (Mar. 27, 1980).

16. Cancer is the second most common cause of death in the United States. In 1983, more than 440,000 Americans died of cancer. NATIONAL TOXICOLOGY PROGRAM, U.S. DEPT. OF HEALTH & HUMAN SERVS., PUBLIC HEALTH SERV., FOURTH ANNUAL REPORT ON CARCINOGENS 5 (1985) [hereinafter FOURTH ANNUAL REPORT ON CARCINOGENS]. A high percentage of cancers are now thought to be caused by "environmental factors," but the term "environment" in this context means "anything that interacts with humans, including substances eaten, drunk, and smoked, natural and medical radiation, workplace exposures, drugs, aspects of sexual behavior and substances in air, water, and soil." *Id.* The FOURTH ANNUAL REPORT ON CARCINOGENS, *supra,* listed 148 carcinogenic agents; of these, 113 were industrial products or occupational exposures, including 13 pesticides, 33 industrial chemicals and by-products, 20 dyes and pigments, 14 combustion products, 7 solvents, 6 metals, and 6 analytical and research chemicals. *Id.* at 3-4.

Suspected carcinogens comprise a much larger group, but the bases of suspicion vary with the data and the authors of the estimates. The National Institute of Occupational Safety and Health (NIOSH) is charged with the responsibility of listing toxic substances. 29 U.S.C. §§ 669(a)(16), 669(e), 671 (1982). In 1973, NIOSH listed more than 25,000 entries, involving 11,000 different substances. More than 2,400 of these were identified as suspected carcinogens. NATIONAL INST. FOR OCCUPATIONAL SAFETY & HEALTH, U.S. DEPT. OF HEALTH, EDUC., & WELFARE, SUSPECTED CARCINOGENS: A SUBFILE OF THE NIOSH REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES ix (2d ed. 1976). Other lists of suspected carcinogens have also been prepared and these vary greatly in length. In addition, while cancer has been the disease of greatest public concern, chemical exposures have been linked to other types of health damage, including acute toxic effects and neurological problems. *See infra* notes 40-41, 49.

some time. Indeed, some diseases, such as cancer, have latency periods of several decades. Consequently, the individual causal event often passes unnoticed or is, in fact, a series of exposures which are relatively unremarkable in themselves.

Scientists approach the problem by developing statistical estimates of the likelihood of causal connections between a chemical and a disease. They gather data from human populations exposed to a chemical, particularly in the workplace, to produce epidemiological studies, and they subject living cells and animals to exposures in controlled laboratory tests. Animal studies are commonly called bioassays. Toxicity data can then be used to estimate the health risks posed to broader human populations exposed to the same chemical.[17]

Both toxicity and exposure data are basic components of health risk assessments.[18] The supply of this information guides the course of research and chemical regulation and its scarcity shapes the entire system. This health data is also used in medical treatment and research, government planning and regulation, insurance, industrial hygiene, and corporate product development and production. Data is accumulating and our understanding of the biological mechanisms at work in disease is growing. However, research on chemical health effects has not kept pace with chemical production and dissemination.

In 1984, the National Research Council of the National Academy of Sciences issued a report, *Toxicity Testing — Strategies to Determine Needs and Priorities,*[19] evaluating the nation's need for information on chemical exposure and its health effects. The Council determined that, for the great majority of chemicals, information essential for hazard assessment is lacking. Of the chemicals sampled by the Council, there were adequate data to make a full risk assessment of only 10% of pesticides, 2% of cosmetic ingredients, 5% of food additives, and 18% of drug ingredients.[20] For a higher percentage of these materials there

17. *See, e.g.,* NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983); Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment,* 5 YALE J. REG. 89 (1988). *See infra* notes 56-60 and accompanying text.

18. COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, COMMN. ON LIFE SCIENCES, NATL. RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 19-20 (1983) [hereinafter RISK ASSESSMENT IN THE FEDERAL GOVERNMENT].

19. *See* TOXICITY TESTING, *supra* note 10, at ix, 19.

20. *See id.* at 12. The study first identified a "select universe" consisting of 65,725 substances that are of possible concern to the National Toxicology Program because of their potential for human exposure. *Id.* at 33. Through a random sampling process, it then selected a subset of 675 substances covering seven categories. *Id.* at 43-44. These were (1) pesticides and inert ingredients; (2) cosmetic ingredients; (3) drugs and excipients; (4) food additives, and three groups of chemicals in commerce: (5) those produced in quantities of one million pounds per year or more; (6) those produced in quantities of fewer than one million pounds per year; and (7) those chemi-

were at least minimal data available upon which a limited assessment could be made: 15% for food additives, 21% for drugs, 24% for cosmetics, and 26% for pesticides.[21] Most striking was the Council's conclusion that no information at all is available on the toxicity of approximately 80% of the 48,000 chemical substances in general commercial use. The Council concluded, "Although it can be convincingly argued that many chemicals do not need to be tested, because of their low potential for human exposure or for toxic activity, it is clear that thousands or even tens of thousands of chemicals are legitimate candidates for toxicity testing related to a variety of health effects."[22]

The need for exposure data is also quite acute. The most basic exposure data generally have been unavailable or unassembled.[23] In *Toxicity Testing,* the National Research Council emphasized that the shortage of exposure data is an obstacle to producing adequate toxicity

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cals for which production quantities were unknown. *Id.* at 38. The seventh category (for which there was no information regarding production quantity) was almost as large as categories (5) and (6) combined. A subsample of 100 chemicals, about which there was at least some minimal toxicity information, was selected and examined in depth to determine the availability of toxicity information. *Id.* at 43-50.

Another source estimates that fewer than 1% of the chemicals in routine use have been partially tested and that synergisms are virtually ignored. F. THOMPSON & L. JONES, *supra* note 8, at 213. The inadequacy of available data is routinely acknowledged by government agencies as a condition of and a constraint on regulation. *See, e.g.,* OSHA's Hazard Communication Standards, 29 C.F.R. § 1910.1200, app. A (1988).

21. *See* TOXICITY TESTING, *supra* note 10, at 12; CHEMICALS AND HEALTH, *supra* note 9, at 87-100.

The differences in data supply for drugs, pesticides, and "chemicals in commerce" reflect different legal requirements for testing of these groups of chemicals. 21 U.S.C. §§ 301, 342(a), 348, 355 (1982) (food, drugs, and cosmetics) and 7 U.S.C. § 136 (1982) (pesticides) require *ex ante* testing, while the toxics provisions of environmental and occupational health statutes do not. *See infra* text accompanying notes 87-92 (comparing and explaining *ex ante* and *ex post* regulation).

22. TOXICITY TESTING, *supra* note 10, at 14. The report did not specifically address the further problem of identifying effects of exposure to multiple pollutants or to mixtures of pollutants, though the state of present knowledge of cumulative and subadditive effects is quite limited. *See* F. THOMPSON & L. JONES, *supra* note 8, at 213.

23. TOXICITY TESTING, *supra* note 10, at 13, 16, 51-53, 73, 123-24. The National Toxicology Program publishes an annual report to Congress on carcinogens and exposure to them. In 1985, it stated:

> Several problems are encountered in developing the information required for the Annual Reports on Carcinogens. Estimating the number of people potentially exposed to a substance and identifying the nature, route, and intensity of this potential exposure are difficult tasks. It is often impossible to obtain accurate production volume and use patterns for most chemicals.

FOURTH ANNUAL REPORT ON CARCINOGENS, *supra* note 16, at 1.

Potential exposure data have generally been drawn from publicly available descriptions of manufacturing processes, general industrial literature, and more recently, reports to regulatory agencies. *See, e.g.,* P. BARTH & H. HUNT, WORKERS' COMPENSATION AND WORK RELATED ILLNESSES AND DISEASES 55-60 (1980) (detailing the very rough estimates of exposure relied upon by OSHA). Employment duration and job categories are also used as rough measures of exposure. *See* Landrigan, Melius, Rinsky & Thum, *Approaches to the Estimation of Exposure in Occupational Epidemiology,* in BANBURY REPORT 19: RISK QUANTIFICATION AND REGULATORY POLICY 65 (1985).

assessments.[24] The report concluded: "In view of the great importance of exposure data and indexes of hazard assessment and the nearly complete absence of such data, the committees recommend that planning begin for the development of much more extensive, detailed, and accurate data bases than now exist for exposure assessments."[25]

Current data describing which chemicals are being used and where they are being used often support only rough estimates.[26] Epidemiologists have repeatedly called for improved linkage of databases and records to facilitate exposure estimates.[27] An essential part of such linkage is the distribution of chemical identity data.[28]

Identification of chemical substances is a precondition to effective study of toxics.[29] Chemicals may be closely related in structure and

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24. TOXICITY TESTING, *supra* note 10, at 124. Several committees of the National Academy of Sciences, as well as other health agencies that have surveyed the problem of inadequate toxicity data, have reached a similar conclusion. *See, e.g.*, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 18, at 150; FOURTH ANNUAL REPORT ON CARCINOGENS, *supra* note 16, at 1-2; INST. OF MEDICINE, NATL. ACADEMY OF SCIENCES, COSTS OF ENVIRONMENT-RELATED HEALTH EFFECTS: A PLAN FOR CONTINUING STUDY 50 (1981) [hereinafter COSTS STUDY]; CHEMICALS AND HEALTH, *supra* note 9, at 1-2.

25. TOXICITY TESTING, *supra* note 10, at 124.

26. *See* U.S. EPA Guidelines for Estimating Exposures, 51 Fed. Reg. 34,042, 34,046 (1986) [hereinafter Estimating Exposures]; TOXICITY TESTING, *supra* note 10, at 123. Several kinds of information that would be useful in developing exposure data are unavailable. There are great variations in the quantities of chemicals produced and the context in which they are used. Some have short lifespans in the market (the average is five years). CHEMICALS AND HEALTH, *supra* note 9, at 108. Many are produced in limited quantities, reducing extended exposure but also making it difficult to determine toxic effects. Seventy-five percent of all chemicals in production in the United States have annual production volumes of less than 100,000 pounds. LYNDON B. JOHNSON SCHOOL OF PUBLIC AFFAIRS, POLICY RESEARCH PROJECT NO. 50, THE TOXIC SUBSTANCES CONTROL ACT: OVERVIEW AND EVALUATION 121 (1982) [hereinafter TSCA: OVERVIEW AND EVALUATION]; *see also* Hoerger, *supra* note 9, at 439-40. Annual production volume figures are not available for many chemicals in commercial use. There is also a great variation in the numbers of people who are exposed to each chemical, the forms of exposure, and the reactions to exposure. CHEMICALS AND HEALTH, *supra* note 9, at 27-28.

The National Research Council's exposure estimates for food, drugs, cosmetics, and pesticides were based on the intended uses of the products. The Council based its environmental and occupational exposure estimates on "production volumes, environmental fate, and disposal data," but found that "few data of these types were available." TOXICITY TESTING, *supra* note 10, at 73.

27. Where possible chemical exposures are known, the epidemiological study can proceed to identify the possible effects from this exposure:

> [W]e have found that it is far more efficient and useful to approach the problem from the point of view of exposure. Hence, the name of the game is to first answer the question "To what chemicals are members of the population exposed?" and only after this has been answered, go on to the question of "What effects might we expect from such exposure?". Searching for exposures to chemicals of known toxicity may be more dramatic and more fun but, in the long run, it is less profitable.

Fisher, *Information Required for Decision Making: Early Warning and Forecasting*, in SYMPOSIUM ON THE HANDLING OF TOXICOLOGICAL INFORMATION 148, 149 (1976).

28. *See infra* Part IV.

29. Chemical identity is the starting point for any activity that evaluates chemical health effects. *See, e.g.*, Estimating Exposures, *supra* note 26, at 34,042, 34,046; U.S. DEPT. OF HEALTH & HUMAN SERVS., NATIONAL TOXICOLOGY PROGRAM: REVIEW OF CURRENT DHHS, DOE,

yet have very different health impacts.[30] For instance, benzene and toluene are very similar in molecular structure, but only benzene has been shown to cause leukemia in humans. Disclosure of chemical identity is the starting point for establishing the fact of exposure and determining and preventing adverse effects.

Recognizing the need to identify and study chemicals' health impact, Congress enacted the Toxic Substances Control Act (TSCA) in 1976.[31] The TSCA directs the Environmental Protection Agency (EPA) to maintain an inventory of all chemicals in use and to screen new chemicals for risks before they enter the environment. In 1978, the National Toxicology Program (NTP) was established within the Department of Health and Human Services to coordinate federal toxicological research.[32] And in 1980, the Agency for Toxic Substances Disease Registry (ATSDR) was mandated by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) to manage data related to hazardous waste sites.[33] Additional authority and appropriations for study are scattered throughout the statutory scheme, but these legislative responses, discussed more fully below, have not produced data at a satisfactory rate.

While the government and the private sector produce data, the management and distribution expenditures of both are difficult to quantify.[34] In fiscal year 1987, the federal government allocated $210

AND EPA RESEARCH RELATED TO TOXICOLOGY, FISCAL YEAR 1987 (toxicology testing organized by chemical name and CAS number) [hereinafter NATIONAL TOXICOLOGY PROGRAM: REVIEW]; TOXICITY TESTING, *supra* note 10, at 185, 191; OSHA Proposed Hazard Communication Rules, 47 Fed. Reg. 12,092, 12,105 (1982) (to be codified at 29 C.F.R. § 1910) (proposed Mar. 19, 1982) (identity information is an essential element in a hazard communication system).

Collection and coordination of data is an increasingly important dimension of regulation, *see infra* text accompanying note 171. Several toxics data coordination schemes, including the Interagency Toxic Substances Data Committee and the Chemical Substances Information Network, are described in LAYMAN'S GUIDE, *supra* note 10, at 9. *See also* COSTS STUDY, *supra* note 24, at 37-38 (describing federal information systems and data related to environmental hazards and human exposure); TOXIC CHEMICALS AND PUBLIC PROTECTION: A REPORT TO THE PRESIDENT BY THE TOXIC SUBSTANCES STRATEGY COMMITTEE 21-33 (1980) [hereinafter TOXIC CHEMICALS AND PUBLIC PROTECTION].

30. TSCA: OVERVIEW AND EVALUATION, *supra* note 26, at 47-48.

31. 15 U.S.C. § 2601 (1982).

32. U.S. DEPT. OF HEALTH & HUMAN SERVS., NATIONAL TOXICOLOGICAL PROGRAM: FISCAL YEAR 1987 ANNUAL PLAN 1 (1987). *See generally* NATIONAL TOXICOLOGY PROGRAM: REVIEW, *supra* note 29.

33. 42 U.S.C. §§ 9061, 9064(i) (1982). The agency began to operate only in 1983.

34. NATIONAL TOXICOLOGY PROGRAM: REVIEW, *supra* note 29, at 4, reports that $156 million was allocated to chemical testing and $54 million to toxicological methods development. In 1980, the NTP budget was $65.7 million and in 1988 it was $79.1 million (or $48 million in 1980 dollars). For fiscal year 1972, the President's Science Advisory Committee reported that the federal effort in environmental health research amounted to $98 million, not counting research on biological disease agents and on ionizing and electromagnetic radiation. CHEMICALS AND HEALTH, *supra* note 9, at 88.

State spending on scientific research in general is considerably less than federal spending. In

million for toxicological research, but in real dollars, the budget for chemical testing was smaller than the 1980 budget.[35] The benefits of these expenditures are limited further by the fact that most government data management has been conducted within individual agencies with limited data distribution.[36] Figures on private research expenditures are hard to come by, and the National Research Council found little private data available to assist it in preparing its 1984 report.[37] Moreover, much private data held by the government is treated as confidential and was not released to the Council.[38] The Council noted that this private data, therefore, "did not exist" for purposes of toxicity screening.[39]

Present levels of data production are insufficient to meet the needs of a variety of uses. For instance, because of the absence of information about chemical exposures that might otherwise explain symptoms, doctors may have to use risky or harmful diagnostic procedures and remedies. Dr. James Robins, of the Harvard School of Public Health, has described examples of the difficulties faced by occupational health professionals in treating their patients:

> I saw a worker with severe progressive lung disease . . . caused by beryllium metal or a non-work-related disease called sarcoidosis. If beryllium

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fiscal year 1977, the states together spent $600 million on all research and development; federal expenditures were more than $20 billion. NATIONAL SCIENCE FOUNDATION, RESEARCH AND DEVELOPMENT IN STATE AND LOCAL GOVERNMENTS, FISCAL YEAR 1977, DETAILED STATISTICAL TABLES 1 (1978); U.S. OFFICE OF MANAGEMENT AND BUDGET, SPECIAL ANALYSES: BUDGET OF THE UNITED STATES GOVERNMENT 1978, at 306.

Private sector research conducted by individual companies is especially difficult to quantify. Some research has been supported on a cooperative basis. The Chemical Industry Institute of Toxicology was formed in 1974 by 36 companies. In 1983, it had a budget of approximately $10 million and had conducted long-term studies on eight chemicals and was working on seven others. *See* Hoerger, Beamer & Hanson, *The Cumulative Impact of Health, Environmental, and Safety Concerns on the Chemical Industry During the Seventies,* 46 LAW & CONTEMP. PROBS. 59, 73-74 (Summer 1983) (describing several joint industry research projects).

35. *See supra* note 34. The number of new toxicity and carcinogenicity starts has also decreased, from 40 prechronic and 44 carcinogenicity studies started in 1980 to 28 prechronic and 10 carcinogenicity studies started in 1988. *See* Letter to the author from Ernest E. McConnell, D.V.M., National Inst. of Envtl. Health Sciences (July 1, 1988) (on file with the *Michigan Law Review*) [hereinafter McConnell Letter].

36. OFFICE OF TECHNOLOGY ASSESSMENT, INFORMING THE NATION: FEDERAL INFORMATION DISSEMINATION IN AN ELECTRONIC AGE 29 (1988) [hereinafter INFORMING THE NATION].

37. *See supra* note 34. The authors of *Toxicity Testing* sought the assistance of firms and trade associations in a health assessment of 40 chemicals in commerce selected for study, but received only partial responses. The industry information which was secured was largely organized in a way that made it difficult to retrieve pertinent data. TOXICITY TESTING, *supra* note 10, at 194-96. When private research and development figures are publicly available, research on substance side effects is typically not separated from total research and development. *See* CHEMICALS AND HEALTH, *supra* note 9, at 89-90.

38. *See infra* note 217 and accompanying text (discussing protection of trade secrets).

39. TOXICITY TESTING, *supra* note 10, at 53.

was the cause, the proper treatment was removal from further exposure while, on the other hand, the treatment for sarcoidosis was corticosteroids. Corticosteroid treatment is associated with potentially severe side effects including diabetes, cataracts, fractured bones, and infections. Thus it was medically necessary to know whether the worker had been exposed to beryllium at work. But in the absence of a right-to-know law, I was unable to obtain this information from an uncooperative employer fearful of a compensation suit. As a consequence the worker had to undergo a painful and potentially dangerous operation to remove a piece of lung for beryllium analysis.[40]

Medical research and reporting also rely upon identifying the nature of chemical exposures.[41] The links between the causes of occupational disease and disease in the broader community can only be established or studied if better information is available.[42] One of the early steps of epidemiological studies, the phase in which an "informed hunch" develops, is often handicapped by poor identification of the class of persons exposed to specific chemicals.[43] The lack of information also

40. Testimony of James Robins, M.D., before the Massachusetts Joint Committee on Health Care, Mar. 9, 1983. In the same testimony, Dr. Robins reports another story:

> As another example, a patient was seen with fever and a chest X-ray suggesting pneumonia. The patient had been cutting barrels containing an unknown substance with a blow torch prior to becoming ill. The worker knew only the trade name on the barrel label. We were unable to track down the generic chemical name in a prompt manner. Therefore antibiotics were administered because it was felt that the patient had typical pneumonia caused by bacteria. Later, after much leg work, we discovered that the barrel had contained a teflon-like compound that was known to cause a pneumonia-like illness when heated. Thus, antibiotics had been improper treatment.

Dr. Robins has estimated that more than half of the time spent by occupational health professionals evaluating patients suspected of being ill from chemical exposure is devoted to tracking down the names of chemicals for which the worker can give only a brand name. *Id.*

41. Medical diagnosis of chemical diseases may be made difficult or impossible because of an inability to connect symptoms with chemical exposures. For example,

> [i]n the Vesicol Chemical plant in Bayport, Texas . . . workers were being exposed to a number of neurotoxic agents, including a highly hazardous pesticide called Leptophos. Various workers had experienced neurological symptoms and sought treatment from their personal physicians. A number of them were independently diagnosed as having encephalitis or multiple sclerosis because their symptoms and clinical examinations were thought to be consistent with these disorders. According to NIOSH investigators, there are subtle differences in the symptoms and type of nerve damage resulting from pesticide poisoning rather than these diseases, but encephalitis and multiple sclerosis could mimic those caused by neurotoxic chemicals encountered in the workplace. Since the sick workers had been seen by different physicians who may not have been able to elicit a good occupational history, and since appropriate toxicological information about the relevant workplace chemicals might not have been immediately available to the attending physicians, it is not surprising that the diagnosis of encephalitis or multiple sclerosis was considered rather than pesticide poisoning.

