Report for Recommendation 90-3

Risk Communication as a Regulatory Alternative For Protecting Health, Safety and Environment

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Introduction

Risk communication has become an important component of regulatory policy in the United States and other industrial nations for the social control of hazardous technologies. Mandated by several laws and regulations, risk communication is now being used to mitigate and prevent technological risks to workers, community residents and product users.[1]

The term "risk communication" is commonly used to describe procedures by which public agencies and private firms produce and distribute information about the hazardous attributes and risk consequences of technological activities and products to exposed and vulnerable persons.[2] Thus, risk communication includes traditional regulatory requirements for industrial labeling of dangerous products (e.g., pesticides); agency provision of environmental impact statements on proposed projects to the public; agency disclosure of records and data regarding risk issues to "any person" invoking the federal Freedom of Information Act; and the voluntary provision of risk information by agencies to the public to promote risk avoidance (e.g., household radon hazards).[3]

However, over the past decade, Congress and federal agencies have acted to create another form of risk communication which essentially requires industrial firms to communicate directly with persons at risk, or with certain

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[1] *See* generally, Symposium Proceedings, "Multinational Corporations and Their New Responsibilities to Disclose and Communicate Risk Information," *Boston Univ. Int'l. Law Jnl.*, v. 6, n.1 (spring 1988); which describes and evaluates risk communication developments in the United States, the European Community, the United Nations and various international and private industrial organizations. *Also, see* M. Baram, "Corporate Risk Management and Risk Communication in the European Community and the United States," *Harvard Jnl. Law and Technology*, v. 2 (spring 1989) 85.

[2] "Risk communication" generally denotes the disclosure of both hazard and risk information. It should be recognized that hazard information differs from risk information. Hazard information pertains to the dangerous attributes of an activity in the abstract sense (e.g., the carcinogenicity of a chemical); whereas risk information includes the estimated effects of the hazards on human health or the environment under specified conditions of exposure. Therefore, risk information may include data on emission levels, exposure circumstances, and potential biological responses. More succinctly, "The hazard presented by a substance is its potential to cause harm . . . the risk from a substance is the likelihood that it will harm you in the actual circumstance of use . . . ,"*Hazard and Risk Explained*, Health and Safety Executive, London, U.K. (1988). For further discussion, see L. Jourdan, "Information on Hazards of Substances at the Individual Workplace," Conseil European des Federations de L'Industrie Chemique (CEFIC), Brussels, Belgium (April 1987); and M. Baram, "Risk Communication: Moving From Theory to Law to Practice," in *Effective Risk Communication*, note 3 *infra*.

[3] *See* V. Covello, D. McCallum, M. Pavlova, "Inventory of Government Risk Communication Programs," in *Effective Risk Communication*, Plenum Press (1989).

designated representatives of such persons. These enactments are the "right to know" laws and rules which have raised special issues of administration and enforcement. They have also informed and aroused the public and stimulated new initiatives in legislative, regulatory and judicial forums to curb risky technological activities. And they have displaced traditional design and performance standards as the primary means of coping with certain technological hazards.

The purpose of this study is to evaluate these recent federal programs which rely on industrial risk communication as an enforceable policy instrument to protect workers, community residents, and product users from specified hazards; and to develop findings and recommendations for improving the design and administration of federal risk communication programs.

To achieve these goals, three major federal programs have been evaluated: OSHA's "Hazard Communication Standard (HCS) or "Worker Right to Know" Rule,[4] the Emergency Planning and Community Right to Know Act (EPCRA)[5] implemented by EPA; and FDA's Patient Package Insert Program (PPI),[6] which was terminated after a brief experiment. The resultant findings and recommendations are divided into two categories: Those which apply to existing risk communication programs, and others which are of generic applicability to future federal use of risk communication as a regulatory alternative.

I. Concepts and Premises

Diverse interest groups support use of industrial risk communication as a regulatory device to prevent technological harms. But when this support is examined, differing concepts of how such risk communication should work, and differing policy rationales and premises, are encountered.

Policy analysts and legislators have supported industrial risk communication as a regulatory reform which has the potential to reinforce traditional approaches to regulating risk (such as standard setting), to remedy deficiencies in agency performance, and to enlarge agency capability for

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[4]29 CFR §1910.1200 (1988), originally promulgated with a 60 page explanatory preamble at 48 Fed. Reg. 53,280 (1983).

[5]Title III of the Superfund Amendments and Reauthorization Act of 1986 ("SARA"), 42 U.S.C. §§11,001-050 (Supp. IV 1986), which is designated as the Emergency Planning and Community Right to Know Act of 1986 ("EPCRA").

[6]21 CFR §203 (1980), originally promulgated at 45 Fed. Reg. 60,753 (1980), and officially revoked at 47 Fed. Reg. 39,147 (1982).

dealing with risks which would otherwise elude its grasp.[7] For example, by using OSHA authority to promulgate its HCS requiring employers to communicate risk information to employees, workers are informed and can be expected to exercise greater care to avoid harm, thereby reinforcing OSHA's prescriptive standards and the "general duty" of employers to maintain a safe workplace. The generic HCS also remedies to some extent OSHA's inability to set prescriptive standards and exposure limits for all hazardous substances in the workplace because of resource limitations.[8] Finally, the rule enables OSHA to address risk problems which are not amenable to the "substantial evidence" and "significant risk" criteria the agency must meet when it uses a prescriptive standards approach.[9] Environmentalists, labor, and consumer groups also support industrial risk communication as a regulatory reform because of its potential for improving agency programs and achieving greater reduction of risk.[10] But in addition, these interest groups promote such communication because it is apparent that the information to be disclosed will enhance their ability to petition regulatory agencies, lobby legislators, and litigate in regulatory and judicial forums for preventive standards, and to secure compensation for personal injuries and injunctive relief.[11] This empowering function of risk communication is now being demonstrated as environmental groups use recent industry disclosures of toxic air pollutant

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[7] *See* for example, P. Harter, G. Eads, "Policy Instruments, Institutions and Objectives: An Analytical Framework for Assessing "Alternatives" to Regulation," *Admin. Law Review*, v. 37 (1985) 221; M. Baram, et al, *"Alternatives to Regulation,"* D.C. Heath (1982) at 120; R. Mayer, F. Nicosia, "Consumer information: Sources, Audiences, and Social Effects," in *Protecting Consumer Interests*, R. Katz, ed., Ballinger (1976) at 41; and various papers in *Effective Risk Communication*, note 3 *supra*.

[8] *See* OSHA's HCS preamble, note 4 *supra*.

[9] *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980). Also *see* note 65 *infra* and accompanying text.

[10] *See* for example, S. Krimsky, A. Plough, Executive Summary, Project Report on *Improving Risk Communication*, U.S. EPA (Feb. 1988); R. Kasperson, "Six Propositions for Public Participation and Their Relevance for Risk Communication," CENTED Reprint 54, Clark University (Nov. 1986); "Strenghtening Worker/Community Right to Know," Policy Statement 8714, Am. Public Health Association.

[11] *Id.* Also see H. Otway, "Experts, Risk Communication and Democracy," *Risk Analysis Jnl.* v. 7, n. 2 (1987) at 125; C. Chadd, J.O'Malley, "Superfund Amendments Offer Hope for Plaintiffs in Toxic Tort Actions," *Natitonal L. Jnl.* (March 21, 1988) 16; A. Babich, "Enforcement of EPCRA: A Practical Guide for Citizens, States and Local Governments," *Toxics Law Rptr.* (Sept. 7, 1988) 463; D. Hayes, "Superfund Spillover: Title III and ATSDR," *Toxics Law Rptr* (Aug. 26, 1987) 377; K. Gray, D. Pike, "Turning on the Lights: Reporting Under SARA Title III Illuminates Tort and Environmental Liabilities," *Environmental Professional Jnl.*, v.11 (1989) 56.

emissions, mandated by EPCRA, to petition and lobby for new air toxics standards to protect community health.[12]

Industrial support has come about reluctantly. Most firms have perceived risk communication as a threat to their trade secrets and management autonomy, and as fuel for public anxieties and new controversies over risk which can lead to more stringent and costly regulatory requirements, tort litigation, and loss of reputation.[13] However, as state and local "right to know" laws have proliferated,[14] many firms now look to federally-established risk communication programs for uniform requirements which would be less troublesome to their commercial activities which are conducted on a national scale.

Several large firms which produce hazardous chemicals have now discovered that risk communication actually presents new opportunities for improved loss control and greater profitability. These major producers are now using HCS and EPCRA requirements as frameworks for voluntarily providing additional safety information and advisory services to their "downstream" customers. This is being done to reduce the incidence of risks arising from customer use of their products, and to thereby reduce the current high volume of "upstream" litigation against them by their customers and injured persons (usually customer employees claiming their injuries arose from the producer's failure to warn). These firms now engaging in the voluntary communication of risk information to prevent risk and liability have also found this to be an effective feature for marketing their chemical products and gaining customer loyalty.[15] Industrial risk communication also has the extraordinary characteristic, for a regulatory device, of satisfying very different political viewpoints about how to deal with technological hazards in a democratic system, and this may explain why it enjoys such broad political support. For proponents of the "new federalism" who aim to reduce the federal role in solving social problems and shift responsibility to state and

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[12]"Section 313 Reports of Toxic Air Emissions Said to Reveal Need for Pollution Prevention," *Environment Reporter* (May 19, 1989) 154; "Data Said to Reveal Need for Pollution Prevention," *Right to Know Planning Guide* (Jan. 1989) 4.

[13]M. Baram, note 1 *supra*; D. Hayes, note 11 *supra*.

[14]Over twenty states have worker right to know laws, and a similar number have recently enacted community right to know laws or amendments. Numerous municipalities also have enacted community right to know ordinances. *See* "Digest of State Right to Know Laws" in *Right to Know Planning Guide*, Bureau of National Affairs, Inc.

[15]Dow Chemical is the leading practitioner of voluntarily "going beyond regulatory requirements" in transmitting risk information to its distributors and customers as part of its Product Stewardship Program and marketing efforts. Other chemical producers are now following suit. Personal communications (1988, 1989).

local levels of government.[16] EPCRA channels industrial risk information to state and local boards and mandates that they address industrial accident hazards.[17] For conservatives who have long argued that market forces are a more cost-effective and suitable means for influencing corporate activities, but who have had to contend with liberal opponents who argue that the market is ineffective due to inadequate information, the HCS and EPCRA programs have cured this deficiency.[18] For Jeffersonians and other critics of governance by experts, and who premise democracy on the voluntary exercise of choice by an informed citizenry, the risk communication programs have restored some measure of power to the people.[19] And as noted earlier, liberals have favorably viewed industrial risk communication as a regulatory device which empowers them.

There are less obvious but possibly even more fundamental sources of support for industrial risk communication, which may further explain its widespread appeal. One of these is the moral view that one with knowledge that his action is creating a latent risk for another has a responsibility to disclose this information to enable the vulnerable person to avoid the harm, or choose to be exposed to it on a voluntary and informed basis. This view is imbedded in the common law[20] and is most concretely expressed in the duty to

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[16]*See The Status of Federalism in America*, Domestic Policy Council, Office of the President (1987); and R. Manley, "Federalism and Management of the Environment," *Urban Lawyer*, Am. Bar Assoc., v. 19, n.3 (1987).

[17]EPCRA establishes new state and local units of government and expressly mandates their responsibilities for emergency response planning. As for the inspection of industrial facilities for accident hazards and the taking of preventive regulatory measures. EPCRA is silent. Since EPA has no clear authority under any of its statutes to regulate industrial safety, but state and local governments have long used their "police powers" to inspect and regulate plants to protect communities from accident hazards, the reasonable inference is that Congress intended that accident prevention authority remain exclusively with state and local governments. Congressional intent can also be inferred, in this case, from its rejection of the competing approach set forth in Congressman J. Florio's bill, the proposed Chemical Manufacturing Safety Act, H.R. 965, 99th Congress, 1st Sess. (1985), which would have created a new federal regulatory program to regulate safety in facilities producing or using hazardous chemicals.

[18]See discussion in S. Breyer, *Regulation and its Reform*, Harvard Univ. Press (1982) at 161-164; and R. Posner, *Economic Analysis of Law, 2d ed.*, Little Brown Co. (1977) at 271-281

[19]P. Stenzel, "The Need for a National Risk Assessment Communication Policy," *Harvard Env. L. Rev.*, v. 11, n.2 (1987) at 381-413, quoting among others, Thomas Jefferson: "If we think [the people are] not enlightened enough to exercise their control with a wholesale discretion, the remedy is not to take it from them, but to inform their discretion." T. Jefferson letter to Wm. Jarvis (Sept. 28, 1820).

[20]For example, in the nineteenth century, it became established in tort law that the operator of a railroad has the duty to signal before crossing a public road in order to warn persons at the intersection. An operator who failed to signal would be liable for resulting injuries. H. Buswell,

warn theory of products liability law which, since the advent of asbestos litigation a decade ago, has become the primary basis for securing recovery from industry for product-related harms.[21] Risk communication programs can, therefore, be viewed as a regulatory codification of this common law principle, and it may be more than mere coincidence that the "worker right to know" movement progressed concurrently with the flood of asbestos suits by diseased workers who claimed that asbestos firms had failed to warn of their product's foreseeable hazards, and worse, had done so willfully, in many instances.[22]

Another fundamental support for industrial risk communication can be found in the now widespread recognition that the ultimate risk issue, "how safe is safe enough," is essentially trans-scientific and subjective, and cannot be conclusively or satisfactorily answered by experts for a pluralistic society like the United States.[23] As a result, agency attempts to use technical expertise to set quantitative risk limits in prescriptive standards have failed to satisfy the public, and reliance on public opinion informed by risk communication can be viewed as a more acceptable method of risk management. Industrial risk communication also fits comfortably in the mosaic of American regulatory law which includes other communication requirements such as the Freedom of Information Act (FOIA),[24] EPA labeling requirements for pesticides,[25] OSHA rules on worker access to employer-held medical and exposure records,[26] and the numerous reporting requirements found in most statutes which authorize social and economic regulatory programs. These laws and rules, which afford various duties to disclose and rights of access to information, reflect persistent public anxieties about technologies, traditional

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The Civil Liability for Personal Injuries Arising Out of Negligence 303, (2d ed. 1899). Also see, "Appendix: Product User Risks and Communication Requirements in the United States" in M. Baram, *Corporate Risk Management: Industrial Responsibility for Risk Communication in the European Community and the United States*, Commission of the European Communities, Report EUR 11555 EN (1988).

[21]The seminal decision is *Borel v. Fibreboard Paper Products, Inc.*, 493 F.2d 1076 (5th Cir. 1973). Also see V. Schwartz, R. Driver, "Warnings in the Workplace: The Need for a Synthesis of Law and Communication Theory," *Cincinnati L. Rev.*, v. 52 (1983) 38.

[22]*See* P. Brodeur, "The Asbestos Industry on Trial," four-part series in the *New Yorker*, (June, July 1985).

[23]For variations on this theme, *see* H. Otway, note 11 *supra*; S. Krimsky, note 10 *supra*; R. Kasperson, note 10 *supra*; and A. Rip, "Experts in Public Arenas," in *Regulating Industrial Risks*, H. Otway, M. Peltu, eds., Butterworth's Ltd., London (1985).

[24]5 U.S.C. §552 (1982).

[25]40 CFR 162.10.

[26]29 CFR 1910.20 (1988).

mistrust of government and industry, and historical commitment to participatory government, aspects of American culture which also support industrial risk communication.

Finally, increasing the public's right to risk information now appears to be an irreversible process because it is constantly stimulated by several forces at work in modern society. These include rapid scientific progress which enables the discovery of new risks, aggressive media coverage of risk issues, industrial use of safety in promoting products against competitors, and growing public concern about technological risks as threats to health and well-being. These are dynamic forces which increase the public appetite for risk information.[27]

Where will industrial risk communication lead? Will it stimulate new market forces as persons exposed to hazardous technologies and products take more effective risk avoidance and other self-help measures? Will it promote greater public participation in government decision-making to reduce risks to levels deemed socially "appropriate?" Will it enhance the use of tort litigation to secure injunctive relief and compensation for injuries and anxieties, and thereby deter risky technological activities?

Or will the very availability of numerous communication programs paradoxically instill in the public greater confidence and disinterest in industrial and agency decision-making, and lead to diminished public activism? Will risk communication be used by industry and agencies to manipulate the public into acceptance of risky technologies? Will it overload or confuse the public and thereby be blunted as an instrument for reducing risk?[28]

Despite these diverse views and unanswered questions, this study is designed to address some pragmatic issues at this early stage in the use of industrial risk communication:

> -how well are existing programs being carried out in terms of the production and distribution of useful materials?

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[27]M. Peltu, "The Role of Communications Media," in *Regulating Industrial Risks*, note 23 *supra*.

[28]*See* M. Hinds, "As Warning Labels Multiply, Messages are Often Ignored," *N.Y. Times* (March 5, 1988) 1; S. Soumerai, et al, "Effect of Government and Commercial Warnings on Reducing Prescription Misuse: The Case of Propoxyphene" (finding of no effect on certain misuses), *Am. Jnl. Public Health*, v. 77, n.12 (Dec. 1987) 1518; and H. Otway, "Risk Communication in the European Communities: Background, Status and Trends," in *Boston Univ. Int'l. L. Jnl.*, note 1 *supra*, who predicts that "as risk communication requirements are implemented, they will increase the public's appetite for information especially in environments where little information has been available . . . Paradoxically, the demand for information and participation in decision processes is always greater if access to them is difficult. [Ultimately] The ready availability of information and the possibility of influencing decisions tend to enhance the credibility of decisionmakers and reduce the demand for participation."

-do the programs reinforce or impair other regulatory functions and legal doctrines for preventing risk?

-are corrective measures needed to improve the design and administration of the programs?

-what general principles should govern the design and administration of future federal programs for industrial risk communication?

To answer these questions, three programs are now examined: OSHA's "Hazard Communication" standard (HCS),[29] the Emergency Planning and Community Right to Know Act (EPCRA) implemented by EPA,[30] and the FDA's "Patient Package Insert" Rule (PPI).[31]

II. OSHA's Hazard Communication Program

A. Introduction

After an extensive rulemaking process, the Occupational Safety & Health Administration (OSHA) promulgated its Hazard Communication Standard (HCS) on November 25, 1983, to take effect by May 25, 1986.[32] OSHA had found that large numbers of workers were being exposed to hazardous chemicals in the workplace, usually without the complete and accurate knowledge of either employees or employers.[33] Based on the concept that workers have both "a need and right to know the hazards and identities of the chemicals they are exposed to when working,"[34] OSHA adopted a broad hazard communication rule that applies to all hazardous substances in the workplace. This generic standard, which differs from OSHA's usual substance by substance approach, has been described by one former high-ranking OSHA

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[29]Note 4 *supra*.

[30]Note 5 *supra*.

[31]Note 6 *supra*.

[32]48 Fed. Reg. 53,280 (1983). The Hazard Communication Standard is found at 29 CFR 1910.1200 (1987).

[33]48 Fed. Reg. 53,323 (1983).

[34]53 Fed. Reg. 29,852 (1988). Guidelines for Employer Compliance, Proposed Appendix E to 29 CFR 1910.1200.

official as "the most significant regulatory action ever taken by the agency."[35] The promulgation of the HCS was broadly supported by labor, much of industry, academics and professionals.[36]

The HCS imposes duties on the manufacturers, distributors and importers of hazardous chemicals to furnish their industrial customers with labels and data sheets for the hazardous chemicals they purchase; and requires both manufacturers and industrial customers as employers to then provide this information to all their employees who are exposed to the chemicals together with special education or training programs. Concommitantly, the HCS vests in these employees the "right to know" such information. Thus, the HCS provides for an enforceable program of risk communication designed to protect worker health and safety

B. History and Scope

The 1970 OSHA Act authorized OSHA to issue standards which ensure "that employees are appraised of all hazards to which they are exposed."[37] Efforts to promulgate a generic hazard communication standard began in 1974, but it took almost a decade of preparation and rulemaking for the final rule to be published, during which time there were numerous changes, criticisms and delays.[38] When the final standard was finally published in 1983, it was immediately challenged in court by trade unions, a public interest organization, and several states.[39]

Although several provisions of the HCS were contested in the immediate court challenges, the most important was the scope of the standard. OSHA had applied the HCS only to firms and employees in the manufacturing sector, based on its finding that the greatest risks to employees from exposure to hazardous substances occurred in that sector of industry.[40] On judicial review, petitioners sought expansion of the standard to other industrial sectors. The

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[35]Tyson, *The Preemptive Effect of the OSHA Hazard Communication Standard on State and Community Right to Know Laws*, 62 *Notre Dame L. Rev.* 1010, 1011 (1987).

[36]*See* 48 Fed. Reg. 53,282-83 (1983).

[37]29 U.S.C., 655(b)(7) (1970).

[38]*See* 52 Fed. Reg. 31,852-53 (1987) and *United Steelworkers of America v. Auchter*, 763 F.2d 728, 732 (3rd Cir. 1985) for a description of the events leading up to the promulgation of the final standard.

[39]These early challenges were consolidated in the Third Circuit and decided in *United Steelworkers*, 763 F.2d at 728 (1985).

[40]48 Fed. Reg. 53,284 (1983).

Third Circuit Court of Appeals ruled that the OSHA standard must apply to all sectors of industry unless the agency can show it is not feasible for particular industries to comply with the standard.[41] Because OSHA had not made such a finding for nonmanufacturing industries, the court ordered OSHA to apply the HCS to these other sectors unless it could "state reasons why such application would not be feasible."[42]

Following the court's decision, several industrial sectors sought to convince OSHA that they should be exempted from the HCS. For example, small businesses argued that it would be too burdensome for them to comply with the standard's requirements. OSHA rejected this argument on the grounds that it would not be "appropriate to determine the extent of protection afforded an employee by the size of business he/she is employed in."[43] Other industries complained that the application of the HCS to their sector would be impractical because hundreds or thousands of different chemicals are used.[44] Again, OSHA rejected the relevance of this factor for determining whether or not employees should be warned of exposure to hazardous substances.[45] Finally, certain industrial sectors argued that industries that do not expose workers to significant risks should be exempted from the HCS.[46] OSHA responded that if potentially hazardous substances were present in the workplace, the level of actual risk was not a valid reason for exempting or limiting application of the standard.[47]

While OSHA was in the process of compiling a rulemaking record for extending the scope of the HCS, the Third Circuit determined that a new record was unnecessary and ordered OSHA to publish a final rule within 60 days.[48] In August 1987, OSHA complied with the court's order and revised the standard to apply to all firms that use, sell, store or transport hazardous

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[41] *United Steelworkers v. Auchter*, 763 F.2d at 738 (1985).

[42] *Id.* at 739.

[43] 53 Fed. Reg. 29,822 (1988).

[44] *Id.* at 29,827. A representative of the National Association of Home Builders commented that because of the large number of substances used by the construction industry, "I have this vision of a truck pulling up to the site and behind it is the trailer and on the trailer is the file cabinet of MSD sheets."

[45] *Id.*

[46] *Id.* at 29,826.

[47] *Id.*

[48] *United Steelworkers of America v. Pendergrass*, 819 F.2d 1263 (3rd Cir. 1987). The United Steelworkers had returned to court to argue that a new round of rulemaking was an unnecessary delay in complying with the court's earlier decision ordering OSHA to reconsider the scope of the HCS. The Third Circuit agreed, and on May 29, 1987 ordered OSHA to publish a new final rule based on the existing record within 60 days.

chemicals.[49] The expanded standard now applies to approximately 4.5 million workplaces and 58.9 million potentially exposed employees.[50] Although the expanded HCS went into effect on May 23, 1988, the scope of the standard continued to be the subject of major controversies,[51] until February 1989 when the agency announced that "all provisions of the rule are now in effect in all segments of industry."[52]

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[49]52 Fed. Reg. 31,852 (1987).

[50]*Occupational Safety & Health Reporter*, (BNA), May 5, 1988 at 1851.

[51]The Associated Builders and Contractors inc. challenged the application of the HCS to the construction industry in the D.C. Circuit Court of Appeals. On May 20, 1988, three days before the expanded HCS was to go into effect, the D.C. Circuit issued a temporary stay of the standard's application to the construction industry, and transferred the challenge to the Third Circuit for final ruling. Occupational Safety & Health Reporter (BNA), May 25, 1988 at 1867. On November 25, 1988, the Third Circuit rejected the procedural and substantive challenges to the expanded HCS by the construction industry and other industrial petitioners. Associated Builders and Contractors, Inc. v. Brock, 862 F.2d 63 (3rd Cir. 1988). Further requests for a stay were denied by both the Third Circuit and U.S. Supreme Court Justice William Brennan (Nos. 88-1070, 88-1075). See 54 Fed. Reg. 6886, 7 for the historical record of the litigation. Another ongoing controversy has involved the OMB's criticisms of the expanded rule. OSHA slightly modified the HCS when it expanded it to other industrial sectors, by including a new provision requiring employers at multiemployer worksites to exchange hazard information, 29 CFR 1910.1200(e)(2), and providing partial exemptions for many consumer products, 29 CFR 1910.1200 (b)(6)(vii) and drugs, 29 CFR 1910.1200(b)(6)(viii). OMB disapproved the three new provisions, Office of Management and Budget Letter Extending Approval for Hazardous Communication Provisions, April 13, 1988, reprinted in *Occupational Safety & Health Reporter* (BNA), April 20, 1988 at 1715. On August 8, 1988, OSHA published a Notice of Proposed Rulemaking to consider OMB's criticisms and other comments it had received on the expanded scope of the HCS, 53 Fed. Reg. 29.822 (1988). Less than two weeks later, the Third Circuit Court of Appeals ruled that OMB was not authorized to disapprove the new provisions of the HCS because they did not involve "collection of information" and embodied policy making discretion entrusted to OSHA. *United Steelworkers of America v. Pendergrass*, 855 F.2d 108 (3rd Cir. 1988). United Technologies Corp. and the Department of Justice petitioned the Third Circuit on September 2, 1988 to rehear the case *en banc, Occupational Safety & Health Reporter*, September 9, 1988 at 788. The court denied this petition on November 2, 1988, as well as requests for a stay of the decision. A further motion by industry for a stay was denied by U.S. Supreme Court Justice William Brennan on January 24, 1989. For these and other maneuvers, see 54 Fed. Reg. 6886 (1989).

[52]54 Fed. Reg. 6886 (Feb. 15, 1989).

C. Applicability

A critical aspect of the HCS is the process by which chemicals are to be evaluated and found to be hazardous. OSHA has adopted a hybrid procedure incorporating two different approaches for determining which chemicals are "hazards" and therefore covered by the HCS. First, the standard specifies that all chemicals on two designated lists of hazardous chemicals and four official lists of carcinogens are automatically to be considered "hazardous" under the HCS.[53] These lists provide a "floor" of approximately 2400 hazardous chemicals to which the HCS applies, but represent only a small percentage of the total number of hazardous chemicals in the workplace.[54]

The second hazard determination approach adopted by the standard is for manufacturers and importers of a chemical not on the designated lists to evaluate whether the chemical is hazardous using "available scientific evidence."[55] The standard provides guidance for companies making hazard determinations in two appendices which describe the types of hazards covered[56] and the criteria to be applied.[57] For example, the standard specifies that one statistically significant study "conducted in accordance with established scientific principles" is sufficient to establish that a substance is hazardous.[58] However, the standard does not prescribe specific procedures for hazard determination, because "a completely specified weighting procedure for the hazard evaluation would suggest certainty where certainty does not exist."[59] Instead, chemical suppliers are told to make hazard determinations based on their "professional judgment."[60]

Exemptions or limitations of the standard's requirements are provided for laboratories, pesticides, food and drugs, many consumer products, and

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[53] 29 CFR 1910.1200(d)(1987).

[54] Waldo and Hinds, *Chemical Hazard Communication Guidebook,* Executive Enterprises Publications Co., Inc., (1988) at 13. OSHA's decision not to rely on a much larger list of potentially hazardous substances compiled by NIOSH because the list is likely to be overinclusive was upheld by the court in *United Steelworkers v. Auchter,* 763 F.2d at 739 (1985).

[55] 29 CFR 1910.1200 (d) (1987). Note that because a chemical supplier need only evaluate "available" scientific evidence, there is no affirmative duty on a manufacturer or importer to research the possible adverse health effects of a substance.

[56] 29 CFR 1910.1200 Appendix A (1987).

[57] 29 CFR 1910.1200 Appendix B (1987).

[58] 29 CFR 1910.1200(d)(2) (1987).

[59] 48 Fed. Reg. 53.326 (1983).

[60] *Id.* at 53,296. Since the HCS applies only to hazardous substances known to be in the workplace, chemical reaction intermediates and other undetected substances are exempt. The standard also imposes no affirmative duty on employers to discover unknown hazardous substances which are preessent in the workplace. 29 CFR 1910.1200(b)(2) (1987).

"articles."[61] Mixtures are also exempted if they contain hazardous substances in very low concentrations, which is defined as one percent of the mixture by weight or volume for health hazards in general and 0.1 percent for carcinogens.[62]

Except for such mixtures with small concentrations of hazardous substances, the HCS does not provide for exemption of de minimis risks. Although the Supreme Court has held that an OSHA standard must be supported by a finding of "significant risk,"[63] OSHA made a significant risk finding for the HCS as a program rather than for particular chemicals, worksites or industrial sectors.[64] This generic finding was recently affirmed by the Third Circuit which held that for a "standard covering thousands of chemical substances used in numerous industries . . . the significant risk requirement must of necessity be satisfied by a general finding concerning all potentially covered industries."[65]

Following its programmatic finding of significant risk, OSHA determined that it was not "appropriate to include concepts of degree of exposure or risk into the definition for health hazard."[66] OSHA's rationale was that since the HCS puts the burden of identifying and labelling hazards on upstream suppliers,[67] there is no way they can know with certainty whether exposure in downstream workplaces will result in significant risks.[68] OSHA's determination to not provide an exemption for insignificant risks was upheld by the D.C. Circuit Court of Appeals in General Carbon Co. v. OSHA.[69] The court agreed with OSHA that the requirements imposed by the HCS were "in no way contingent on anticipated conditions at a particular downstream site."[70] However, while the court upheld OSHA's interpretation of the HCS as not providing an exemption for insignificant risks, the court twice emphasized that the validity of the standard for not allowing such an exemption might "more plausibly" be challenged.[71] Such a challenge is likely in a future HCS enforcement action, given the court's prompting.

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[61] 29 CFR 1910.1200(b)(3) & (4) (1987).

[62] 29 CFR 1910.1200(d)(5) (1987).

[63] *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 639 (1980).

[64] 48 Fed. Reg. 53,321 (1983).

[65] *Associated Builders and Contractors v. Brock*, 1988 WL 124304 (3rd Cir. 1988).

[66] 48 Fed. Reg. 53,295 (1983).

[67] *See infra* note 74.

[68] 48 Fed. Reg. 53,295 (1983).

[69] 1988 WL 117401 (D.C. Cir.). The court's decision was announced November 8, 1988.

[70] *Id.*

[71] *Id.*

D. Requirements

The HCS has three major inter-related risk communication components. First, chemical producers and importers must label all containers of hazardous chemicals they sell with the identity of the hazardous substance, "appropriate" hazard warnings, and the name and address of the supplier.[72] All employers, whether producers or their downstream customers, thereafter have responsibility for ensuring that all containers of hazardous substances in their workplace are properly labelled.[73]

Second, chemical producers and importers must prepare or obtain a material safety data sheet (MSDS) for each hazardous substance they produce or import.[74] Along with other information, the MSDS must designate the substance's identity, physical and chemical properties, health hazards, appropriate safety guidelines and first aid procedures.[75] All firms using or storing the hazardous substances must be provided with a copy of the MSDS for each substance by the producer or importer.[76] Thereafter, the producers and downstream firms which have received the MSDS's must make these documents readily accessible to their employees at the worksite during each work shift.[77] The third major component of the HCS is that these employers must inform and train their employees about the hazards present in the workplace, hazard detection and protection methods, the requirements of the HCS, and the details of the facility's hazard communication program, including the location of MSDS's.[78] Employers must also maintain a written hazard communication program that describes the hazards present in the workplace and the steps taken to comply with the HCS.[79]

According to OSHA, none of the three major components alone "can be demonstrated to be completely effective in communicating hazards."[80] However, labels, MSDSs and employee training taken together complement and reinforce each other and provide an integrated communication program. For example, labels provide an immediate and obvious warning of the most serious health effects, while the MSDS makes available more detailed information. Requiring all information to be put on the label would likely

[72] 29 CFR 1910.1200(f)(1) (1987).
[73] 29 CFR 1910.1200(f)(4) (1987).
[74] 29 CFR 1910.1200(g)(1) (1987).
[75] 29 CFR 1910.1200(g)(2) (1987).
[76] 29 CFR 1910.1200(g)(6) (1987).
[77] 29 CFR 1910.1200(g)(9) (1987).
[78] 29 CFR 1910.1200(h)(1987).
[79] 29 CFR 1910.1200(e) (1987).
[80] 48 Fed. Reg. 53,311 (1983).

cause information overload and would be much more expensive.[81] Since labels and MSDSs may be ignored by some employees, mandatory worker training is needed to assure that workers are informed and address risk implications.

E. Regulatory Approach

The HCS is distinctly and purposively "performance oriented," in that it does not require employers to follow specific procedures, but sets goals for employers to meet, and provides for monitoring of their performance.[82] As discussed earlier, OSHA rejected a "cookbook" approach of specific procedures for hazard determination, and instead directed chemical producers to use "a large degree of professional judgement" when determining whether substances are hazardous.[83] Labels do not have to follow a standardized format,[84] and are only required to provide an "appropriate" hazard warning.[85] Similarly, material safety data sheets may be "in any form" as long as they provide adequate information.[86] Finally, "[t]he format of the education and training program was left to the discretion of the employer."[87]

The main advantage OSHA cited for using this performance-oriented approach is that it provides flexibility in adapting the HCS to a great diversity of employers and worksites.[88] A secondary reason for the performance-oriented standard is to permit employers "who have voluntarily instituted

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[81] *Id.* at 53,326.

[82] In a proposed new appendix to the standard to assist employer compliance, OSHA explains: "One difference between this rule and many others adopted by OSHA is that this one is performance-oriented. That means that you have the flexibility to adapt the rule to the needs of your workplace, rather than having to follow specific, rigid requirements. It also means that you have to exercise more judgement to implement an appropriate and effective program." Guidelines for Employer Compliance, Proposed Appendix E to 29 CFR 1910.1200, 53 Fed. Reg. 29,853 (1988). *See generally* O'Reilly, *The Impact of Performance-Oriented Rules on Administrative Enforcement: The Case of OSHA Hazard Communication Rules*, 2 *Lab. Law.* 695 (1986).

[83] 48 Fed. Reg. 53,296 (1983).

[84] 48 Fed. Reg. 53,301 (1983).

[85] 29 CFR 1910.1200(f)(1)(ii) (1987).

[86] 29 CFR 1910.1200(g)(9) (1987).

[87] 48 Fed. Reg. 53,327 (1983).

[88] 48 Fed. Reg. 53,326 (1983).

effective programs of hazard communication for their employees [to] continue to use them without substantial modification."[89]

However, there are several disadvantages to this performance-oriented approach. The lack of clearly specified hazard determination procedures and communication formats inevitably leads to inconsistency, and discrepancies between firms leads to unequal protection for workers.[90] A related problem is that, without clearly specified requirements, many companies attempting to comply with the standard will be confused or tempted to postpone compliance indefinitely.[91] A performance-oriented standard may also be more difficult for OSHA to enforce because of these same ambiguities.[92]

Finally, performance-oriented regulations have often failed because of the different values of government regulators and industry managers.[93] Performance-oriented standards require value judgments as well as technical determinations, and it is obvious that corporate values usually differ from the broader goals and values which are held by regulatory officials. Accordingly, the interpretation and application of the HCS that seems most reasonable to an employer is likely to deviate from the views of the regulators.

F. Relation to State Hazard Communication Laws

By the time OSHA published its hazard communication standard in 1983, many states and municipalities had already enacted their own worker right-to-

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[89] *Id.* at 53,282. For a discussion of the relative advantages and disadvantages of performance-based standards and the more common "command" approach for OSHA regulation, see McGarity & Shapiro, "OSHA Regulations, Regulatory Alternatives and Legislative Reform," Administrative Conference of the United States Report for Recommendation 87-10, 1987 ACUS 999 (1987). Some other advantages of the performance approach is that it allows experimentation and evaluation of alternative implementation techniques, it is less intrusive, and it lets the party with the most information (i.e., the firm) choose the most cost-effective means of compliance. *Id.* at 1010, 1022. The authors recommend that OSHA use performance standards whenever they offer the same degree of protection as alternative approaches, can be easily understood and enforced, and will result in cheaper compliance costs. *Id.* at 1022.

[90] *See, e.g.,, Occupational Safety & Health Reporter (BNA),* April 24, 1986 at 1166. (different manufacturers often provide conflicting hazard information on a particular chemical). Also see Occupational Safety & Health Reporter (BNA), Nov. 30, 1988 at 1201 (MSDS's found to be variable, often incomplete, and inadequate on chronic toxicity information).

[91] *Occupational Safety & Health Reporter (BNA)*, June 12, 1986 at 27.

[92] *See infra* note 170.

[93] *See* Henderson & Pearson, "Implementing Federal Environmental Policies: The Limits of Aspirational Commands," 78 *Colum. L. Rev.* 1429 (1978).

know laws.[94] Multi-state employers facing the increased cost of complying with many different state and local right-to-know laws[95] lent their support or acquiescence to OSHA's proposal for a national standard "to establish uniform requirements for hazard communication."[96]

Although trade unions argued that the federal HCS should act as a "safety floor" which would permit states to enact stricter laws,[97] OSHA sought to establish that its standard would preempt state and local laws.[98] The OSH Act provides that nothing "shall prevent any State agency or court from asserting jurisdiction under State law over any occupational safety or health issue with respect to which no standard is in effect.[99] However, the HCS is "intended to address comprehensively the issue of evaluating and communicating chemical hazards to employees . . . and to preempt any state law pertaining to this subject."[100]

In addressing this conflict, several courts held that OSHA's original HCS expressly preempted state laws with respect to hazard communication to employees in the manufacturing sector.[101] Now that the HCS has been extended to nonmanufacturing sectors,[102] state right to know laws will also be preempted for these other sectors as well. Although the HCS only expressly preempted state and not local laws, one court has held that the HCS also preempts local right to know laws pertaining to occupational safety and health.[103]

A remaining problem with respect to the preemptive effect of the HCS is state or local right to know laws that apply to both occupational and environmental (or community) hazards. The HCS expressly preempts only

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[94]48 Fed. Reg. 53,324 (1983). Many of the state right-to-know laws differed from the HCS with respect to hazard determination, trade secret protection, regulatory approach, and the right of workers to refuse work when the law is not being followed. *See* Baram, "The Right to Know and the Duty to Disclose Hazard Information," 74 AM. J. PUBLIC HEALTH 385, 389 (1984); Feitshans, "Hazardous Substances in the Workplace: How Much Does the Employee Have the "Right To Know?," 1985 *Det. C.L. Rev.* 697, 702-15 (1985); Tyson, *supra* note 35 at 1016.

[95]No footnote.

[96]48 Fed. Reg. 53,281 (1983).

[97]*See*, "The New Meaning of Right to Know," *Chemical Week*, June 19, 1985 at 24.

[98]48 Fed. Reg. 53,322-23 (1983).

[99]29 U.S.C. 667(a) (1982).

[100]29 CFR 1910.1200(a)(2) (1987).

[101]No footnote.

[102]Note 49, *supra*.

[103]*Ohio Manufacturers' Association v. City of Akron*, 801 F.2d 824 (6th Cir. 1986), cert. denied 108 S.Ct. 44 (1987). OSHA has subsequently revised 29 CFR 1910.1200(a)(2) to specifically provide that both state and local right to know laws pertaining to occupational safety and health are preempted by the HCS. 52 Fed. Reg. 31,860 (1987).

those parts of state laws that pertain to protection of employee health and safety.[104] However, the intent of a federal regulation to preempt state right to know laws will be implied if it is impossible to comply with both the federal and state standards, or the state standard stands as an "obstacle" to the effective implementation of the federal rule.[105] In determining whether the HCS preempts state laws that require companies to disclose hazard information to both workers and the community, courts have evaluated the state laws section by section for implied preemption.[106] Thus far, the courts have upheld sections of state laws with purposes other than protecting occupational health (e.g., communication of risk information to the community or its police and fire personnel), even though the laws thereby impose dual labelling requirements and other additional hazard communication duties on employers already subject to the HCS requirements.[107]

The OSHA Act also permits states to submit a state plan to OSHA to assume responsibility for regulating an occupational safety and health issue for which OSHA has issued a standard.[108] OSHA shall approve a proposed state plan only if it will be "at least as effective" as the federal standard, and when applicable to products in interstate commerce, is "required by compelling local conditions" and does not "unduly burden interstate commerce."[109] OSHA intends to "scrutinize carefully" any state plan containing hazard communication requirements because of the "strong policy justification for uniform application throughout the distribution system of a national hazard communication standard."[110]

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[104] *N.J. State Chamber of Commerce v. Hughey*, 774 F.2d at 587 (1985).

[105] *N.J. State Chamber of Commerce*, 774 F.2d at 592 (1985), citing *Silkwood v. Kerr-McGee Corporation*, 464 U.S. 238, 248 (1984).

[106] *N.J. State Chamber of Commerce*, 774 F.2d at 587 (1985); *Manufacturers Association of Tri-County v. Knepper*, 801 F.2d 130 (3rd Cir. 1986), *cert. denied* 108 S.Ct. 66 (1987).

[107] *Mfrs. Ass'n of Tri County*, 801 F.2d 130; *Occupational Safety & Health Reporter (BNA)*, February 2, 1988 at 1435. *Also see N.J. Chamber of Commerce v. Hughey*, 13 OSHC 2040 (3rd Cir., Feb. 28, 1989), upholding the "universal labelling requirements" of the New Jersey Right to Know Act, despite resulting duplicative requirements for firms. Nevertheless, two chemical industry groups have now petitioned a federal district court to determine if the HCS preempts the warning regulations enacted under California's Proposition 65. *Chemical Manufacturer's Association v. California Health and Welfare Agency*, D.C. E. Calif., No. CIV-S-88-1615-Lkk-JFM. December 16, 1988. *See Chemical Regulation Reporter* (BNA), Dec. 23, 1988 at 1453.

[108] 29 U.S.C. 667(b) (1982). The state plan provision is incorporated in the HCS at 29 CFR 1910.1200(a)(2) (1987).

[109] 29 U.S.C. 667(c) (1982).

[110] 48 Fed. Reg. 53,322-23 (1983).

G. Trade Secret Protection

The HCS permits an employer or chemical supplier to withhold the specific chemical identity of a substance if it is a bona fide trade secret.[111] In many instances, a company's most important confidential business information will already be protected, because the HCS does not require disclosure of a substance's proportional composition or production steps. "A recipe is less valuable when it only gives names of ingredients."[112] Although the identity of a chemical may be kept confidential, all other information on the MSDS must be disclosed to the worker, including all hazard information.[113] Therefore, the standard's objective of communicating hazard information to employees is substantially achieved even if the chemical's name is not identified.

The trade secret provision of the HCS was successfully challenged in court in two respects, shortly after the original standard was promulgated in 1983.[114] First, the court held that the definition of trade secret in the HCS was too broad, and that OSHA was not authorized by the OSH Act to provide trade secret protection greater than that afforded by state law.[115] The scope of trade secret protection under state law is usually defined by section 757 of the Restatement of Torts,[116] which sets forth six factors that must be weighed in determining whether particular information would be classified as a trade secret.[117] The court ruled that the trade secret definition in the original HCS "enlarges considerably" the Restatement definition because it provides protection for a chemical identity that can be discovered by reverse engineering.[118] The court therefore remanded the HCS trade secret definition to OSHA to develop a new definition that "shall not include

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[111] 29 CFR 1910.1200(i)(1) (1987)

[112] O'Reilly, *supra* note 82 at 704

[113] 29 CFR 1910.1200(i)(1)(ii) (1987)

[114] *United Steelworkers v. Auchter*, 763 F.2d at 728 (1985).

[115] *Id.* at 739

[116] *Restatement of Torts*, section 757, comment (b) (1939)

[117] The six factors are: (1) The extent to which the information is known outside of the business; (2) the extent to which it is known by employees and others involved in the business; (3) the extent of measures taken by the business to guard the secrecy of the information; (4) the value of the information to the business and its competitors; (5) the amount of effort and money expended in developing the information; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others. Quoted from 51 Fed. Reg. 34,592 (1986).

[118] *United Steelworkers v. Auchter*, 763 F.2d at 740 (1985). "Reverse engineering" consists of using analytical chemistry techniques on a chemical sample to discover the substance's identity.

chemical identity information that is readily discoverable through reverse engineering."[119]

The court's decision has been criticized as contradictory. On one hand, the court required the standard's trade secret provisions to be consistent with the six factor balancing test of state law, while on the other hand the court elevated one of the six factors into a legally determinative test of "readily discoverable."[120] OSHA subsequently amended the HCS by incorporating the Restatement trade secret definition as an appendix to the standard.[121] However, OSHA determined that it was "unnecessary" to include any specific reference to reverse engineering capability in the revised standard despite the court's emphasis on this factor.[122] It is not clear whether a chemical identity that otherwise passes the six factor Restatement balancing test but may be reverse engineerable would be protected as a trade secret by the courts or OSHA.

The Third Circuit also decided that the access to trade secret information provided by the standard was overly restrictive.[123] The HCS originally required trade secret chemical identity information to be disclosed on certain conditions to health professionals but not employees.[124] The court determined that the restriction on employee access was not supported by substantial evidence, since OSHA had not shown that employees are any more likely than health professionals to breach a confidentiality agreement.[125] OSHA complied with the court's decision by extending access to trade secrets to employees and their designated representatives.[126]

Except during emergencies, employers are required to disclose trade secrets to health professionals, employees or designated representatives only under certain conditions. The requester must state in writing with "reasonable detail" why access to the information is necessary for one of seven approved

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[119] *Id.* at 741-42. The court did not define what is meant by "readily discoverable." It will be difficult for an OSHA inspector, who will often lack technical expertise, to determine whether a particular chemical's identity is "readily discoverable." Furthermore, economic constraints and not technical feasibility often determines whether reverse engineering is feasible. O'Reilly, *supra* note 82 at 711.