OSHA, U.S. DEPARTMENT OF LABOR, FINAL REGULATORY IMPACT ANALYSIS AND REGULATORY FLEXIBILITY ANALYSIS OF THE HAZARD COMMUNICATION STANDARD, at II-24 (1983) [hereinafter FINAL REGULATORY IMPACT ANALYSIS]; *see also* P. BARTH & H. HUNT, *supra* note 23, at 86-89.

42. Davis, Bridbord & Schneiderman, *supra* note 11, at 296, point out that for many workplace exposures, there is no way to identify an unexposed control group because the chemicals are present in products and environmental pollution to which the general population is also exposed.

43. *See, e.g.*, Austin, *An Industry-Sponsored Mortality Surveillance Program*, in BANBURY

means that chemically related diseases are likely to be underreported.[44]

The costs of the lack of this information are often ignored because concepts of the value of information are not incorporated into decisionmaking.[45] Among these costs are the prevention of pollution treatment, cure, convalescence, and rehabilitation; costs attributable to pain and suffering; loss of income on future earnings; adverse effects on productivity; loss of tax revenues resulting from decreases in earnings and productivity; costs to welfare and unemployment compensation systems and government programs of health benefits; and other related direct and indirect costs.[46] The National Academy of Sciences Institute of Medicine has identified some indirect and related costs. These include nonhealth sector costs, direct costs borne by individuals and their families (*e.g.*, relocating, household help, special diet and physical care, counseling), and losses from depressed value of property damaged by pollution.[47]

Toxicity and exposure data thus have numerous scientific, medical, and economic uses. The government uses this information to set exposure standards and to assess the benefits of regulation. The lack of

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REPORT 9, *supra* note 9, at 347; Beebe, *Record Linkage and Needed Improvements in Existing Data Resources,* in BANBURY REPORT 9, *supra* note 9, at 661; Hoar, *Epidemiology and Occupational Classification Systems,* in BANBURY REPORT 9, *supra* note 9, at 455. Epidemiologists are particularly constrained by lack of exposure data. S. EPSTEIN, POLITICS OF CANCER 41 (1978).

44. Only two to three percent of all workers' compensation payments are made for occupational illness, and one third of these are for minor ailments, such as skin rashes. Schroeder & Shapiro, *supra* note 4. The 1980 Bureau of Labor Statistics Supplementary Data System noted only 234 workers' compensation awards for cancer. This figure contrasts sharply with estimates for asbestos-related cancers, which alone range from 4000 to 12,000 per year.

Another factor that compounds this difficulty is that most doctors have not been educated on chemical risks, although the percentage has been rapidly increasing. *See* Levy, *The Teaching of Occupational Health in United States Medical Schools: Five Year Follow-Up of an Initial Survey,* 75 AM. J. PUB. HEALTH 79, 79-80 (1985). The National Academy of Sciences' Institute of Medicine recently reported that most family doctors are inadequately trained to recognize and treat illnesses that stem from unhealthy home or work environments. *Gap Found in Averting Workplace Diseases,* N.Y. Times, Dec. 13, 1988, at C12, col. 4.

45. *See* TOXICITY TESTING, *supra* note 10, at 295-96. Much publicly supported toxicity research has not been specifically aimed at producing data immediately useful to decisionmakers. As the National Research Council has noted, "[t]he concept of the value of information is an important contribution to systematic priority-setting. . . . [T]he 'cost' of not knowing the degree of toxicity of a chemical (or the degree of human exposure to it) lies in misclassifying its hazard — *e.g.*, believing it is innocuous, when it is actually toxic." TOXICITY TESTING, *supra* note 10, at 15.

In Appendix E to its report, the Council explores the ramifications of an error of judgment as to toxicity of a substance. It concludes that the costs of underestimating toxicity are likely to be greater than the costs of overestimating and establishing regulatory controls. *See* TOXICITY TESTING, *supra* note 10, app. at 363-79 ("The Costs of Misclassification").

46. 42 U.S.C. §§ 1395-96 (1982). *See generally* Health Services Research, Health Statistics, and Health Care Technology Act of 1978, Pub. L. No. 95-623, 92 Stat. 3443 (codified in scattered sections of 42 U.S.C.).

47. *See generally* COSTS STUDY, *supra* note 24.

solid information undermines the credibility of the government's risk assessments and makes it difficult for consumers or employers to make intelligent and informed decisions.[48] Insurers, employers, and unions can also use exposure and toxicity data to reduce liability and occupational health problems.[49] Consumers and consumer service organizations could use the information to evaluate products, if it were available in sufficient quantity and in appropriate format.

Once the information is collected, it has the characteristics of a "public good": that is, it becomes a good whose consumption by one user does not diminish its availability or benefit to any other user. Also, it can be transferred relatively easily and used in a variety of contexts. This flexibility means that it can be very productive at a low marginal cost, once the initial investment is made.[50]

While there is disagreement over the adequacy of our current level of investment in toxicity data collection, there is a consensus that the

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48. One reason for the success of EPA's lead phase-down program under the Clean Air Act, in spite of intense industry and OMB opposition, was that the estimated population exposure used "real information." School systems and local public health boards had accumulated very substantial records of exposure to lead, using regular school blood tests.

49. Chemical awareness and information could have prevented the following incident:

> On August 20, 1975, Ted Phillips died while working in an unventilated pit. The employer had given him a bucket of solvent from a drum labeled only with the trade name "axothene." Several hours after Ted Phillips entered the pit, the foreman went to look for him and found his body. "Axothene" is methyl chloroform, which in high concentrations causes dizziness, unconsciousness, and eventual death. It can also trigger heart attack by interfering with the system controlling the heartbeat. Apparently, Ted Phillips became dizzy and spilled the solvent. Not knowing the danger he was in, he got a second bucket and reentered the pit. Methyl chloroform evaporates quickly; the concentration in the pit was fatal.

FINAL REGULATORY IMPACT ANALYSIS, *supra* note 41, at II-24.

Some "downstream" manufacturers, who purchase chemicals to use in their production processes, have been vocal in supporting dissemination of chemical identity and health effects data. Both downstream employers and unions participating in OSHA's hazard communication rulemaking proceeding generally opposed strict protective measures for trade secrets, questioning the seriousness of the economic threat posed by access to them. For example, a representative of the American Paper Institute stated:

> A manufacturer should not be allowed to withhold the chemical identity of any chemical which "contributes substantially" to the hazards of a mixture and for which there is a need to know the specific chemical identity in order to provide a safe workplace. Downstream employers, for example, may need to know the specific chemical identity of an ingredient in order to monitor the level of airborne contaminants.

American Paper Inst., Exhibit 1973, 48 Fed. Reg. 53,313 (1983). A representative of the Caterpillar Tractor Company stated:

> We feel that the latitude provided chemical manufacturers in identifying most chemicals by the broad generic chemical classification will substantially hinder the efforts of safety and health professionals to determine the requirements for safe usage of specific products. . . . We feel the benefits to be derived in fully disclosing the constituents of a hazardous material far outweigh the risk (real or imagined) that may be incurred by chemical manufacturers as a result of disclosing this information.

Caterpillar Tractor Co., Exhibit 19-201, 48 Fed. Reg. 53,313 (1983).

50. *See* Barry & Hardin, *Introduction,* in RATIONAL MAN AND IRRATIONAL SOCIETY? 181 (B. Barry & R. Hardin eds. 1982). Technical information, like any technical good, is rendered more useful and more flexible if it is enhanced by combination and interpretation.

data are useful. Since this information has many useful applications, why does the market not produce it?

II. DISINCENTIVES TO DATA PRODUCTION

The market for chemicals will not produce and distribute data on toxicity and exposure unless an incentive structure is developed and maintained. Several factors work to prevent the current system from providing such incentives.

The dearth of toxicity data is in part due to the "public good" nature of the information.[51] The virtues of flexibility and ease of transfer that characterize public goods become liabilities in commerce, because public goods cannot easily be held for exclusive use. If only one person "buys" the information, others may still benefit; the costs of producing the data cannot be recouped by multiple individual sales. Because public goods are difficult to own and to control, the market produces them at lower levels than may be desirable.

Information is an especially problematic public good, because purchasers do not know its value until it has been acquired.[52] Research is affected by this dynamic. It is also a risky investment because one cannot know ahead of time whether the effort will yield anything of value. In spite of these handicaps, research and development are traditionally a major area of investment. Private research has been supported by legal protections, such as copyright and patent law.

Cost-reducing inventions are one kind of information likely to be produced privately. But toxicological data has a less ready marketability than many cost-saving inventions. It has value only to those who bear the costs that it reduces. Since even the individual victims of chemical-related disease can rarely identify its specific cause, little demand has developed for assurance of safe or low-risk chemical products.[53]

A further disincentive to private research is the fact that the information produced is often inexact. Toxicologists currently have three basic tools with which to gather data: laboratory cell analyses, bioas-

51. *See* Barry & Hardin, *Individual Actions and Collective Consequences,* in RATIONAL MAN AND IRRATIONAL SOCIETY?, *supra* note 50, at 31-33; Joskow & Noll, *supra* note 8, at 26; F. MACHLUP, THE PRODUCTION AND DISTRIBUTION OF KNOWLEDGE IN THE UNITED STATES 28 (1962) ("The production of knowledge is, for the greater part, not guided by the market mechanism.").

52. *See* Arrow, *Economic Welfare and the Allocation of Resources for Invention,* in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609, 615 (1962).

53. *See* P. Landrigan & S. Markowitz, Occupational Disease in New York State 17 (Feb. 1987) (Report to N.Y. State Legislature) ("workers often are not aware of or cannot remember their exposure to dangerous materials").

says, and epidemiology. Each has strengths and weaknesses that support different levels of confidence in their results.

The cheapest and easiest methodology is laboratory analysis of the effects of a chemical on the DNA of cell cultures or on bacteria, yeast, or fruit flies.[54] If a chemical causes a change in a cell's DNA, it is considered a mutagen. However, while mutagenicity and carcinogenicity are statistically related, this kind of test is not reliable enough to provide a basis for human exposure decisions.[55]

The bioassay is the most controversial tool of toxicologists. Protocols for laboratory testing for carcinogenicity establish procedures for exposing animals to controlled high doses of chemicals, but the application of animal test data to humans has been the center of heated debate over the validity of inferences drawn from these studies.[56] So far, accumulating test experience demonstrates that most chemicals proved by epidemiological studies to be human carcinogens also cause cancer in animals.[57] However, the reverse is not clear: since human data is available for few chemicals, only limited confirmation of animal test results is possible.[58]

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54. *See* COSTS STUDY, *supra* note 24, at 51.

55. OFFICE OF TECHNOLOGY ASSESSMENT, IDENTIFYING AND REGULATING CARCINOGENS 164-66 (1987) [hereinafter REGULATING CARCINOGENS]; *see also* Ames, *Identifying Environmental Chemicals Causing Mutations and Cancer,* 204 SCIENCE 587 (1979). Laboratory cell analysis is often cited as the type of methodological breakthrough necessary to cope with screening the large number of untested chemicals. Research on basic cell functions includes NIEHS work in the role of oncogenes in the carcinogenesis process. New developments in understanding the disease process will speed toxicity screening, but the outcome of this research is still uncertain. Allison, *Current Trends in Toxicological Research,* in PROCEEDINGS OF THE FIRST INTERNATIONAL CONGRESS ON TOXICOLOGY: TOXICOLOGY AS A PREDICTIVE SCIENCE 387 (G. Plaa & W. Duncan eds. 1978) [hereinafter TOXICOLOGY AS A PREDICTIVE SCIENCE]. Even if speedy, inexpensive screening devices were available, exposure data would still be necessary. TOXICITY TESTING, *supra* note 10, at 7.

56. *See e.g.*, Health Effects Testing Guidelines, 40 C.F.R. § 798.1100 (1987); *see also* Rall, *Validity of Extrapolation of Results of Animal Studies to Man,* in PUBLIC CONTROL OF ENVIRONMENTAL HEALTH HAZARDS, *supra* note 15, at 85 *passim* (arguing that animal test data apply to humans). *But see* Breslow, *Comment: Risk Assessment: Science or Policy?,* 3 STAT. SCI. 28 (Feb. 1988); Freedman & Zeisel, *From Mouse-to-Man: The Quantitative Assessment of Cancer Risks,* 3 STAT. SCI. 3 (Feb. 1988).

57. S. EPSTEIN, *supra* note 43, at 59.

58. Therefore, we do not have a firm sense of the extent to which animal tests may be underestimating or overestimating disease for humans. Samuel Epstein notes that few epidemiological studies have been done on substances found to be carcinogens in rodents. The lack of this particular type of data is sometimes spoken of as evidence of noncarcinogenicity in humans. Some industry representatives have argued that regulation should primarily, if not exclusively, be directed at the few carcinogens identified by human epidemiologic studies. Epstein cites a *reductio ad absurdum* put forward by Vaun Newill, Medical Director of Exxon Corporation:

> A regulatory program based on experimental screening models to evaluate new chemicals prior to their introduction into the environment, however, will hinder the better documentation of this correlation [between human and animal carcinogenicity data] than we have presently. When a carcinogen is prevented from entering the environment on the basis of screening results, there can be no data regarding that exposure in man.

Epidemiology is the science of statistical correlation of human exposure and disease symptoms to indicate the prevalence of disease in an exposed group.[59] Epidemiologists most often study industrial workplace settings, in an effort to get a focused look at more intensive levels of exposure than occur in the general population.[60] But even in work settings, epidemiological data suffer from many confounding factors, including multiple exposures, undetermined exposures, and poor record-keeping.[61] Also, the latency periods of some diseases are twenty years or more, longer than many chemicals have been in use.[62] However, while it is of limited sensitivity and cannot easily detect low incidences of disease, epidemiology may confirm human carcinogenicity.[63]

Epidemiological studies and bioassays are both costly.[64] Moreover, the cost of an individual bioassay has risen dramatically during the past decade.[65] Firms will be reluctant to make substantial invest-

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S. EPSTEIN, *supra* note 43, at 59 (quoting 29 CANCER BULLETIN 177-78 (1977)); *see also* REGULATING CARCINOGENS, *supra* note 55, at 166-67.

59. *See* E. CALABRESE, METHODOLOGICAL APPROACHES TO DERIVING ENVIRONMENTAL AND OCCUPATIONAL HEALTH STANDARDS 4 (1978); G. FRIEDMAN, PRIMER OF EPIDEMIOLOGY 8-10 (1980); A. LILIENFELD, FOUNDATIONS OF EPIDEMIOLOGY 13 (1976). For surveys of the results of recent epidemiological work, see Davis, Bridbord & Schneiderman, *supra* note 11, at 290-91; Selikoff, *Constraints in Estimating Occupational Contributions to Current Cancer Mortality in the United States,* in BANBURY REPORT 9, *supra* note 9, at 4.

60. For many diseases there is currently no way to single out one cause and link it with an effect. While some substances, such as DES, have been linked with a particular symptom or set of symptoms shown not to be caused by other exposures, many diseases are not so easily categorized. Often the only possible linkages will be demonstrations of increased statistical incidences in exposed human populations, but these may not show up for low levels of exposures.

61. *See* J. HIGHLAND, M. FINE & R. BOYLE, MALIGNANT NEGLECT 48 (1979).

62. *See* 29 C.F.R. §§ 1910, 2000 app. B; P. BARTH & H. HUNT, *supra* note 23, at 62-70; S. EPSTEIN, *supra* note 43, at 58 *passim*; Davis, Bridbord & Schneiderman, *supra* note 11, at 293-94; Muir, *Limitations and Advantages of Epidemiological Investigations in Environmental Carcinogenesis,* in PUBLIC CONTROL OF ENVIRONMENTAL HEALTH HAZARDS, *supra* note 15, at 153, 159-60; Selikoff, *supra* note 59, at 3, 5.

63. Henschler, *Introductory Remarks,* in TOXICOLOGY AS A PREDICTIVE SCIENCE, *supra* note 55, at 221.

64. The costs of study vary with the methodology and the chemical. Thus, while the National Research Council cited the figure "up to a million dollars" as the cost for laboratory study of a single chemical, it also recommended establishing priorities on "which chemicals to test and which tests to perform." TOXICITY TESTING, *supra* note 10, at 14, 199-295. Several studies have estimated costs on a more refined basis, with more specific estimates tied to types of testing. Cost estimates vary depending on the type of testing. "Biodegradation tests, for example, cost in the neighborhood of $5,000 to $12,000 to perform, while subchronic health tests may cost $100,000 or more and chronic toxicity and oncogenicity studies may cost $300,000 to $700,000." TSCA: OVERVIEW AND EVALUATION, *supra* note 26, at 121. *See also* Portney, *Toxic Substance Policy and the Protection of Human Health,* in CURRENT ISSUES IN U.S. ENVIRONMENTAL POLICY 136 (1978) (estimating that the standard laboratory tests necessary to determine the toxicity of a single chemical cost from $200,000 to $750,000). The cost of epidemiology is harder to estimate because of the variety of study designs. *Cf.* COSTS STUDY, *supra* note 24, at app. E-1.

65. The rising cost of bioassays is due in part to inflation and in part to the fact that a wide spectrum of toxic insults and effects is now the subject of each bioassay. Also, quality assurance

ments in research that produces uncertain health data, instead of new products.[66]

Of course, the price of toxicological knowledge cannot be understood as a simple function of the expense of conducting individual studies. Toxicological research as a social enterprise has produced a substantial amount of health information in a relatively short span of time, and as the field matures, it is developing new methodologies. A developed and accessible database on chemical characteristics is itself a powerful research tool.[67] Also, as toxicology identifies sources of disease, it fills out the cost-benefit equation: it identifies the externalities of chemical toxicity. In addition, it may allow for continued use of a chemical by making possible preventive medicine and by reducing the cost to society of using the chemical.[68] Unfortunately, these benefits may not be recovered by individual firms, or their impact may not be easily identifiable as the results of one company's research. Thus, firms are unlikely to undertake costly testing, because the benefits are public and cumulative and not reflected in the corporate balance sheet. Toxicological data collection is beyond the reach of the individual and is a problematic investment for firms.

Another important influence on data production is the simple fact that toxicity and exposure are negative features of chemical products. As long as no way exists for buyers to identify the toxic effects of specific chemicals, there is no commercial incentive for chemical producers to identify and publicize them.[69] Sellers will not willingly reveal negative characteristics of their products.[70] Comprehensive and accessible toxicity rating systems would support affirmative advertis-

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methods have been instituted. In 1980, the primary concern was to determine the target organs of toxicity and whether or not the chemical was a carcinogen. Thus the price range for bioassays in 1980 was $150,000 to $1.1 million; today, it is $470,000 to $2.9 million. McConnell Letter, *supra* note 35.

66. Whether or not firms can afford to conduct bioassays is a separate question. In 1978 Samuel Epstein estimated that annual costs for testing the 700 chemicals that reach commerce annually, at $200,000 each, would be .2% of the 1975 gross sales of the chemical industry, or $140 million of its $5.5 billion after-tax profits. S. EPSTEIN, *supra* note 43, at 72-73.

67. *See infra* Part IV.

68. *See* Hodgson, *Social and Economic Implications of Cancer in the United States,* in MANAGEMENT OF ASSESSED RISK, *supra* note 5, at 189 (discussing the economic costs of cancer).

69. TOXICITY TESTING, *supra* note 10, at 124 ("There is little incentive for voluntary reporting of either production or exposure data in the open literature or in accessible agency files, and the few data available are often reported in forms that limit their comparability.").

70. Latin points out that producers are not always in the best position to know the effects of their products, even though they know the products' components. *See* Latin, *Environmental Uncertainty, supra* note 4, at 218. However, there are also strong commercial influences in favor of data manipulation. Where firms have market power, they may have incentives to exploit or even create uncertainty or imperfect information. *See* Beales, Craswell & Salop, *The Efficient Regulation of Consumer Information,* 24 J. L. & ECON. 491, 507-09 (1981); Nelson, *Information and Consumer Behavior,* 78 J. POL. ECON. 311 (1970); Rothschild, *Models of Market Organiza-*

ing, but without a developed information context, there is no incentive to study a chemical: the long-term health effects remain invisible for one's own products and for those of one's competitors.

A series of market dysfunctions arises from these factors.[71] The invisibility of chemical toxicity has destructive effects on the market for chemicals. If product quality cannot be gauged by consumers, the overall quality of products in the market will be affected. Buyers' inability to screen products removes any incentive for manufacturers to differentiate between toxic and nontoxic products and to screen before production. The result is a higher overall level of toxicity in products than would result if toxicity were a visible characteristic. Chemical products with lower toxicity will be penalized by the presence in the market of some unknown number of toxics.

Indeed, as long as the information market remains undeveloped, ignorance of toxicity may be an advantage to a product. New or unstudied chemicals will do better in relation to chemicals that have been shown to have some indication of toxicity. Ignorance will tend to prevail.[72]

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tion with Imperfect Information: A Survey, 81 J. POL. ECON. 1283, 1289-301 (1973); Salop, *Information and Monopolistic Competition,* 66 AM. ECON. REV. 240 (1976).

71. In his paper, *The Economics of Information,* 69 J. POL. ECON. 213 (1961), George Stigler proposed to factor into economic analysis the costs of a search for information. He pointed out, for instance, that price dispersion is a measure of ignorance about prices. *Id.* at 214. Stigler's proposed model of how a search proceeds has been criticized. *See* Rothschild, *supra* note 70, at 1286-89. But search costs are now a standard notion in economic analysis:

> Whenever market participants lack information, there is a potential for reduced efficiency and distributional damage (however defined). If workers are unaware of more advantageous employment possibilities, labor markets will not allocate labor efficiently. If investors are unaware of potentially profitable investments, capital markets will not allocate capital efficiently. If consumers are unaware of better purchase opportunities or the characteristics of the goods they purchase, markets will not guide production efficiently. When public goods and externalities distort the informational content of relative prices, aggregated decisions will not allocate resources efficiently. All of the above distortions and deviations created by insufficient information also create a pattern of income gains and losses for different participants relative to perfectly functioning markets.

R. BARTLETT & U. APTE, *supra* note 8, at 22.

72. This dynamic is illustrated by economist George Akerlof's simplified model of the used car market. When cars are new, neither the seller nor the buyer will know if a given car is a lemon. Therefore, there is a risk of getting a lemon, yet the buyer will pay the same price because she cannot tell the difference. The problem intensifies, however, in the used car market. Good cars are less likely to be traded or sold, leaving lemons to make up a relatively larger share of the used car market. This will deflate the price of used cars generally and force good cars off the market because sellers cannot get full value, making it a market for lemons. The effect is analogous in a field of chemical products, though the parallel is inexact. There is no advantage to manufacturers in producing chemical products with demonstrated nontoxicity and incurring the expense of testing, because products cannot be told apart on this basis anyway, given the invisibility of toxicity. *See* Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market Mechanism,* 84 Q. J. ECON. 488 (1970) (discussing implications of buyers' limited ability to judge the quality of products of varying grades); Wilson, *The Nature of Equilibrium in Markets with Adverse Selection,* 11 BELL J. ECON. 108 (1980). The basic incentive to maintain a level of ignorance about toxicity may be enhanced where the producing sector is concentrated, as it is in parts

While normal market responses to the dysfunctions described here include advertising, pooling of buyer resources, and development of third-party information providers and product rating services,[73] none of these can develop without accessible chemical identity data. A fundamental information asymmetry in the chemicals market is created by the fact that the chemical producer knows what the chemical is, while the buyer often does not. Without the chemical identity of the product, the buyer cannot seek assistance in developing information independently.[74] Chemical manufacturers can be thought of as free riders in this context, "riding" on consumer ignorance: they benefit by not providing toxicity data, at the expense of consumer uncertainty and injury. Absent regulation, the information is likely to remain undisclosed and unexamined, since the interests of its holders are adverse to those of the beneficiaries of disclosure.

Furthermore, when toxicity data is produced privately, for example in response to regulation, market incentives may detract from its quality. Producers tie information production to the product's budget. The result may be a cheaper grade, lower quality product and a cheap grade of information.[75] Thus, while valuable information has been produced by industry sources, particularly under statutory schemes which require *ex ante* registration of chemical products, its volume and its quality have been affected by the constraints of the commercial

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of the synthetic chemicals industry. *See, e.g., In re* "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740, 828 (E.D.N.Y. 1984).

73. Stigler notes that advertising and the development of specialized traders are obvious responses to high search costs. Stigler, *supra* note 71, at 216-17. Akerlof notes that guarantees, brand name goods, and licenses are responses to situations in which product quality is obscure to the consumer. Akerlof, *supra* note 72, at 499-500. Salop suggests that advertising, which is costly for the firm, may also complicate the consumer's search. Salop, *supra* note 70, at 244.

74. Normally, purchasers may bargain for data. However, in the chemicals context, the data's invisibility and complexity and the lack of accessible assistance in managing it have discouraged this approach. Beales, Craswell & Salop point out that "consumers may underestimate the value of additional information simply because they lack other data that would tell them of their need to learn more." Beales, Craswell & Salop, *supra* note 70, at 491, 506. Market-based obstacles to workers' access and use of data about occupational disease are also discussed by Schroeder & Shapiro, *supra* note 4, at 1237-44. They note that the existing general lack of information discourages individuals and unions from bargaining for occupational health information and tangible preventive measures. *See also* O'Reilly, *Driving a Soft Bargain: Unions, Toxic Materials, and Right to Know Legislation,* 9 HARV. ENVTL. L. REV. 307 (1985) (discussing why unions infrequently bargain with management for chemical data).

75. *See* Oi, *The Economics of Product Safety,* 4 BELL J. ECON. & MGMT. SCI. 3, 5-19 (1973). Oi assumes that producers are liable for the injuries of consumers, but they have no mechanism to lessen the damage costs of individual consumers; consumers are assumed to have perfect information about product risks, to know their expected damage costs, and to be able to obtain inexpensive, actuarially fair insurance. On these assumptions, producer liability leads to an inefficient outcome because producers essentially must bear the costs of the product and an insurance policy for heterogeneous consumers. Strict consumer liability allows the consumer to purchase separately the optimal quality of product and the optimal insurance policy. The model's assumptions identify the elements of the information problem.

context.[76]

Even when privately produced information is of high quality, the commercial context diminishes its credibility and, thus, its value.[77] Information that is complex and easily manipulable will be particularly undervalued, unless it can be independently corroborated. Indeed, deception certainly occurs and is often perceived as widespread. These factors limit the usefulness of toxicity data generated by private chemical producers.[78]

The market disincentives to production and obstacles to independent evaluation of private data make public intervention necessary to ensure that accurate data are produced and distributed optimally. In-

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76. *See* Shapiro, *Divorcing Profit Motivation from New Drug Research: A Consolidation of Proposals to Provide the FDA with Reliable Test Data,* 1978 DUKE L.J. 155, 161-68 (citing evidence that drug manufacturers' safety research is influenced by the profit motive and that contractual commercial relationships between researchers and drug sponsors are themselves a strong influence on the quality of data).

77. Viscusi suggests that, because the value of information often cannot be known before it is purchased, information that is cheap or free in a competitive marketplace will be viewed by recipients as having little value. Indeed, he maintains that much information that is now provided to workers is not intended to enable them to assess risks more accurately, but to lower their assessment of their risks. "The most widespread claim by firms is that National Safety Council statistics indicate that the worker is safer at work than at home — a statement that . . . is intentionally misleading." W. VISCUSI, RISK BY CHOICE 71-75 (1983). Information provided cheaply to workers must be relatively favorable, since otherwise the firm will be forced to pay higher wages.

A. SPENCE, MARKET SIGNALLING: INFORMATION TRANSFER IN HIRING AND RELATED SCREENING (Harvard Econ. Stud., vol. 143) (1974) describes the process of communication in transactions as signalling and examines the inefficiencies that occur when firms invest in making a product appear to have characteristics that it lacks. *See infra* note 150.

78. Epstein, *Constraints in Decisionmaking,* in PUBLIC CONTROL OF ENVIRONMENTAL HEALTH HAZARDS, *supra* note 15, at 309-17, and Peto, *Distorting the Epidemiology of Cancer: The Need for a More Balanced Overview,* 284 NATURE 297 (Mar. 27, 1980), agree on the prevalence of manipulated toxicity data. Richard Peto writes that "[s]o many examples of financially motivated bias exist that the motives and work of industrial scientists and consultants are inevitably distrusted." Peto, *supra,* at 297. Epstein cites cases of poor-quality data and data manipulation which not only increase the costs of regulation, but also cause considerable loss of private investment. He suggests that both conscious and unconscious motivations to produce positive data are inherent in the market situation:

> Escalating evidence has shown that constraints of data, ranging from gross inadequacy, biased interpretation, manipulation, suppression, and even to outright destruction, are commonplace, especially when profitable technologies, both products and processes, are involved. Alarmingly, such evidence now justifies *a priori* reservations regarding the validity of any data developed by institutions or individuals whose economic interests are directly or indirectly affected.

Epstein, *supra,* at 309.

Portney discusses the problem of firms' incentives to choose testing procedures most likely to shed favorable light on the substances they wish to market. In some cases, incentives are strong enough to cause firms to falsify or withhold test data. Portney suggests three means by which to combat these incentives. First, well-defined testing procedures should be established and applied by all agencies regulating toxic substances. Second, federal agencies should expedite verification of controversial data. Third, stiff penalties should be levied for violating protocols or falsifying results. Portney, *supra* note 4, at 138.

Deception has also been an issue in toxics litigation. *See, e.g., In re* "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740, 828 (E.D.N.Y. 1984).

terventions, however, must be designed to fit the needs of the situation and to minimize unintended secondary effects. Legal strategies in the toxics area have generally not met these conditions.

III. The Failure of Traditional Regulatory Strategies

Regulatory schemes that have attempted to correct these market dysfunctions have not succeeded. Neither the liability system nor regulation has effectively located responsibility for the toxic side effects of chemicals. Indeed, the law not only fails to encourage the production and distribution of toxicity data, it has tended to discourage it.

Liability rules increase the costs of private production of such knowledge. The tort system is predicated upon the existence of information linking cause with effect, but the manufacturer often is the only party in a financial position to perform the research necessary to prove a causal connection. Potential liability is therefore another influence that discourages manufacturers from producing this information. Compensation schemes are similarly dependent on existing data to prove causation.[79]

Products liability rules have stimulated safety research where the reasons for plaintiffs' injuries are apparent or can be determined with relatively inexpensive expert assistance. The same dynamics could develop with respect to chemicals, if the means of producing toxicity data were accessible to parties other than manufacturers, particularly to those who are exposed or their representatives. If there were independent sources of data, the potential costs to a manufacturer of not producing its own information might be high. Producing data and warning of negative effects would become a form of protection against the costs of liability. The existence of independent sources of data would also encourage higher quality in manufacturers' tests, because a third party would be able to check results. The liability system's deterrent effect thus depends upon a developed information context, with independent researchers.

Although courts are generally in no position to mandate major research initiatives and must await independent documentation of causal links, the need for testing has drawn some judicial attention. In *Beshada v. Johns Manville Products Corp.*,[80] the Supreme Court of New Jersey faced the fact that manufacturers control the production of data on toxicity. Using "cheapest cost avoider" reasoning, the

79. Viscusi, *Structuring an Effective Occupational Disease Policy: Victim Compensation and Risk Regulation*, 2 YALE J. REG. 53, 62-75 (1984); Schroeder & Shapiro, *supra* note 4, at 1244-56.

80. 90 N.J. 191, 447 A.2d 539 (1982).

court found that manufacturers' ability to conduct safety research precluded a state-of-the-art defense to a strict products liability claim for injury from asbestos exposure.[81] Later, the court retreated somewhat from this position, and its present stance is unclear.[82] However, awareness of producers' advantages in obtaining information is a persistent theme in toxic tort decisions. For instance, in *Borel v. Fibreboard Paper Products Corp.*,[83] the Court of Appeals for the Fifth Circuit recognized a chemical manufacturer's duty to test in conjunction with the duty to warn, but did not elaborate on the extent of testing required.[84] This duty to test was apparently drawn from the line of cases dealing with a manufacturer's duty to test and label dangerous drugs, a rule with early statutory roots. The idea of prospective testing was also present in the "Agent Orange" litigation, in which Judge Weinstein approved a settlement agreement, in part on the ground that the federal government planned to conduct research on the health effects of "Agent Orange."[85]

Statutory solutions, which rely on controlled screening by administrative agencies, have also been attempted.[86] But the regulatory strategies of the past two decades have been only partial improvements over the liability system. Agencies acquire and develop data in the course of regulating specific chemicals, although the process is influenced by the same market factors that handicap the liability system. Agencies also can issue reporting requirements and invest directly in research.

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81. 90 N.J. at 206-07, 447 A.2d at 548 (relying in part on Calabresi & Hirshoff, *Toward a Test of Strict Liability in Torts*, 81 YALE L.J. 1055 (1972)). This position is supported by the U.S. Court of Appeals for the Third Circuit, which has held that barring the state-of-the-art defense in asbestos cases, but not in others, does not violate the Equal Protection Clause. *In re* Asbestos Litig., 829 F.2d 1233 (3d Cir. 1987), *cert. denied*, 108 S. Ct. 1586 (1988).

82. The limit on *Beshada* was articulated in a separate context, a case involving an injury related to a prescription drug. Without discussion, the court seemed to confine the *Beshada* rule to the asbestos context. *See* Feldman v. Lederle Laboratories, 97 N.J. 429, 479 A.2d 374 (1984).

83. 493 F.2d 1076 (5th Cir. 1973).

84. 493 F.2d at 1089 (stating only that tests "must be commensurate with the dangers involved").

85. *In re* "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740, 851-57 (E.D.N.Y. 1984). However, government-sponsored studies have been hampered by lack of data. *Lack of Military Data Halts Agent Orange Study*, N.Y. Times, Sept. 1, 1987, at A1, col. 3.

86. This "purchasing agent" model of consumer protection has been criticized on the grounds that it imposes costs on consumers who may prefer to use cheaper, more dangerous products. Reich, *Toward a New Consumer Protection*, 128 U. PA. L. REV. 1, 25 (1979). However, government intervention in a market is appropriate when there are hidden costs, nonrepeat sales, and low levels of competition; the first of these is certainly present in the chemicals market. Reich recommends that interventions avoid taking control over product quality or seller conduct; rather, they should overcome information weaknesses and facilitate independent information brokers, which may need to be subsidized by government. *See id.*, at 26, 31-39. *But see* Latin, *Environmental Uncertainty*, *supra* note 4, at 222-33.

The last approach generally has been more successful in generating useful data than have regulatory proceedings.

There are two basic methods for setting standards for human exposure to chemicals, normally accomplished by reviewing the health effects of one chemical at a time.[87] The first approach is *ex ante* regulation, which is used to control the effects of food additives, drugs, and pesticides. Substances so classified must be proved safe prior to marketing through a registration process in which the product's proponent has the burden of proof. In contrast, most environmental and occupational controls, like tort liability, are applied *ex post* — *i.e.,* only when research establishes both significant exposure to and toxicity of a chemical.[88] In both approaches, the agency makes a determination of an acceptable level of human exposure, based upon the available information on toxicity.

In *ex ante* regulation, while the agency must either produce parallel data or carefully check the toxicity data generated by a product's proponent,[89] the product's proponent must generate some information in order to get the product to the market. Product registration has yielded stronger informational support for regulators than has the *ex post* approach.[90] The results of the National Research Council's survey in *Toxicity Testing* confirm that *ex ante* regulation is superior from the point of view of producing relevant health information.[91]

In *ex post* regulation the agency, usually the EPA and OSHA, must collect the initial toxicity and exposure information. Since environmental and occupational regulations impose costs which had been successfully externalized, the pressures of the market are arrayed

87. Regulation by groups of chemicals is less common. RCRA authorizes EPA to regulate "waste" as such, rather than each element of a waste stream. 42 U.S.C. § 6921 (1982). Congress has occasionally directed EPA to regulate a list of pollutants. *E.g.,* 42 U.S.C. § 7422 (1982); *see also* Federal Water Pollution Control Act, 33 U.S.C. § 1317(a) (1982). In the late 1970s, several agencies adopted "carcinogen policies" designed to settle basic scientific questions concerning the causes of cancer and to simplify the approach to regulation of suspected carcinogens. *See, e.g.,* National Emission Standards for Hazardous Air Pollutants; Policy and Procedure for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer, 44 Fed. Reg. 58,642 (1979). This approach was set aside by the Reagan administration.

88. Richard Stewart suggests that firms today generally have the burden of demonstrating acceptable social performance before operation or marketing; *ex post* regulation consists of policing, recalls, and registration cancellation based on new information. *See* Stewart, *Regulation, Innovation, and Administrative Law, supra* note 4, at 1269 & n.36. This framework assumes that agencies have complete information on the risks in their jurisdiction and adequate resources to fully regulate based on such information.

89. *See* Shapiro, *supra* note 76, at 181-83.

90. *See* TOXICITY TESTING, *supra* note 10.

91. See *id.,* and CHEMICALS AND HEALTH, *supra* note 9, at 93-94, both of which recommend continuing to place responsibility for testing on industry before allowing the marketing of drugs or food additives.

against *ex post* limits on chemical use and exposure. The regulated industry's incentive to produce data is limited to minimizing the costs of regulation, once regulation appears to be a likely outcome. Businesses can avoid or mitigate the costs of regulation by minimizing the amount or credibility of any existing information which indicates toxicity. Regulated firms have strong incentives to produce studies aimed at increasing uncertainty about any suspected toxic effects of chemicals under review. Regulatory proceedings may continue for some time in a tug-of-war over the validity of toxicity data.[92] A bottleneck develops as agency resources are absorbed in accumulating masses of data on the same limited problem and attention is channeled into a narrow, even obsessive focus.

While standard-setting proceedings generate less useful information than might be desired, there are other ways for agencies to obtain it. Since World War II, the government has built an extensive infrastructure that supports and advances public environmental and health research.

Today the National Toxicology Program (NTP) coordinates toxicology and related research programs conducted by the National Institute for Environmental Health Sciences, the FDA's National Center for Toxicological Research, and the Centers for Disease Control's National Institute for Occupational Safety and Health. The National Cancer Institute and other branches of the National Institutes of Health also perform or oversee research related to toxicology. The NTP publishes an annual list of all funded research projects to help

92. The commentators often note failed or congested rulemaking processes in this context. *E.g.*, Schroeder & Shapiro, *supra* note 4, at 1256-64; *see also* McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 730-31 (1979); Stewart, *Regulation, Innovation, and Administrative Law*, *supra* note 4, at 1269, 1283-84.

An example of this phenomenon is the EPA's implementation of the National Emissions Standards for Hazardous Air Pollutants, mandated by § 112 of the Clean Air Act. After designating five pollutants as hazardous in the early 1970s and completing the required rulemaking within the statutory time limits, the EPA litigated the vinyl chloride designation with the plastics industry. Since then, the EPA has designated few chemicals as hazardous, even though many pollutants in the ambient air pose serious health risks. The format of the rulemaking proceeding and of judicial review makes it worthwhile for regulated businesses to litigate every aspect of an agency decision, as litigation will generally be cheaper than installing technological controls to reduce pollution. As a result, § 112 has consumed considerable agency resources and produced little health protection.

Even where Congress has directed the EPA to issue rules controlling toxics within specific time periods, the process has bogged down. The history of 42 U.S.C. § 7422 (1982) is educative. *See, e.g.*, New York v. Gorsuch, 554 F. Supp. 1060 (S.D.N.Y. 1983); 40 C.F.R. §§ 61.160-.186 (1988). *See generally* Shapiro, *Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA's Public Board of Inquiry*, 1986 DUKE L.J. 288, 304-07 (discussing whether adversary proceedings are appropriate for scientific issues); Pederson, *Formal Records and Informal Rulemaking*, 85 YALE L.J. 38 (1975).

funding agencies avoid duplication in giving grants for research.[93]

However, the National Research Council has noted problems with existing patterns of toxicological research and testing, including inadequate coverage and duplication. The Council recommended numerous changes in priority-setting and coordination of the research process, building upon existing procedures and methodologies.[94]

Congress has begun to experiment with private funding for public toxicological research. The Superfund Amendment and Reauthorization Act of 1986 (SARA) expanded the authority of the Agency for Toxic Substances Disease Registry (ATSDR) and directed the EPA to promulgate regulations to require, where appropriate, payment by chemical manufacturers and processors of the costs of the ATSDR's research on 100 priority toxics found at hazardous waste sites.[95] However, the EPA does not perceive this provision to be a mandate to establish a significant research program.[96]

A more substantial proposal for private funding of agency research was included in recent amendments to the federal pesticide regulatory scheme. The impetus for this amendment was the finding that, at current funding levels, the EPA would take forty years to complete testing of products now on the market. The 1988 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) amendments give the EPA the authority to set fees for the use of active pesticide ingredients and for registering pesticide products. The system is expected to generate $150 million for EPA pesticide administration and research, though

93. *See* NATIONAL TOXICOLOGY PROGRAM: REVIEW, *supra* note 29, at 173; CHEMICALS AND HEALTH, *supra* note 9, at 88.

94. *See* TOXICITY TESTING, *supra* note 10.

95. The ATSDR was established under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), within the Public Health Service. CERCLA directed the ATSDR to develop an inventory of literature on the health effects of toxic substances and to "conduct periodic survey and screening programs to determine relationships between exposure to toxic substances and illness." CERCLA § 104(i), 42 U.S.C. § 9604(i) (1982). The agency finally began operation under a 1983 consent decree following litigation over the Reagan administration's failure to implement the ATSDR. Environmental Defense Fund v. Heckler, 13 Envtl. L. Rep. (Envtl. L. Inst.) 20,630 (D.D.C. 1983).