[120] Id. at 707, n.105

[121] 51 Fed. Reg. 34,592 (1986). The Restatement's trade secret definition is reprinted as Appendix D to 29 CFR 1910.1200 (1987)

[122] 51 Fed. Reg. 34,592 (1986).

[123] No footnote.

[124] 48 Fed. Reg. 53,318 (1986).

[125] *United Steelworkers v. Auchter*, 763 F.2d at 743 (1985).

[126] 51 Fed. Reg. 34,595 (1986). The trade secret access provisions are found at 29 CFR 1910.1200(i)(3) (1987).

reasons.[127] The requester must also explain in detail why other information not protected as a trade secret, such as hazard data, is not sufficient to satisfy the purpose for which the chemical identity is requested.[128] Finally, the requester must be willing to sign a confidentiality agreement that may specify a reasonable liquidated damages remedy in the event of a breach.[129] These conditions for trade secret access were upheld as reasonable by the court.[130]

H. Implications for Common Law Tort Remedies

One of the original rationales for the HCS was to improve the usefulness of the tort system to force chemical manufacturers to give greater consideration to product safety and means of reducing harms to product users, in particular, the employees of their downstream customers.[131] Fear of tort liability had traditionally deterred the manufacturers from disclosing product risk information, since without the information, injured employees downstream would be less likely to litigate claims against them, and less likely to succeed if they did litigate.[132]

These downstream employees are generally barred from suing their employers because of the "exclusivity of remedy" provision of state workers' compensation laws, and can only sue third parties in tort, such as the manufacturer or supplier of the chemical. The HCS now aids them in these tort actions. First, the standard is "action forcing," in that it requires manufacturers to create records that may be used to establish liability.[133] Second, the required disclosure of this information to employees should ease considerably their burden as potential plaintiffs of getting information through costly and time-consuming discovery procedures.[134] Finally, the manufacturer's failure to fully comply with the requirements of the HCS might be negligence per se or at least evidence of lack of due care.[135]

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[127] 29 CFR 1910.1200(i)(3) (1987).

[128] 29 CFR 1910.1200(i)(3)(iii) (1987).

[129] 29 CFR 1910.1200(i)(3)(iv) & (i)(4)(ii) (1987).

[130] *United Steelworkers v. Auchter*, 763 F.2d at 742-43 (1985).

[131] No footnote.

[132] *Id.*

[133] O'Reilly, *Driving a Soft Bargain: Unions, Toxic Materials, and Right To Know Legislation, 9 Harv. Envtl. L. Rev.* 307, 318 (1985).

[134] *Id.*

[135] For a violation of a statute or regulation to be negligence *per se*, a plaintiff must demonstrate the "violation of a statute which is intended to protect the class of persons to which

Nonetheless, the HCS may prove to be more useful to chemical suppliers in defending against these tort suits. Defendants can be expected to use their regulatory compliance with the HCS as evidence of providing sufficient warnings and exercising due care, although courts have found regulatory compliance to be an insufficient defense in the past.[136] Chemical producers may also assert a more compelling version of the defense of assumption of risk, arguing that a worker's voluntary decision to accept exposure to a fully disclosed risk absolves the manufacturer of liability. Although assumption of risk defenses have also proved to be not particularly useful, courts may now be more receptive to the defense, given the defendant's compliance with the comprehensive hazard disclosure requirements of the HCS.[137] Widespread acceptance of the assumption of risk defense could make "tort law recovery relatively obsolete in future industrial toxic illness cases."[138]

The performance-oriented approach of the HCS will have important implications for tort litigation. Since a failure to comply with the HCS would be introduced by injured plaintiffs as evidence of the manufacturer's failure to use due care, manufacturers will be very careful to comply with the standard's requirements. Under the HCS, a performance standard, criteria for determining the adequacy of a hazard communication program are not clearly specified. Courts, like OSHA, will probably compare a company's performance to that of the rest of the industry when determining compliance. Therefore, a company that under-estimates or under-states the risks of a particular substance relative to other producers of the same chemical may be legally vulnerable. Since no firm will want to appear less protective than its competitors, companies may thereby be induced to adopt the "highest common denominator" of protection.[139]

In other words, the threat of tort liability is likely to serve as a continuing force which enhances manufacturer compliance with the performance-based HCS. Nevertheless, trade unions fear that leaving hazard determination to the judgment of chemical manufacturers might tempt them to downplay chronic

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the plaintiff belongs against the risk of the type of harm which has in fact occurred." *Melerine v. Avondale Shipyards, Inc.*, 659 F.2d, 706,709 (5th Cir. 1981).

[136]*See* O'Reilly, *Risks of Assumptions: Impacts of Regulatory Label Warnings Upon Industrial Products Liability*, 37 *Cath. U.L. Rev.* 85, 92 (1987). *Also see* M. Baram, "On Advantages of Living in the New Fishbowl," *National Underwriter* 23 (March 21, 1988).

[137]*Id.* Although not involving the HCS, a recent case in the Fifth Circuit accepted the assumption of risk defense when the injured worker was aware of the hazard, and may signal a new receptivity to this defense. *Sprankle v. Bower Ammonia & Chemical Co.*, 824 F.2d 409 (5th Cir. 1987)

[138]O'Reilly, *supra* note 136 at 87.

[139]O'Reilly, *supra* note 82 at 709

health risks in order to reduce liability exposure.[140] Finally, given the "exclusivity of remedy" rule of state workers' compensation law, a no-fault system for workers to secure "benefits" only from their employers, the HCS is unlikely to affect employer immunity from the tort system.

I. Relationship to Regulations of Other Agencies

OSHA's HCS interacts with regulations of other agencies in at least two ways. First, pesticides, food and drugs, and consumer products are subject to the labelling requirements of other agencies, and have been exempted by OSHA from labelling requirements under the HCS.[141] However, labelling regulations issued by other agencies for these products usually do not address their workplace use and the risks they pose at the high levels of occupational exposure often encountered. Therefore, OSHA is still in the process of determining how and when it will defer to, or cooperate with, other agencies with authority to require hazard disclosures for these products when they are used in the workplace.[142]

The second type of interaction with regulations of other agencies is the incorporation of certain definitions and provisions of the HCS into the new community right to know law (EPCRA) administered by EPA, which is discussed in the next section in this report. For example, EPCRA requires any employer who must prepare or have available MSDS's under the HCS to submit copies to state and local officials.[143] Therefore, when OSHA decided to expand the HCS to include nonmanufacturing sectors, it also substantially expanded the scope of the community right to know law,[144] but also caused delays in its regulatory compliance schedule.[145] Similarly, since EPA has incorporated the HCS definition of "article,"[146] OSHA's current proposal[147] to modify its definition will also affect EPA's community right to know

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[140]"Chemical Companies Face Up to Hazard Communication," *Chemical Week*, November 20, 1985 at 56, 58.

[141]29 CFR 1910.1200(a)(4) (1987).

[142]*See, e.g.*,, 53 Fed. Reg. 29,833-36 (1988); *Occupational Safety & Health Reporter (BNA)*, November 16, 1988 at 1146; December 14, 1988 at 1374; and December 21, 1988 at 1397 for controversies now arising.

[143]42 U.S.C. 11021.

[144]52 Fed. Reg. 31,859 (1987).

[145]*See* Waldo and Hinds, *Chemical Hazard Communication Guidebook* at 43.

[146]*See* 53 Fed. Reg. 29,830 (1988).

[147]53 Fed. Reg. 29,828-33 (1988).

requirements. Thus, linkage between the HCS and EPCRA is a source of disruption of the latter program.

J. Relation to Other OSHA Standards

The HCS provides that labels and other forms of warning used in a hazard communication program satisfying the requirements of the HCS must also meet the requirements of any applicable substance-specific OSHA standards.[148] OSHA's compliance directive for hazard communication programs further states that the HCS "was designed to prevent duplication with other OSHA standards" and that in some cases duties under other standards can be "interfaced with the requirements of the HCS to result in simplified compliance."[149] For example, according to OSHA, some of the requirements of the HCS and the Access to Employee Exposure and Medical Records standard[150] could be merged.[151]

The HCS compliance directive also provides that "the HCS defers labelling requirements to [a] specific standard when one exists."[152] Nevertheless, the OMB refused to approve all hazard communication provisions in a proposed OSHA standard for formaldehyde that exceeded the requirements of the HCS.[153] The hazard communication provisions of the formaldehyde standard were finally approved by OMB after OSHA assured OMB that the standard would impose no further hazard communication requirements beyond those of the HCS.[154] Therefore, it seems that the HCS may act as a ceiling rather than a floor for hazard communication provisions required by OSHA, a development likely to generate new controversies.

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[148] 29 CFR 1910.1200(f)(3) (1987).

[149] OSHA Instruction CPL 2-2.38B(M) (August 15, 1988).

[150] 29 CFR 1910.1200 (1987).

[151] OSHA Instruction CPL 2-2.38B(M)(1) (August 15, 1988).

[152] *Id.* at (M)(2).

[153] *Occupational Safety & Health Reporter (BNA)*, February 3, 1988 at 1374.154.

[154] *Occupational Safety & Health Reporter (BNA)*, October 19, 1988 at 1039. Following this, OSHA announced its decision to stay the hazard communication provisions of the formaldehyde standard and to incorporate the HCS requirements instead. 53 Fed. Reg. 50198 (Dec. 13, 1988).

K. Enforcement

The OSHA Act does not provide for a private right of action to enforce standards.[155] Furthermore, unlike most state right to know laws, the HCS does not expressly grant employees the right to refuse work if the employer has not complied with hazard communication requirements.[156] Enforcement of the HCS therefore primarily depends on inspections of workplaces by OSHA inspectors on their own initiative[157] or at the request of employees who believe that a violation exists that threatens physical harm.[158] If OSHA detects a violation, it is authorized to issue a citation to the noncomplying employer.[159]

Despite limited resources, OSHA has been aggressive in enforcing the HCS in its early stages of implementation. By April 1988, OSHA had issued over 32,000 citations, and subsequently reported 18,163 violations in fiscal year 1988 alone.[160] While the vigor of OSHA's enforcement efforts is encouraging, the pervasiveness of violations suggests that employers are either uninformed or having problems implementing the HCS, or unwilling to comply. The vast majority of citations issued by OSHA are for a complete absence of one or more of the key hazard communication components required by the standard.[161] In FY 1987, the first full year of enforcement of the standard, 43% of inspections in the manufacturing sector detected violations of the HCS.[162] A recent study that sampled MSDSs prepared by chemical manufacturers found most to be incomplete or inadequate, particularly with respect to chronic toxicity information.[163]

Poor compliance with the HCS may be attributable in part to its performance-based orientation, which requires subjective evaluation of the

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[155] *Rabon v. Automatic Fasteners, Inc.* 672 F.2d 1231 (5th Cir. 1982); *United Steelworkers of America, AFL-CIO-CLC v. Marshall*, 647 F.2d 1189 (D.C. Cir. 1980), cert. denied 453 U.S. 913 (1981).

[156] *See* Feitshans, *supra* note 94 at 703.

[157] *See* Feitshans, *supra* note 94 at 703.

[158] 29 U.S.C. 657(f) (1982).

[159] 29 U.S.C. 658(a) (1982).

[160] *Occupational Safety & Health Reporter (BNA)*, April 13, 1988 at 1662, and February 17, 1989 at 1675, respectively.

[161] *Id.* Approximately 75% of the citations in 1988 were for absence of a written hazard communication program, employee training program, material safety data sheets or container labels.

[162] *Id.*

[163] *BNA Occupational Safety & Health Daily*, Dec. 1, 1988. The study, conducted by a lecturer at the Harvard School of Public Health, analyzed about 200 MSDSs.

standard's requirements by firms. Widespread confusion and many questions of interpretation about complying with the HCS have been reported in the manufacturing sector.[164] Even greater problems are expected for small businesses, whose compliance OSHA has not even begun to enforce yet.[165] OSHA attempts to provide compliance assistance to firms have generally lagged.[166]

OSHA's enforcement efforts for the HCS are likely to be controversial for two different reasons. OSHA's enforcement system has traditionally been oriented "to a distinct command and control performance, which reduced subjectivity and eschewed the 'performance' approach to regulation."[167] There is evidence that OSHA's enforcement of the HCS is following a similar pattern,[168] even though the standard takes a strong performance-oriented approach. OSHA has issued instructions to its compliance officers that are very specific and seemingly at odds with the performance-oriented "spirit" of the standard.[169] The apparent inconsistency between the regulatory and enforcement approaches of the HCS is likely to cause future legal and compliance problems.

The second source of controversy with OSHA's enforcement efforts will be that accused violators will be more likely to challenge their citations. Since the standard is written in performance-oriented language that requires subjective evaluations, differences in interpretation will likely result in "[g]reater numbers of contests, more hearings, more technical disputes, more discovery problems and more interlocutory appeals."[170] A company's

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[164] *See, e.g., Occupational Safety & Health Reporter (BNA)*, June 12, 1988 at 27; *Occupational Safety & Health Reporter* (BNA), September 24, 1986 at 420 (One OSHA official told industry representatives that "[i]f you're having trouble interpreting [the HCS], then we must be having trouble enforcing it, and we are.").

[165] *See, e.g.*, Jacobs, "Small Business Slowly Wakes to OSHA Hazard Rule," *Wall St. J.*, November 22, 1988 at p. B22. Mounting pressure is being exerted on OSHA to give greater assistance to small businesses attempting to implement the HCS. *See, e.g., Occupational Safety & Health Reporter* (BNA), November 9, 1988 at 1124.

[166] *Occupational Safety & Health Reporter* (BNA) May 25, 1988 at 1868. OSHA has, however, recently proposed an advisory appendix to the HCS to assist employers with compliance. Guidelines for Employer compliance, Proposed Appendix E to 29 CFR 1910.1200, proposed at 53 Fed. Reg. 29,852 (1988)

[167] O'Reilly, *supra* note 82 at 702.

[168] Goldsmith "OSHA's Hazard Communication Standard: The Early Returns," 12 Employee Relations L.J. 313, 316 (1986).

[169] Id. The most recent enforcement instructions are in OSHA Instruction CPL 2-2.38B, August 15, 1988.

[170] O'Reilly, *supra* note 82 at 730. An employer can contest a citation at a hearing of the Occupational Safety and Health Review Commission. 29 U.S.C. 659(c) (1982). The

incentive to contest a citation is enhanced by its increased exposure to tort liability that might result from a finding that the company has an inadequate hazard communication program.[171]

L. Effectiveness of Standard for Reducing Workplace Illness

When OSHA promulgated the HCS, it proclaimed that "[t]he result of this hazard communication program will be to reduce the incidence of chemical source illnesses and injuries."[172] OSHA further asserted that the HCS will prevent about 20% of chemically caused injuries and illnesses in the workplace.[173] The agency has also estimated that extension of the HCS to the nonmanufacturing sector is expected to prevent 74,200 cancer deaths and an equal number of nonfatal cancers, 119,200 chronic disabling illnesses, and more than one million other workplace injuries and illnesses over the next forty years.[174] These benefits are expected to result from "increased worker use of personal protective devices, improved work practices, and other precautionary measures when handling hazardous substances" as well as more safety-enhancing investments by employers.[175]

However, several factors might limit the effectiveness of the HCS. First, workers may not get the hazard information they need to reduce exposure. The hazard information in MSDSs is frequently inadequate and incomplete.[176] Even if the information is contained in the MSDS, workers may refrain from requesting access to the forms out of fear of retaliation by the employer.[177] The required worker training programs, for which the standard does not present any specific guidelines, are frequently brief, ineffective sessions

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commission's order can then be appealed to a federal court of appeals. 29 U.S.C. 660 (1982). The first of what promises to be a steady stream of HCS interpretive problems that will end up in the courts was decided in late November, 1988, *General Carbon Co. v. OSHA*, 1988 WL 117401 (D.C. Cir. 1988) (rejecting company's challenge of OSHA's interpretation of HCS to not provide an exception for insignificant risks).

[171] *See Occupational Safety and Health Reporter* (BNA), June 6, 1985 at 4.

[172] 48 Fed. Reg. 53,281 (1983).

[173] 52 Fed. Reg. 31,861 (1987).

[174] *Id.* at 31,869.

[175] 48 Fed. Reg. 53,328 (1983).

[176] *Supra* notes 90 and 163. This problem also bears on the ability of the worker's personal physician to diagnose problems. See Himmelstein, "The Right to Know About Toxic Exposures," *N.E. Jnl. of Medicine*, v. 312, n.11 at 687.

[177] *Occupational Safety & Health Reporter* (BNA), May 16, 1985 at 994.

featuring standardized video presentations.[178] The trade secret provisions of the HCS may also restrict worker access to the identity of some hazards.

Second, even if the worker is presented with the appropriate hazard information, it may have no effect. The worker may suffer from information overload. Especially without a de minimis exemption, the standard might require warnings of so many substances that the impact will be diluted. The dual warning labels that may be required by the HCS and nonpreempted state laws may also lead to overload. There is also some evidence that the communication of hazard information may be ineffective because "workers ignore the information, are not rational in their decisionmaking due to personal biases and heuristics, and each worker may evaluate the information differently."[179] It will be particularly difficult to effectively communicate long term risks to workers.[180] Finally, unions may not have the resources to properly analyze hazard data for completeness and accuracy as well as to detect patterns of illness.

Even if the hazard information is communicated to workers and it induces them to take protective actions, their options might be quite limited. While employees may be able to reduce some risks by taking their own precautions, many occupational risks can only be addressed by changes in industrial processes or work practices initiated and approved by the employer. Given the disparity in power between the employer and employees, workers may not be able to significantly influence hazardous work practice. There is evidence that "workers in unregulated labor markets have been unable to obtain protection from hazards even when those hazards are well-known to the workers."[181] Also, the possible emergence of more effective defenses to tort actions by downstream workers may reduce the usefulness of tort suits for influencing industry practices.

Despite these potential problems, the HCS is nevertheless likely to have an important effect in reducing occupational injury and illness. There is empirical evidence suggesting that better hazard communication will increase workplace safety.[182] Workers can take precautions to reduce at least some risks. Disclosure of health hazards may also increase the "risk premium" in wages paid to workers, thereby providing a financial incentive for employers to

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[178] *Id.* at 993.

[179] Edwards, "Worker Right-To-Know Laws: Ineffectiveness of Current Policy-Making and a Proposed Legislative Solution," 15 *Envtl. Affairs* 1, 20 (1987). *(citations omitted).*

[180] *See* McGarity & Shapiro, *supra* note 89 at 1024-25, and n.153, *supra*.

[181] McGarity & Shapiro, *Id.* 1025.

[182] *See*, O'Reilly, *supra* note 136 at 111.

reduce risk.[183] Other market and economic forces may also induce companies to reduce risks.[184] Downstream employers will be able to reduce their costs by choosing suppliers with less risky products. Insurance companies will have better information for setting differential premiums for workplaces based on their different risk levels. Finally, independent of the effect of the HCS in reducing illness, disclosing the information is important for moral reasons. "Without full knowledge of the hidden but discoverable health risks that result from exposure to toxic substances, workers cannot be said to have accepted the risks voluntarily."[185]

Unfortunately, there is no persuasive empirical evidence at this time about the effectiveness of OSHA's hazard communication program for reducing occupational illness. Although various hypotheses have been offered with predictions of several beneficial effects, the actual positive effects may not be as great as OSHA has predicted because of the limitations on the effectiveness of the standard discussed above. Consequently, while the HCS is a useful supplement to other OSHA standards, it has not been proven to be an adequate substitute for other regulations requiring reductions in exposure levels to specific hazardous substances.[186]

M. Conclusion

The stated purpose of the HCS is to "establish uniform requirements" in a generic hazard communication rule for workers.[187] The burdens and inefficiencies of having different requirements in every state and municipality across the country would be too high for companies doing business in interstate commerce. However, the goal of uniformity and the use of a single generic rule are in tension with the tremendous diversity of industrial workplaces and hazardous substances that must be regulated by a national

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[183]Note, "Occupational Health Risks and the Worker's Right to Know," 90 *Yale L.J.* 1792, 1802 (1981).

[184]See Baram, *supra* note 94 at 388.

[185]Note, *supra* note 183, at 1800.

[186]The Administrative Conference of the United States has recently recommended that OSHA continue "to approve information disclosure requirements as a *complement* to regulatory standards." Administrative Conference of the United States, Recommendation 87-10,(3)(b) 1987 ACUS 56 (1987) (emphasis added). *See also* McGarity & Shapiro, *supra* note 89 at 1025 (recommending that "OSHA should adopt information approaches to complement regulatory commands, but they should not be used as a substitute for health and safety standards.")

[187]48 Fed. Reg. 53,281 (1983).

standard. OSHA has attempted to address this tension by adopting a performance-oriented approach that attempts to provide flexibility for employers to implement the most reasonable hazard communication program for each workplace situation.

Two fundamental problems hamper implementation of the HCS. First, while a performance-oriented standard has many advantages, it raises many problems of interpretation and compliance because of its subjective nature. OSHA must address this problem by devoting greater emphasis and resources to compliance guidance and assistance. The second problem is that even with the flexibility of a performance-oriented standard, the uniform application of a generic hazard communication standard to all workplaces and all potentially hazardous materials is inevitably over-inclusive. OSHA needs to have some mechanism for permitting limited variances and modifications of the standard for workplaces in which the advantages of nonconformity outweigh the needs of uniformity. In this regard, OSHA should consider the option of adopting a de minimis exemption for workplace hazards that present insignificant risks. Such an exemption would not only reduce the compliance costs and burdens of industry, but would also enable workers to focus their attention and priorities on the serious hazards that most need to be addressed.

III. EPCRA and EPA's Community Right to Know Program

A. Introduction

The tragic accident at Union Carbide's chemical production plant in Bhopal, India caused over 3,400 deaths and an estimated 200,000 injuries.[188] It also prompted Congress to consider the need for a federal law to protect the residents of communities in the United States from industrial accident hazards. After considering several options,[189] Congress enacted the Emergency

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[188]Note 277 *infra*.

[189]For example, the Chemical Manufacturing Safety Act, H.R. 965, 99th Congress, 1st Sess. (1985), proposed by Congressman James Florio to establish a federal program for licensing chemical facilities and regulating their safety.