In 1986, Congress significantly expanded the authority and responsibilities of ATSDR. Today, the ATSDR and the EPA must prepare and periodically expand a list of at least 100 substances that pose a health threat to humans because of their presence at designated Superfund waste sites. The ATSDR must collect existing health data on these substances and, where inadequate, must perform additional study. The EPA is directed to promulgate regulations to provide, where appropriate, for payment of the costs of research by manufacturers and processors identified through the TSCA and FIFRA registration process. 42 U.S.C. § 9604(i)(2)-(5) (Supp. IV 1986).

96. The proposed revised National Oil and Hazardous Substances Pollution Contingency Plan discusses treating documentation costs as clean-up costs, under certain circumstances, but it does not expand on SARA's direction to establish private funding for new health effects research. *See* 53 Fed. Reg. 51,394, 51,402 (1988) (to be codified at 40 C.F.R. § 300.160(d)) (proposed Dec. 21, 1988).

the latter will be literature searches, rather than production of new data.[97]

The limited budget for publicly supported research is supplemented by administrative reporting requirements. The 1976 Toxic Substances Control Act (TSCA)[98] is the major federal vehicle for collecting and managing existing private data.[99] The TSCA also gives the EPA limited authority to require manufacturers to conduct new tests of their products.[100] When enacted in 1976, the TSCA represented an important regulatory innovation. The EPA, in testimony before a House Subcommittee, declared:

> [T]he Nation's population and environment provide testing grounds for determining the effects a toxic substance has on human or environmental health. The authority contemplated by the Toxic Substances Control Act would establish requirements for testing substances believed to pose an unreasonable risk before they are dispersed by various means throughout the environment and are difficult, if not impossible, to control.[101]

However, the TSCA has not fulfilled its early promise.[102] It has pro-

97. In September 1988, Congress reauthorized FIFRA. The new law requires the EPA to assess, within nine years, the health and environmental effects of about 600 active pesticide ingredients, many of which were approved based on testing procedures that are now outdated. The process, called reregistration, was required by the 1978 amendments to FIFRA, but at the current funding and pace of testing the agency could not complete the task before the year 2024. To help speed the process, the 1988 FIFRA amendments will require all manufacturers of each active pesticide ingredient to share a fee of up to $150,000 and each product registrant to pay a fee of up to $425 for each year of the reregistration program. *FIFRA Reauthorization Passes Senate,* 3 Toxics L. Rep. (BNA) No. 20, at 626 (Oct. 12, 1988).

98. 15 U.S.C. § 2601 (1982).

99. Numerous other statutes require agencies to collect data and report to Congress. For example, the 1978 amendments to the National Cancer Act require the Department of Health and Human Services to prepare an annual report on all widely exposed chemicals that "may reasonably be anticipated to be carcinogens," including exposure data, an indication of whether the substance has been regulated, and an assessment of regulatory efficiency in reducing exposure. 42 U.S.C. § 241(b)(4) (1982). Moreover, a number of federal laws give agencies broad authority to request and subpoena data from regulated firms. *See, e.g.,* Clean Air Act, 42 U.S.C. §§ 7401, 7607 (1982). Some also require routine reporting of discharges of specified pollutants. *See, e.g.,* Federal Water Pollution Control Act, 33 U.S.C. §§ 1251, 1318 (1982).

100. 15 U.S.C. § 2603 (1982). For an early history of the TSCA, see R. DRULEY & G. ORDWAY, THE TOXIC SUBSTANCES CONTROL ACT (1981).

101. *Toxic Substances Control Act: Hearings on H.R. 7229, H.R. 7548, and H.R. 7664 Before the Subcomm. on Consumer Protection and Finance of the Comm. on Interstate and Foreign Commerce,* 94th Cong., 1st Sess. 213 (1975) (statement of John R. Quarles, Jr., Deputy Administrator, EPA).

102. In H.R. REP. No. 968, 96th Cong., 2d Sess. 5 (1980), the House Committee on Interstate and Foreign Commerce noted that the EPA had failed to meet a number of statutory and internal deadline provisions. *See also Recent Developments, Hazardous Substances — Environmental Protection Agency's Final Notification Rule Under the Toxic Substances Control Act, Section 12(b),* 16 TEXAS INTL. L.J. 546, 548 (1981).

TSCA's enactment was accompanied by the expectation that there would be a dramatic increase in the testing of chemicals. Companies such as Monsanto and Allied Chemicals increased their laboratory capacity and a number of companies joined to support the Chemical Industry Institute in conducting tests. The expected demand for testing never developed, however, and by

duced an inventory of chemicals in use, but has not generated or distributed significant amounts of exposure or toxicity data.[103] Even the inventory generated by the TSCA is incomplete, and large parts of it are unavailable for use outside the EPA's Office of Toxic Substances.[104]

The TSCA directs the EPA to screen toxics entering the market. The EPA keeps an inventory of all chemical substances used, manufactured, or imported in the United States. Manufacturers and importers of new chemicals must notify the EPA and submit information, in the form of Premanufacture Notices (PMNs), concerning each new chemical's structure, its intended uses, expected quantities of production, estimates of potential human exposure, and any health effects data that the manufacturer may have: no new testing is required. Based on the PMN information, the EPA is to screen each chemical to determine whether it presents an unreasonable health risk.[105] Most PMNs, however, do not contain much useful data. A 1983 study by the Office of Technology Assessment found that only fifty-three percent of the notices contained any health or safety data at all. Data that were supplied dealt primarily with acute, relatively apparent effects. Only about twenty percent contained data relevant to

1984 Dr. James Liverman, of Litton-Bionetics, estimated that private testing labs were operating at less than 60% of capacity. *See* W. DRAYTON, AMERICA'S TOXIC PROTECTION GAP 76 (1984).

103. Under TSCA, the EPA has established the basic inventory of existing chemicals and a number of related data systems. These systems rely primarily on the data that manufacturers submit to the EPA in their premanufacture notices, but are also supplemented by the EPA staff. Interagency coordination of data management has also been a focus of TSCA implementation. *See* LAYMAN'S GUIDE, *supra* note 10, at 6-9. Many of these new substances are bioengineered products.

104. The Bureau of Labor Statistics refuses to give any of its firm-specific data to OSHA or any other group. W. VISCUSI, *supra* note 77, at 84-85.

105. 15 U.S.C. § 2604 (1982). The EPA usually compares the physiochemical properties of each chemical to others that have known effects as a coarse screen for selecting suspect chemicals for further testing. On this limited basis, the agency decides whether to require the manufacturer to conduct tests or to limit production. A chemical structure that is similar to a proven health hazard provides some basis for concern about its possible effects, but similarity is not determinative, as in the example of benzene and toluene. *See supra* text accompanying note 30. Critics of this approach point out that screening by analogy, as opposed to relying on direct test data, may be a convenient proxy, but can be greatly deficient; for instance, this method would almost certainly have failed to identify PCBs as a risk, since they have low acute toxicity and are inert. *See* W. DRAYTON, *supra* note 102, at 72.

TSCA also authorizes the EPA to monitor changes in production levels and uses of chemicals. The EPA may determine by a rule that certain uses of chemical substances are "significant new uses." 15 U.S.C. § 2604(a)(2) (1982). Persons subject to a Significant New Use Rule (SNUR) must report. TSCA 1986 REPORT, *supra* note 10, at 13-15. Section 8 of TSCA directs the EPA to promulgate rules to require record-keeping and reporting. Manufacturers and certain processors must maintain records of "significant adverse reactions." 15 U.S.C. § 2607(c) (1982). The EPA required submission of such records for the first time in 1986.

such long-term effects as cancer.[106]

The EPA's authority under the TSCA to require development of new information is limited.[107] To require further tests or to limit production, the EPA must conduct a rulemaking procedure, which must begin within ninety days of the PMN filing. The EPA may order testing only if it demonstrates that the chemical may pose an unreasonable risk to human health.[108] This involved process discourages agency action. The EPA has issued few orders requiring production of data beyond the initial submissions of manufacturers.[109] Instead, it has tended to engage in lengthy analyses of a few chemicals in order to support its findings of unreasonable risk.[110]

TSCA's requirement that the EPA issue a rule before requiring testing distinguishes it from food, drug, and pesticide regulations, which mandate production of safety data prior to marketing. The TSCA standard essentially establishes a presumption of safety,[111] which the agency must overcome before it may require further testing of a chemical. Thus, the TSCA's use of strict rulemaking standards inhibits the very information production the statute was written to encourage.

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106. OFFICE OF TECHNOLOGY ASSESSMENT, THE INFORMATION CONTENT OF PREMANUFACTURE NOTICES 50-51 (1983).

107. The institutional capacity for implementing TSCA has developed slowly and is still inadequate. TSCA's basic inventory is being updated now for the first time. TSCA 1986 REPORT, *supra* note 10, at 4.

108. The Administrator may issue a rule requiring further testing by the manufacturer if he finds that the chemical "may present an unreasonable risk of injury to health or the environment" or that there "may be significant or substantial human exposure to [it]" and where there are insufficient data to determine reasonably its effects. 15 U.S.C. § 2603(a) (1982). If the Administrator finds that the chemical "will present an unreasonable risk of injury to health or the environment," he may issue a rule regulating its production or distribution. 15 U.S.C. § 2605(a) (1982).

Section 2603(e) of TSCA establishes the Interagency Testing Committee (ITC), which is directed to select and recommend to the EPA a list of no more than 50 chemicals each year whose risks warrant priority consideration. 15 U.S.C. § 2603(e)(1)(A) (1982). The EPA must then either initiate rulemaking to require testing by the manufacturer or publish its reasons for not doing so. 15 U.S.C. § 2603(e)(1)(B) (1982).

109. As of 1983, the EPA had required testing on 4% of new chemicals. An additional 2% were voluntarily tested, and 1% were made subject to use controls. *See* W. DRAYTON, *supra* note 102, at 69. As of 1984, the EPA had issued no final rules requiring testing processes and had obtained 84 voluntary agreements to test. *Id.* at 72. In 1986, the EPA issued orders controlling exposure to 67 new chemicals, pending development of new data, pursuant to section 5(e) of TSCA, 15 U.S.C. § 2604(e) (1982). Forty-five other chemicals were withdrawn after the EPA announced it would take 5(e) or 5(f) actions. This represents action on 112 out of the year's 1693 PMNs. TSCA 1986 REPORT, *supra* note 10, at 9. Of the existing backlog of thousands, only 76 chemicals were reviewed. Of those, six were referred for information-gathering rules and 51 are being evaluated further. *Id.*

110. *See, e.g.*, Natural Resources Defense Council v. United States Envtl. Protection Agency, 595 F. Supp. 1255, 1258 (S.D.N.Y. 1984).

111. Harlow, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553, 567 (1986).

While the ambition of TSCA to collect and produce useful data on chemicals has been only partially realized, the statute does recognize the central role of a comprehensive database for chemicals regulation. It also acknowledges, though only in a limited way, the validity of public authority to order private toxicity testing. This precept has now been expanded by the SARA and FIFRA provisions for private funding of public data management. The TSCA approach represents a transition, which is being followed by more sophisticated uses of data, including broad data dissemination.

IV. Distributing Data in the Market

Traditional regulatory approaches have neglected to distribute the information they do collect. The information access provisions in most environmental statutes have been, at best, unambitious reformulations of the Freedom of Information Act.[112] They have simply provided for access to agency files, with exemption from disclosure for certain categories of information, such as trade secrets, and they have encouraged none of the potential uses of information to warn or guide private decisionmaking. Indeed, past laws have sometimes seemed to encourage behavior that has the characteristics of information hoarding.

Right-to-know laws change existing information dynamics, making chemicals visible in a new way, by providing new information to actors in the marketplace. The laws direct disclosure of both the identity of chemicals and information about chemicals' effects. Disclosure is currently limited to chemicals already known to have toxic potential.

These disclosure requirements appear in both state and federal occupational health and environmental regulations. Many states enacted right-to-know laws in the late 1970s and early 1980s.[113] State laws covering workers are now partially preempted by OSHA's Hazard

112. *Compare* 5 U.S.C. § 552 (1982) (FOIA) *with* 42 U.S.C. § 7414(c) (1982) (Clean Air Act).

113. *See supra* note 2. The first state laws were in New York and California. *See* N.Y. Public Health Laws §§ 4800-4808 (McKinney 1985); N.Y. Labor Law §§ 875-883 (McKinney 1985); Cal. Labor Code §§ 6360-6399 (West Supp. 1988). California has supplemented its original right-to-know statute with the more expansive Proposition 65. Cal. Admin. Notice Reg. 87, No. 11-Z (Mar. 13, 1987) (codified at Cal. Health & Safety Code §§ 25180.7, 25249.5-.13 (West Supp. 1988)). The proliferation of other state regulations is well reported. *See generally* BNA Special Report, Right-to-Know: A Regulatory Update on Providing Chemical Hazard Information (1985) [hereinafter Right-to-Know: A Regulatory Update] (twenty-five states had enacted worker right-to-know provisions as of 1985).

Communication Standard.[114] After the disastrous leak of methyl isocyanate at the Union Carbide pesticide plant in Bhopal, India, and several chemical accidents in the United States in 1985,[115] Congress enacted the federal Emergency Planning and Community Right-to-Know Act (EPCRA), Title III of the Superfund Amendment and Reauthorization Act of 1986 (SARA).[116] The EPCRA does not preempt state laws.[117] Consequently, the OSHA Hazard Communication Standard, Title III of SARA, and those state laws that relate to disclosure outside the workplace together establish a broad program of data distribution.

OSHA's Hazard Communication Standard contains a set of rules which have emerged as the basic framework of the overall information system. Originally written to apply only to the manufacturing sector, covering about 14 million workers in 300,000 establishments, OSHA was ordered in 1987 to expand its rules to cover all employees.[118] The OSHA rules require employers to identify and to warn workers only of known chemical hazards.[119] There is no requirement that employers

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114. *See, e.g.,* New Jersey State Chamber of Commerce v. Hughey, 774 F.2d 587 (3d Cir. 1985) (New Jersey Right-to-Know Act expressly preempted by the OSHA Hazard Communication Standard only insofar as the New Jersey Act pertains to the health and safety of manufacturing employees); Manufacturers Assn. v. Knepper, 801 F.2d 130 (3d Cir. 1986), *cert. denied,* 108 S. Ct. 66 (1987) (Pennsylvania Worker and Community Right-to-Know Act was not preempted outside the manufacturing sector; education and training requirement was preempted as to manufacturing employees, but hazard survey, labeling, and Material Data Safety Sheets Requirements were only partially preempted); Ohio Mfrs. Assn. v. City of Akron, 801 F.2d 824 (6th Cir. 1986), *cert. denied,* 108 S. Ct. 44 (1987) (the OSHA Hazard Communication Standard preempted the City's right-to-know ordinance, although Congress did not expressly preempt local regulation of health and safety in the area of toxic and hazardous substances by provisions in OSHA).

115. The most notable of these occurred in August 1985, when a cloud of toxic aldicarb oxime gas leaked from a Union Carbide plant in Institute, West Virginia, sending 135 people to the hospital for treatment. *See Union Carbide: New Accidents Revive Safety Issues,* 63 CHEM. & ENG. NEWS 4 (1985); *Reducing the Risk of Chemical Accidents: The Post-Bhopal Era,* 16 Envtl. L. Rep. (Envtl. L. Inst.) 10,300 (Oct. 1986); *supra* note 13.

116. 42 U.S.C. § 116 (Supp. IV 1986).

117. 42 U.S.C. § 11041(a) (Supp. IV 1986).

118. *See* United Steelworkers v. Auchter, 763 F.2d 728 (3d Cir. 1985); 29 C.F.R. § 1910.5 (1988).

119. 29 C.F.R. § 1910.1200(b), (d)(2) (1988) (any health impact for which there is statistically significant evidence of effects from occupational exposure must be reported; "significant evidence" exists when there is at least one positive study conducted in accordance with established scientific principles). OSHA's rules also establish standards for assessment of mixtures by employer-users downstream from the manufacturer. 29 C.F.R. § 1910.1200(d)(5) (1988). If an employer uses a process that produces chemicals to which employees may be exposed, that employer becomes a "chemical manufacturer" within the meaning of the rules and is required to evaluate the hazard of the chemical. 29 C.F.R. § 1910.1200(c) (1988).

OSHA presumes chemicals to be hazardous if they are listed under Subpart Z of the OSHA standards for hazardous and toxic substances, if they are listed as carcinogens by the National Toxicology Program (NTP) or the International Agency for Research on Cancer (IARC), or if a Threshold Limit Value (TLV) has been adopted for the chemical by the American Conference of Governmental Industrial Hygienists. 29 C.F.R. § 1200(d), apps. A, B, and C (1988). A number

perform new tests on chemicals' health effects. However, the results of each existing study that indicates an adverse health effect must be communicated, whether the employer agrees with the study or not.[120] The rules also specify labeling requirements for containers and conduits, require posting of warning notices in the workplace, and mandate chemical safety training, which is an essential element of any information program from the worker's point of view.[121]

The basic medium of information exchange has been the Material Safety Data Sheet (MSDS). This form contains information about the chemical substance, including its chemical identity, the name used on the container label, its physical and chemical characteristics, health hazards, primary routes of entry or exposure, the regulatory provisions applicable to it, safety precautions, emergency first aid procedures, the date of preparation of the MSDS, and the name, address, and telephone number of the person responsible for preparing it.[122] The information is comprehensive and to the point. Unfortunately, OSHA requires no standard MSDS format and some states require disclosure of more information than does OSHA. MSDS formats and computerized information services are developing in incompatible formats, limiting the potential for comparing and combining

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of state laws have provided specifically for inclusion of additional lists of suspected hazardous chemicals and a few have established procedures for defining hazardous chemicals which are not currently on any list. For example, Pennsylvania provides for automatic updating of its hazardous substance list whenever any of its constituent lists is changed. PA. STAT. ANN. tit. 35, § 7303(b) (Purdon Supp. 1988).

120. 29 C.F.R. § 1910.1200(b), (d)(5) (1988).

121. Pursuant to OSHA's rules, employers are responsible for training workers who handle hazardous chemicals at the time of their initial assignment and whenever a new hazard is introduced to the workplace; training includes informing workers about their rights under the hazard communication rules. 29 C.F.R. § 1910.1200(h) (1988). Employers must have a written plan outlining their methods of communication with employees and listing all covered chemicals. 29 C.F.R. § 1910.1200(e) (1988).

122. *See* 29 C.F.R. § 1910.1200(g) (1988). OSHA and most states require that for each chemical the manufacturer must prepare an MSDS. MSDSs have been in use for more than a decade, but previously were not mandatory. Support for mandatory and automatic provision of MSDSs by manufacturers and importers was very strong at the OSHA hearings and came from many sectors of business that use but do not manufacture chemicals. *See* 48 Fed. Reg. 53,280, 53,305-07 (1983).

The Material Safety Data Sheets must be made available to all buyers and employees. Several states provide for definite time periods for employer responses to an information request, while OSHA requires an immediate response. Several provide that a worker need not work with a substance for which the information has not been provided and several stipulate that a worker may not be discriminated against because of an information request. For a digest of the federal and state laws, see RIGHT-TO-KNOW: A REGULATORY UPDATE, *supra* note 113; HAZARDOUS MATERIALS: RIGHT-TO-KNOW NEWS, Nov. 15, 1985, at 5-12.

OSHA and 17 states require labeling of hazardous chemical containers, and 23 states require training of employees handling chemicals. *See* RIGHT-TO-KNOW: A REGULATORY UPDATE, *supra* note 113.

information.[123]

Although the chemicals it covers are in part selected according to different standards, the EPCRA's communication requirements build upon OSHA's rules. The EPCRA is designed primarily to enable localities to prepare an emergency response to chemical accidents. Section 301 of the EPCRA mandates the formation of state and local emergency response committees, which are responsible for local planning.[124] Section 312 requires that every firm subject to OSHA's rules complete an inventory of chemicals covered by those rules and provide it to the local committee. The inventory must contain a description of the amount and storage location of hazardous chemicals.[125] Industrial facilities that use chemicals on the EPA's list of "extremely hazardous substances" must notify the local committee of the presence of these chemicals, immediately report any unexpected releases, and participate in the committee's planning activities.[126] The local committee has discretion to determine whether all of the section 312 inventory data are to be made available to the public.[127]

The EPCRA also directs the EPA to begin compiling a national database on routine toxic discharges into the environment. Section 313, the national toxics inventory provision, requires that firms locate and quantify discharges into the environment of any of 329 specified chemicals.[128] These must be reported annually to the EPA, which is to use them to assess the nation's use of chemicals. The national toxics inventory will also provide the basis for more sophisticated regulatory planning,[129] and the inventory data must be made accessible to

123. *See infra* notes 172, 204 and accompanying text.

124. 42 U.S.C. § 11,001 (Supp. IV 1986).

125. 42 U.S.C. § 11,022 (Supp. IV 1986).

126. 42 U.S.C. § 11,004 (Supp. IV 1986).

127. 42 U.S.C. § 11,022(e)(3) (Supp. IV 1986). Delaware, Florida, Maine, Washington, and West Virginia have established poison information centers which give out information on toxics to the public. *See* RIGHT-TO-KNOW: A REGULATORY UPDATE, *supra* note 113, at 109, 114, 129, 209, 212. Illinois has established a Health and Hazardous Substances Registry and requires the new Epidemiological Studies Division of the Department of Public Health to gather data about hazardous substance use in the state. *Id.* at 24.

128. 42 U.S.C. § 11,023(c) (Supp. IV 1986).

129. The reported data are subject to the market influences outlined *supra* in Part III, which may result in some distortion. Also, currently available statistics on domestic production and consumption do not quantify how much of a chemical agent comes into contact with the population; rather they reflect only the amount potentially available for exposure. *See* Davis, Bridbord & Schneiderman, *supra* note 11, at 296. These gaps will be partially remedied by the EPCRA inventory, which will begin to identify the amount of chemicals released into the environment and the locations where they are released. In addition, the EPA recently received a report from a panel it commissioned to study the agency's need for data on pollution levels in the environment. The report recommends the creation of an environmental institute, to be separate from the EPA, to help the agency set up programs to monitor basic ecological systems. *Problems with Data Collection Hinder Efforts on Pollution, Experts Say,* N.Y. Times, Nov. 8, 1988, at C4, col. 1.

any person on a reasonable cost reimbursement basis.[130]

The new laws require a widespread exchange of information,[131] and entail significant expense, particularly the start-up costs of identifying chemicals and exposures.[132] However, their benefits are likely to be substantial.

The normative rationales for disclosure are also impressive and standing alone may justify right-to-know programs. Right-to-know laws articulate minimum standards of warning and informed consent for hazardous chemicals. They are a logical legislative response to the duty to test and warn recognized in *Borel v. Fibreboard Paper Products Corp.*[133] The content and scope of the manufacturer's duty to warn has been a major preoccupation of the tort system in the fifteen years

130. 42 U.S.C. § 11,023(l) (Supp. IV 1986). The first results from the inventory are being released. Environmental groups have compiled the EPA data into reports on specific geographic regions, focusing on air pollution as the largest category of pollution. Environmental groups are distributing the information and calling on industry to reduce air emissions by 90% in four years, as the Monsanto Company has stated it will do. *Environmental Groups Compile Reports Based on EPCRA Section 313 Emissions Data,* 3 Toxics L. Rep. (BNA) No. 16, at 509 (1988).

131. One estimate of the number of MSDSs being prepared is 20 million, but the extent of duplication is difficult to gauge. COMMUNITY RIGHT-TO-KNOW NEWS, May 8, 1987.

132. The new laws require firms to invest in collecting and communicating information. Both the EPA and OSHA have analyzed the costs of their rules. OSHA conducted an extensive regulatory impact analysis in 1983. It concluded that the benefits of the hazard communication rules will greatly exceed their costs. The total cost of the rules (present value) was estimated to be $3,374 million, using a 10% discount rate over a 40-year period. Initial costs were expected to be $603.926 million, or $43 per employee, with annual costs of $158.87 million, or $11 per employee. The total benefits from lessened health impacts, reduced search, and standardized federal rules will be $6,141.821 million, discounted at a 10% rate over a 40-year period. Benefits in the first year, $290.155 million, will increase to $1,050.782 million in the twentieth year, and to $2,354.561 million in the fortieth year. *See* 48 Fed. Reg. 53,280, 53,327-29 (1983).

The EPA has estimated that the § 313 reporting requirements of TSCA will apply to approximately 32,760 manufacturing facilities and that an average facility will have four chemicals and one mixture to report. The EPA's proposed inventory form would involve a cost of $12,467 for the average facility in the first year and $9,427 in subsequent years. The bulk of the first-year cost would be generated by the firm's initial research to identify its own toxic discharges. EPA also estimated that only three percent of small businesses in manufacturing will have reporting obligations. The costs to EPA for developing and maintaining the § 313 database will range from $4.1 million to $14.3 million in 1988. EPA did not attempt to estimate the benefit of the rules. Regulatory Impact Analysis in Support of Proposed Rule Making Under Section 313, Superfund Amendments and Reauthorization Act of 1986, OPTS-EPA, May 1987. The Agency is now in the process of comparing actual costs for the first year with its estimates.

These Agency estimates do not indicate the full benefits of these laws. Even OSHA's analysis omitted significant potential beneficial effects, including secondary influences on manufacturers and employers to substitute safer products and to support research in toxicity.

Some observers suggest that companies overestimate the costs of new regulations. A classic example was the industry opposition to OSHA's vinyl chloride standards. Although the industry predicted that compliance costs would reach between $65 billion and $90 billion, the actual cost totaled less than $1 billion. In addition, the standard increased the industry's productivity by improving housekeeping, encouraging innovation, and avoiding potential public health problems caused by exposure to vinyl chloride. *Chemical Hazards at Work: Whose Business?,* 9 HARV. ENVTL. L. REV. 331, 345 (1985) (panel discussion remarks of Caron Chess, Right-to-Know Coordinator, N.J. Dept. of Envtl. Protection).

133. 493 F.2d 1076 (5th Cir. 1973), *cert. denied,* 419 U.S. 869 (1974).

since *Borel.* The courts most often have discussed information issues in the familiar terms of the common law of torts: you have a duty to warn others of a danger you have created; you are entitled to choose the terms on which your body is touched by someone else.

The laws also appear to be justified on utility grounds. The economic function of disclosure is to correct the market failure caused by the basic asymmetries of information, inherent in the chemicals market.[134] During OSHA's hazard communication rulemaking proceedings, some industry representatives urged the agency to require communication only of risk estimates. They argued that this would have the same effect on workers' caution as more specific disclosure. OSHA chose instead to require notice of chemical identity and all documented health effects. OSHA's approach puts workers, commercial purchasers, and consumers in a position to make their own choices as to exposure and to seek assistance in making these decisions.

A case history illustrates the way disclosure can work. Male workers at an Occidental Petroleum plant, which manufactured pesticides, were talking over lunch and learned that none were fathering any children. Through their union they had sperm counts taken, which confirmed their suspicion of sterility. Because FIFRA requires that pesticide ingredients be chemically identified, the workers were able to identify their exposures. The union's researchers then were able to specify three chemicals, including debromochloropropane (DBCP), that were possible causes of sterility. When the workers raised the subject with Occidental, they discovered that the company already had internal data suggesting that DBCP is a cause of infertility.[135]

134. *See* Beales, Craswell & Salop, *supra* note 70, at 491, 513; Reich, *supra* note 86, at 20; Schwartz & Wilde, *Intervening in Markets on the Basis of Imperfect Information: A Legal and Economic Analysis,* 127 U. PA. L. REV. 630, 632 (1979); Schwartz & Wilde, *Imperfect Information in Markets for Contract Terms: The Examples of Warranties and Security Interests,* 69 VA. L. REV. 1387, 1388-89 (1983).

As Professors Beales, Craswell, and Salop have expressed it,

> information remedies allow consumers to protect themselves according to personal preferences rather than place on regulators the difficult task of compromising diverse preferences with a common standard. At the same time, information remedies place the burden of enforcement of quality on informed consumers in conjunction with marketplace forces. This is often a more efficient enforcement mechanism, since consumers are constantly monitoring in the course of their market search, thus relieving regulators of this task. Firms then self-enforce their own compliance out of competition-induced profit motives rather than from the fear of government compliance actions.

Beales, Craswell & Salop, *supra* note 70, at 513-14.

For an application of the information economics literature to occupational health issues, see Schroeder & Shapiro, *supra* note 4, at 1231. *See also* EMPLOYMENT HAZARDS — AN INVESTIGATION OF MARKET PERFORMANCE (1979); Viscusi, *supra* note 79, at 53.

135. Another source reports that the company doctor at the plant where these men worked had himself conducted rodent tests indicating that testicular atrophy resulted from exposure to DBCP. However, when the workers questioned the doctor as to why they had not been informed of his test results, he told them that there was no evidence of such effects in humans and there-

This conclusion was confirmed by tests at other plants, where workers exposed to the other two suspect chemicals, but not to DBCP, were found to have healthy, normal sperm counts.[136] Occidental then substituted a new chemical in the manufacturing process.

This story illustrates how access to chemical identity data allows the market, medical, and liability systems to function. Providing workers with health effects and exposure information places them in a position to seek assistance, to make choices about their own exposure, and to negotiate for less toxic conditions in the workplace.[137] In addition, if the suspect chemical is a consumer product, exposure to toxics may be reduced in the general population through increased vigilance by manufacturing workers. It is not feasible for agencies to make medical use of the data at the individual level and to oversee the myriad market transactions involving chemicals. Administrative agencies' centralized collection and management of data is complemented by distribution, which decentralizes responsibility for health and safety and lightens the administrative agencies' burden of regulation.[138] Critics of right-to-know laws claim that these laws will needlessly alarm the public and trivialize warnings by requiring unnecessary notices. However, individually and in groups, people already handle substantial amounts of complex information. Indeed, they are already called upon by the economic system to estimate the health risks of chemicals, though without the assistance of specific information.

It may not be necessary for all consumers or workers to be active in using the new information to bargain for better product quality. A small group of energetic "comparison shoppers" can have significant

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fore he had no obligation to tell them anything. *Chemical Hazards at Work: Whose Business?, supra* note 132, at 354 (panel discussion remarks of Charley Richardson, Mass. Commn. on Occupational Safety & Health).

136. *See* FINAL REGULATORY IMPACT ANALYSIS, *supra* note 41, at II-24.

137. Information exchange about job risks already takes place to some degree but the accuracy and efficiency of the exchange is limited. There is evidence that workers who believe their jobs are risky are in fact paid risk premiums, but these premiums might be different if the workers were fully cognizant of the risks they face. W. VISCUSI, *supra* note 77, at 43-44, 93-113; *see also* M. BAILEY, REDUCING RISKS TO LIFE (1980). Viscusi maintains that there is a "quit" response to risks that are revealed by on-the-job experience and that firms can reduce costs by eliminating the job risk-quit response relationship. *See* W. VISCUSI, *supra* note 77, at 64-75.

Viscusi also argues that the safety incentives created by market mechanisms may be considerably stronger than those created by OSHA exposure standards. He finds that a conservative estimate of the total 1979 job risk premiums for the entire private sector was $69 billion, almost 3,000 times the total annual penalties levied by OSHA. OSHA penalties were only 34 cents per worker, while risk premiums per worker were $925 annually. *Id.* at 44.

138. Information remedies, in conjunction with marketplace forces, place part of the burden for enforcement of product quality on consumers. This may be a more efficient enforcement mechanism, since consumers can monitor quality in the course of their market search, and relieve regulators of this task. Businesses may self-enforce out of competition-induced profit motives. *See* Beales, Craswell & Salop, *supra* note 70, at 491, 502.

effects.[139] This option may be most available with consumer products,[140] but it could evolve in other contexts. Unions and nonprofit public interest groups have adopted this function to a limited extent, by sifting through information and organizing to acquire more of it.

Third-party service providers of information services would be an important development in toxics control. Professional environmental services, such as the emerging environmental auditor, and consumer and worker-oriented data and diagnosis services, could evolve as a part of an independent market for toxicology, as the costs of exposure are identified and as research to prevent harmful side effects becomes more valuable. It is possible that a market in data could be sustained, if the law supported it by funding research to satisfy the comparison shoppers, both consumer and business. It has also been suggested that once toxicity data is generally available, the incentives of chemical manufacturers may be reversed, because lower toxicities will communicate an advantage. Voluntary testing and disclosure could become the pattern in competitive markets.[141]

Disclosure of chemical identity also forges a new link in the liability system. It should affect the number and specificity of tort and worker compensation claims and add to the incentive to screen products for toxicity. One OSHA official maintains that there already have been visible signs of change effected by right-to-know laws. Before the rules were enacted, workers typically complained to OSHA in only vague terms about health symptoms. Complaints now refer to symptoms more specifically and connect them to chemicals identified under

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139. Schwartz and Wilde have applied work on search strategies to consumer law and suggest that "consumers who invest in information [*i.e.*, comparison shoppers] exert a positive (pecuniary) externality on those who choose to purchase at random — the searchers police the market." Wilde & Schwartz, *Equilibrium Comparison Shopping*, 46 REV. ECON. STUD. 543, 551 (1979).

140. David Roe, a principal author of California's Proposition 65 and an attorney with the Environmental Defense Fund, pointed out that results were prompt: "Several national snack-food makers pulled back their products because they had excessive lead in them. Who ever suspected there was lead in snack foods? I didn't." Hinds, *As Warnings Multiply, Messages Are Ignored*, N.Y. Times, Mar. 5, 1988, at A1, col. 3; *see also* Beales, *Benefits and Costs of Label Information Programs*, in BANBURY REPORT 6: PRODUCT LABELING AND HEALTH RISKS 243, 247 (1980).

141. Viscusi suggests that a voluntary disclosure or "unraveling" process may occur and continue until all the firms have disclosed or until a stable equilibrium is established, with some participants withholding information. Unraveling is most likely to occur from the top down; that is, the best firm discloses and others follow. Viscusi suggests that publicity of the conditions in the worst firms is likely to have the opposite effect. *See* W. VISCUSI, *supra* note 77, at 134-43. He recommends disseminating information through government mechanisms that operate similarly to right-to-know laws, but amplified by public or independent rating of safety levels. Once measurements are accessible most firms will have incentives to disclose their health and safety performance and to compete for quality in this dimension. *Id.* at 71, 84-87.

the rules.[142] Insurance companies are also taking an interest in the quality of hazard communication programs, regarding them as an indication of the insured's sophistication in preventing liability.[143] In the tort area, the new notice requirements are double-edged. While disclosure will help plaintiffs identify defendants and may prove causation, it will also warn potential plaintiffs and thus remove one of the major grounds for toxic tort recovery.[144] These benefits have begun to be recognized by the regulated community.[145]

Right-to-know laws also will establish a more specific and broader base of information for researchers. The EPCRA requires businesses to maintain an inventory of each point of exposure to toxic chemicals and to make this data available to researchers. This process is creating a much more detailed record of exposure than has existed before and should help to yield more specific measurements.

Federal right-to-know laws grew out of state law experiments. In the past few years, several states have established some innovative variations on the disclosure theme. The most celebrated — or infamous — elaboration is California's Proposition 65, which requires businesses to warn the general public of any potential exposure to chemicals identified in the statute.[146] Another innovation, New Jersey's Environmental Cleanup Responsibility Act,[147] requires parties to real estate transactions to assess the toxicity of the soil and groundwater at the site, arrange for its cleanup prior to closing, and secure state certi-

142. *See A Look at the First Full Year of the HC Standard Implementation and Beyond,* HAZARDOUS MATERIALS RIGHT-TO-KNOW NEWS, May 15, 1987, at 6-8 (statement of Jennifer Silk, health scientist with OSHA's Office of Health Standards). *But see* Staten & Umbeck, *A Study of Signalling Behavior in Occupational Disease Claims,* 29 J. L. & ECON. 263 (1986). However, Staten and Umbeck focus on stress claims, which are more manipulable than other symptoms.

143. HAZARDOUS MATERIALS RIGHT-TO-KNOW NEWS, Mar. 15, 1987, at 10-11.

144. Chemical identity disclosure may also expand the liability of unions. *See* O'Reilly, *supra* note 74, at 307, 320-22. *But cf.* Hinds, *supra* note 140 (suggesting that most product liability claims are not precluded by warnings).

145. *See* J. O'Reilly, Why OSHA Hazard Communication Offers You Real Benefits in Return for Its Real Costs, Presentation at Executive Enterprises, Inc. conference entitled *Right to Know: Bringing Industry into Compliance* (Feb. 25, 1986).

146. "Proposition 65" is the popular name for the Safe Drinking Water and Toxic Enforcement Act of 1986. CAL. HEALTH & SAFETY CODE §§ 25180.7, 25249.5-.13 (West Supp. 1989). The law mandates that no business may exposé people to chemicals that cause cancer or birth defects without giving a "clear and reasonable" warning. The law also shifts the burden of regulation onto industry by providing that exceptions to the warning requirement are allowed only if companies meet the burden of proving "no significant risk" of human cancer or, with respect to birth defects, "no observable effect" at 1000 times the level of exposure. These standards are not required to be set by the administrative agency, but industry has pushed for rules to limit its liability, which might otherwise be litigated under the warning requirements of the law. Twenty-nine substances are now listed in the Act. Cal. Admin. Notice Reg. 87, No. 11-Z, at A-16 (Mar. 13, 1987).

147. N.J. STAT. ANN. § 13:1k-6 (West Supp. 1988).

fication of the adequacy of the cleanup plan. New York State has enacted requirements that notice be given of potential exposure from pesticide application prior to each occurrence.[148] Another trend is toward increased medical monitoring of exposed workers, such as that required by New York's, and several other states', worker right-to-know laws; similar federal legislation is pending in Congress,[149] and OSHA is considering promulgating medical monitoring rules.[150] The New Jersey Supreme Court has recognized medical monitoring as a tort remedy for townspeople exposed to toxic groundwater pollution.[151] A related development is the emergence of a new environmental profession, the environmental auditor, whose function, in part, is to act as an independent interpreter of toxicity information.[152]

It is too soon to measure the impact of right-to-know laws. While recent developments are promising, the market resources of chemical producers and users are unequal. Small businesses, workers, and the public-at-large generally do not have the financial means to purchase data interpretations or comparisons. Also, even where toxicity information is available, individuals may not be able to act on it. Workers are particularly vulnerable with respect to occupational health risks. Geographic and economic factors limit their discretion to choose among risks. Those who bear more general environmental risks are often subject to the same factors; families rarely can move to secure better air or water quality. The comparison shopper market will be limited, not only by the transaction costs of organizing into a body capable of reviewing and selecting among the research priorities, but also by the high cost of testing.

Not only individuals, but small organizations, including local and even state governments, have difficulty acquiring and managing this data. The EPCRA is inadequately funded, even to accomplish its ex-

148. N.Y. ENVTL. CONSERV. LAW §§ 33-0905, 33-1003 (McKinney 1984 & Supp. 1988).

149. A Senate filibuster defeated a medical monitoring bill, the High Risk Occupational Disease Notification and Prevention Act, S. 79, 100th Cong., 2d Sess., 134 CONG. REC. 53,233 (daily ed. Mar. 29, 1988). Its sponsors, however, may reintroduce it. *See Bill Is Rejected on Toxin Warnings,* N.Y. Times, Mar. 30, 1988, at A23, col. 1 (quoting the bill's sponsor, Sen. Metzenbaum, as saying: "[A]s long as workers are kept in the dark about occupational hazards, we will continue to try to bring them light.").

150. OSHA has initiated two generic rulemaking proceedings that would set new requirements for exposure monitoring and medical surveillance for employers. 53 Fed. Reg. 37,591, 37,595 (1988).

151. *See* Ayers v. Township of Jackson, 106 N.J. 557, 525 A.2d 287 (1987).

152. Several states now license environmental auditors. Scagnelli, *Protocol,* 3 WORKING PAPERS — A NEWSLETTER FROM THE INST. FOR ENVTL. AUDITING 5 (June 1987). See also New Jersey's Toxic Catastrophe Prevention Act, N.J. STAT. ANN. § 13:1K-19 (West Supp. 1988), which requires companies to perform environmental audits and develop risk management programs.

plicit goal of preparing localities for accidents. The statute places primary responsibility on state and local governments which do not have the funds to finance the transition into this new role. While computerized services are developing, many local emergency planning committees cannot afford to study their own needs nor to establish the connections that would allow them to function. Instead, they are opting to take the data in hard copy, where it often sits in boxes unused.

The prospects for more active market participation in toxicity data are substantially improved by right-to-know laws, but a central role for public intervention remains unfulfilled. The legal system could be designed to orchestrate greater and more efficient investments, in both data production and management.

V. RESTRUCTURING PRIVATE RESEARCH INCENTIVES

Dean Calabresi noted in *The Costs of Accidents,*[153] "[o]ne could build a whole theory of primary cost avoidance in terms of incentives to discover cures. . . . Usually, however, we apparently do not believe that a different allocation of most disease costs would do much to spur reduction of their number or severity."[154] Incentives to discover cures can be supported in the chemical toxicity context, if the market's information dynamics are taken into account.

Among the laws which aim to stimulate private research, such as the patent system and product liability law, two models provide for direct funding of research. One might be called the "seed money" model, a variant of which has been proposed to encourage research on superconductivity.[155] In this model, public money is provided as an inducement for research and development in a particular sector of the economy, in the hope that it will lead to the long-term development of marketable products. Another approach is to select a particular goal and fund efforts to attain it. For example, Congress has enacted a program to spur research on "orphan drugs," those which treat rare diseases and therefore have little commercial value.[156] The orphan drug program finds sponsors for research on rare diseases and pro-

153. G. CALABRESI, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS (1970).

154. *Id.* at 44. Dean Calabresi suggests that occupational diseases and product-related diseases can be treated in the same way as accidents, in that they can be reduced in number and severity by the same methods, including methods aimed at primary cost reduction.