Planning and Community Right to Know Act (EPCRA) in October 1986,[190] with broad support from industry, labor, public interest groups, and community officials across the nation.[191]

EPCRA is patterned to a considerable extent after the European Community's "Seveso Directive."[192] It mandates that operators of industrial facilities which make or use certain chemicals must provide accident hazard information to designated state and local officials, and requires these officials to use this information to develop emergency response plans for vulnerable communities within their jurisdiction.[193] EPCRA further requires the establishment of new state and local organizations responsible for emergency planning,[194] authorizes EPA to enact regulations to implement of the law,[195] requires industry to develop annual reports of all "chemical releases" to the environment,[196] and establishes that the accident hazard and chemical release information reported by industry must be made available on request to community residents.[197] However, EPCRA does not authorize EPA evaluation of facility safety, nor EPA regulation to prevent accident hazards (e.g., by regulation of facility siting, design or operations).[198] EPCRA is therefore unique among federal programs of social regulation in its reliance on risk communication between industry, state and local officials, and community residents to protect public health and safety. By its silence on the critical need for improving the siting, design and safe operation of industrial activities in

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[190]Title III of the Superfund Amendments and Reauthorization Act of 1986 ("SARA"), 42 U.S.C. §§11,001-050 (Supp. IV 1986), which is designated as the Emergency Planning and Community Right to Know Act of 1986 ("EPCRA").

[191]No footnote.

[192]Council of the European Communities, Directive on Major Accident Hazards of Certain Industrial Activities, 82/501/EEC (24 June 1982), as amended by 87/26/EEC (19 March 1987) and 88/8610/EEC (24 Nov. 1984); commonly referred to as the "Seveso Directive," Seveso being the Italian town where a Hoffman-LaRoche plant accident contaminated the community with dioxin. See discussion in H. Otway, note 28 *supra* at 10,11.

[193]For a useful summary of EPCRA provisions, *see Title III Fact Sheet*, U.S. Environmental Protection Agency (Aug. 1988), 194.

[194]EPCRA §§301.303.1

[195]EPCRA §328.

[196]EPCRA §313.

[197]EPCRA §324.

[198]In contrast, the Seveso Directive orders private firms to conduct an evaluation of accident risks and safety measures at their facilities, and to provide the resulting evaluation ("safety case") to national officials for review. The officials may then use their national authority to inspect and order corrective measures. Note 192 *supra*, article 5. *See* discussion in M. Baram, "Risk Communication Law and Implementation Issues in the United States and the European Community" in Symposium Proceedings, Boston Univ. Int'l. L.J., note 1 *supra*, at 28.

order to prevent accidents in the first instance, the law implicitly relies on forces other than federal regulation to deter and remedy inadequate management of industrial facility safety. Thus, EPCRA is a prototype of a "new federalism" statute: it eschews federal licensing, inspection and standard-setting to solve a public health and safety problem and instead fosters state, local and private initiatives.[199]

B. History

Over 6900 accidents involving the release of "acutely toxic substances" occurred in the United States from 1980 to 1985. These accidents led to 138 deaths and 4,717 injuries, temporary evacuation of some 217,000 persons, and other consequences yet to be measured (latent disease risk, environmental contamination, emotional distress, for example). In addition, the accidents are believed to have had an "average estimated cost" of approximately $30 million each (in 1984 dollars) with one accident "resulting in more than $100 million in estimated damages." Some 200 different substances were released in the events which caused death and injuries, including four high volume, industrial chemicals (chlorine, ammonia, sulfuric and hydrochloric acids) which were involved in 25 percent of the events causing deaths. Seventy-five percent of these accidents occurred in-plant, and the remainder during transportation, with the former accounting for 65 percent of the events causing death or injury. The chemical and allied products industry and the petroleum refining industry together accounted for 34 percent of the injuries and more than half of the deaths.These preliminary findings of a continuing study by the U.S. Environmental Protection Agency (EPA)[200] demonstrated that accidents involving chemicals are a ubiquitous and significant problem in the United States despite numerous federal, state and local laws which have been in effect for decades. The EPA findings, together with the occurrence of the major accident at Bhopal in 1984 and daily reports of new industrial accidents promoted strong public support for new federal laws to prevent accidental releases and promote emergency response planning, and to provide local

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[199] *See* note 16 *supra*.

[200] See "Executive Summary" of *Acute Hazardous Events Data Base Report*, Industrial Economics, Inc., Cambridge, Mass., Report for U.S. EPA, Washington, D.C., No. EPA-560-5-85-029 (Dec. 1985). For further information on transport accidents, not dealt with in this study, *see Transportation of Hazardous Materials*, U.S. Congress, Office of Technology Assessment, Washington, D.C. (July 1986).

officials and community residents the "right to know" company risk information.[201]

Faced with this growing pressure, Congress, state and local legislators, agency officials, industrial firms and trade associations reponded. In 1985, EPA, without clear legal authority at that time to address industrial accident risks, developed and disseminated across the nation a guidance document for state and local officials and company managers, the *Chemical Emergency Preparedness Program (CEPP); Interim Guidance*[202] based on several features of the Seveso Directive[203] of the European Community and similar measures developed by the World Bank.[204]

At the same time, the Chemical Manufacturer's Association (CMA), the major trade association for chemical producers, developed its Community Awareness and Emergency Response Program (CAER) to demonstrate the chemical industry's willingness to share certain types of risk information (the Material Safety Data Sheets or MSDS's disseminated to workers under the OSHA Hazard Communication rule) with communities where chemical facilities were located.[205] CAER represented an about-face for the chemical industry which had traditionally restricted public disclosure of risk information.[206] Major chemical producers also voluntarily began to re-evaluate safety at their facilities, reduce quantities of hazardous chemicals stored on site, and impose more stringent measures to prevent accidents.[207]

But these efforts by EPA and industry did not deter states and municipalities from also acting. By late 1986, over 20 states and hundreds of municipalities had enacted new laws and regulations which mandated industrial risk communication and local emergency response planning. These enactments, based on state "police power," reinforced longstanding state and local laws for public safety e.g., laws authorizing fire marshall inspection,

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[201]For example, *Report of Joint Public Hearings on Toxic Chemical Accidents in New York State*, Office of Attorney General of New York State, Albany, N.Y. (June 1986), documents a greater incidence of chemical accidents than the EPA report.

[202]CEPP was published by EPA in November 1985, and an estimated 20,000 copies were distributed over the next month.

[203]Note 192 *supra*.

[204]*See Guidelines for Identifying, Analyzing and Controlling Major Hazard Installations in Developing Countries*, and *Manual of Industrial Hazard Assessment Techniques*, World Bank (1985).

[205]For discussion of CAER and its implementation, see 1986 *CAER Program Report*, Chemical Mfr's. Association.

[206]No footnote.

[207]Personal communications from corporate officials and field research at Dow Chemical, Occidental Chemical, Vista Chemical and other chemical producers (1988-89).

licensing of petroleum storage installations, and health officer control of activities which pose health risks to the community.[208] Some citizens' groups sought action by local officials to close industrial facilities which used toxic chemicals, and were successful.[209] The culmination of these developments was Congressional enactment of the federal Emergency Planning and Community Right to Know Act (EPCRA) in October, 1986.[210]

EPCRA requirements for risk communication and emergency planning are allocated among federal, state and local officials and industry. These requirements are set forth in sections of the law on emergency planning, emergency notification, community right to know reporting, and chemical release reporting, which are discussed below in terms of their main features, EPA implementation, and the issues now arising as enforcement begins.

C. Emergency Planning

EPCRA provides that new state and local units of government be created to receive and use industrial risk information for preparation of local emergency response plans, and to make risk information available to the public on a right to know basis.[211] To develop this infrastructure, the governor of each state must designate a state emergency response commission (SERC) whose members have appropriate expertise.[212] The SERC must, in turn, establish local emergency planning districts within the state, and a local

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[208]For a review of these developments to early 1986, see M. Baram, "Chemical Industry Accidents, Liability and Community Right to Know," *Am. Jnl. Public Health*, v.76, n. 5 (May, 1986) 568. A current compilation of state laws is found in *Right to Know Planning Guide*, Bureau of Nat'l. Affairs.

[209]Citizens of Cambridge, Mass. succeeded in shutting down a special research laboratory at the A.D. Little Co. where research on the detoxification of chemical warfare agents was being conducted under U.S. Department of Defense contracts. The city's Health Officer issued the shut down order later justified by a risk assessment which concluded that risk to citizens from an accidental release was very remote but that there was a reasonable basis for the order. *See A.D. Little v. Commissioner of Health of City of Cambridge*, 395 Mass. 535 (S.J. Ct., 1985).

[210]Title III of the Superfund Amendments and Reauthorization Act of 1986 ("SARA"), 42 U.S.C. §§11,001-050 (Supp. IV 1986), which is designated as the Emergency Planning and Community Right to Know Act of 1986 ("EPCRA").

[211]EPCRA §§301, 303.

[212]EPCRA §301 (a).

emergency planning committee (LEPC) for each district, composed of local officials and citizens representing certain skills and interests.[213]

Each LEPC is thereafter responsible for preparing the emergency plan for its district, based in part on information that industry is required to provide--e.g., notifications from local industrial firms which have determined they are subject to EPCRA, and risk information from these firms, both to be submitted in accordance with EPCRA's report requirements.[214] LEPC's are also required to determine the resources they need, but federal funds to meet these needs are not provided by the Act.[215]

The emergency plan for each district must designate the local industrial facilities subject to the Act, community and facility emergency coordinators, persons in charge of emergency equipment, the local routes used for transporting certain hazardous substances, and other facilities which, due to their location, either exacerbate accident risks (e.g., natural gas facility) or pose special emergency response problems (e.g., hospital, school).[216] The plan must then delineate the operative features of emergency response including the measures to be taken by facility operators and local emergency and medical personnel in the event of an accidental release of a designated substance; methods for notifying emergency responders and the public; methods for determining the occurence of an accidental release and the population or area likely to be affected; and population evacuation plans.[217]

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[213]EPCRA §301 (b), (c). The districts may be existing political subdivisions (e.g., municipalities, counties) or newly defined regions. LEPC members are to include state and local safety officials, representatives of the media and community groups, and operators of facilities subject to the Act.

[214]EPCRA §303. Owners of facilities in the district which are subject to the Act have an affirmative duty to notify the SERC of this fact. EPCRA §302 (b)(2). A facility is subject o EPCRA "if a substance on the list [of extremely hazardous substances] is present at the facility in excess of the threshold planning quantity established for such substance [by EPA]." EPCRA §302 (b)(1).

[215]EPCRA §303 (b). EPCRA §305 authorizes the Federal Emergency Management Agency to provide $5 million to the states for hazardous materials program training.

[216]EPCRA §303 (c).

[217]*Id.*

Upon completion, the plan must be reported to the SERC for evaluation,[218] and is subject to review by Federal "regional response teams."[219]

To develop its plan, the LEPC must adopt rules which assure public notice and comment opportunities, public meetings, LEPC response to comments, and plan distribution.[220] The LEPC must also provide the industrial risk information it has received to members of the public, upon request, to implement the "community right to know" goals of EPCRA.[221]

Implementation has varied widely among the 50 SERC's and 3800 LEPC's nationwide,[222] due, in part, to the Act's limitations. For example, EPCRA does not preempt state or local law;[223] lacks detailed requirements for implementation; and does not provide EPA with authority to enforce emergency planning by SERC's and LEPC's. The Act therefore fails to promote uniformity. As a result, several variables in each state have influenced implementation and created a great diversity of results.[224] These variables include the availability of state funding and expertise for SERC's and LEPC's; the presence of industrial associations and public interest groups and their influence on government; and the multitude of preEPCRA laws and programs for protecting public safety in each state and the extent to which they conflict with and promote turf battles with the newly-authorized SERC's and LEPC's.[225] Given these variables, state implementation has been

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[218]SERC evaluation is to assure the coordination of the plan with the plans for other districts. EPCRA §303 (e). However, the SERC is not precluded from using other evaluation criteria to assure that the plan is adequate (e.g., criteria developed by state fire and safety officials under state law).

[219]These teams were established pursuant to the National Contingency Plan of the federal "superfund" law for the cleanup of hazardous wastes, the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9601 et seq.

[220]EPCRA §301 (c).

[221]*Id.* Community "right to know" is provided by EPCRA §324, but is subject to trade secret protection, §322, and other restrictions, §312 (e).

[222]*See* the semi-monthly *Right to Know Planning Report*, Bureau of National Affairs, Inc. for implementation information (hereinafter RTK Report).

[223]EPCRA §321 (a)(1).

[224]An extraordinary diversity exists. *See generally*, *RTK Reports*, for information and anecdotes. For example, New Jersey's division into 588 districts, whereas the entire state of Georgia has been designated a single district. *RTK Report*, v. 1, n. 21 (July 7, 1988) 4.

[225]*Id. Also see State Implementation of EPCRA*, National Governor's Association (Sept. 1988). For example, responses to EPCRA may vary in accordance with the following characteristics: whether a state is "rural" and relies on volunteer fire departments, or industrial and has trained marshalls and full-time safety personnel; whether a state has vigorous public interest groups or is dominated by industrial chemical complexes and industry associations (e.g., Texas, Louisiana, New Jersey); whether a state has "home rule" and vested considerable authorty

"contextual." Some states have carefully integrated SERC's and LEPC's into the network of state and local agencies for public safety and provided new funds, some have subordinated EPCRA requirements to more stringent state programs, and others have simply let SERC's and LEPC's flounder amidst the complex array of state and local authorities.[226]

In addition, many firms have failed to meet their initial responsibility of determining whether they are subject to EPCRA, and if so, of notifying the cognizant SERC.[227] This is a critical determinant of the adequacy of subsequent LEPC planning functions, since firms which fail to notify also later fail to provide the risk information reports required by EPCRA, thereby further obstructing the development of appropriate emergency plans.

This breakdown in company compliance became apparent when 60% of the firms believed by EPA to be subject to the Act failed to so inform their SERC's by the May 17, 1987 deadline.[228] Noncompliance persists, but has evoked only mixed responses from EPA. In October 1987, an agency official acknowledged that EPA had taken no enforcement actions and was providing a "grace period" until industry awareness increases.[229] In December 1987, another official indicated that EPA would "possibly" take enforcement actions against "knowing violators."[230] And one year after the notification deadline, a third agency official said that EPA would "soon announce its enforcement strategy, targeting facilities that are "flouting the law."[231]

In addition, industrial compliance requirements have been blurred by EPA's efforts to change the list of substances and threshhold quantities, which is used to determine which firms are subject to notification.[232] This "section 302 list" of "extremely hazardous substances" and their threshhold quantities is subject to continuing modification and each modification is a lengthy process. EPA proposals to delete or add substances or modify threshholds take time to develop, are followed by Office of Management and Budget reviews, at glacial

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in local officials, or has a strong central government. State and local programs also rely on a wide variety of funding sources. *See RTK Report*, v. 1, n. 5 (Nov. 26,1987) 4.

[226] *Id.* For example, New Jersey's state program forges beyond EPCRA requirements, *RTK Report*, v. 2, n. 2 (Oct. 27, 1988) 2; whereas Massachusetts has recently shut down its right to know office and failed to reconcile conflicting state laws with EPCRA, Notification, Dept. of Environmental Protection (August 1989).

[227] EPCRA §302. *See* note 214 *supra*.

[228] *RTK Report*, v. 1, n. 2 (Oct. 15, 1987) 1.

[229] *Id.*

[230] *RTK Report*, v. 1, n. 6 (Dec.10, 1987) 2.

[231] *RTK Report*, v. 1, n. 18 (May 26, 1988) 2.

[232] EPCRA §302. *See* note 214 *supra*.

pace, and then are subject to judicial review. Compliance requirements have therefore become uncertain for many firms.[233]

Thus, diversity of implementation among the states is a consequence of many factors, including EPCRA's loose design, differing state contexts and the variables therein, industrial noncompliance, and EPA uncertainties about enforcement. Further, the agency has recently affirmed that it lacks authority under EPCRA to enforce emergency plan preparation by SERC's and LEPC's, and will rely on "strong incentives" instead.[234] Given these circumstances, it is not realistic to expect that EPCRA will achieve substantial uniformity in the development of emergency programs and plans among fifty states.

But this diversity can be viewed as a positive attribute if it produces plans which accurately respond to the differing accident considerations in each state and represent optimal use of the resources available in each state. The EPCRA challenge for EPA is to therefore accept diversity but somehow assure that 50 SERC's and 3800 LEPC's produce these positive results.

Thus, EPA must address three generic problems which thrive in this diversity and obstruct positive outcomes: the persistent low level (about 50%) of industrial notifications, the slow pace of emergency plan preparation by LEPC's, and major inadequacies in the content of many completed plans.

Analysis of industrial failures to notify SERC's has led EPA to conclude that this first problem lies mainly with smaller firms which purchase EPCRA-designated chemicals from large chemical manufacturers for various purposes[235] (e.g., to make paper, textiles, chips for computers, polyvinyl products, etc.). Although these firms routinely receive material safety data sheets (MSDS's) and labels with the chemicals they purchase in accordance with OSHA's hazard communication standard,[236] many do not consider themselves to be "chemical firms" and do not review EPCRA requirements, or

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[233]For example, the agency announced plans to delete 36 substances from the §302 list in November 1986. But OMB review followed, and EPA did not make its final deletion decision until Feb. 25, 1988. *RTK Report*, v. 1, n. 12 (March 3, 1988)1. Deletion of four other substances was made under court order. See A.L. Laboratories v. EPA, D. Ct., D.C., No. 87-1991-OG, and consolidated cases (Dec. 10, 1987). *See* EPA's Regulatory Agenda for its planned rulemakings to revise the list and quanitites, 54 Fed. Reg. 17,258 (April 24, 1989).

[234]*RTK Report*, v. 2, n. 9 (Jan. 19, 1989) 1. EPA's "strong incentives" include potential liability of public officials who fail to fulfill the planning process in the event of accident injuries, citizen lawsuits against SERC's and LEPC's for not providing risk information or completed plans, and voter dissatisfaction.

[235]Discussed by EPA officials at EPA Workshop on Chemical Accident Prevention, Washington, D.C. (July 24, 25, 1989).

[236]29 CFR 1910.1200 (1988).

lack the expertise or funds to understand and comply with the requirements, and have decided to forgo compliance and risk EPA enforcement.[237]

Delays in plan preparation by LEPC's, the second problem, have been considerable. Although plans were to be completed and submitted to SERC's by October 17, 1988, EPA reported in January 1989 that only 50 to 60 percent of LEPC's had done so, and that the quality of the plans varied widely.[238] For example, the Michigan SERC had received plans from only 14 of the state's 98 LEPC's, covering only 55 of the 1500 facilities in the state believed subject to EPCRA, by mid-January 1989.[239] Causes of this problem may include lack of LEPC funding and expertise, lack of LEPC accountability to EPA, SERC disinterest in supervising LEPC's, or conflicts and turf battles among state and local authorities, as discussed earlier. Another possible cause is lack of public interest in LEPC activities and few instances in which the "community right to know" has been exercised to secure information from LEPC's, circumstances which tend to diminish the urgency and importance of plan preparation.[240]

In addition, the potential tort liability of LEPC members for injuries which would be caused during use of an emergency plan, has been raised in many states, and has probably retarded LEPC progress. According to a SERC official in West Virginia, almost 85 percent of persons asked to serve on LEPC's refused unless protected from tort liability.[241] This personal concern about vulnerability to negligence actions and liability has been recognized as a "vexing problem" by EPA.[242] Because of uncertainities about state liability and immunity doctrines, advisory opinions have been sought in many states from private attorneys and state attorneys general.[243] To encourage LEPC membership, new inmmunities have been promulgated by legislative and executive actions in several states.[244]

A survey of state laws, conducted for EPA concluded that LEPC members in most cases are afforded significant protection from liability even if proven negligent in performing their duties, that the relevant legal doctrines vary considerably among the states, and that LEPC members should seek further

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[237]Note 235 *supra*.

[238]*RTK Report*, v. 2, n. 10 (Feb. 2, 1989) 4.

[239]*Id.* at p. 2. Other examples are provided by Arizona, where the SERC reported receiving only 3 plans from the State's 15 LEPC's by the October deadline, *RTK Report*, v. 2, n. 4 (Nov. 10, 1988) 2; and New Hampshire, which anticipated receiving plans from only 15 of its 234 LEPC's by the deadline, *RTK Report*, v. 2, n. 3 (Oct. 27, 1988) 1.

[240]Note 238 *supra*.

[241]*RTK Report*, v. 1, n. 9 (Jan. 21, 1988) 2.

[242]*RTK Peport*, v. 1, n. 18 (May 26, 1988) 2.

[243]*RTK Report*, v. 1., n. 20 (June 23, 1988) 4; v. 2, n. 2 (Oct. 13, 1988) 4.

[244]*Id.*

advice from an attorney knowledgeable in the subject. According to Professor John Pine, the director of the study, LEPC members may be protected by various doctrines, including sovereign immunity, special statutory immunity, immunity for public officials performing discretionary or governmental functions, or statutory indemnification and insurance programs.[245]

The need to cure major inadequacies in the content of emergency plans, the third problem, ultimately involves the individual review of 3800 plans by 50 SERC's, and monitoring by EPA and regional response teams.[246] Many types of inadequacies have been found including lack of detail and serious omissions.

According to EPA, one LEPC's plan consisted of a mere two page addendum to a civil defense program and compared poorly with a detailed 275 page plan developed by another LEPC for a similar district.[247] The Michigan SERC found that the plan prepared for Midland County, home of major chemical producers, failed to designate procedures for fire and medical services, evacuation, and other offsite emergency functions.[248] The deaths of six firefighters in an explosion and chemical fire in Kansas City, Missouri, motivated Congressional scrutiny and led to a finding that loss of life could have been avoided if better information had been available about the chemicals at the site.[249]

Each of these three problems must be resolved if suitable emergency plans are to be properly provided, distributed and used. This will require several EPA initiatives and new collaborations with SERC's, OSHA, and chemical producers.

For example, to address the first problem of industrial failure to notify, largely by small firms which purchase and use the designated chemicals, a feasible approach for EPA would involve one or more of the following strategies.

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[245]J. Pine, "Tort Liability in Emergency Planning," U.S. EPA (1988). *Also see* Pine's earlier report, "Tort Liability of Government Units in Emergency Actions and Activities," U.S. Federal Emergency Management Agency (1988).

[246]Note 219 *supra*.

[247]Note 238 *supra*.

[248]*Id*. at p. 2.

[249]*See* "Fire and Explosion in Kansas City: Lack of Information About Hazardous Materials Jeopardizes Firefighters," 2d Rpt., Committee on Government Operations, 101 st Congress, 1st Sess., House Rpt. 101-124 (July 11, 1989). *Also see* "Explosion Reveals Holes in Right-to Know Programs," *RTK Report*, v. 2, n. 8 (Jan 5, 1989) 4; and reports of other accidents which endangered fire fighters due to inadequate information, e.g., *RTK Reports*, v. 1, n. 14 (March 31, 1988) 2; v. 1, n. 22 (July 21, 1988) 2.

(1) Promote efforts by SERC's for educating and counselling small businesses about EPCRA notifications, and provide SERC's with EPA technical support for identifying the small businesses likely to be subject to EPCRA.[250] SERC's include state officials who monitor and regulate many industrial firms in their other regulatory capacities (e.g., as state fire marshalls, state air toxics officials). Their experience and outreach systems should be fully used and reinforced with EPA technical assistance. EPA could promote SERC initiatives by holding regional meetings and training programs for SERC members, which would also enable knowledge transfers between SERC's. An EPA policy statement, guidance memorandum, and training programs for SERC's could stimulate SERC's to more aggressively deal with notification failures.