155. *Panel Asks Strong U.S. Push to Develop Superconductors,* N.Y. Times, Jan. 4, 1989, at A1, col. 1 (natl. ed.).

156. *See* HOUSE COMM. ON ENERGY AND COMMERCE, REPORT ON THE ORPHAN DRUG ACT, H.R. REP. NO. 840, 97th Cong., 2d Sess. (1982), *reprinted in* 1982 U.S. CODE CONG. & ADMIN. NEWS 3577.

vides them with financial incentives in the form of grants and tax breaks.[157] These approaches are useful where the need for the information is limited or as yet undeveloped. That is not the case, however, with the need for chemical toxicity data.

Chemicals in commercial use, far from being orphans, affect huge numbers of people and businesses. This circumstance provides opportunities for adjusting research incentives in the chemicals market. The recent amendments to FIFRA and SARA recognize the option of making industry pay for the research required by its externalities, but these laws would simply tax the industry to finance limited government efforts and fail to take full advantage of market dynamics to stimulate private production of data.

A more ambitious and promising approach would be to adapt the design of the national hazardous waste clean-up program to foster private research sponsored by the users of chemical products. The current deficit of toxicity and exposure data is analogous to the current hazardous waste problem. Both have hidden impacts and delayed effects and require costly public initiatives to remedy, and both are externalities generated by the same group of industries. In addition, CERCLA attempts to involve all the parties who have an interest in a site (whether that interest is past or prospective) and to provide those who want to remedy the hazardous condition with the financial support to do so. This type of mechanism is needed to mobilize latent forces in the market to generate more toxicity data.

Hazardous waste cleanup is being carried out pursuant to CERCLA, commonly called "Superfund," and the 1986 amendments to the Superfund contained in SARA. Pursuant to CERCLA, the EPA has published a National Priority List, which identifies the hundreds of locations that require attention. The statute's Superfund and liability provisions provide funding for the actual cleanup. The basic fund itself is derived from taxes on the petrochemical industry and from general revenues. Cleanup operations may be financed from this fund or by "potentially responsible parties" (PRPs), who, when identifiable, are held liable for clean-up costs. PRPs may be waste generators, or haulers, or property owners, or tenants — virtually anyone associated with the presence of the waste at the site. The cleanup may be carried out by local, state, or federal agencies or by private parties,

157. *Id.* Biomedical research takes place in three contexts: the federal government; nonprofit medical centers, which are chiefly in medical schools and are largely funded through the federal grant system; and the pharmaceutical industry. In 1982, the FDA reported to Congress that it had approved approximately 960 drugs for rare diseases. But of these, only 34 were developed and marketed by companies; with 24 of these 34, a government agency or a university had assisted in either the financing or the research. *Id.* at 3579-80.

who then may seek reimbursement from the fund or from identifiable PRPs. Most CERCLA cases are initiated by the EPA or state agencies which then negotiate for further involvement by PRPs.

The Superfund program thus combines three elements: (1) a plan for action, formulated and published by the government; (2) a source of funding that attempts to link the costs of cleanup to the parties most responsible for the hazardous condition; and (3) open participation in the process, with financial support made available to any party interested in undertaking to clean up a site. While the Superfund program has been criticized as unwieldy, some of its problems surely are attributable to the nature of its difficult task. In any event, the design of the Superfund is instructive as a model program to address current chemical research needs, a program which I will call "super study," for lack of a better name.

In a "super study" program, research would be conducted according to a general plan, by a combination of private and public institutions.[158] Private laboratories or government agencies could conduct studies according to test protocols specified by the plan and then register the test results. The costs of different types of study could be standardized. Documented research, with peer review completed, would be reimbursed from the general fund. Reimbursement to the fund by chemical producers would be mandated when studies showed adverse health effects from their individual chemicals or identified mixtures. Basic screening and research, and methodological research, would also be reimbursed from the general fund.

Reimbursement actions against manufacturers would be managed by a separate custodian of the fund, so that research results would not be influenced by the need to support the fund. Responsible parties, producers comparable to the Superfund PRPs, could be identified through the TSCA, the new inventory provisions of the EPCRA, the registration provisions of the FDA, and the pesticide laws. Joint and several liability could be established by law, with liability apportioned on the basis of human exposure rates. Long-term epidemiological studies could also be funded by dischargers, based upon the extent of human exposure caused by their discharges.

A national study plan would be published and managed by the National Toxicology Program, the National Institute of Environmen-

158. *See* Shapiro, *supra* note 76, at 175-82 (discussing possibility of both limited and complete third-party testing, either by the government or by independent contractors); CHEMICALS AND HEALTH, *supra* note 9, at 96 (urging that serious consideration be given to supporting the National Center for Toxicological Research with a contractual laboratory, associated with academic sciences, and perhaps through a consortium of universities).

tal Health Sciences (NIEHS), or another suitable agency. It could be managed as a more formalized version of the present national toxicology research agenda and grants programs, or it could adopt the National Research Council's recommendations for toxicological research published in *Toxicity Testing.*[159] The National Research Council has reviewed a variety of screening proposals and recommended a system that would operate in several stages, selecting chemicals for further research at each stage, based on their human exposure and potential toxicity.[160] The *Toxicity Testing* approach is not the only planning resource available, of course; the public health research community is a ready repository of expertise in research management.

One basic appeal of a "super study" program, in contrast to the Superfund hazardous waste program, is that the investment would come at the beginning of the production process, when information can be useful in many environmental and health dimensions. A research program's benefits would also be broader than the Superfund's focus on hazardous dump sites, because much of the data produced would be applicable across different media. The current Superfund allocation of $8.6 billion for waste site cleanup is addressing only part of a broader pollution problem. The amount of waste discharged into other media, particularly air, is greater than that disposed in landfills.

The rationale for taxing the entire petrochemical industry to support research is also stronger than it is for hazardous waste cleanup. Research would benefit the entire system, including the industry itself, by providing a better basis for product screening in the marketplace and by removing the pall cast over safe products by uncertainty about toxicity. Moreover, a tax that is imposed on future behavior, before

159. *See* TOXICITY TESTING, *supra* note 10.

160. In stage one, fragments of available information would be collected, including all indicators of exposure, and fed into a computer program. A set of rules would be applied by the computer to determine whether the levels of exposure and known toxicity indicators suggest that further examination is needed. If certain indicators were triggered, the chemical would then be passed on to stage two, with grades keyed to priorities for further research. The grades would also indicate the appropriate amount of funding to be spent on the research.

In stage two, the stage-one dossier would be reviewed by two experts, one in toxicity and one in exposure. If no tests were currently in progress, each expert would design and conduct a research strategy using currently available data. After considering all relevant factors, they would make a recommendation concerning further study. Stage three would consist of a more thorough assessment by a committee of experts. Stage four would entail actual field or laboratory research.

When these four stages were completed, the results would be fed back into the system to check reliability. Final study results would be used by regulators and would be evaluated with respect to public policy and their relevance to further refinement of the selection process. At each stage, the cost of further study and the usefulness of the information to the regulatory system would be integrated into the process. The stages would be coordinated, with the value of the information as the primary consideration. *See id.* at 16, 205-26, app. A; NATIONAL ACADEMY OF SCIENCES, PRINCIPLES FOR EVALUATING CHEMICALS IN THE ENVIRONMENT (1975).

the externality is created, sends a more direct signal to the industry than the after-the-fact Superfund tax. Firms would be taxed for activities they can control, rather than for existing harms whose cause they may not be able to identify.[161] The tax structure could be designed in an innovative manner to encourage waste reduction. For instance, the tax could be keyed to levels of waste or human exposure, rather than production. The data on pollution discharges that would be needed to implement this approach is now being pulled together by the EPA pursuant to the EPCRA.

A research super study also should be easier to administer than the current national Superfund program. CERCLA implementation must struggle with a number of unwieldy obstacles that would not be present in the super study program. Chief among these obstacles is the need to treat and to relocate millions of tons of poisonous and contaminated material. A research program would have few such logistical problems because it would produce prospectively useful information, as opposed to trying to destroy or neutralize useless, dangerous waste.

Each hazardous waste site is a complex ecological problem, unlike the relatively standardized procedures in toxics testing. Waste sites are located in a wide variety of natural and societal settings, and can be handled by several different technologies, and treated to different grades of remediation. In practice, cleanup usually is too expensive and uncertain for the proponent of the cleanup, usually a state agency or the EPA, to complete it before seeking to involve PRPs through reimbursement. Therefore, the agency initiates legal action against PRPs and then litigates and negotiates the question of "How clean is clean?" for the particular site. The structure of the situation leaves the amount and the time frame of liability uncertain and allows disputes to persist among potentially responsible parties, thus discouraging enforcement.[162]

A super study program could be designed to produce less uncertainty as to liability for study costs. Study costs could be standard-

161. *See* White, *Economizing on the Sins of Our Past: Cleaning Up Our Hazardous Wastes,* 25 HOUS. L. REV. 899, 908-11 (1988). Retrospective regulation is no longer limited to waste disposal sites. The Asbestos Information Act requires manufacturers of asbestos-containing building materials to provide the EPA with information on the years of manufacture, the types and classes of products, and other identifying data. The legislation is intended to assist the EPA in regulating asbestos cleanup and to simplify asbestos "cost recovery" litigation brought by owners of buildings constructed with asbestos materials. These lawsuits are often brought against large numbers of manufacturers because the plaintiffs cannot identify the maker of the particular product on which the claim is based. *Congress Passes Bill Requiring Firms to Provide Product-Identification Data,* 3 Toxics L. Rep. (BNA) No. 22, at 688 (1988).

162. *See* Anderson, *Negotiation and Informal Agency Action: The Case of Superfund,* 1985 DUKE L.J. 261 (thorough analysis of CERCLA's history and its lessons).

ized, just as research grants already are defined and limited. If reimbursements for studies were made from the general fund upon a showing that the study was conducted according to defined research protocols, liability for each study's cost could not be avoided by failing to cooperate, because the study would be completed before reimbursement was sought.

An important issue in the design of the super study program would be how to answer the parallel question to "How clean is clean?"; that is, "How toxic is toxic?" As a threshold distinction, the meaning of "toxic" differs in different testing and regulatory settings. An indicator of toxicity that suggests further testing is advisable may be much weaker than the data required to impose a limitation on human contact with a substance. The super study program administrators could select a formal means of defining indicators of toxicity sufficient to warrant further study or warning. These judgments are already being made in the course of administering federal research grant programs. The National Research Council's work in *Toxicity Testing* suggests that they may be further formalized.

This brief outline suggests that it is possible to redesign information laws to correct the present imbalance in the private research market and bring into play actors who are disadvantaged by market dynamics.[163] A super study program could support research efforts outside the present government and manufacturing framework. Labor and consumer organizations and environmental consulting firms serving small businesses could take advantage of the program's reimbursement provisions to engage private laboratories to conduct research. This would change existing incentives by presenting chemical manufacturers with the possibility that another party would produce information on their products or pollution. The prospect of third-party testing would encourage businesses to do their own studies, to do them accurately, and to curtail human exposures and substitute less toxic chemicals to reduce any damage that research linked to their chemicals.

163. This proposal would attempt to influence the market to attend more fully to public research priorities. Another current controversy on the commercialization of science, particularly biology and biotechnology, centers on the reverse issue: the appropriateness of privately driven guidelines for public supported research. The role of independent, noncommercial institutions in basic and applied scientific research has been the topic of debate during the past decade, as many universities and businesses have joined forces to conduct research, particularly in bioengineering. Perhaps the most radical proposal to combine commercial and public research is the Reagan administration's suggestion that the NIH be converted into a private research center, financed with money from the government, industry, and foundations. The proposal was made, in part, to allow for greater support for the biotechnology industry. *See U.S. Weighs Turning Agency Into Private Health Institute,* N.Y. Times, Dec. 16, 1987, at A1, col. 4.

Chemical toxicity is a complex phenomenon. Research is an unpredictable investment and we do not know if any national research program would substantially reduce the problem of uncertainty in chemicals regulation. However, since we are already investing in research and have designed much of the regulatory system to depend upon information in order to function, the efficiency with which the private sector produces and uses the data should be a primary concern. The law can be better designed to support private incentives to produce toxicity and exposure data. The same can also be said about the law's role in distributing data.

VI. THE DATA SYSTEM AS A PUBLIC UTILITY

The history of chemical information services in this country is a story of repeated flirtation with and hesitation over commitment to the concept of a national data system.[164] In the late 1970s, in the wake of the enactment of TSCA, an integrated national data system was planned, but when the Reagan administration took office, information policy shifted in a different direction. The EPA in particular has suffered from inconsistent goals and support of its data project. Both private and public toxics data services are now evolving rapidly in response to new disclosure laws.[165] Meanwhile, basic questions about what kind of long-term data resources the nation will have are being answered on an *ad hoc* basis, without the benefit of a considered legislative policy.

Two current developments outside the field of chemical regulation will shape the future of availability of this data. The first is the rapid diversification of telecommunications which has followed the restructuring of the telephone system and is fueled by the continuing evolution of computer technology.[166] The second is the reassessment of federal information policy, now taking place as government agencies

164. As early as 1962, President Kennedy noted:

> The accumulation of knowledge is of little avail if it is not brought within reach of those who can use it. Faster and more complete communication from scientist to scientist is needed, so that their research efforts reinforce and complement each other; from researcher to practicing physician, so that new knowledge can save lives as swiftly as possible; and from the health professionals to the public, so that people may act to protect their own health.

Special Message to the Congress on National Health Needs (Feb. 27, 1962), *reprinted in* PUBLIC PAPERS OF THE PRESIDENTS OF THE UNITED STATES: JOHN F. KENNEDY 169 (1963).

165. *See, e.g.*, Cooper, *Secondary Information Services in Science and Technology: A Wide-Angle View*, 33 J. AM. SOCY. INFO. SCI. 152 (1982); *Perspectives on the Federal Government and Health Information: Patterns, Impact, Expectations*, 38 J. AM. SOCY. INFO. SCI. 25 (1987); Williams, *Electronic Databases*, 228 SCIENCE 445 (1985).

166. Noam, *The Public Telecommunications Network: A Concept in Transition*, 37 J. COMM. 30 (1987).

move from paper to electronic media.[167] Some of the major issues on the congressional agenda in this area are equality of access to data, coverage and structure of data resources, quality of information, the appropriateness of duplication in some systems, and the proper balance between public and private services.

As information dissemination is receiving attention, the time is right to design a data management and distribution system to serve environmental, occupational, and public health needs. Toxicity information presents a special case for distribution, with both unique problems and possibilities. Given the market disincentives to disclosure of toxicity, there is a basic role for the government in data distribution.

The concept of the public utility provides an appropriate organizing principle for structuring that role. Widespread exposure to toxic chemicals makes toxicological knowledge a "good" needed by many sectors of society, but it must be developed and maintained in order to be useful. The market for this data has characteristics which have justified public utility treatment in other industries: a wide variety of users or potential users, with differing needs and different abilities to pay; even for those who are unable to pay, there are strong public policy reasons for providing them with the service.

Traditional public utility regulation builds upon the notion of a "natural monopoly," which is said to exist when the structure of an industry is such that a single firm can meet the demand more efficiently than can several or many firms.[168] Toxicology is a resource that in key respects is like the familiar utility services in energy, transportation, and communications. We normally think of utilities as

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167. INFORMING THE NATION, *supra* note 36, at 209; *see also* G. BASS & D. PLOCHER, STRENGTHENING FEDERAL INFORMATION POLICY: OPPORTUNITIES AND REALITIES AT OMB (Benton Found. Proj. on Comm. & Poly. Options No. 6) (1989); J. SHATTUCK & M. SPENCE, A PRESIDENTIAL INITIATIVE ON INFORMATION POLICY (Benton Found. Proj. on Comm. & Info. Poly. Options No. 7) (1989).

168. The legal notion of a public utility has early common law origins, but began to develop into its present form in the latter half of the nineteenth century. *See* Munn v. Illinois, 94 U.S. 113 (1877); Hamilton, *Affectation with Public Interest,* 39 YALE L.J. 1089 (1930); McAllister, *Lord Hale and Business Affected with a Public Interest,* 43 HARV. L. REV. 759 (1930). Today its most important applications are to common carriers regulated according to statutory mandate. *See, e.g.,* Communications Act of 1934, ch. 652, tit. III, § 301, 48 Stat. 1081 (1934) (codified as amended at 47 U.S.C. § 301 (1982)). An excellent history and analysis of communications services and their regulation is I. POOL, TECHNOLOGIES OF FREEDOM (1983).

Recent developments in the regulation of industries traditionally treated as natural monopolies are discussed in TELECOMMUNICATIONS REGULATION TODAY AND TOMORROW (E. Noam ed. 1983); BREAKING UP BELL — ESSAYS ON INDUSTRIAL ORGANIZATION AND REGULATION (D. Evans ed. 1983) [hereinafter BREAKING UP BELL]; *see also* VIDEO MEDIA COMPETITION — REGULATION, ECONOMICS, AND TECHNOLOGY (E. Noam ed. 1985) [hereinafter VIDEO MEDIA COMPETITION]; DEREGULATION AND THE NEW AIRLINE ENTREPRENEURS (J. Meyer & C. Oster, Jr. eds. 1984).

large regulated monopolies which invest in real estate and hardware and provide energy and carriage service. In an "information economy," an investment in the research and training necessary to accumulate and maintain useful knowledge may provide a basis for utility status.

Moreover, the particular character of modern transportation and communications utilities as systems, which increase in usefulness as they connect different geographic areas and segments of the society, is also applicable to chemical health information. Because toxicology is a body of knowledge that grows, expands, and corrects itself as it is fed with new data, it benefits from integrated communications channels. As a system, it is advanced most efficiently by making data interconnections accessible to all possible users. The role of the database is central because it supports inferences that affect the study of related chemicals and also feeds basic understanding of the physical dynamics of the problem. The NTP has declared:

> The very body of NTP test data — an expanding body of comprehensive, comparable, reliable test results — is itself emerging as a research tool for developing or evaluating assay methods. . . . Toxicological characterization can be an immediate effective tool in prevention of chemically induced disease; in the long-run, this growing body of data can become its driving force.[169]

Computerization has made possible the linkage of toxicity databases, has sped their development, and has increased their productivity. The large amount of data that is being accumulated can be put to work if properly managed.[170]

Data resources thus would benefit from a specific and coherent federal policy on toxicity data management. Instead, we have been investing in a fragmented system that is developing in a haphazard fashion, according to principles that do not fit the character of information as a process or a product. A brief history of recent federal information policy will be useful background for further examination of the issues.

With the passage of the TSCA in 1976, the EPA was directed to coordinate agency data activities and, in 1978, the EPA established the Interagency Toxic Substances Data Committee to guide database development. The TSCA also directed the Council on Environmental

169. UNITED STATES DEPT. OF HEALTH & HUMAN SERVS., NATIONAL TOXICOLOGY PROGRAM: FISCAL YEAR 1987 ANNUAL PLAN 2.

170. *See* Bloom, *Introduction: Science, Technology and the National Agenda,* in FRONTIERS IN SCIENCE AND TECHNOLOGY 9-10 (1983). Bloom, Director of the Arthur V. Davis Center for Behavioral Neurobiology, the Salk Institute, stresses the importance to scientific and engineering progress of the effective use of new communication technologies to research and development as a whole.

Quality (CEQ) to study and report on the feasibility of a uniform chemical identification convention and an integrated data system.[171] The CEQ reported that, although coordinated data systems would vastly enhance the federal effort to control toxic substances, no integrated network existed. Rather, more than 220 separate systems had been developed by agencies involved in chemical regulation, "each serving different needs and organized in a different way. Some [were] sophisticated computer systems; others [were] simply manual files."[172] Data had been compiled pursuant to at least fifteen different statutes[173] which were generally pollution or product quality control statutes that did not focus on data needs.[174]

The CEQ, in conjunction with the EPA and HEW, recommended the adoption of a uniform chemical coding system and the development of a broad-based network of data systems, which it called the Chemical Substances Information Network (CSIN).[175] The network was conceived of as "a collection of discrete information sources which employs identical or compatible communication facilities, file structures, computer languages, or other means of retrieving data from the multiple sources."[176] This "loosely coupled" network of various types of databases, rather than one central system, would include "all major federal chemical databases," as well as private systems and services.[177] Major components would include a directory of the infor-

171. *See* 15 U.S.C. §§ 2609(b), 2624(b) (1982).

172. TOXIC CHEMICALS AND PUBLIC PROTECTION, *supra* note 29, at 21. The report elaborated:

> Timely and convenient access among these systems has been very difficult. Information is often incompatibly described, categorized, and filed. One agency is frequently unaware that needed information exists in another system. Private users of chemical information have difficulty learning about or obtaining federally maintained information. Additional data systems are maintained by states, industry, and other private institutions without being linked to each other or to similar federal systems. Although information may exist that would be valuable in understanding and controlling certain chemical hazards, it may not be readily available or usable for such purposes to scientists, public interest groups, and government and industry decisionmakers.

Id.

173. *See* OFFICE OF TOXIC SUBSTANCES, U.S. ENVTL. PROTECTION AGENCY, CHEMICAL REPORTING AND RECORDKEEPING AUTHORITIES (1978). Elsewhere it has been estimated that there are 10,000 to 12,000 statutory provisions requiring the collection of information. *See* Berninger, *Some Reflections on Federal Policy for Secondary Information Systems and Sciences, 1945-1981,* 33 J. AM. SOCY. FOR INFO. SCI. 161 (1982) (citing COMMITTEE ON THE RIGHT OF PRIVACY, U.S. DOMESTIC COUNCIL, NATIONAL INFORMATION POLICY: REPORT TO THE PRESIDENT OF THE UNITED STATES (1977)).

174. *See* Chartrand, *The Politics of Information,* 36 J. AM. SOCY. INFO. SCI. 376, 377 (1985) (citing CONGRESSIONAL RES. SERV., U.S. LIBRARY OF CONGRESS, INFORMATION POLICY: PUBLIC LAWS FROM THE 97TH CONGRESS 11 (N. Miller ed. 1983)).

175. *See* TOXIC CHEMICALS AND PUBLIC PROTECTION, *supra* note 29, at 24.

176. *Id.*

177. *Id.* at 25. As proposed by the CEQ, the network would contain two major divisions: all

mation on each system in the network so users could identify the systems that would meet their needs. It would also contain "[c]hemical identification data for an estimated one million chemicals with cross-references to other files containing information on individual chemical substances," and a reference system for toxicological data and other relevant information.[178]

The EPA was to be the lead agency in the development of the network, assisted by the CEQ and the National Library of Medicine.[179] The EPA began developing a means of classifying data within the system, while the National Bureau of Standards was charged with the development of quality assurance measures for the system.[180]

Both the EPA and the National Library of Medicine already had experience in developing databases in this area. In 1973, the EPA began to share with the National Institutes of Health (NIH) the management of a network of twenty chemical databases; this network, known as the Chemical Information System (CIS), was more limited than the CEQ's CSIN proposal. However, by 1984, the CIS contained a wide variety of physical and regulatory data on some 350,000 compounds. This database was available around the clock for emergencies. Forty percent of its users were federal agencies; the rest were businesses, universities, and foreign governments.[181]

In addition to EPA resources, the National Library of Medicine has maintained a Toxicology Information Program for more than twenty years. That program has now developed a number of online information retrieval services, including the Registry of Toxic Effects of Chemical Substances (RTECS), produced by the National Institute for Occupational Safety and Health. RTECS today contains acute toxicity data for 76,000 substances.[182]

When the Reagan administration took office in 1981, the CSIN

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the data collected under TSCA in one and a subfile of all the nonconfidential data to be available to the public in the other. *Id.*

178. *Id.* at 25-26.

179. *Id.* at 26.

180. *Id.* at 29-30.

181. *See* Fox, *EPA Dumps Chemical Data System,* 226 SCIENCE 816 (1984). Even as the largest service that provided such information in 1983 the CIS' total number of current hours was under 7,000. *See* Williams, *supra* note 165, at 447. Today, as right-to-know laws are being implemented, that figure should rise.

182. *See* Lindberg, *Section II. Health Science Libraries. National Library of Medicine: The View at 150 Years,* 38 J. AM. SOCY. INFO. SCI. 34, 37 (1987). The largest of the Library's online retrieval services is TOXLINE, with about 2 million references and information on human and animal toxicity studies, effects of pollution, and adverse drug reactions. The Library also maintains CHEMLINE, a file of more than one million names for chemical substances representing 650,000 unique compounds. MEDLINE is a medical information service of the same type, which contains abstracts of biomedical information. TOXNET contains toxicological data re-

was little more than a proposal, and it was quickly shelved. The new administration's approach to government information services emphasized private management of data to a far greater extent than had previous administrations. The Office of Management and Budget (OMB) directed that government information assets be commercialized and privatized on a broad scale.

The Paperwork Reduction Act has been cited as the authority for the OMB's attempt to control federal information policy. The Act directs the OMB to supervise federal reporting and data collection, but does not deal explicitly with data dissemination.[183] Relying on its interpretation of the Act, the OMB has issued a series of directives establishing a policy of cost recovery for government products, prohibiting government competition with the private sector in information services or goods, and directing the transfer of many service-oriented activities to the private sector.[184] At the same time that these directives were issued, budgets for information development and services were reduced, particularly at the EPA. These decisions constituted a dramatic and controversial change in information policy.[185] Many information experts have complained that this policy has been disastrous: user costs have increased dramatically;[186] numerous

lated to the environment, emergency situations, and regulatory issues. The TOXNET system is "user friendly" and operates around the clock. *Id.*

Another major center of related databases is the National Cancer Institute. *See* Berninger, *supra* note 173, at 165; Masys & Hubbard, *Technical Information Programs of the National Cancer Institute,* 38 J. AM. SOCY. INFO. SCI. 60 (1987).

183. *See* 44 U.S.C. § 3501 (1982).

184. *See* OMB Circular No. A-25, "User Charges," 52 Fed. Reg. 24,890 (1987) (Draft Revision); OMB Circular No. A-130, "Management of Federal Information Services," 50 Fed. Reg. 52,730 (1985); INFORMING THE NATION, *supra* note 36, at 261-70. Critics have also charged that the OMB has intruded into the substance of environmental regulation without legal authority to do so. Shattuck and Spence report that a congressional study showed that the OMB was more likely to disapprove research projects with environmental and occupational health topics than those that concerned infectious diseases. Research on worker exposure to dioxin and EPA regulation designed to protect consumers and workers from asbestos were blocked based on OMB cost-benefit assessments. J. SHATTUCK & M. SPENCE, *supra* note 167, at 17. Bass and Plocher suggest that the OMB has failed to assist the EPA in its implementation of the EPCRA national toxics inventory. G. BASS & D. PLOCHER, *supra* note 167, at 38-39. *But see* Steinberg, *OMB Review of Environmental Regulations: Limitations on the Courts and Congress,* 4 YALE L. & POLY. REV. 404 (1986).

185. *See, e.g.,* Palmer, *Effect of Federal Programs on Health Sciences Libraries,* 38 J. AM. SOCY. INFO. SCI. 40-47 (1987) (citing a steady and disturbing decline in federal appropriations for health sciences libraries). Some viewed this trend as part of an overall tendency of the Reagan administration to restrict access to information. *See Group Assails U.S. Information Flow,* N.Y. Times, May 12, 1988, at C33, col. 1 (in the past five years, one out of every four government publications has been eliminated and government data is increasingly available only through computer access and with high user charges).

186. *See* Smith, *Online Government Databases: Into the Maelstrom,* DATABASE, June 1988, at 56 (citing two examples of changes in rates after privatization). AGNET, a system developed by the Department of Agriculture, was contracted out to Martin Marietta in 1985. Before privatization, access charges were $60 a year, plus a $42 per hour connect charge. Costs are now

databases that were not of immediate market value, but had research value, have disappeared;[187] and, in the meantime, databases have not been enhanced nor has quality control been ensured.[188]

Chemical toxicity databases were included in the new policy. The NIH reduced its support of the CIS to one part-time coordinator in 1982. In 1983, partially pressured by budget cuts, the EPA began to consider phasing out all of its CIS management and coordination activities and transferring them to the private sector. The EPA's support of the system was reduced and input was frozen for nearly twelve months: anyone taking over the system would face the very substantial costs of updating the database.[189]

In early 1984, the EPA convened two panels, one of government experts and one of private sector representatives, to review EPA information policy. The government panel, citing budget constraints, concluded that the CIS databases should be turned over to the private sector, but only after a transitional period of federal guidance and support. The private sector panel suggested several alternatives,[190] but basically recommended that the government continue to manage development of the system's data, while allowing most of its distribution to be handled by the private sector. The panel concluded that the CIS should not be required to become entirely self-supporting because some valuable databases, which cannot currently support themselves on the market, should have continued government support.[191] In spite of the panel recommendations, the EPA decided abruptly to hand over its databases to two private contractors, providing no federal support for updating them. The OMB rejected a proposal to allow the National Science Foundation to oversee the transfer. Public and private users criticized the action, arguing that the system would become

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$1800 per year if accessed through the contractor or $25 per year plus $96 per hour if accessed through DIALOG. The Federal Elections Commission also privatized its database in 1985. Online charges went from $22 per hour to $4,000 per year for unlimited access under the new contractor. *Id.* at 60; *see also* Seghers, *Computerizing Uncle Sam's Data: Oh, How the Public Is Paying*, BUS. WK., Dec. 15, 1986, at 102-03.

187. *See* Wolfe, *Evolution of Contractor-Supported Health Information Activities*, 38 J. AM. SOCY. INFO. SCI. 71 (1987); Fox, *supra* note 181; Smith, *supra* note 186.

188. *See* Heller, *The Chemical Information System and Special Databases*, 25 J. CHEM. INFO. & COMPUTER SCI. 224, 225 (1985).

189. *Id.* at 229.

190. *See* Life Systems, Inc., Chemical Information System: A Blue Ribbon Panel Review (U.S. EPA, Aug. 1984) EPA — 200-02-80-002, PB 84-217777 [hereinafter Life Systems, Inc.]; Chemical Information Systems: A Government Panel Review (U.S. EPA, Aug. 1984) EPA — 200-02-84-003, PB 84-217769 [hereinafter A Blue Ribbon Panel Review]; Kadec & Jover, *Transfer of the Chemical Information System (CIS) to the Private Sector*, 9 ONLINE REV. No. 4, at 297-304 (1985).

191. *See* A Blue Ribbon Panel Review, *supra* note 190, at 1-2, 3-11, 3-12; Heller, *supra* note 188, at 229.

more costly and would deteriorate.[192] The two contractors then made different plans for the system's future.[193]

Diversity of formats and decentralization are now dominant traits of toxicity information development. In the past few years, right-to-know laws have opened up a new market for data that has spawned a variety of new information services geared to handling the Material Safety Data Sheets (MSDS),[194] but an early move to standardize the MSDS format languished after large firms objected that they were satisfied with their own existing systems.[195]

The issue of a central data system has remained alive, however. Indeed, the problem of how to organize and support data distribution is more pressing today than ever before. Local governments and the nonbusiness public now need data access in order to evaluate information being distributed pursuant to right-to-know laws. Federal agencies that must comply with hazard communication and right-to-know requirements, such as the Department of Defense, are a major new user group of this data. Several proposals to meet their needs are being discussed. For instance, the Chemical Manufacturers' Association has informally proposed that it develop and maintain a database. Meanwhile, the General Services Administration is being considered as a candidate to develop a system to support federal agency compliance.

Federal information policy recently has been reviewed by the General Accounting Office and the Office of Technology Assessment (OTA). The OTA issued a report on federal information dissemination by all agencies.[196] In *Informing the Nation,* the OTA concluded that legislation is urgently needed to set the direction of federal information policy for the years to come. The OTA stated that the government is at a crucial point, at which the opportunities presented by new information technologies are substantial,[197] but the stakes, including the preservation and enhancement of public access to government in-

192. Critics of the move, "including members of the panels, now accuse the agency of using the reports as a 'smokescreen' and ignoring their recommendations." Fox, *supra* note 181, at 816.

193. *See* Fox, *supra* note 181. Private firms now may purchase the data through the National Technical Information Service (NTIS) and resell it to their clients. A description and analysis of the NTIS is contained in INFORMING THE NATION, *supra* note 36, at 13-14, 295-319.

194. *See, e.g.,* Heller, *Computers in Chemistry: Numeric Databases for the PC,* INDUS. CHEMIST, May 1988, at 40.

195. Letter of James E. Brower, Ph.D., Manager of the Center for Assessment of Chemical and Physical Hazards, Brookhaven National Laboratories (Aug. 3, 1988).

196. INFORMING THE NATION, *supra* note 36.

197. *See id.* at 163 (comparing the yearly cost of distribution of the *Congressional Record* to depository libraries: paper copies cost $632.83, microfiche $83.62, CD-ROM $10.05).

formation,[198] are high and need to be carefully balanced by Congress. The OTA suggests that greater definition is needed of what are inherently governmental information functions, as is a better understanding of the conditions for cost-effective contracting for information services.[199]

Toxicity and exposure data are a special instance of the broader problem which the OTA addressed. While federal information policy as a whole is being reexamined, legislators should reevaluate the CSIN concept of the 1970s and update it with increased participation by the private sector. Unassisted, the market will not produce an integrated universal service to support the economic, scientific, and governmental systems that use toxicity data, but a chemical toxicity data system would be a resource of such long-term value that it should not be left to develop on an *ad hoc* basis. National information policy should distinguish between the resources the private sector can offer and those it cannot, and design an approach to support and supplement the market.

It was suggested earlier that data production, enhancement, and maintenance exhibit characteristics traditionally associated with the "natural monopoly" concept. Distribution of the data also has several characteristics which may justify structuring the service like common carriers. The telecommunications system illustrates how a data system might be designed to provide needed information services. The new "open" structure of the telecommunications network — now a "network of networks" — provides a model for adapting the CSIN model to the contemporary mixed public/private information service market.[200] Indeed, the telecommunications system provides a useful analogy on several levels.

For example, there is a parallel between the capital investment that forms a telephone company's rate base and the research and management necessary to develop a data system. Toxicological information is expensive to produce and maintain. As data accumulates it must be updated and the data must also be consistent in terminology and production methods.[201] Quality control is an essential and costly condi-

198. *Informing the Nation* surveys the many federal statutory provisions that mandate public access to government information and recommends that Congress renew the commitment to public access in legislation that would reflect the changing conditions and needs of the computer age. *Id.* at 207-37, 255-60.

199. *Id.* at 269.

200. Noam, *supra* note 166, at 40.

201. *See* Williams, *supra* note 165, at 446 (noting that one commercial strength of Lexis and Westlaw legal database systems is that everything entered in the database continues indefinitely to have value). Patent databases are similar.

tion of its value. Therefore, a service providing toxicological knowledge must be based upon substantial long-term investment. Training, equipment, and the existing information are imbedded costs, analogous to traditional telephone rate bases. As toxicology evolves, the nature of these costs may change. The early telephone system was a natural monopoly by virtue of its reliance on buried coaxial cable for transmission. The transmission lines were expensive and limited in their carriage capacity, making long distance telephone start-up costs similar to those of railroads. When the telecommunications system shifted from cable to microwave transmission in the 1950s and 1960s and most recently to fiber optics, the new technologies' increased capacity and lowered costs removed the underpinnings of much of the monopoly rationale. Emerging biological research tools, computer-assisted statistical research, and medical breakthroughs may eventually have a similar impact on toxicology. For the present, production and maintenance of toxicological knowledge require substantial investment.

This investment also requires at least some centralized planning. Even the diversified market of today's emerging telecommunications system is dependent on a basic shared infrastructure.[202] The underlying network was developed by the Bell System according to the vision put forth by Theodore Vail, the president of AT&T from 1907 to 1919.[203] In the health sciences related to chemical toxicity, the federal government has for the most part provided the affirmative investment and stewardship which the market tends to discourage in this area. Public health and environmental agencies have functioned as a loosely coordinated consortium that invests in equipment, training and research; judges the value of data; fosters the compatibility of different segments of the discipline; forecasts the future needs; and provides a range of data services. Coordination and combination are key productive functions here. These are functions that private firms are in no position to fulfill. However, federal policy has also failed to carry them out consistently, in part because of shifting policies.

Another characteristic of toxicity data that supports the natural monopoly analogy is the fact that there is little value in duplicating the basic product. Repetitive bioassays or epidemiological studies are desirable up to the point that a scientific consensus is reached on the toxicity of a chemical, but duplication is not an efficient response to market preferences.

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202. Noam, *supra* note 166, at 41-42.

203. Bornholz & Evans, *The Early History of Competition in the Telephone Industry*, in BREAKING UP BELL, *supra* note 168, at 12-13.

In addition, compatibility of data formats and terms is essential to combining and comparing data.[204] But the market encourages diversity, rather than integration. Variety of format is the very quality that data management firms offer in order to distinguish themselves from competitors. This is their defense against use of their product by other vendors, since the information otherwise is easily transferred. Small services with overlapping databases are developing, as in the very early history of telephone service in this country. Images of that quagmire are evoked by one user's complaint concerning the division of the EPA's CIS: "The two data bases soon will not be the same. For me, as an agency coordinator, it means we will be needing both. That means twice the overhead and twice the work."[205] While the market might eventually coalesce and provide the standard, implied services, the seriousness of the present lack of information precludes a "wait-and-see" attitude. With public health regulation dependent upon the coordination of exposure and toxicity data, the current fragmentation cannot be justified on the grounds that diversification is good or convenient. Current laws do practically nothing to encourage the development of coherence in toxicity data systems.

Distribution of toxicity data services also has characteristics which are analogous to telecommunications. Data systems offer opportunities for cross-subsidies among various types of services. Different groups with information needs — industrial hygienists, researchers, consumers, public safety officers — will have different abilities and incentives to pay for the data. This capacity provides both pitfalls and opportunities. One criticism of the OMB's privatization scheme is that it institutionalizes public subsidies of private information services. Subsidies could work the other way, however. In a properly structured or supervised market, data services could make use of this variety by establishing price schedules keyed to each sector's ability to pay, with particular support for consumers, universities, and medical services.[206] Subsidies by commercial users of chemicals would be appropriate in this context even more so than the telecommunications

204. *See, e.g.*, Lindberg, *supra* note 182, at 39:

> For decades it has been recognized that the major impediment to the development and widespread adoption of broad computer-based information systems in medicine has been the standard vocabulary, terminology, definitions, and criteria for recording the results of biomedical research and the events of clinical patient care. The result has been the inability of any medical-information system to communicate with another. The [National Library of Medicine] is working to remedy this deficit by developing a Unified Medical Language System . . . .

205. Fox, *supra* note 181, at 226 (statement of Laurence Dusold of the FDA).

206. The CIS service now offered by Fein-Marquart Associates has clients which include government, businesses, universities, and public interest groups. However, the firm discontinued its discount service for universities in 1988, and a substantial number discontinued their subscrip-

system's subsidy of local service by long distance and business services. Here the consumer's very need for the data is caused by chemical firms' failure to internalize their health costs. Industrial rates might appropriately subsidize consumer services.[207]

The telecommunications model provides another feature that applies in this context, *i.e.,* a two-way communication capacity. A well-designed and well-supported toxicity data system could foster positive interaction. It could collect exposure and medical data from health professionals and industrial hygienists at the clinical level, while distributing important diagnostic and treatment toxicity information in return. The tools and prototypes for such a capacity are already being developed, as medical and industrial facilities are increasingly computerized and investing in communication with data resources such as poison information centers and the National Library of Medicine services.[208]

If we view toxicology as a service the public needs and therefore as a potential public utility, with "natural monopoly" characteristics, a variety of organizational options becomes apparent. The telecommunications model is the most elaborate. It would entail the establishment of a regulated entity that would provide a basic system, on the common carrier model, from which other sectors in the market and the nonprofit private sector could develop derivative services. Telephone service developed in the nineteenth century as a competitive service,[209] then as a complex regulated monopoly. In the past decade, the telecommunications system has evolved into a mix of monopoly and competitive services, all working from a shared infrastructure. The most recent economic format of the telecommunications system is similar in several respects to the CEQ's original CSIN proposal and to more recent suggestions for the data system. Indeed, the private sec-

tions. The administrative job of keeping the accounts open was not considered worthwhile by the firm.

207. The problem of designing a rate structure and, indeed, whether a system could support itself under any rate scheme, is beyond the scope of this Article. However, the size of the system would be a function of its resources. Also, the present limited system is heavily subsidized by general revenues. With continued public support and an increase in private support, a basic system which at least services federal, state, and local agencies, nonprofits, and universities seems feasible.

208. *See* Lindberg, *supra* note 182, at 36-39; Hushon & Conry, *Using the Micro-CSIN Workstation to Provide Chemical Hazard Information,* in HAZARD COMMUNICATION: ISSUES AND IMPLEMENTATION 176 (J. Brewer ed. 1986) [hereinafter HAZARD COMMUNICATION]. Hushon and Conry list more than 50 factual and bibliographic databases usable in a chemical emergency. The National Academy of Sciences has announced that it will recommend the establishment of an informational clearinghouse on occupational and environmental medicine, so doctors can get the information they need in a single telephone call. *See Gap Found in Averting Workplace Diseases, supra* note 44.