(2) Promote use of MSDS's which include guidance to all firms which purchase EPCRA-designated chemicals as to the EPCRA status and reportable quantities of the chemicals, and notification responsibilities (the MSDS's and labels now accompany most chemicals purchased by smaller firms). Several large producers of chemicals now do this on a voluntary basis,[251] and one now provides additional guidance materials and seminars for its customers.[252] EPA could promote an expansion of these valuable communications by all chemical producers, so that ultimately all EPCRA-designated chemicals, when sold by any domestic producer or importer, are accompanied by enlarged MSDS's which notify purchasers of EPCRA requirements, and how they can determine their own notification status. Modification of MSDS's to accomplish these results would require OSHA

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[250]For example, EPA's "chemical crosswalk" system, designed to help regional offices, SERC's and LEPC's to identify facilities likely to be subject to EPCRA. *RTK Report*, v. 2, n. 18 (May 25, 1988) 2.

[251]For example, Occidental Chemical, Vista Chemical. Personal communications and MSDS's received from these firms (1989).

[252]Dow Chemical is the major practitioner of this approach, as part of its marketing and product stewardship efforts. Personal communication and seminar materials received from D. Rausch and other Dow officials (1988-89). *See*, in particular, Dow's materials for its Regulatory Issues Seminar, distributed to its customers and distributors.

rulemaking to amend its hazard communication standard,[253] or alternatively, EPA use of its EPCRA and Toxic Substances Control Act[254] regulatory authority to promulgate a rule which requires this information in an addendum to all MSDS's for chemicals designated on EPCRA's "section 302 list."

(3) Promote efforts by trade associations at national and state levels to affirmatively provide EPCRA guidance to their member firms and their customers. Several associations now voluntarily provide regulatory information on request, such as the Chemical Manufacturer's Association, the Chlorine Institute, and the Vinyl Institute.[255]

(4) Develop a final position on EPA and SERC enforcement of industrial notification requirements.[256]

To address the second and third problems, namely the laggard performance of LEPC's and their preparation of inadequate plans, EPA must rely heavily on SERC's (which are authorized by EPCRA to supervise LEPC's) since it lacks enforcement authority against LEPC's. But since EPA also lacks authority to compel SERC's to more stringently supervise their LEPC's, the agency must resort to other measures similar to those suggested for the first problem discussed above. These include convening regional meetings to educate and train SERC members, and to promote the exchange of information among SERC's on how to stimulate and evaluate LEPC performance. EPA could

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[253]29 CFR 1910.1200 (1988). *See* discussion in Part II *supra*.

[254]The Toxic Substances Control Act, 15 U.S.C. 2601 (1976). Section 6 provides EPA with broad authority to regulate chemicals in commerce which pose unreasonable risks. If EPA finds that regulatory jurisdiction over a chemical posing an unreasonable risk lies with another agency (e.g., OSHA for chemical risks in the workplace), Section 9 sets forth procedures for EPA to follow, which essentially require EPA to initially refer the matter to the other agency, and to then regulate the chemical if the other agency chooses not to do so itself.

[255]Personal communications with members of several chemical user firms who have received useful information on regulatory issues from these associations, and review of various publications widely distributed by these associations. (1988-89). *Also see* note 205 *supra*. For a brief discussion of early CMA programs, *see Chemical Emergencies: Preparedness for and Response to Accidental Chemical Air Releases*, U.S. General Acctg. office, GAO/RCED-86-117BR (June 1986) 37.

[256]Pursuant to EPCRA §325. The policy should clarify EPA enforcement responsibilities vis-a-vis state and local enforcement under state law and under EPCRA §326, which provides in part that "Any state or local government may commence a civil action against an owner or operator of a facility for failure to . . . (i) provide notification . . . under section 302(c)."

also provide technical assistance to SERC's on how to evaluate emergency plans, and the methods of analysis and planning they should convey to LEPC's. Other options available to EPA are problemmatic: to exhort SERC's to use state law to enforce LEPC performance; to encourage citizen suits against SERC's "for failure to provide a mechanism for public availablity of information."[257]

D. Emergency Notification

An important risk communication required by EPCRA is emergency notification, the Section 304 requirement that when an industrial facility accidentally releases a designated amount of a listed chemical offsite, its management must immediately notify LEPC's and SERC's for the regions likely to be affected. This reporting function enables rapid mobilization of fire departments and other emergency responders, and timely use of emergency response plans.[258]

The requirement is triggered by the accidental release of any of some 725 substances on the CERCLA hazardous substance list, or the 360 substances on the EPCRA list of "extremely hazardous substances," in amounts which exceed designated quantities.[259] (Many chemicals appear on both lists.) If the release is contained on-site without human exposure off-site, or is a continuous or federally-permitted release off-site as defined by CERCLA, an EPCRA Section 304 report is not required.[260]

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[257]EPCRA authorizes such citizen suits, but success would depend on whether the lack of a plan, or an inadequate plan, constitutes a violation of EPCRA § 324(a) requirements that plans be made publicly available.

[258]EPCRA §304.

[259]CERCLA, 42 U.S.C. §9601, requires emergency notification for release of its designated chemicals, at section 103 (a). The CERCLA list and its reportable quantities (RQ's) appear in 40 CFR §302.4. The EPCRA list is mandated by section 302 (a)(2), as previously discussed. *See* 52 Fed. Reg. 13,378 (April 22, 1987); and 40 CFR §355, App. A. Each list designates reportable quantities, or is subject to a statutory RQ: e.g., EPCRA provides that the RQ shall be one pound for substances on its §302 list until EPA establishes another RQ by regulatory action.

[260]On site releases are exempted from reporting under EPCRA §304 (a)(4), but are not exempted by CERCLA §103. EPCRA §304 (a) (2) (A) exempts continuous releases defined by CERCLA §103 (f) and federally-permitted releases defined by CERCLA §101 (10). 40 CFR 355. However, other laws will require reports for such incidents (e.g., to OSHA, State Air Toxics Board, etc.).

Notice must be given "immediately after the release" by telephone, radio or in person to the LEPC's and SERC's,[261] and must include the chemical name or identity, and estimates of the quantity, time and duration of the release.[262] Additionally, the company's notice must contain information about the medium (e.g., air, water) into which the chemical was released, known or anticipated health risks (acute and chronic), medical advice for exposed persons, evacuation and other precautions, and persons to be contacted for further information.[263] Further information on these matters must be provided by the firm in a follow-up report done "as soon as practicable after a release," and must also describe actions taken by the firm to contain the release and otherwise respond to it.[264] The initial notification and subsequent follow-up report provided by the firm are publicly available.[265]

Among its many enforcement functions under EPCRA, EPA claims it has accorded highest priority to violations of Section 304 emergency notification duties "by larger firms which present major risks," but has indicated it would be lenient with small firms not aware of EPCRA requirements.[266] Violators also face other enforcers. State and local officials, with greater awareness of accidents within their jurisdictions, have considerable enforcement authority under CERCLA,[267] and various state laws requiring spill notifications; and citizen suits are authorized by EPCRA against a firm which fails to provide its follow-up information,[268] unless EPA is pursuing enforcement.[269] Significant penalties are authorized by EPCRA: from $25,000 per day to $75,000 per day for repeated violations.[270]

In October 1988, EPA levied its first fine for a violation of Section 304 against a chemical laboratory for failing to provide a written follow-up report

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[261]EPCRA §304 (b)(1). Special directions are provided for releases during transport of the designated substances.

[262]EPCRA §304 (b)(2).

[263]*Id.*

[264]EPCRA §304 (c).

[265]EPCRA §324. Although public availability is subject to the trade secret restrictions of §322, §323 provides for disclosure of trade secrets to medical and health personnel under certain conditions.

[266]*RTK Report*, v. 1, n. 12 (March 3, 1989) 4. *Also see* EPA's interim final rule on penalty assessment under EPCRA §325; 54 Fed. Reg. 21,174 (May 16, 1989); following its "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties," 40 CFR 22.

[267]*See* discussion in *RTK Report*, v. 1, n. 16 (April 28, 1988) 2.

[268]EPCRA §326 (a)(1)(A)(i).

[269]EPCRA §326 (e).

[270]EPCRA §325 (b).

after it had accidentally released an estimated 180,000 pounds of chlorine in Springfield, Massachusetts. In addition to the $78,500 EPCRA penalty, the firm was assessed an additional $25,000 fine for failing to provide CERCLA notification. Class actions seeking $620,000 in damages were also filed against the firm.[271]

At this time, it is not known if there is substantial compliance with the emergency notification requirement, which for many substances, is triggered by an accidental release of only one pound.[272] Numerous chemical spills and other accidents are reported in the media, but EPA has not released any data on Section 304 compliance, and to date, has not renounced its early view that small firms "unaware of EPCRA" should be dealt with "leniently."[273]

As EPA modifies the reportable quantities of many substances, which it is authorized to do by CERCLA and EPCRA, it will inevitably reduce the number of releases which merit emergency notification, since in most instances to date, the agency has acted to increase the release amount which requires the report.[274] In addition, potential tort liability may persuade some firms to remain silent, particularly for small spills, since the information required in the notification and follow-up report could be used to prove exposure, injury causation and increased risk of disease in personal injury actions arising from an accidental release.[275] Industrial reporting may also be significantly reduced by the outcome of the Agency's pending regulation which would define what air releases of toxic chemicals ought to be exempted, as "federally-permitted releases," from Section 304 notification requirements.[276]

> But there is a more fundamental issue raised by Section 304 than compliance or the scope of its applicability, namely its efficacy. Given compliance, would it really trigger timely emergency responses and protect public safety as Congress intended? Since Bhopal, much concern has been given to the problem of sudden airborne releases of toxic materials, and the rapidity with which toxic clouds travel into populated

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[271] *In re All Regions Chemical Labs, Inc.*, No. EPA 1-88-108. *See* discussion in *RTK Report*, v. 2, n. 3 (Oct. 27, 1988) 1.

[272] EPCRA §304 (a)(1)(C). *See* note 259 *supra*.

[273] *See* note 266 *supra*.

[274] *See* 54 Fed. Reg. 33,418 (Aug. 14, 1989) for EPA action raising reportable quantities for six hazardous substances on the EPCRA list, for 121 substances on the CERCLA list.

[275] However, firms must also consider the consequences of noncompliance for negligence actions. Noncompliance could be used to establish negligence per se. *See* discussion in *RTK Report*, v. 2, n. 20 (June 22, 1989) 4.

[276] *RTK Report*, v. 2, n. 22 (July 20, 1989) 1, discussing EPA's request for public comment on the issue, 54 Fed. Reg. 29, 306 (July 11, 1989).

> areas. After reviewing 2,151 toxic chemical accidents in New York state from 1983 to 1988, the state's Attorney General's findings cast considerable doubt on the efficacy of emergency notification for protecting the public: "A cloud of toxic gas can travel great distances in short times, depending on the wind and topography. If the wind is blowing at 3.4 miles per hour,. the cloud will cover a distance of about one mile in 17.6 minutes. This poses a nearly impossible challenge for emergency responders. It took emergency workers one and a half hours to evacuate 500 students from a school next to the FMC Corporation in 1984 after methyl isocyanate leaked from the plant. The chemical cloud took less than a minute to enter the school, which was 500 yards away. Two weeks later, the same chemical was released from the Union Carbide facility in Bhopal, India, resulting in over 3,400 deaths and 200,000 injuries.
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> Clearly, the high speed of dense clouds leaves very little time for spill detection, hazard appraisal, government and public notification, and finally, taking protective measures."[277]

Therefore, the efficacy of emergency notification is a problem which transcends industrial compliance. Notification will not be effective in many foreseeable accidents where the chemical being released poses acute hazards, is heavy and disperses rapidly in dangerous airborne concentrations, and where residences and institutions such as schools and hospitals are in proximity to the accident site. Section 304 notification requirements take time to implement, especially in the midst of an accident which demands company attention to workforce protection and the deployment of special equipment and personnel to contain and terminate the releases. For example, Section 304 requires that plant officials consult several chemical lists, and provide accurate information about the nature of the release, its anticipated hazards off-site, medical advice and other precautions. Care is required in developing this information, which consumes critical minutes, since faulty information may lead to special harms and will also have tort liability consequences. Once notifications are acomplished, additional time is needed for the emergency response plan to be implemented.

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[277] *New York Under a Cloud: The Need to Prevent Toxic Chemical Accidents*, Attorney General, N.Y. (May 1989) 17, 18.

Some large firms have developed methods for rapidly identifying releases, mapping gas cloud dispersions, and notifying LEPC's and others.[278] But small firms do not have, and cannot afford, these capabilities. Therefore, Section 304 fails to assure timely emergency action for many accident situations, a serious deficiency in EPCRA which requires that EPA and Congress re-evaluate and re-design emergency notification requirements, and place more emphasis on accident prevention, perhaps by providing for regulation of industrial safety practices and contingency plans.

Therefore, Section 304 raises two issues which should initially be evaluated by EPA, although action by others will be needed to address the problems that EPA is likely to find. First, there is uncertainty about industrial compliance with the Section 304 notification requirements, a matter which deserves EPA study and SERC data gathering in each state. If compliance is found to be low for certain industrial sectors (e.g., small businesses), or for certain types of releases (very small spills), EPA has sufficient authority to take various corrective measures: enactment of a more vigorous education program to reach small businesses; enactment of a more vigorous enforcement policy; promulgation of a rule requiring that the MSDS's for chemicals on the CERCLA and EPCRA lists contain an addendum setting forth reportable quantities and other emergency notification instructions for the particular chemical (as suggested earlier to rectify compliance problems under Sections 301-303 of EPCRA); and finally, promoting a greater effort by SERC's to supervise industrial reporting within their jurisdictions.

The second issue EPA should address is more fundamental, namely to determine whether Section 304's emergency notification is an effective means of deploying emergency response plans to protect the public, and to determine under what accident conditions it is likely to fail. The results of the study should be used by EPA or Congress to correct deficiencies.

For example, EPA could, by rule, define vulnerable zones, request SERC's to map these "vulnerable zones" where accident conditions are likely to overwhelm notification, as has been done in New York State, and then request that the SERC's take special measures to expedite notifications and otherwise improve public safety in these zones. The special measures could include, for example, SERC use of state fire marshall or other safety authority to inspect and evaluate the safety of certain industrial activities, to review the adequacy of facility contingency plans to cope with accidents in vulnerable zones and contain them onsite, and to order by state regulation more stringent safety

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[278]For example, many large chemical producers employ the SAFER system, or similar computerized systems for calculating gas cloud dispersions, graphically identifying areas at risk, and electronically notifying LEPC's, plant workers, and others. Personal communications with officials at Occidental Chemical and other firms (1988-89).

measures and contingency plan efforts at risky facilities to prevent accidents. Another potential use of the study results would be for EPA to propose that Congress amend EPCRA to authorize EPA itself, or in conjunction with OSHA, to carry out such inspection, evaluation and regulation functions to prevent accidents in vulnerable zones; or alternatively, to provide EPA with authority to enforce SERC initiatives on vulnerable zones.

E. Chemical Inventory Reporting

Many firms which produce, use or store chemicals are now required by EPCRA to communicate additional risk information to state and local officials in the form of Material Safety Data Sheets (MSDS's) and Chemical Inventory Reports. These communications inform the recipients about chemicals at facilities within their jurisdiction, and thereby enable them to prepare coherent emergency response plans.

Under Section 311, facilities subject to OSHA Hazard Communication Standard (HCS) requirements for MSDS's must provide the MSDS's or a list of MSDS's, to the LEPC, SERC and local fire department.[279] Thereafter, the firms are under a continuing obligation to provide additional MSDS's (or a revised list) for any new chemicals brought on-site which are subject to the HCS,[280] and to provide a revised MSDS to replace one earlier filed when "significant new information" is discovered about a chemical.[281] However, MSDS reporting applies only when the HCS chemicals equal or exceed designated threshhold quantities.[282]

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[279]EPCRA §311. The original deadline of Oct. 17, 1987 was provided in §311 (d)(1)(A). At that time, only manufacturing facilities were subject to the OSHA HCS and had to file under EPCRA §311. The HCS was expanded by OSHA to apply to nonmanufacturing facilities, effective June 24, 1988. As a result, these additional firms became subject to EPCRA §311 requirements three months later (Sept. 24, 1988) in accordance with EPCRA §311 (d)(1)(B). See discussion of OSHA's revision of the HCS in Part II of this report. The option of filing a list is subject to requirements that the chemical or common name of each substance be included and that the list be organized by "hazard categories" which have been set by EPA as "immediate health hazard," "chronic health hazard," "fire hazard," "sudden release of pressure hazard," and "reactive hazard," 40 CFR 370.2.

[280]EPCRA § (d)(I)(B).

[281]EPCRA §311 (d)(2).

[282]EPCRA §311 (b). 40 CFR 370.20 (b)(1) provides thresholds for "extremely hazardous substances" (on the Section 302 list) at 500 pounds (or 55 gallons), or a threshold planning quantity (TPQ) set by EPA, whichever is less. For all other MSDS chemicals, a threshold of

The LEPC, if given a list of MSDS's, can secure the actual MSDS's from the firm;[283] and must thereafter provide them to "any person" on request.[284] It must also provide public notice that these materials are available.[285] Firms subject to MSDS reporting must then comply with Section 312 by filing an annual Chemical Inventory Report with the SERC, LEPC and fire department[286] on any MSDS chemicals present at the facility during the calendar year in quantities above designated thresholds.[287] The Inventory Report can be filed in either of two information formats, Tier I or Tier II, at the firm's election.[288] However, the recipients can secure the more detailed Tier II report on request.[289]

The Tier I format of the Inventory Report simply provides the firm's estimate of the maximum amount of the MSDS chemicals at the facility at any time during the year, their average daily amount, and their "general location."[290] Tier II requires that the same information be provided and in addition, the chemical or common name of each substance, a description of how each is stored, and its specific location.[291] Both types of reports are then available to the public, on request to the LEPC,[292] except that Tier II information on specific locations may be withheld at the firm's election.[293]

EPA has advised firms to secure Inventory Report forms from their SERC; "since many state commissions have additional requirements or have incorporated federal contents in their own forms."[294] The firms are also required by EPCRA to allow on-site inspection by the local fire department.[295]

10,000 pounds is in effect until Oct. 17, 1989, when it declines to zero pounds unless EPA sets another TPQ.

[283]EPCRA §311 (c)(1).

[284]EPCRA §311 (c)(2) and §324(a).

[285]EPCRA §324(b).

[286]EPCRA §312 (a)(1). March 1st is the annual filing date. §312(2).

[287]EPCRA §312(b). The thresholds are at 40 CFR 370.20 (b) (2) and are 500 pounds or an EPA-promulgaged threshold planning quantity, whichever is lower, for "extremely hazardous substances; and for all other MSDS chemicals, a series of declining threshold levels over a three year period, culminating in zero pounds for calendar year 1989, the third year. EPA is expected to revise the ultimate thresholds for many chemicals above zero.

[288]EPCRA §312(d); 40 CFR370.25.

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[290]EPCRA §312 (d) (1). *See Tier One Instruction*, U.S. EPA (Oct. 15, 1987).

[291]EPCRA §312 (d) (2). *See Tier Two Instructions* U.S. EPA (Oct. 15, 1987).

[292]EPRCA §324; 40 CFR 370.30; EPCRA §312 (e)(3).

[293]EPCRA §312 (d)(2)(F); EPCRA §324(a); 40 CFR 370.31.

[294]Title III Fact Sheet, U.S. EPA (Aug. 1988) 5.

[295]EPCRA §312 (f).

LEPC's are expected to use the MSDS's and Inventory Reports in preparing emergency response plans, SERC's in evaluating LEPC plans, and fire departments in properly responding to chemical emergencies without endangering fire-fighter safety. But the Section 311 and 312 communication requirements also stimulate other safety functions not expressly required by EPCRA, namely voluntary initiatives by firms and regulatory actions by local officials to prevent accident occurrence.

Many firms had never before systematically collected information on the quantities and location of chemicals at their facilities. These firms, particularly larger firms with multiple facilities dispersed across the nation, now find that compiling data for these reports provides them with several opportunities to reduce risks and liability at their installations. As a result, large chemical producers and end users (e.g., paper firms) are using the data to take voluntary initiatives to improve safety--for example, by ordering each facility to reduce the quantities of chemicals stored on-site, and to improve their siting and storage practices.[296] These initiatives are often cost-effective as well, since they enable firms to buy chemicals only as needed, to coordinate the purchasing functions of their multiple facilities, and to use information systems for better supervision of the chemicals they produce, purchase, store and use. Some firms have set and achieved the goal of reducing the amounts of hazardous chemicals stored on site below the threshold reporting levels for Sections 311 and 312, thereby reducing their regulatory burdens and improving community safety simultaneously.[297]

In addition, public availability of MSDS's and chemical inventories now provides the opportunity for community members and local officials to become informed about the chemicals in their midst, and to thereafter take various actions under state and local law to prevent accidents. For example, public pressure can stimulate fire department inspections and orders to improve safe storage of chemicals, and municipal appropriation of funds for the purchase of new emergency response equipment (e.g., warning sirens, chemical fire equipment). Thus, pressure from these informed citizens can lead to the exercise of state and local "police power" to more stringently inspect, regulate

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[296] Personal communications with officials at several large firms producing chemicals and at several large firms using chemicals in various manufacturing activities (1988-89). *See* fn. 302 *infra* regarding field research at several firms in a parallel project.

[297] *Id.*

and even shut down risky industrial activities.[298] Further, residents acting individually or in a class action can use the public and private nuisance doctrines afforded by state law to seek compensation and injunctive relief in suits against facility owners.[299] These protective actions at the local level are unimpeded by EPCRA, which expressly provides that it does not preempt state or local law.[300]

Thus, by requiring industrial risk communication under Section 311 and 312 to enable local planning on how to effectively respond to an accident, EPCRA has also set two forces in motion for preventing accidents in the first instance without authorizing federal safety standards: industrial voluntary action and community activism. It does this by first requiring the industrial communications and creating a public right to know the industrial information, and by then relying on subsequent community concern to stimulate industry initiative and local control. In this fashion, EPCRA provides a "new federalism" model for preventing accidents, one which relies heavily on the desire of facility managers and other corporate staff to prevent liability and costly conflicts with citizens and local officials, and their ability to take the voluntary actions needed to improve safety and public trust in order to avoid the conflicts and costs.[301] As indicated earlier, evaluation of industrial responses to EPCRA indicate that many firms are indeed acting rationally to prevent accidents and losses.[302]

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[298]The state's police power function is grounded in the U.S. Constitution, and has long been exercised to provide state officials (e.g., fire marshalls, building inspectors) and municipal and county officials (e.g., fire chiefs, zoning and health boards) with ample powers to regulate the siting, design and operation of industrial facilities which endanger the public. See note 209 supra for discussion of use of municipal health officer authority in Cambridge, Massachusetts to shut down a research lab testing chemical warfare materials. For another recent shutdown, *see* "Suffolk Chemical Co. To Close Plant Under Consent Order With State Agency," *Toxics Law Rptr.*, BNA, Inc (March 18, 1987) 1155.

[299]Provision of injunctive relief or restraining order by a state court is rarely available in American tort law when the defendant is a firm whose operations are of economic value to the community. *See Boomer v. Atlantic Cement* (denial of petition to shut down cement plant in N.Y. state), 26 N.Y. 2d 219, 309 N.Y.S. 2d 312 (1970). Nevertheless, in some situations, such relief has been provided. *See Spur Industries v. Del Webb Development Co.*, 108 Arizona 178 (1972).

[300]EPCRA §321. The Act does preempt state law which would restrict fire department access to Section 312 facilities. EPCRA §312 (f).

[301]*See* M. Baram, *Corporate Risk Management*, note 1 *supra* at pp. 89-97, 145-149, for further discussion and early examples of voluntary initiative. *Also see* "Going Beyond EPCRA to Avoid Community Chemophobia," *RTR Report*, v.1, n.1 (Oct. 1, 1987) 4.

[302]*Id.* Also see EPA Report, note 303 *infra*. In addition, a two year study nearing completion, supervised by the Author at the Tufts University Center for Environmental Management, has involved extensive field research at the corporate headquarters and major

A "new federalism" approach does not assure uniform results or equal protection from industrial accidents, such as could theoretically be achieved by federal regulation of industrial safety. But the diversity of industrial activities involving numerous chemicals, community risk contexts, and public views of appropriate safety levels would defeat any uniform approach involving national standards. Accident risk is highly contextual in that it is subject to many local variables, as EPA has recognized:

> "chemical facilities are complex and require site-specific safety assessment and contingency planning ... [and] close collaboration between industry and the community ...."[303]

> "there is no single method of technology that works best in every situation ... the determination of what constitutes a state of the art technology for a particular facility depends on the individual circumstances of the facility -its location and layout, its process, the chemicals handled, and the hazards. ... Each facility must be considered individually. ..."[304]

Therefore, the Section 311 and 312 reports are vital features of EPCRA because they support both emergency planning and accident prevention functions. However, despite their importance, implementation has not been fully evaluated to date in terms of company compliance, LEPC use of the reports for planning purposes, or community use of the reports to prevent accidents.

What is known is that many larger firms are taking diverse steps to prevent accidents, as previously discussed, but these initiatives cannot be conclusively measured as to their effectiveness at this early time.[305] Also, it is now apparent that citizens have had difficulty securing and understanding the

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facilities of eight firms producing and using hazardous chemicals, in order to determine voluntary actions to reduce accident risks and routines releases, and to improve emergency response and risk communication with communities hosting major facilities. The report, to be published in late 1989, will indicate the nature, scope and results of numerous corporate voluntary initiatives. *See Corporate Risk Management Under EPCRA*, report to EPA, Tufts Ctr. Env. Mgmt. (forthcoming, fall 1989).

[303] *Review of Emergency Systems*, U.S. EPA (June 1988) at pp. iii, iv, the report to Congress mandated by EPCRA §305 (b).

[304] *Id.* at pp. 12, 13.

[305] The forthcoming Tufts Report note 302 *supra*, documents voluntary actions taken by eight firms, but does not measure overall corporate compliance or the effectiveness of the voluntary actions taken by the eight firms.

MSDS's and Inventories,[306] and that in many states, LEPC's and fire departments have been overwhelmed by the number of MSDS's and Inventory Reports submitted.[307]

Further, it now appears that the information requirements of Sections 311 and 312 may be deficient for emergency planning and endanger emergency responders.[308] For example, polyvinyl chloride (PVC) is not a reportable chemical under Sections 311 and 312 because it is not an OSHA HCS chemical requiring an MSDS (it lacks sufficient toxicity). But when PVC resin or other PVC products are "degraded" by a facility fire, they generate hydrochloric acid (HCL), an acutely hazardous chemical, thereby endangering uninformed firefighters and community residents.[309]

To sum up, Section 311 and 312 reports are essential for local officials to carry out two important public functions: emergency planning and accident prevention. But their usefulness for these dual purposes is uncertain in several respects. At this early stage in the availability of MSDS and Inventory information, EPA should determine if corrective measures are needed and how they can be made consistent with EPCRA's "new federalism" model, and then act to assure the measures are taken.

Therefore, EPA should first evaluate the effectiveness of Section 311 and 312 requirements for enabling LEPC preparation of suitable emergency plans, and for responsibly informing local residents and officials about accident risks. In conducting this evaluation, EPA should once again enlist the participation

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[306]Professor Susan Hadden of the University of Texas surveyed residents of New Jersey and Massachusetts about their access to and use of company reports under EPCRA, and found that many complain of difficulties in obtaining the data from their LEPC's, and subsequent difficulties in understanding the MSDS's and inventories they received. She has concluded that these problems may account for the "low number of requests" being made for the information (200 over 3 years in N.J., 60 over 18 months in Mass.), but that the data has the potential, nonetheless, for having an "explosive effect" on the public, if readily available and understandable. *RTK Report*, v. 1, n. 24 (Aug. 18, 1988) 4.

[307]*See* "Right to Know Laws Burden Fire Departments," *RTK Report*, v. 2, n. 15 (April 13, 1989) 4; and "Sections 311/312 Could Be Paperwork Nightmare," *RTK Report*, v. 2, n. 21 (July 6, 1989) 4.

[308]The deficiencies endanger firefighters and other "first responders" to an accident, and thereby also obstruct effective containment and other response measures. *See* note 249 *supra*.

[309]PVC is not an OSHA HCS-designated chemical, nor does it appear on the consolidated list of chemicals covered in EPCRA, "compiled in *Right to Know Planning Guide*, BNA, Inc., pp. 531:1001-531:2022. HCL is an "extremely hazardous substance" on the EPCRA Section 302 list and the CERCLA §103 list, but it would not be reported under EPCRA §311 and 312 as a by-product of PVC degradation. Thus, a LEPC, firefighters and community residents would not be informed of the HCL hazard at a facility which stores and uses PVC resin and other vinyl products, unless the seller of the PVC resin had used HCS performance criteria, voluntarily designated PVC as an HCS chemical, and provided the PVC purchaser with an MSDS.

of SERC's, since SERC's are authorized by EPCRA to supervise LEPC's and review their plans, and are familiar with interest groups and local officials in the state and their concerns about accidents. The evaluation should be focused on the need for timely production of MSDS's and Inventories by firms, and for timely distribution of these materials to LEPC's and subsequently to citizens on their request. Production and distribution of the materials are compliance issues suitable for EPA enforcement under EPCRA and for SERC enforcement under state law. The evaluation should then focus on the substantive content of the materials in terms of their quality and presentation of information in a manner which is understandable and useful to LEPC's, fire chiefs and concerned citizens.

Following this evaluation, EPA should consider what reforms it can enact within its authority and EPCRA's "new federalism" framework. These may include, for example, EPA provision of model MSDS's and Inventories for educating firms, increasing its enforcement effort against firms in violation, and urging SERC's to supervise LEPC's and firms more stringently. Another possible reform that may be useful is EPA enactment of a rule requiring an addendum to each MSDS which would discuss the chemical in terms of its community risk potential and off-site emergency response needs; or alternatively, convincing OSHA to amend its HCS rule to provide this information (consistent with the Occupational Safety and Health Act which bounds OSHA authority). Many chemical producers are prepared to provide this information in MSDS's, and some do so now when they ship chemicals downstream to their industrial customers.[310] Thus, the MSDS would be modified to better serve the information needs of LEPC's and the community.

Finally, EPA should secure industrial assistance in identifying accident risks which may not be reported under Sections 311 and 312 because they arise as by-products of a chemical accident (such as the generation of HCL when PVC burned). This information is known to chemical producers and should be routinely provided downstream industrial customers in MSDS's, who would then pass this information on to LEPC's and fire departments. EPA (or OSHA) amendments to the HCS, discussed above, could be used to require the transfer of this information to protect emergency responders.

By this approach, EPS could improve the usefulness of Sections 311 and 312 for emergency planning and accident prevention. However, it may later find that citizens and local officials continue to respond insufficiently to accident risk information, despite the improved MSDS's and Inventories they

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[310]Personal communications with corporate officials at Dow Chemical, Rohm and Haas, and Occidential Chemical (1988-89). Also see I. Rosenthal, "The Occupational Safety and Health Act: Where Do We Go From Here," Am. Ind. Hyg. Assoc. Jnl. 49 (March 1988), for similar recommendations on enhancing the MSDS.

have been receiving. Since EPA has no authority to provoke citizen action and local regulation, it would then face the issue of whether it should propose to Congresss that EPCRA be amended to either provide the agency with authority to set national safety standards for industrial activities, or with authority to compel LEPC's or SERC's to inspect and regulate faciltiy safety.[311]

F. Chemical Release Reporting

EPCRA's final requirement for industrial risk communication is set forth in Section 313 which mandates the notorious Toxic Chemical Release Report. This annual report differs from other communications (under Sections 302, 304, 311-312) in that it requires facilities to provide EPA and SERC's with information on their chemical releases to air, water, and land from routine or normal facility operations, as well as from accidents and other unintended occurrences. Although this report contributes information useful for emergency planning, its main purpose is "to inform the public and government officials about routine releases of toxic chemicals to the environment . . . [and to] assist in reseach and the development of regulations, guidelines and standards."[312]

Of all EPCRA requirements, this report has stimulated most industrial concern because public availability of its data on routine releases has high potential to provoke community anxieties about long-term health hazards, and can thereby lead to new and stringent standards governing routine activities at industrial facilities This type of regulation would be more intrusive than traditional pollution controls in that it would necessitate deep changes in industrial processes which would be costly to implement.

Plant managers were warned early of this potential by the Chemical Manufacturer's Association:

> " Section 313 gives people in your community the opportunity to see estimated quantities of chemicals routinely or accidentally released. A national data base to be maintained by EPA will allow anyone to access this quantitative data about your facility directly. This may significantly affect your community relations, and you should

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[311] No footnote.

[312] *Title III Fact Sheet*, U.S. EPA (Aug. 1988) 6.

> prepare now [July 1987] to respond to questions and concerns, especially about impacts on public health."[313]

Subsequent developments have justified this industrial concern. Now that Section 313 reports have become publicly available, numerous campaigns are under way to regulate firms more intrusively and stringently than ever before.[314]

Section 313 provides that facilities[315] which manufacture, process or use chemicals on the "toxic chemicals list," in quantities exceeding designated thresholds during a calendar year,[316] must prepare a Chemical Release Report for such chemicals and submit it to EPA and the cognizant SERC by the following July 1st.[317] The "toxic chemical list" is different from the "extremely hazardous substance list" of Section 302, and other lists which apply to other EPCRA report requirements. EPA, by using its authority to add or delete substances,[318] or to modify the thresholds of listed substances,[319] can dramatically change the numbers of firms subject to

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[313] *A Manager's Guide to Title III*, Chemical Mfr's Association (July 1987) 57.

[314] See "Taking Inventory of 7 Billion Toxic Pounds: The Top 500 Counties--The Most Common Chemicals," USA Today (Aug. 1, 1989) 6A, 7A; and "TRI Data cited in Call for Air Toxics Controls," RTK Report, v. 2, n. 14 (March 30, 1989) 4.

[315] A facility subject to Section 313 reporting is one which has 10 or more full-time employees, is in Standard Industrial Classification Codes 20-39, and "manufactured, processed or otherwise used" the designated chemicals in quantities exceeding their specified threshold levels during a calendar year. EPCRA §313 (b) (1). Additional facilities can be designated by EPA, or by a state governor (regarding facilities in the state) if warranted by various risk factors (e.g., toxicity, proximity to population or other facilities, etc.). EPCRA §313 (b)(2).

[316] EPCRA §313 (a), (c). For the current list of 308 chemicals and 20 broadly defined compounds, see 40 CFR 372.65. The original "toxic chemical list" was specified by Congress, EPCRA §313 (c), and was based on the lists used for similar reporting by the states of New Jersey and Maryland, which contained 329 chemicals. Title III Fact Sheet, U.S. EPA (Aug. 1988) 6. EPA is authorized to modify the list, provided its action is supported by specified findings, EPCRA §313 (d)(1), (2), (3).

[317] EPCRA §313 (a). The report is to be provided on EPA Form R, the Toxic Chemical Release Inventory Reporting Form, devised by EPA in accordance with EPCRA §313 (g) requirements.

[318] EPCRA §313 (d)(1), (2), (3).

[319] EPCRA §313 (f)(2). The thresholds prescribed by EPCRA are 10,000 pounds of a listed substance used at a facility per year; and for listed substances made or processed at the facility, are 75,000 pounds for calendar year 1987, 50,000 for 1988, and 25,000 for 1989 and years thereafter. For definitions of "manufacture," "process," or "otherwise used," see EPCRA §313 (b)(1)(C), and EPA's regulation on §313 reporting at ___ Fed. Reg. ___ (Feb. 16, 1988). EPA's final rule provides additional details. For example: if more than one threshold applies to a facility (e.g., manufacture and use thresholds), the operator must report, if it exceeds any of the thresholds, on all activities at the facility involving the listed chemical. 40 CFR 372.25 (c); if the

Section 313 reporting. In its Chemical Release Report, the firm must provide information on the business conducted at the facility; whether each chemical is made, processed, or "otherwise used" at the facility (including categories of use); the maximum amount of each chemical at the facility during the year; the waste treatment and disposal methods used and their efficiency; off-site locations to which the firm sends toxic wastes; and the annual quantity of each chemical released into environmental media (air, water, land).[320] EPA has defined "releases to the environment" broadly to include intentional and routine releases of pollutants (e.g., "Stack Air Emissions"), sudden accidental releases (such as spills) and slow, unintended releases such as leaching and leaking (e.g., "fugitive emissions" from joints and valves).[321] To calculate the release inventory EPCRA permits the use of "readily available data" (such as monitoring data collected under permits which authorize certain releases) and "reasonable estimates;" and provides that the Act does not impose any new monitoring requirements.[322] Nevertheless, compliance has been complex and costly for industry, necessitating the training of personnel, many hours of expert analysis, and new instrumentation and methods for measuring certain types of releases (e.g., fugitive emissions).[323] Chemical producers are also required to inform certain industrial customers about the chemicals they are purchasing to enable customer compliance with Section 313. The "Supplier Notification Requriements" enacted by EPA for this purpose[324] requires producers (and importers) of listed chemicals (or of mixtures containing listed chemicals) to notify their customers who use these products in subsequent manufacturing activities (e.g., paper mills and other end users of the chemicals) or who subsequently distribute the products to their own customers for use in manufacturing.[325] The "supplier notification" must be in writing

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listed chemical is present in a mixture in a concentration below 1 percent of the mixture (or .1 percent if a carcinogen), the operator need not not consider the quantity of the listed chemical in the mixture when determining whether a threshold has been met, or in determining the amount of the release (the "de minimis" exemption). 40 CFR 372.38. Other exemptions are provided for "articles," certain product uses and laboratory activities. Id.

[320]320. EPCRA §313 (g)(1)(C) (i-iv).

[321]40 CFR 372.3. Also see EPA Form R, note 317 *supra*, at pp.19.20. However, the Agency has refused to adopt proposals by environmental groups to require "peak release data." RTK Report, v. 2, n. 22 (July 20, 1989) 4.

[322]EPCRA §313 (g) (2).

[323]"Title III Reporting: What Are the Costs," K. Kelley, et al, Hazmat World (Sept. 1988) 18. Personal communications with officials at several large firms producing or using the listed chemicals (1988-89).

[324]40 CFR 372, Subpart C.

[325]The producer's duty to notify downstream distributors, brokers and users assures that the information will be distributed throughout most industrial sectors of the product life cycle, and

and accompany or be included in any MSDS's required by the OSHA HCS to be distributed to downstream customers. Customers must also be informed by the producer that the notification must accompany any MSDS's they are subsequently required (by the HCS) to provide to their own customers.[326] The contents of the notification must include a statement that the product or mixture contains a toxic chemical(s) subject to Section 313 report requirements; the name of the chemical and its Chemical Abstracts Service (CAS) number; and the percentage by weight of each listed chemical in the product or mixture.[327] However, if the producer considers a chemical's identity to be a trade secret, a generic chemical name can be substituted, provided it is descriptive of the structure of the chemical. Similarly, if the producer considers the specific percentage by weight of the chemical to be a trade secret, the producer may substitute information on the "upper bound" of the chemical concentration in the product instead.[328]

The Chemical Release Reports are to be submitted annually to EPA and state officials[329] to inform the public about releases to the environment, and "to assist government agencies, researchers, and other persons . . . to aid in the development of appropriate regulations, guidelines, and standards . . ."[330] Once submitted, each report is publicly available,[331] and is to be entered in an EPA-administered "national toxic chemical inventory" for the purpose of providing release data "by computer telecommunication and other means to any person . . ."[332] Uses of the data by EPA, other federal agencies, the states, and the public are to be evaluated by the Comptroller General and reported to Congress by mid-1991.[333] Over 19,000 facilities filed their first Release Reports covering the 1987 calendar year in 1988. On June 19, 1989, EPA announced that its computerized data base (the "toxic release inventory"

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enable these downstream firms to comply with Section 313 report requirements. 40 CFR 37246. Also see Supplier Notification Requirements, U.S. EPA, 560/4-88-008 (Sept. 1988).

[326]Id. 40 CFR 372.46.

[327]Id. Notification is not required if the listed chemicals are present at "de minimis" levels, e.g., below 0.1 percent by weight for carcinogens, and below 1 percent for other listed chemicals.

[328]Id.

[329]EPCRA Sec. 313 (a).

[330]EPCRA Sec. 313 (b).

[331]EPCRA Sec. 324 (a).

[332]EPCRA Sec. 313 (j). EPA is also required to have the National Academy of Sciences carry out a "mass balance study" for several purposes, e.g., to determine the efficiency of waste reduction measures at facilities and the efficacy of toxic chemical regulations enacted under other laws. EPCRA Sec. 313 (i).

[333]EPCRA Sec. 313 (k).

or TRI) was available to the public. It also released a report analyzing the data, The Toxic Release Inventory: A National Perspective - 1987,[334] which indicates that enormous quantities of toxic chemicals are being routinely released by industrial facilities into all environmental media. The data has had a considerable impact on the public, whether presented on a nationally aggregated basis (18.0 billion pounds of TRI chemicals released in the U.S., including 2.7 billion to the air, and 9.6 billion to surface waters), or on a local basis (76 facilities in Memphis, Tennessee reported releasing 82 million pounds).[335] Media uses of the data have proliferated,[336] and environmental interest groups have campaigned in many states for remedial measures.[337] EPA has found the releases "unacceptably high" and "underscoring a need for a pollution prevention program to complement existing regulatory efforts";[338] and federal and state legislators have called for additional funding of regulatory efforts and stronger legislation to control toxic air releases, in particular.[339] Industry has sought to calm public anxieties and reduce pressures for new regulatory programs with a flurry of public announcements. These describe, for example, corporate policies for waste minimization and pollution prevention, new equipment and expenditures, declining amounts of chemical releases over the past several years, studies showing no discernable health effects on their work force exposed to the chemicals for many years, new commitments to reduce releases by 90% or more, and methods that should be used by the public to assess their health risks (e.g., risk comparisons, risk-benefit analysis, etc.).[340] Many of these representations about waste

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[334]"Chemicals-in-Progress Bulletin," Office of Toxic Substances, U.S. EPA, v. 10, n.3 (Sept. 1989) 2.

[335]*The Toxics Release Inventory: A National Perspective - 1987*, U.S. EPA, 560/4 - 89 - 005 (June 1989) 4, 309.

[336]*See*, for example, "The Top 500 Counties - The Most Common Chemicals," *USA Today* (Aug. 1, 1989) 6A.7A showing county rankings beginning with Calhoun County, Texas (Number 1 with 579,242,000 pounds).

[337]Public Interest Research Groups (PIRG's) have campaigned in many states and introduced bills for toxic release reduction. For general background on such campaigns, see L. Martin, "Demanding Waste Reduction: The Roles of Public Interest Organizations in Promoting the Institutionalization of Waste and Toxics Reductions," *Env. Professional Jnl.*, v. 11, n.2 (1989) 132.

[338]*International Environmental Rptr.*, (May 1989) 254.

[339]*International Environmental Rptr.* (April 1989) 192; *Environment Rptr.* (May 19, 1989) 154; (June 16, 1989) 436.

[340]*See* company case studies and chptr. 6 on Release Reduction in forthcoming report to EPA, note 302 *supra*, for detailed information on eight corporate responses to EPCRA Sec. 313. *Also see* EPA's *TRI Report*, note 335 *supra* at 259; and various public announcements by 3M, Monsanto, Dow, etc.; for example: "Waste Reduction: Public Knowledge is Key to Continued

minimization or release reduction are supported by data showing declining release levels in company reports filed for calendar years 1987 and 1988.[341] Thus, Section 313 requirements have stimulated larger firms, often acting with their trade associations, to take these positive steps. EPA has three functions under Section 313: (1) to assure that the Release Reports are produced and distributed by industry as required, by providing guidance and using its enforcement powers;[342] (2) to assure that the reported data is stored in the Toxics Release Inventory and accessible to the public;[343] (3) to use the reported data to set priorities; allocate responsibilities among federal, state and local agencies; and use its own regulatory authority under its various enabling statutes when appropriate.[344] For the guidance and enforcement function, the agency initially provided educational programs and materials (on analytic and other aspects of measuring and reporting releases).[345] This facilitated industrial compliance; however, only some 19,000 facilities of the 30,000 believed to be subject to Section 313, filed Release Reports.[346] Despite this underreporting, EPA recieved a large amount of information for calendar year 1987 which was useful for several analytic purposes, and when the information became available to the public, it stimulated public pressures and positive responses from leading firms. Thus, underreporting did not prevent considerable public education and industry initiatives, and did not necessitate immediate and rigorous enforcement by EPA. Beginning in 1988, the agency outlined its enforcement program which involves a two-pronged strategy.[347] For firms which reported but committed minor errors, a lenient approach is to be taken, involving noncompliance notification and a short-time period for

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Improvement," Dow Chemical (Aug. 15, 1989), describing a 44 per cent reduction in Section 313 chemical releases between 1984-1988, crediting employee efforts in Dow's waste reduction and product stewardship programs; and *Community Relations Kit*, Dow Chemical (1989) for customers to use in addressing public concerns about release data.

[341] *Id. Also see Safeguards Report*, NICS (Kanawha Valley), (Nov. 1986) 24; "Chemical Release Reduction Policy," Chemical Mfr's. Ass'n. (April 1989), adopted by CMA members; and R. Bringer, et al, "Pollution Prevention as Corporate Policy: A Look at the 3M Experience," Environmental Professional Jnl., v.11, n.2 (1989) 117. Note that the changes in measuring and analytic methods account for release reductions reported by some firms [e.g., fugitive emissions].

[342] EPCRA §325 (c) provides for a civil penalty of up to $25,000 for each violation of a Section 313 requirement.

[343] EPCRA §313 (j).

[344] EPCRA §313 (h-l.).

[345] For example, "Estimating Releases and Waste Treatment Efficiencies for the Toxic Chemical Release Inventory Form," U.S. EPA (1988); several industry-sepcific guidances; and *EPA Form R*.

[346] *Int'l. Environment Rptr.* (April 1989) 192.