209. *See* Bornholz & Evans, *supra* note 203, at 7.

tor panel that advised the EPA in 1984 on the options for handling the CIS recommended that the government continue to produce and maintain an integrated system containing all the most frequently used files, those that are little used but have long-term scientific value, and an integrated directory system. The panel suggested that additional revenues for the government system could come from private enhancement and commercial use of the files with market potential.[210] The OTA, in *Informing the Nation,* envisions a similar layered approach to public and private use of federal data.[211]

A mix of monopoly and competitive services could be fostered and new environmental and health services could develop, making use of the basic system. For example, the embryonic waste reduction movement, which encourages industries to reduce their use of toxic chemicals, relies on exchanging information about successful process substitutes. This kind of an information service could be added to a fundamental database. Product rating services and labeling, and new data communication businesses, might also spin off as distinct entities.[212]

Regulatory models vary in their treatment of entry, rates, and interconnection.[213] The specific strategies that could be borrowed and applied to a toxicity data system are beyond the scope of this Article. However, entry regulation may be unnecessary if a national basic service is guaranteed.[214] The new information industry vigorously opposes "government competition" and argues that government should

210. Life Systems, Inc., *supra* note 190, at 3-8, 9.

211. *See* INFORMING THE NATION, *supra* note 36, at 269.

212. *See generally* Freifeld, *Labels and Material Safety Data Sheets in Hazard Communication,* in HAZARD COMMUNICATION, *supra* note 208, at 39; Hadden, *Labelling of Chemicals to Reduce Risk,* 46 LAW & CONTEMP. PROBS. 235 (Summer 1983).

The new information laws have stimulated demand for protocols of safe transport and use of chemicals and information services, such as toxic chemicals inventories and environmental information clearinghouses. Government and private databases are being developed and made more accessible. Local fire departments, which are being inundated with MSDS forms, are contracting with consulting firms to manage this data. CHEMTREC, one of the largest emergency response communication centers, contains about 230,000 MSDSs, and its 3,000 member companies can access the database through a toll-free telephone number. HAZARDOUS MATERIALS RIGHT-TO-KNOW NEWS, Oct. 10, 1987, at 4-6. Region VI of the Federal Emergency Management Agency has set up a region-specific, computer bulletin board on toxics. The database will be accessible by telephone and by computer. COMMUNITY RIGHT-TO-KNOW NEWS, June 27, 1987, at 4. EPA will establish an expanded public database, which in its first phase will contain information from the 140,000 to 160,000 annual release forms required by § 313. *See* 42 U.S.C. § 11023(j) (Supp. IV 1986); COMMUNITY RIGHT-TO-KNOW NEWS, May 22, 1987, at 1-2.

213. *See generally* BREAKING UP BELL, *supra* note 168; DEREGULATION AND THE NEW AIRLINE ENTREPRENEURS, *supra* note 168; TELECOMMUNICATIONS REGULATION TODAY AND TOMORROW, *supra* note 168; VIDEO MEDIA COMPETITION, *supra* note 168.

214. *See supra* notes 172, 207. The EPA is preparing distribution of a number of data products derived from EPCRA's new National Toxics Release Inventory. The agency will produce and distribute to federal, state, and county level libraries data derived from the inventory in hard

not enter the market where the private sector is already operating. However, some basic needs are not met by the market and, in any event, the public sector is the main supplier of data that the industry wishes to sell.[215] In light of the public source of so much of the data, it is appropriate to consider making a federal agency the basic data service provider.

A simpler approach than system development on the telecommunications model, and one that is closer to hand, would be to authorize and fund an agency — for example, the NTP or NIEHS — to study the adequacy of the present data system connections and to provide supplemental services to those who cannot afford access to private services or who need data not offered by firms. This is already being done in certain areas by the National Library of Medicine and the EPA. The supplemental services should be subsidized, either through the sale of data to private firms or through a fund such as the one discussed in Part V.

A narrower program — indeed, the minimum government role — would be promulgation of standards to ensure compatibility and quality of data. There is precedent for standard-setting in the work of the National Bureau of Standards and, in the private sector, in the American Society for Testing and Materials, which has actively sought either legislation or a consensus on standard MSDS formats.

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copy, microfiche, and CD-ROM form. Telephone conversation with Gerard Brown, Chief of Nonconfidential Information Service Section, EPA Office of Toxic Substances (Jan. 24, 1989).

The federal government has long provided information and information carriage. Its constitutional mandate to provide a postal system is the most definite authority for this activity, but broader, more substantive participation may stem from the commerce clause and, for the states, from the police power.

Professor Pool maintains that entry and exit controls in communications media are unconstitutional restrictions on speech. Pool, *Comments on "The Future of Telecommunications Regulation"*, in TELECOMMUNICATIONS REGULATION TODAY AND TOMORROW, *supra* note 168, at 68; *see also* I. POOL, *supra* note 168. Would government regulation or provision of services in this area raise first amendment issues? Although we are accustomed to thinking of "science" as an academic pursuit, in its role as chemical hazard communication, it may be seen as commercial information excluded from the ambit of the first amendment. The first amendment implications are discussed in Z. CHAFEE, GOVERNMENT AND MASS COMMUNICATIONS (1947), and T. EMERSON, THE SYSTEM OF FREEDOM OF EXPRESSION 697-714 (1970).

215. *See Giving Public U.S. Data: Private Purveyors Say No,* N.Y. Times, Mar. 4, 1989, at A1, col. 4. When the Federal Maritime Commission planned to make its electronic lists of shipping rates accessible to anyone with a computer, private companies that have made a business of providing this information to the public objected. As federal agencies move to put their information on electronic media, it will become more accessible, thus bypassing firms that have been packaging it electronically while the agencies were still relying on paper. According to *The New York Times,* there has been no opposition to the idea of putting the information on computers, but the OMB, the Information Industry Association, and the Journal of Commerce have opposed allowing the public to dial in to the agencies to read the filings directly. *See id.;* INFORMING THE NATION, *supra* note 36, at 207-36. More recently, the OMB has suggested that it will reconsider its position. *OMB Proposes Switch in Information Policy,* N.Y. Times, June 10, 1989, at A28, col. 1.

This discussion admittedly leaves open many issues: it attempts only to draw the broadest outlines of possible systems and to suggest that, as with data production, the law related to data distribution could be structured to generate more efficient data use. Right-to-know laws recognize and rely on communication as a powerful regulatory instrument. Computers and information science provide tools that could be utilized to achieve a level of exchange that would strengthen regulation and improve the market's own screening functions.[216]

VII. Some Problems and Principles

The information economics drawn upon here suggests that there are better ways of investing in information than the present law encourages. This analysis has attempted to point out some directions the law might take, if information production and use were to be given a more central role in toxics control.

One major issue that has not been addressed here is the question of how to treat trade secrecy in the context of a comprehensive information scheme. Current right-to-know laws provide some protection for trade-secret information. Neither OSHA nor the EPCRA require disclosure of the identity of chemicals claimed to be trade secrets, even though the exempted chemicals are hazardous.[217] However, these arrangements do not seem satisfactory. On the one hand, firms would prefer not to disclose valuable information at all, since secrecy is fragile and may easily be lost. On the other, confidentiality agreements are burdensome and may inhibit research and medical practice. Exempting trade-secret chemicals on a basis unrelated to the purposes of the information system may also have systemic repercussions, affecting the development of research and information services.

The solution to the conflict between the two systems — toxics con-

216. *See Access to Information: The Dream and Reality,* 36 J. Am. Socy. Info. Sci. 383 (1985); S. Zuboff, In the Age of the Smart Machine: The Future of Work and Power 7 (1988) (discussing information technology as a tool for developing economic and human potential of "work organizations").

217. Trade secret protection was one of the more controversial issues in the development of the OSHA Hazard Communication Standard. The definition of "trade secret" in OSHA's final standard is essentially the same as that of § 757 of the *Restatement of Torts (First)*, which is commonly used by state courts in adjudicating trade secret disputes. *See* 29 C.F.R. § 1910.1200(c) (1984). The Third Circuit rejected OSHA's earlier attempt to exempt chemical identity data from disclosure by redefining trade secrecy. *See* United Steelworkers v. Auchter, 763 F.2d 728, 740 (3d Cir. 1985).

Some state laws provide for more government oversight of exemption claims than does OSHA. *See* Hazardous Materials: Right-to-Know News, Nov. 15, 1985, at 5-12; Right-to-Know: A Regulatory Update, *supra* note 113. The California, Illinois, and Montana agencies rule on the validity of trade secret claims as they are submitted. *Id.* EPCRA's § 313 requires publication of the fact of each trade-secrecy claim made in reports to the National Toxics Release Inventory.

trol and intellectual property law — will only come from careful analysis and compromise.[218] We do not yet know how big a problem trade secrecy will be in the right-to-know context. The databases being developed under right-to-know laws will begin to indicate how large a portion of chemicals in the market is claimed as confidential.[219]

Separate from the problem of producing and distributing data is the question of how the law should use toxicity data. Do legal standards for toxicity reflect rational and consistent recognition of the value of this information? Not surprisingly, the answer is definitely "no."

Laws may require five types of actions with respect to chemicals: (1) mere disclosure of the identity of the chemical agent to which humans are exposed; (2) warning of its known hazards; (3) testing to determine hazards; (4) curtailing the exposure by reducing the discharge of the chemical; and (5) compensation for any injuries proved to be caused by chemical exposure. Each entails different costs and will affect differently the individuals exposed and the public health system. For instance, the monetary and social costs of disclosure, warning, and testing normally will be less than the cost of reducing or eliminating discharges or fully compensating groups of injured individuals. One would expect the law to establish separate but graduated tests of responsibility, tests that would call for different grades of proof and would reflect not only the costs and benefits inherent in each action, but also established jurisprudential norms. Tort law and chemical regulation statutes contain legal standards for warnings, testing, exposure, and civil liability, but they do not form a coherent system. There are similar standards for very different activities and different standards for the same activity.

For example, the standard incorporated in the TSCA which the EPA must meet before it may order a manufacturer to conduct testing on a chemical, is "may present an unreasonable risk of injury to health or the environment."[220] This "unreasonable risk" test is similar to

218. *See* McGarity & Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies,* 93 HARV. L. REV. 837 (1980).

219. In a 1972-1974 survey, the National Institute for Occupational Safety and Health (NIOSH) asked 5,000 manufacturers for the ingredients of 85,000 products, but was able to determine the composition of only 40,000. The NIOSH survey determined that approximately 18,000 of these contained at least one OSHA-regulated chemical and a large proportion was claimed as a trade secret. *See* Graney, *Toxic Substances and Trade Secrecy,* in PROCEEDINGS OF A NATIONAL CONFERENCE TO INVESTIGATE RIGHTS AND RESPONSIBILITIES 78 (1977). However, initial figures for trade secrecy claims made to the EPCRA National Toxics Release Inventory are much lower. Out of approximately 70,000 filings with the EPA, there were about 50 trade secrecy claims. Telephone conversation with Gerard Brown, Chief of the Nonconfidential Information Service Section, EPA Office of Toxic Substances (Jan. 24, 1989).

220. 15 U.S.C. § 2603(b)(2)(A) (1982).

language used for standards that determine actual human exposure, as opposed to disclosure, warning, or testing. "Risk" is a relatively general concept. The amount and kind of information suggesting an "unreasonable risk" requiring further testing usually will not be the same as that which would support making rules to limit exposure. Physical similarity to a known toxic compound, with substantial levels of exposure, may establish the first, while a full-blown risk assessment indicating the likelihood of a significant number of cancers may be required for the second. Most laws do not address the levels of information required for regulation[221] or differentiate among bases appropriate for separate kinds of agency actions.

At the same time, similar rules often establish very different information standards for the same legal function. OSHA's Hazard Communication Standard and the EPCRA use different methods to determine which chemicals are toxic and therefore must be accompanied by warnings. OSHA requires that manufacturers and employers determine for themselves what hazards are posed by all of the chemicals they handle, and the rules define "hazard" very broadly.[222] However, the rules also presume chemicals to be hazardous if they appear on any one of several lists of suspect chemicals which have been prepared by independent health research organizations.[223] Manufacturers may tend to rely on the agency-endorsed lists, which means the open-ended definition probably does not expand the rules' coverage. To the extent that OSHA requires businesses to engage in health effects research — even library research — the rules burden smaller businesses.[224] The open-ended coverage also results in unequal distri-

221. OSHA's Hazard Communication Standard and the FDA's Delaney Clause are exceptions. *See supra* notes 118-23 and accompanying text (explaining OSHA's rule). The Delaney Clause provides that if there is any evidence that tumors form following ingestion of a substance that would be a food additive, the substance cannot be used in food. 21 U.S.C. § 348(c)(3)(A) (1982). However, the two provisions illustrate the same point. Both require action based on the existence of one scientific test showing adverse effects, but the two actions — warning and banning — are very different.

222. 29 C.F.R. § 1910.1200 (1988). The term "health hazard" includes chemicals that are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents that act on the hematopoietic system, and agents that damage the lungs, skin, eyes, or mucus membranes. 29 C.F.R. § 1910.1200 app. A (1988).

223. *See supra* note 119.

224. 17 Envtl. L. Rep. (BNA), at 2148 (Apr. 24, 1987). The National Research Council of the National Academy of Sciences has recommended that the U.S. Department of Commerce develop educational resources to help small businesses acquire the information on chemical regulatory matters that is routinely available to large corporations and associations. NATIONAL RESEARCH COUNCIL, DECISIONMAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 26. The costs of researching and communicating the results of all studies will discourage data production and again discriminate against smaller businesses. If chemical identity were universally disclosed and a unified toxicity database were made broadly accessible, then single study adverse effects could be easily revealed at the initiative of interested parties.

bution of information to workers in different businesses.

The EPCRA uses two approaches to determine coverage. The emergency planning provisions, sections 301 and 312, incorporate OSHA's standard. The emergency releases provisions, section 303, limit reporting to one list of chemicals and section 313, on routine releases, uses another list. Using lists prepared by independent experts is preferable to employer assessment, as it assures credibility, clarity, and consistency. It also lightens the research burden on businesses and allows them to focus on the task within their bailiwick: identifying sources of exposure.

However, now that these lists have been codified, they are unlikely to be revised appropriately in the future, since the EPCRA authorizes additions to its lists and to the incorporated OSHA lists only by rulemaking. To be added to EPCRA's lists for reporting to the national inventory, chemicals must be shown to cause or to be reasonably anticipated to cause "significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequent releases."[225] This is a high standard for warning and is inconsistent with the use of the right-to-know scheme. As with the TSCA's testing authority, the EPCRA standard for expanding coverage parallels the standards for setting permissible levels of human exposure.[226] Standards for warning — as for testing — need not be as high as those used to set exposure levels. Experience with the TSCA indicates that the EPA will not be able to add to these lists without engaging in lengthy review of the health effects of chemicals to be added and that private resources will be devoted to keeping chemicals off the lists.[227]

Warning and testing standards require some level of suspicion about a chemical's health effects. However, where no data exist to implicate a chemical, disclosure of human exposure has not generally been addressed by the law. What should be the legal significance, if

225. 42 U.S.C. § 11023(d) (Supp. IV 1986).

226. *E.g.*, Clean Air Act, 42 U.S.C. § 7410 (1982).

227. The EPA has announced a policy for reviewing petitions to change the § 313 list. *See* 52 Fed. Reg. 3479 (1987). The agency will base its review largely on the information submitted by the petitioner. *Id.* at 3481. Even with the heavy presumption in favor of toxicity established by the statute, this approach does not adequately account for biases in information presentation. Indeed, because of the commercial incentive described *supra* in Part II, businesses seeking to have chemicals removed from the list, rather than added to it, will dominate the listmaking process.

Litigation concerning the lists of hazardous substances is already in full swing. *E.g.*, Calumet Indus. v. Brock, 807 F.2d 225 (D.C. Cir. 1986) (oil manufacturers sought precise interpretation of OSHA's carcinogen labeling requirement, but were denied standing); *see also* COMMUNITY RIGHT-TO-KNOW NEWS, Oct. 22, 1987; COMMUNITY RIGHT-TO-KNOW NEWS, Feb. 8, 1987, at 5.

any, of an unwanted or unbargained-for exposure to a chemical not yet tested for toxicity? Does exposure necessarily trigger any individual rights or interests?[228] Is it of any concern to society if there are no apparent ill effects at the time the exposure occurs? Economic analysis suggests that the answer to these questions should be yes, but under current right-to-know laws only chemicals that have already been shown to have some toxic effect are covered by disclosure requirements. Like the regulation and liability systems, right-to-know laws rely on the existence of health-effects data to trigger their affirmative disclosure requirements. Of the approximately 67,000 chemicals in commercial use, only about 300 will be included in the EPCRA national inventory. A considerable number of chemicals are still "invisible" to their users.

The principle of favoring broad disclosure should be basic to information regulation. Catch-22 reasoning underlies the present *de facto* presumption of confidentiality of much chemical identity data: exposure data will not be gathered and need not be disclosed, unless the substance can be shown to be toxic. However, it cannot be shown to be toxic unless its effects are studied, and they will not be studied if the chemical identity is not released. Common law principles support disclosure of chemical identity data. There are strong normative arguments for an entitlement to chemical identity data inherent in the exposure situation.[229] Indeed, it is ironic that there is such ethical concern surrounding FDA guidelines for testing on humans, while outside the food and drug context, uncontrolled human exposure to toxic and unstudied chemicals is so widespread. Under economic tests for assignment of liabilities and entitlements, a disclosure requirement also fares well. Economic and medical transactions are facilitated by provision of chemical identity, but the costs of these transactions are prohibitive absent disclosure. The "cheapest cost avoider" is the re-

228. Do individual preferences have any legal significance in this context? Under the law of battery, an unwanted or offensive touching is actionable, but if a contact is socially useful, it may not be, even though it is a nuisance.

Statutes have treated exposure in a variety of ways. *Ex ante* regulation of food and drugs requires proof of safety or low risk prior to exposure. This approach implies an interest in testing before exposure, but does not disclose to the individual who is exposed. Some statutes, such as the Clean Air Act, provide that agencies should release data in their files to those who request it, if it concerns pollution and is not considered confidential by the firm it concerns, but agency regulations may more specifically provide that health and safety data are generally considered nonconfidential. 42 U.S.C. § 7414(c) (1982); 40 C.F.R. § 2.301(a) & (c) (1988).

229. The common law recognizes the interest in information that belongs to a recipient of an unwanted contact or intrusion, such as an actual or potential chemical exposure or the more standard tort of trespass. *See generally* R. FADEN & T. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT (1986).

searcher or the exposed person who can monitor and prevent health effects more easily, knowing the nature of the exposure.

Selective application of disclosure requirements may also have undesirable secondary impacts on scientific research. Data collection based on proven toxicity channels scientific and economic resources along lines which may be neither the most protective nor the most efficient. If exposure data is not fully available, research and regulatory resources may be allocated to chemicals that are less toxic, while chemicals that are still "invisible" are ignored. Investments in labeling, training, and medical care, as well as research in health effects, inadvertently may be guided to chemicals of lesser toxicity, if disclosure requirements are not consistently applied.

Comprehensive disclosure is important because information behaves like the system it is; it does not consist of objects like conventional products. This systemic character of information gives rise to other imperatives for information strategies in toxics regulation. Access to chemical identity data facilitates the evolution of independent producers, interpreters, and verifiers of complex data. Access rights to information should be clear and the information should be available to all the relevant players to encourage the entry of those who do have incentives to provide information. Following the CERCLA model, those with incentives to produce the cost-reducing information should be linked to the most appropriate economic source of financial support for data production. Here, as with hazardous waste, that source is the activity which causes human exposure to risky chemicals and produces the need for health data. Regulation designed to foster production and use scientific information must also incorporate unity of format, interconnection, and access to basic repositories of data. This unity is a prerequisite to communication and makes possible not only the development of new knowledge, but also standards and rating systems. Incentives to distort or minimize the negative commercial implications of information can be controlled, at least partially, by disclosure of simple, nonmanipulable data, such as chemical identity.

CONCLUSION

Technologies that cause disease and environmental damage impose special burdens on the economy and the public. Just as certain benefits are "public goods" in that everyone cannot help but benefit from them, certain costs may be termed "collective bads."[230] Uncertainty about chemical toxicity has been so widely and successfully external-

230. *See* Barry & Hardin, *supra* note 51, at 31-33; Barry & Hardin, *supra* note 50, at 181-84.

ized that it is now a "collective bad." Present toxics laws are designed to rely on information, but the costs of uncertainty and of arranging for identification, study, and cure have been left to the public. At the same time, the market dynamics that discourage private production of toxicity information have shaped law and science policy. The notion of "uncertainty" itself and the ways it is expressed in regulation have been influenced by economic factors. Health and environmental laws can be written with these influences more consciously in mind and research and dialogue at a much higher level — both of volume and sophistication — than exists today could be produced. The words of Samuel Johnson express the spirit that should inform the law: "Knowledge is of two kinds. We know a subject ourselves, or we know where we can find information upon it."[231]

231. I J. BOSWELL, THE LIFE OF SAMUEL JOHNSON 558 (1791) (Everyman ed. 1906).