[347] *RTK Report*, v. 1 n. 14 (March 31, 1988) 2.

corrections to be made. If the notice is ignored, the agency is to assess a small fine and issue a second notice, which if also ignored, will lead to a larger fine.[348] For firms which ignored the report requirements, more aggressive enforcement action is promised,[349] with "highest priority" given to facilities in large population areas and in "sensitive environments."[350] As of May 1989, EPA had filed 51 enforcement actions, with fines assessed ranging from $5,000 (a Spokane electroplater) to $721,000 (large steel firm).[351] By September 1989, the agency announced it had sought $3.95 million in fines in actions against 85 firms for violations of 1987 calendar year reporting, and had issued 1,318 notices of noncompliance.[352] Its second function involves administration of the national data base and the provision of public access to the data. EPA has developed the data base, feeds it new report data, runs diverse analyses of releases (by region, industry, firm, chemical, etc.) and is routinely providing public access.[353] It has also sought to help state and local officials, health professionals and the public, interpret the data and understand its significance for human health by offering various guidances.[354] Thus, EPA has expanded its second function so that it now serves as the "learned intermediary" in Section 313 risk communications between industry and the public. This will be a challenging role, one subject to public mistrust of agency objectivity, advocacy uses of the data, and the technical uncertainties it faces in interpreting what the abstract and incomplete data indicates about the health status of specific persons. In doing so, the agency has adopted one of the premises for risk communication expressed by environmental health interest groups, namely, that risk is essentially a matter of public perception and values and should not be relegated to experts, or, as put by one of its senior officials: "TRI challenges the old theory that decisions about control of toxics should be left to the "experts," since the data are made available directly

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[348] *Id.*

[349] *Id.*

[350] *RTK Report*, v. 2, n. 16 (April 27, 1989) 1.

[351] "Legal Matters," listing the first 25 penalties, *Hazmat World* (Feb. 1989) 24.

[352] "Chemicals-in-Progress Bulletin," U.S. EPA, v. 10, n. 3 (Sept. 1989) 14.

[353] *Id.* at 15, 16 for examples of agency outreach to the public, offering special regional analyses, waiver of fees for LEPC's, etc. *Also see* note 335 *supra* on the TRI report, which contains diverse analyses as models for public use. 1988 Calendar year data has been promised the public by April 1990. *RTK Report*, v. 2, n. 25 (Aug. 31, 1989) 1.

[354] *See* "Risk Screening Guide for Toxic Chemicals Release Inventory," U.S. EPA, (Aug. 1989), and materials published by the agency's new Integrated Risk Information System" (Oct. 1988).

to the public, without analysis or interpretation."[355] Finally, EPA has grappled with its third function hesitantly and faces considerable problems. It is analyzing TRI data to determine priorities, but has not developed any coherent policy for allocating responsibilities to deal with the health risk implications of the data, nor has it moved far in putting its own considerable regulatory authority fully to use in mitigating the risks.The major regulatory outcome of EPA's analysis of the TRI data for calendar year 1987 has been its deletion of sodium sulfate from the list of Section 313 chemicals,[356] because the "available data do not demonstrate that the chemical causes or can reasonably be anticipated to cause significant adverse health or environmental effects as set forth in Section 31."[357] By this action, EPA deleted the one chemical that accounted for more than half of the releases reported in 1987.[358] The agency has also proposed the deletion of several other chemicals, has decided to retain others that have been challenged, and is reviewing numerous other listed and unlisted chemicals to decide on their status.[359] The agency is considering whether Release Reports to be submitted in the future should contain "peak release data," which is proposed by environmental organizations and strongly resisted by industry because it would necessitate extensive, even continuing monitoring of all releases from many parts of a facility. This data would inform EPA and the public about intense, short-term releases which may cause acute health effects in some instances.[360] Since discharges of Section 313 chemicals to surface waters were the dominant type of release according to TRI data, EPA has designed a major new effort to regulate more stringently these toxic releases from some 879 sources over the next three years. These point sources (627 industrial facilities, 240 municipal, 12 federal)[361] were identified by EPA using information from the states on their surface waters that had not met existing water quality standards, and from

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[355]"Chemicals-in-Progress Bulletin," U.S. EPA, v. 10, n. 3 (Sept. 1989) 2. In keeping with this view, the agency now offers special regional analyses to the public, e.g., special inventories done on Vermont and Massachusetts for the Public Interest Research Groups in those states, etc. Id. at 16; and waives fees for LEPC access to the TRI data base.

[356]54 Fed. Reg. 25,851 (June 20, 1989).

[357]"Chemicals-in-Progress Bulletin," U.S. EPA, v. 10, n. 3 (Sept. 1989) 15.

[358]Total releases of sodium sulfate in 1987, according to TRI, came to more than 12 billion pounds, largely as discharges to surface waters and public sewage treatment systems. *Id.*

[359]*Id.*

[360]*See*, "Industry Asks EPA to Reconsider Peak Release Data Plan," RTK Report, v.__, n. __( ) 4.

[361]Most of the 240 municipal releases were targeted because of significant industrial discharges into their sewage treatment systems; which subsequently lead to municipal release of toxic chemicals. The facilities which dominate the list of 617 industrial releases are mainly in the metal finishing, pulp and paper and natural gas sectors.

corresponding TRI data.[362] These firms will be required to comply with new ad hoc permit restrictions reducing their releases of Section 313 chemicals in order to meet water quality criteria governing the ambient levels of these chemicals in the receiving waters.[363] Regulatory authority to carry out these "individual control startegies for toxic pollutants" is provided to the states by the Clean Water Act, with state efforts subject to EPA review.[364] However, the agency has not developed a regulatory policy for the health hazard of greatest concern--the release of toxic chemicals into the air. These releases include routine emissions (including "peak releases") from facility stacks, nonroutine (accidental) stack emissions, and fugitive emissions (leaks from valves, joints, etc.) which are by-products of routine activities.[365] EPA's hesitation in addressing the air toxics problems revealed by TRI is not surprising, since it has failed to adequately regulate such pollutants since 1970 when the Clean Air Act[366] mandated its regulation of hazardous air pollutants.[367] The 1970 Act provides that EPA set national emission standards for air toxics on the basis of health considerations only, and further by using "an ample margin of safety to protect the public health."[368] EPA has struggled with this mandate and essentially refused to implement it, except for eight pollutants for which it has set standards.[369] Two factors have inhibited EPA: the absence of any safe threshold level for many toxics (e.g., carcinogens) which would necessitate zero emission standards under the statutory mandate, and the severe economic consequences that would follow.[370] Despite a recent interpretation of the Clean Air Act's mandate by the D.C. Circuit Court, which permits the agency to consider nonhealth (e.g., economic) factors after it has determined "safe" emisison levels,[371] the agency remains uncertain as to how to proceed for several reasons, including

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[362]Reported in *Environment Reporter* (June 16, 1989) 433.

[363]The Act, 33 U.S.C. 1251 provides for these special strategies at §1314 (1). (FWPCA §304 (1)).

[364]33 U.S.C. §1314 (1). *Also see* EPA's final rule interpreting this statutory provision, 20 ER 326 (June 2, 1989).

[365]*See* note 321 *supra*.

[366]42 U.S.C. 7401.

[367]42 U.S.C. 7412. For a review of agency performance and problems, see Note: "Toward Sensible Regulation of Hazardous Air Pollutants Under Section 112 of the Clean Air Act," *N.Y.U. Law Rev.*, v. 63 (June 1988) 612.

[368]*Id.*

[369]*See* 40 CFR 61.01 (1987) for the "NESHAPS" for asbestos, beryllium, mercury, vinyl chloride, benzene, radionucleides, inorganic arsenic and coke oven emissions.

[370]*See N.Y.U. Law Rev.* Note, note 367 *supra*.

[371]824 F. 2d 1146 (1987) (en banc).

Congressional criticism of the court decision.[372] Given that the problem of regulating air toxics has persisted throughout four administrations, that Section 313 reports and TRI data clearly affirm the need to regulate air toxics, and that EPA remains baffled as to how to proceed, there is a clear need for Congress to act on the matter. Thus, risk communication under Section 313 has clearly raised the need for regulations, but regulatory response will not be forthcoming until Congress repairs or replaces the existing EPA program under the Clean Air Act. EPA should therefore define alternative approaches for congressional consideration. One that seems reasonable to present to Congress is the enactment of an amendment to the Clean Air Act which would allow EPA to supervise a state-run permit program similar to the "individual control strategy for toxic pollutants" now being applied to reduce the discharge of toxic chemicals into surface waters.[373]

G. Conclusion

EPCRA requires industrial risk communication to inform federal, state and local officials about chemical accident risks and releases of toxic materials to the environment. With this information, these officials are required to develop emergency response plans and other measures to reduce these risks to public safety and health. In addition, EPCRA provides for community right to know, affording public access to information provided by industry. This device ensures that agencies and companies are held accountable to public attitudes about the risks, and that the public can play a more informed and effective role in reducing industrial risks. But it also promotes pressures on industry to take voluntary initiatives which will improve safety and risk management.

This "new federalism" model for addressing public safety and health risks does not assure uniformity of result, but can lead to optimal solutions on a case by case basis. However, success depends on compliance by all parties with their responsibilities, particularly with regard to the timely production and

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[372] *See* S. Rep. No. 426, 98th Congress, 2d Sess. 15 (1984), which is discussed with other views of the *NRDC v. EPA* decision in *N.Y.U.L. Rev.* Note, note 367 *supra*. Also see A. Perellis, "Setting the Limit," *Hazmat World* (May 1989) 70.

[373] Note 364 *supra*. This proposal would contain various features of considerable complexity, e.g., the need to set many new ambient standards and require extensive dispersion modeling and monitoring systems in order to determine what emissions should be permitted at each facility. Another option for EPA consideration is the OSHA regulation on Table Z substances, similarly problematic in many respects. There will be no simple solution. *See* discussion of Congressional and other proposals in *N.Y.U.L. Rev.*, note 367 *supra*.

distribution of materials which will be useful to federal, state and local regulators and to the public.

EPA faces several problems in administering this unique and complex mode. First, it must ensure timely production of the reports and their distribution by industrial firms to designated parties, a task which requires that it now clarify and carryout an effective enforcement program and rely more heavily on the state and local organizations established by EPCRA for assistance. Second, it must ensure timely and effective use of the materials by the state and local officials in preparing plans and developing necessary regulations, but since it lacks authority to compel these functions, it must develop other means of promoting state and local actions, or secure Congressional modifications to EPCRA which will empower EPA.

The third problem for the agency is to consolidate EPCRA's multiple lists and diverse requirements and guidances into a unified package of materials to facilitate industrial compliance and assure that firms provide useful information. In this regard, EPA should work with OSHA to modify the MSDS so that it serves as the basic information document for both worker and community right to know purposes, and provide model MSDS's or other guidances to industry to assure more uniformity and higher quality in risk communication.

Finally, the agency faces the fourth problem of responding to the implications of the reported information with appropriate regulatory actions under its own enabling statutes, or of ensuring that state and local officials have sufficient authority and use it efficiently. This requires EPA to develop intergovernmental regulatory strategies and secure Congressional authorization for their implementation.

IV. FDA's Patient Package Insert Program

A. Introduction

After six years of study, the Food and Drug Administration (FDA) promulgated its final rule requiring patient package inserts (PPI) for prescription drugs in September 1980.[374] FDA had found that patients received oral information of variable quality on these drugs from their

[374] 45 Fed. Reg. 60,754 (1980); 21 CFR 203. Enacted on Sept. 12, 1980, the rule became effective Oct. 14, 1980.

physicians, and random and confusing information from other sources, but were not routinely provided sufficient information about risk or proper use.[375] It had also completed studies showing high rates of patient noncompliance with prescription drug regimens; and a correlation between patient knowledge about drugs and improved compliance.[376] It therefore enacted its PPI rule "to provide patients with information about prescription drug products that will promote their safe and effective use and to provide patients with adequate and meaningful information sufficient for them to participate in evaluating the benefits, risks, and proper use of prescription drug products."[377]

The PPI rule, applicable to ten types of drugs for an intended three year period, required that manufacturers and distributors of these drugs provide consumer information sheets (inserts) to pharmacists and other dispensers, and that the dispensers then provide the inserts to patients filling new prescriptions.[378] The inserts for each drug were required to include information, in nontechnical language, on the drug's common medical uses, circumstances governing its use by patients, side effects and serious adverse reactions, and safety hazards and restrictions on patient activities following medication.[379]

This approach to industrial risk communication for products was short-lived, however. In February, 1982, the agency proposed to revoke the rule on the grounds that the goal of providing information to patients could be more effectively and efficiently achieved by private, voluntary methods.[380] Revocation was made final in September, 1982.[381] Since then, no similarly comprehensive or generic program has been developed by the FDA as a substitute to require drug firms to communicate risk information to the users of their prescription drug products.

B. History

The Federal Food, Drug, and Cosmetic Act requires the FDA to ensure that drug labeling and prescription drug advertising contain accurate

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[375] 45 Fed. Reg. 60754-55. (1980).

[376] 45 Fed. Reg. 60758. (1980).

[377] 45 Fed. Reg. 60759. (1980).

[378] 45 Fed. Reg. 60,782-84 (1980).

[379] No footnote.

[380] 47 Fed. Reg. 7,200 (1982).

[381] 47 Fed. Reg. 39,147 (1982).

information about drug products.[382] Traditionally, over-the-counter (OTC) drug products have been required to have labels which contain adequate instructions for their safe use, since OTC drugs are sold directly to consumers.[383] In contrast, prescription drugs have had minimal labeling requiirements: because the FDA assumed that physicians and pharmacists would adequately inform patients about the drugs they were prescribing and dispensing.[384]

However, in 1960 the FDA enacted "full disclosure" labeling requirements for prescription drug products, which provided that any label making a claim for a prescription drug must provide pharmacists and physicians with information about "safe and effective" use of the drug products, including information about effects, dosages, frequency and duration of usage, hazards and side effects.[385] FDA later required that each prescription drug shipped to a pharmacist or physician must contain information that describes how to properly use the drug product.[386] These regulations were enacted to assure that pharmacists and physicians received adequate information from drug firms to communicate to patients, but did not require manufacturers to prepare risk information for patients using their drug products.

In 1974, the FDA took the further step of initiating a patient prescription drug labeling project to determine if the drug labeling requirements it had imposed for oral contraceptives should be extended to prescription drugs generally.[387] From 1974 through 1979, the FDA met with groups representing physicians, pharmacists, drug manufacturers, health professionals and consumer interests to discuss the concept of patient labeling for prescription drugs. It also sponsored conferences and studies to elicit further information.[388]

During this period, the FDA also began to selectively require manufacturers of certain drugs to provide patient information materials, thereby deviating from its traditional and exclusive reliance on doctors and pharmacists to inform prescription drug users.[389] Thus, by 1979, the agency

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[382] 21 U.S.C. §301 et seq.

[383] 21 U.S.C. §352(f)(1); 21 CFR §201.5.

[384] 21 U.S.C. §353.

[385] 25 Fed. Reg. 12,592 (1960); 21 CFR §201.100(d).

[386] 25 Fed. Reg. 8,389 (1961); 21 CFR §201.100(c).

[387] Patient labeling for oral contraceptives describes their risks, how they work, and how to use them safely and effectively. See 35 Fed. Reg. 9001 (1970); 43 Fed. Reg. 4,212 (1978); 21 CFR §310.501.

[388] 45 Fed. Reg. 60,754 (1980).

[389] FDA requirements that nontechnical information be provided by manufacturers directly to patients applied to a small number of prescription drug products:

had completed several studies, elicited the views of various interest groups, and gained some experience regarding the value of having drug manufacturers communicate risk information directly to drug users.

Based on these developments, the FDA proposed regulations in 1979 that would require most prescription drug products to have "labeling" for fully informing patients.[390] This proposed action was primarily based on its finding that there were significant noncompliance rates for patients using prescription drugs, ranging from 30-80%, due in part to inadequate patient knowledge.[391] According to FDA, the process of successfully communicating drug information from health professionals to patients consists of five basic steps: the patient must (1) be exposed to the information; (2) pay attention to the information; (3) understand the information; (4) accept the information; and (5) remember the information.[392]

Following this model, FDA determined that patient information leaflets (which it referred to as "patient labeling") for prescription drugs, as part of a larger program to improve compliance, would reduce patient misuse of prescription drugs, whether it was due to lack of knowledge or other factors.[393] Further justifications for the proposed rule were also expressed by the agency as expected benefits: it would enable the patient to avoid drug interactions with other drugs and foods, prepare the patient for possible side effects, permit the patient to share in the decision to use the drug product, and enhance the patient-physician relationship.[394]

-Isoproterenol inhalation drug products:

33 Fed. Reg. 8812 (1968); 21 CFR §201.305.

-Oral contraceptive drug products: 35 Fed. Reg. 9001 (1970); 43 Fed. Reg. 4212 (1978); 21 CFR §310.501. (Requiring more detailed information to be provided, instead of the short leaflet which was initially required.)

-Estrogenic drugs: 42 Fed. Reg. 37,636 (1977); 21 CFR §310.515 (PPI is 35 paragraphs long).

-Intrauterine devices: 21 CFR §310.502 (Treating IUD's as prescription drug products); 21 CFR §801.427 (Treating IUD's as medical devices).

-Progestational drugs: 43 Fed. Reg. 47178 (1978); 21 CFR §310.501a (Medroxyprogesterone acetate); 21 CFR 310.50(b) (Diethylstilbestrol [DES]).

[390] 44 Fed. Reg. 40,015 (1979).

[391] 44 Fed. Reg. 40,021 (1979).

[392] 44 Fed. Reg. 40,019-20 (1979).

[393] 44 Fed. Reg. 40,021 (1979).

[394] 44 Fed. Reg. 40,019 (1979).

The preamble to the proposed rule catalogued dissenting views and agency responses. Some opponents argued that the proposed labels (information leaflets) would cause many patients to decide not to take drugs, or attempt self-diagnosis, or prescribe drugs to others. The FDA nevertheless held that patient labeling would reduce the misuse of prescription drugs by informing patients of the importance of using the drugs only as directed, and of the risks of improper use. In addition, the FDA cited the lack of any evidence that patient labeling already required at that time for certain prescription drugs (e.g., oral contraceptives) had any of these detrimental effects.[395]

Other concerns were raised about the psychological effects of the labels, namely that they would cause patients to develop suggestion-induced side effects, and reduce a drug's beneficial placebo effect. The FDA responded that informing patients about the side effects of a drug would have beneficial effects, e.g.,, a reduction in anxiety about possible effects of treatment, and these would outweigh the detrimental effects. As for the placebo effect, the FDA said that this effect was due to patient/physician communications, and would be increased by the patient labeling.[396]

Drug manufacturers, physicians and prharmacists further argued that patient labeling would stimulate litigation and increase their tort liability. The FDA countered that labeling would reduce potential liability by improving patient compliance with physician instructions, and by informing patients that "certain risks inevitably accompany drug therapy and that not all adverse effects are caused by deficiencies in the drug product or mistakes by the prescriber." The FDA also stated its view that it would be inappropriate to base policy on this consideration, since "[p]atient labeling is not intended to define the duty or set the standard of care manufacturers, physicians, pharmacists, or other dispensers owe to the patient who uses the product."[397]

The agency also referred to similar liability arguments made in earlier opposition to its patient labeling requirements for oral contraceptives,[398] and

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[395] 44 Fed. Reg. 40,022 (1979).

[396] 44 Fed. Reg. 40,022-23 (1979).

[397] 44 Fed. Reg. 40,023 (1979).

[398] 43 Fed. Reg. 4,212-15 (1978). Two major concerns about liability were expressed regarding patient labeling for oral contraceptives.

> 1. The partial exemption from strict liability afforded drug manufacturers where the drug product is properly prepared and accompanied by adequate directions and warnings would be substantially eroded and possibly eliminated by a patient labeling provision.

pointed out that its prediction that contraceptive labeling would "not affect adversely the civil tort liability of manufacturers, physicians, pharmacists, and other dispensers of prescription drug products" had not been refuted.[399]

Opponents further argued that the proposed leaflets would interfere with the patient/physician relationship, would increase visits to physicians because patients would need additional reassurance about taking a prescription drug and would lose confidence in their physician's judgment if the physician's statements conflicted with information in the leaflet. Further, physicians would rely on the leaflets to inform patients about drugs and, consequently not talk to their patients. In response, the FDA stated it did not intend patient labeling to be "the sole source of information for patients about prescription drug products," and that in most cases, the leaflet would "merely restate and reemphasize" the information the physician had provided the patient when prescribing the drug. Therefore, patients would not be more alarmed by information in the leaflet, visits to their physicians would not increase, and they would be more likely to comply with the drug regimens recommended by their physicians.[400]

Finally, concerns were raised about the economic burden of the proposed rule on drug manufacturers, distributors and dispensers, including manufacturer costs of printing the leaflets and distributing them to pharmacies with the drugs; and the costs to pharmacists of storing the leaflets and distributing them when dispensing the drugs. But the FDA had analyzed economic consequences, and found that the costs would be "acceptable in view of the anticipated benefits to patients" and that "the potential economic savings" of alternative information systems did "not outweigh the benefits to

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> Manufacturers would be held liable because it would be extremely difficult to write understandable warnings and directions directed to the layman which would be deemed legally adequate.
>
> 2. Patient labeling requirements would expose pharmacists to legal liability predicated on the failure to dispense labeling or on the dispensing of wrong or outdated labeling.

In response, the FDA concluded that "the imposition of a requirement for patient labeling [would not] necessarily affect adversely the standard of civil tort liability which is imposed on drug manufacturers or dispensers." In addition, the FDA was confident "that pharmacists [could] devise distribution systems that [would] ensure that the proper labeling [was] distributed with each oral contraceptive drug product." See further discussion of liability at Note 442 *infra*.

[399] 44 Fed. Reg. 40,023 (1979).

[400] 44 Fed. Reg. 40,023-24 (1979).

patients from patient labeling they would receive under the [proposed] comprehensive information system."[401]

In refuting these arguments, the agency relied on its own extensive studies, its limited experience with patient-informing materials for a small number of prescription drugs, and the supportive views of consumer interest organizations. Nevertheless, it was apparent that the agency proposal, irrespective of its risk-reducing merits, had great potential for interfering with the well-established relationship bewtween patients and physicians, and would indeed establish a new relationship between patients and drug firms which would have tort liability implications.

Thereafter, FDA promulgated its final regulation in September, 1980 establishing requirements for the preparation, content and distribution of "patient package inserts" (PPI's) for ten types of drugs.[402]

C. Requirements

The PPI regulations provided for the development and distribution of patient information leaflets for ten types of drugs and instructed drug firms as to the information to be provided in the leaflets. The ten drug products initially subject to the regulation for an intended three year period were chosen by the FDA on the basis of four selection criteria:

(1) whether PPI's would affect the patient's decision to use the drug;

(2) whether PPI's would help prevent serious adverse effects;

(3) whether PPI's would increase patient adherence to the prescribed course of therapy; and

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[401] 44 Fed. Reg. 40,023-24(1979).

[402] 45 Fed. Reg. 60,754 (1980). 21 CFR 203. In its enactment on Sept. 12, 1980, FDA replaced the term "patient labeling," which it had used to denote information leaflets, with the term "patient package insert" in keeping with terminology in the health care industry at 60,754.

(4) the extent to which the particular drug is prescribed.[403]

Manufacturers of these drugs were made responsible for developing and distributing the PPI's to pharmacists and other drug dispensers. The dispensers were, in turn, required to provide the PPI's to patients when filling their new prescriptions for these drug types.[404] Special provision was made for hospital dispensers of the ten drugs to institutionalized patients and persons undergoing emergency treatment.[405] Exemptions from requirements to provide PPI's were made for prescription refills and for special situations where the prescribing physician had directed in writing that a PPI not be provided a patient.[406]

The rule provided comprehensive requirements for the information content of the PPI's. They were to be written in English, in nontechnical language, exclude "promotional tone or content," provide the established name of the drug, and a summary describing its common uses, proper use instructions, situations when it should not be used, serious adverse reactions and safety hazards.[407]

In addition, the PPI's were required to contain a more detailed discussion about proper use (including a statement that evidence is lacking to support certain uses when a "preponderance of the evidence" so indicates); information which the patient should provide to the physician before taking the drug (e.g., pregnancy); serious adverse reactions and safety hazards (to be printed in boldface type); precautions for the patient while taking the drug (e.g., driving; use of other drugs, foods, alcohol) including a discussion of risks to the mother and unborn child from any use during pregnancy, available data about excretion of the drug in human milk, and risks to the nursing infant; special precautions where warranted for children and elderly patients; and any evidence of carcinogenicity, mutagenicity or effects on reproduction (including animal studies and an explanation of how these relate to risk in humans).[408]

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[403]45 Fed. Reg. 60,773 (1980). The ten drug types chosen were: ampicillins, benzodiazepines, cimetidine, clofibrate, digoxin, methoxsalen, propoxyphene, phenytoin, thiazides, and warfarin.

[404]45 Fed. Reg. 60,782-83 (1980); CFR 203.24

[405]405. 45 Fed. Reg. 60,783 (1980); 21 CFR 203.25

[406]45 Fed. Reg. 60,783(1980); 21 CFR 203.26. Despite the exemptions, the regulation provided for a patient's ability to override the physician's decision: "the dispensers . . . shall provide a patient package insert to any patient who requests it when the drug product is dispensed."407.

[407]45 Fed. Reg. 60,781 (1980); 21 CFR 203.20(a)(b).

[408]45 Fed. Reg. 60,781-82 (1980); 21 CFR 203.20(b).

Further information to be provided pertained to the potential for drug dependance; how the patient should deal with overdosage or a missed dose; possible side effects (in terms of severity, frequency, organ systems affected, and remedial measures); a warning that the drug should be used only as prescribed; special handling and storage conditions; the method of administering (taking) the drug; and the name and address of the manufacturer, distributor, or dispenser.[409] Finally, the FDA specified print size and encouraged imaginative formats;[410] and promised that it would prepare and provide guideline PPI's for specific drugs, use of which would constitute manufacturer compliance with the content requirements of the rule.[411]

The final rule provided that PPI's were intended to promote safe and effective drug use, and enhance patient participation and capabilities for evaluating benefits and risks in drug use decisions.[412] FDA cited its studies and experience in predicting that PPI's would reduce excessive or inappropriate drug use, adverse drug reactions, and noncompliance with drug regimens;[413] and, thereby, lead to various health and economic benefits including a reduction in drug use, fewer visits to doctors and hospital admissions, and fewer lost workdays.[414] FDA presented the findings of its regulatory analysis of the costs and benefits of the rule,[415] which it admitted were incomplete and would necessitate further evaluation during its initial three year period of implementation.[416]

The benefits, based on the assumption that PPI's would lead to a 5% decrease in noncomplying drug use, were estimated to range up to $40 million in savings (from reductions in lost workdays, hospital admissions, physician visits and refilled prescriptions),[417] and exceeded the estimated cost of $21 million which would be borne by drug manufacturers, distributors, pharmacies and hospitals.[418] Finally, the agency promised that further evaluations of the

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[409] *Id.*

[410] 45 Fed. Reg. 60,782 (1980); 21 CFR 203.22.

[411] 45 Fed. Reg. 60,782 (1980); 21 CFR 203.23.

[412] 45 Fed. Reg. 60,759 (1980).

[413] 45 Fed. Reg. 60,779 (1980).

[414] 45 Fed. Reg. 60,776 (1980).

[415] As prescribed by Executive Order 12,044 (March 23, 1978); 3 CFR 152.

[416] 45 Fed. Reg. 60,757 (1980).

[417] FDA estimated that the costs associated with noncomplying prescription drug uses of the 10 drugs and drug classes covered by the PPI program (lost productivity, stays in hospitals, revisits to physicians and refilled prescriptions) ranged from $396 to $792 million. As a result, a 5 percent decrease in noncomplying drug use could produce savings from $20 -$40 million. 45 Fed. Reg. 60,779-60,780 (1980).

[418] *Id.*

efficiency and economic and other consequences of the PPI rule would be used to consider various modifications to the rule.[419]

D. Program Evaluation

To keep its promise to evaluate the effectiveness of the experimental PPI Program, the FDA sponsored a Rand Corporation study to determine how PPI's might best be designed to communicate important drug information to the patient. This research studied alternative leaflet designs for three drugs: erythromycin, a commonly prescribed antibiotic; conjugated estrogens, female hormones used to treat symptoms of menopause; and flurazepam hydrochloride, a drug used to treat sleeping disorders. The study took place in Los Angeles County during the fall, 1979 and winter and spring, 1980.[420] Rand reported the following findings:

1. "PPI's are likely to be widely read . . . about 70 percent of those who received PPI's reported having read them."

2. "Many patients use PPI's as reference documents. Between 45 and 56 percent of those who received a PPI reported having kept it, and between 22 and 32 percent reported having read it more than once."

3. "PPI's lead to reliable gains in drug knowledge . . . PPI's appear to be an effective vehicle for getting more information to more people."

4. "PPI's seem to have little effect on how patients use a drug. [There was] no evidence that patients who received a PPI were any more or less likely to comply with the prescribed regimen or . . . alter their patterns of drug use . . . most . . . elected to take the drug once they had purchased it."

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[419]FDA promised consideration of the following options after full evaluation of the economic consequences of the PPI rule during its initial implementaion stage:

1. Whether and to what degree the agency should increase or reduce the number of drugs covered;

2. Whether to include coverage of refilled prescriptions;

3. Whether alternative delivery systems should be required or permitted;

4. Whether voluntary information systems can satisfy consumer needs; and

5. Whether the current regulation can be improved by building additional standardization or flexibility into distribution, handling, or delivery of patient package inserts.45 Fed. Reg. 60,777 (1980).

[420]Study results were published in D. Kanouse, S. Berry, et al, *Informing Patients About Drugs: Summary Report on Alternative Designs for Prescription Drug Leaflets*, Rand Corporation, Santa Monica (August 1981), (R-2800-FDA). The study produced six reports including a summary, two reports on methodology, and three reports on specific drugs.

5. "The costs of returned prescriptions are likely to be quite low . . . During the study, only three [out of more than 2000 prescriptions dispensed with PPI's] . . . were returned to pharmacies for cash refunds [rather than the one out of 60 originally projected]."

6. "PPI's do not, in general, lead patients to report more side effects." There was no difference in the number of side effects reported by patients who were provided with leaflets and those who were not.

7. "PPI's are unlikely to change the frequency with which patients contact their physicians." There was "no evidence that PPI's had any effect whatsoever on the number of times patients contacted their physicians."

8. "Patients find written drug information helpful . . . Most patients who received PPI's reported that they found PPI's helpful in understanding the drug and its effects."

9. "The amount of explanation provided in a PPI makes very little difference in how much information patients understand or remember . . . There seems to be no advantage in wiriting PPI's that contain large amounts of explanation."

10. "PPI's that contain numerous specific instructions can lead to increased reporting of side effects and other adverse outcomes." It was suspected "that many patients find a barrage of specific behavioral recommendations unsettling and begin to monitor their physical states more closely, which may lead them to notice (or imagine) more side effects and to feel that they have experienced less improvement in their symptoms. Because all the leaflets . . . studied included at least some behavioral recommendations, [the] results do not lead [to the conclusion] that all such recommendations will have deleterious effects."

11. "There is little advantage to be gained by highlighting information about a drug's risks. Patients who received leaflets in which risk information was emphasized displayed no greater knowledge of risks than other patients."

12. "The simplicity with which a PPI is written has surprisingly little effect . . . The leaflet's complexity had no effect on how much respondents learned from them and very little effect on other outcomes."

13. "PPI's in outline format may reach a larger audience but with a different message . . . The outline versions appeared to induce some of the negative outcomes often predicted for PPI's in general - outcomes that [were not found] for most other PPI's . . . studied."

14. "Shorter leaflets convey less information than longer leaflets, but do so no better . . . There is apparently little advantage to be gained in a strategy of selectively presenting drug information in the hope that the reduced message will reach more people who will understand it better. Most patients can

readily handle PPI's of 1000 words or more without suffering information overload.[421]

These findings reported in mid-1981 disputed several key premises for the PPI rule, namely FDA's views that PPI's would reduce drug use and visits to physicians, and improve compliance with drug regimens and patient knowledge of risks. They further undermined the rule's requirements for comprehensive information to be provided the patient, hinted that the PPI's created patient anxieties, and indicated that neither simple nor complex presentations of information would achieve the intended benefits of the rule.

In addition, the Reagan administration had taken office in January 1981 and immediately issued an Executive Order[422] and other mandates for agency review and revocation of existing regulations, causing the FDA in April 1981 to stay the effective dates for the first five drugs subject to the PPI rule, pending evaluation of the rule.[423] According to the FDA, "The stays were justified on the basis that there needed to be further review of the questions that had continued to be raised about the program. Numerous comments had been received expressing the view that mandatory PPI's were unnecessarily burdensome, costly, and not consistent with Executive Order 12,291 . . . [and] that additional review of the PPI program was consistent with the spirit of the Executive Order."[424]

The convergence of the Rand study findings, the new administration's strong views about reducing regulatory burdens on the private sector, the FDA's original promise to continue evaluating and modifying the PPI as warranted by studies of its efficacy and efficiency, and strong opposition from the drug industry, pharmacists, and the health care sector led the FDA to propose revocation of the PPI rule in February, 1982.[425] FDA supported its proposed revocation with new findings that PPI was not necessarily the most effective way of informing patients; that various private sector initiatives could provide consumers with more information than would have been possible with PPI; and that these initiatives would be discouraged if PPI were to be continued. It also cited as serious deficiencies, the PPI design for providing patient information at the time of dispensing rather than at the time of prescribing, the estimated costs of the program, and strong disagreement about its value within the health care community which would impede its successful implementation.[426]

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[421] *Id.* at pp. 3-6.

[422] Executive Order 12,291, 46 Fed. Reg. 13,193 (Feb. 18, 1981).

[423] 46 Fed. Reg. 23,815; 23,739 (1981).

[424] 47 Fed. Reg. 7,200 (1982).

[425] 47 Fed. Reg. 7,200 (1982).

[426] 47 Fed. Reg. 7,200-01 (1982).

However, the agency indicated that the proposed revocation would not apply to PPI requirements that it had individually enacted for specific drugs, nor affect its authority to require individual PPI's for specific drugs through notice and comment rulemaking in the future.[427]

Finally, to demonstrate its continuing concern about patient drug information, the agency announced the establishment of an internal Committee on Patient Education. The Committee would educate consumers, facilitate private sector initiatives, evaluate information systems, and carry out other functions designed to promote better patient education.[428]

E. PPI Revocation and Subsequent Developments

The PPI saga ended when the rule, which had not been implemented, was officially revoked by the FDA on September 7, 1982.[429] FDA cited many of the reasons it had provided earlier in its proposed revocation notice, in particular that its evaluations had shown that alternative private sector programs were likely to be more effective, but would be stifled by PPI continuation; that costs of PPI would be excessive, and that implementation by the health care community would be problematic.[430] However, FDA expressed its continuing commitment to the principle that "patients have both a right and a need to know about the drugs they use," and reaffirmed its view that "consumers have not traditionally had available to them adequate information about prescription drug use."[431]

To support its contention that private sector initiatives held great promise as a superior alternative to PPI, FDA cited several:

1. The American Medical Association [AMA] would provide Patient Medication Instructions (leaflets containing drug information) to be handed out by physicians at the time of prescribing. By 1984, this program would cover some 200 commonly prescribed drugs.

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[427] 47 Fed. Reg. 7,202 (1982). The previously-enacted individual PPI requirements exempted from the proposed revocation are for the prescription drugs listed in note 389 *supra*.

[428] 47 Fed. Reg. 7,201 (1982).

[429] 47 Fed. Reg. 39,147 (1982). Revocation did not affect labeling of over the counter (OTC) drugs, nor existing requirements for professional labeling, at 39,149. Nor did it affect FDA authority to order PPI's for specific drugs on a case by case basis. *See* Note 389 *supra*.

[430] 47 Fed. Reg. 39,153 (1982).

[431] 47 Fed. Reg. 39,148 (1982).

2. The American Society of Hospital Pharmacists had published a "Consumer Drug Digest," (a book about prescription drugs) which was available to consumers at book stores.

3. The United States Pharmacopeial Convention was offering several publications for sale, including "The Physicians' and Pharmacists' Guide to Your Medicines."

4. The Retired Persons Services was providing package inserts with new prescriptions which were filled by its mail-order pharmacy service. This program would eventually cover up to 90 drugs or drug classes.

5. Biomedical Information was selling a layman's version of its "Compendium of Drug Therapy" (a publication originally provided only to physicians) directly to consumers.[432]

These private initiatives indicated to the FDA that consumers would have access to a wide variety of drug information and education programs in lieu of PPI's. The agency acknowledged that it could not guarantee that these programs would be successsful, but felt that "on the basis of their current development and the statements as to future plans by their sponsors, that these privately sponsored voluntary initiatives represent viable, promising alternatives."[433]

Since revocation, FDA has provided consultative and research services to the private sector organizations and "relied on volunteerism, rather than regulation."[434] But private sector performance since revocation of the PPI rule has not matched its initial promise.

According to Louis Morris of FDA's Division of Drug Advertising and Labeling:

> "The pharmaceutical industry, which had long resisted drafting and distributing patient information on their products, began to distribute leaflets describing the medication to the physician as part of their promotional materials. Currently, it is the exception, rather than the rule, for a brand name product not to have a patient information brochure.
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> However, these evaluations . . . [are] focused on the "production" side of the PPI equation. When we began to look on the "distribution" side, quite a different picture

[432] 47 Fed. Reg. 39,151 (1982).

[433] 47 Fed. Reg. 39,152 (1982).

> emerged. Although many different organizations were producing many different drug information leaflets, a relatively small percentage of patients seemed to be receiving any of these documents. A national survey . . . in 1985 indicated that although 25% of patients reported receiving some written information at the pharmacy when they picked up their medication, this information was usually in the form of small stickers affixed to the medication vial. Only 6% reported receiving a brochure and 7% an instruction sheet. Only 9% reported receiving written information at the physician's office. These percentages were almost identical to data collected in 1982"...[435]

Morris found that even special patient education programs have failed. For example, a "multifaceted patient education program for propoxyphene, which can cause fatalities when used in conjunction with certain substances, included the distribution of a special PPI to pharmacies. Although 90% of pharmacies acknowledged receipt of the PPI, "when observers posing as patients filled valid prescriptions, only 5% received the leaflet spontaneously, 32% . . . if it was requested." Morris has contrasted this voluntary effort with the FDA-mandated PPI's for conjugated estrogens, which show 39% for spontaneous delivery to patients, 89% if requested, and concluded that "Whereas the distribution rate for mandatory PPI's was low, the rate for voluntary ones appeared paltry. Neither method seemed to provide assurance that a consumer would receive a necessary warning message."[436]

As a result, FDA has "moved away from [PPI] regulations as a means of assuring patient education and turned toward packaging solutions to assure that PPI's were delivered to the patient," as in the case of Accutane, a drug for cystic acne treatment which is also a known reproductive hazard (a teratogen). Early use of patient brochures proved to be ineffective, as evidenced by "a surprisingly large number of children with birth defects . . . born to women who had taken Accutane." FDA has therefore required that a PPI be an integral part of the product labeling, that the product be prepackaged in unit-of-use blister packs, and that the package have special cardboard panels which contain an extensive warning message and symbols to graphically indicate the reproductive hazard. In addition, "physicians will be supplied with brochures,

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[434]L. Morris, "The FDA's Approach to Patient Package Inserts: The Four Phases of PPI's, "paper presented at International Symposium on Patient Package Insert as a Source of Drug Information, Heymans Institute of Pharmacology, Gent, Belgium (Sept. 26-28, 1988).

[435]*Id.*, p. 7.

[436]*Id.*, p. 8.

checklists, referral telephone numbers, educational materials, and a patient information/consent sheet to help assure that female patients are fully informed . . ."[437]

At this time, the FDA therefore views PPI's as part of a larger program of patient education "involving package solutions, the health professional, and various public communication channels on a case by case basis."[438] In addition, it relies on the practice of many drug firms to voluntarily provide PPI's to physicians for transmittal to patients; has maintained its PPI requirements for oral contraceptives and various hormone-based drugs;[439] and has mandated or recommended PPI preparation and distribution for several other drugs and diagnostic products on a case by case basis.[440]

F. Conclusions

FDA's attempt to establish risk communication between drug firms and patients by enactment of generic PPI requirements encountered formidable problems at every step. It was persistently opposed by drug firms and pharmacists because of the costs it would impose and the liability it would create. It was also opposed by health professionals because it would intrude into the doctor-patient relationship and impose new burdens of unproven value. Evaluations of the untested rule which cast doubt on its efficacy, and political opposition which focused on its efficiency, eventually led the agency to quickly revoke the rule.

The basic premises that patients have a need for drug information, and that government and the private sector should provide it, continue to be recognized by the FDA. Accordingly, the agency is now guiding and evaluating private voluntary initiatives, and dealing with patient information needs on an individual drug basis.

But the multiplicity of private initiatives which are now known to be less effective than the mandatory PPI approach, and the great number of prescription drugs that the agency, under its current policy, must deal with on an individual basis, indicate that revocation of PPI has not led to the more

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[437] *Id.*, p. 9.

[438] *Id.*

[439] Note 389 *supra*.

[440] For example: radiopharmaceuticals, 10 CFR 33; tests for Hepatitis B, 21 CFR 660.41, 3, 5; tests for bacterial endotoxins, 21 CFR 660.102-104; pin-worm treatment products, 21 CFR 357.152; certain new animal drugs, 21 CFR 510.310; menstrual tampons 21 CFR 801.430f; and in vitro diagnostic products, 21 CFR 809.10

efficacious and efficient system for informing patients about drug use that the agency anticipated.[441] Since any drug risk communication program will have limited effectiveness, the challenge facing the FDA is to now conduct a post-mortem on the post-PPI era and develop a new drug risk communication system that is reasonable, reliable and economically feasible, and to separately deal with its limitations through supplemental methods of public communication and patient education.

In this regard, a return to a generic, mandatory PPI program now seems warranted, provided it fully incorporates knowledge gained over the last decade. For example, production of PPI's has proven to be less of a problem for industry, private associations, and the FDA than previously anticipated; and like the preparation of material safety data sheets under OSHA's Hazard Communication Standard, presents minor problems which are remediable over time, as experience is gained. Thus, a new generic PPI rule could provide for an industrial responsibility (either individual drug firms or their trade associations) for PPI preparation, and an FDA responsibility for guidance and oversight. The new rule would place reasonable limits on information content, since studies have shown that complexity and length of message can be counterproductive. However, distribution of the PPI's presents a major problem which should be carefully addressed. PPI distribution through the national network of pharmacies has proven persistently difficult to achieve, a problem similar to the failure of many small businesses under the OSHA HCS to distribute MSDS's and train their employees. Therefore, a new PPI rule could address this problem either by providing for stronger enforcement and compliance education programs for pharmacists, or by abandoning pharmacists as the distributors of PPI's to patients in favor of another agent such as the treating physician. The latter option seems to make most sense since it is consistent with the common law duty of the prescribing physician, as the "learned intermediary" between drug firm and patient, to adequately warn the patient of the risks of drug therapy, a duty which is not imposed on pharmacists or drug firms.[442]

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[441] *See* "Combatting Drug Abuse: Prescription Drugs Out of Control," K. Pappas, Governor's Statewide Anti-Crime Council, Commonwealth of Massachusetts(Feb. 10, 1987): "Prescription drug abuse is a silent epidemic" at 1. *Also see Prescribing Practices: Policies and Guidelines*, Mass. Bd. of Registry in Medicine (Aug. 1, 1989).

[442] Under common law, the duty to warn the patient of prescription drug risks is imposed on the physian, but not on the drug manufacturer or the pharmacist, except in relatively rare cases. *See* D. Marschang, D. Reem, "The Continuing Strength of the Learned Intermediary Doctrine," For the Defense (Sept. 1987) 2: "According to the well-established . . . 'learned intermediary doctrine,' prescription drug manufacturers need warn only the prescribing . . . physician of the drug's potential risks, not the ultimate consumer of the drug; i.e., the manufacturer discharges its duty by warning physicians . . . The long-standing rationale behind the learned intermediary rule

By making the physician the PPI distributor, the provision of PPI's to patients would be virtually compelled by the malpractice theory of liability at common law in all states. Consistency of risk communication regulation with common law rights and duties explains a major success of OSHA's HCS--the vigorous efforts of chemical producers to prepare and distribute high quality MSDS's to their downstream customers. The high level of compliance by chemical producers can be attributed to product liability law which requires that they must adequately inform downstream customers and customer employees of product risks in order to discharge their duty to warn product users and therby preclude liability.

Vesting the duty to distribute PPI's in the medical community would enable doctors to more assuredly avoid malpractice liability when prescribing drugs. It would also follow the "regulatory model" favored by Reagan administration officials who opposed the original PPI, in that it would provide the PPI at the time of prescription rather than dispensation. It would further vitiate one of the main arguments against the original PPI, in that it would enable the treating physician to coordinate or reconcile his/her risk communication and advice with that of the PPI, and largely eliminate conflicting messages to the patient.

The remaining issue that would have to be addressed by the FDA relates to the usefulness of the PPI for educating the patient and beneficially altering patient behavior. Evaluations by FDA and by PPI proponents and opponents of the "efficacy" of the original PPI rule employed several criteria which indicate that the analysts know how patients should behave (e.g., return of drugs, report of side effects, etc.) These criteria of PPI efficacy reflect a common problem afflicting regulators and policy analysts, namely, elitism, which makes them view risk communication as a device for changing human behavior. But the main purpose of risk communication is to inform the recipient, so that this person is better-equipped to make personal decisions about risk, and not to guarantee certain behavioral or psychological responses (e.g., whether to take a drug). Nevertheless, where serious side effects or adverse reactions are foreseen as a certainty from misuse or noncompliance,

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holds that the physician, as a learned individual who intervenes between the manufacturer and the consumer, but is able to make an 'informed choice' and tailor the warnings to better suit the particular consumer/patient's needs." Thus, the duty to warn the patient under common law is the responsibility of the prescribing physician, and the proximate cause of a patient's injury.

Also see "Drug Product Liability: Duty to Warn," *U. Pittsburgh L. Rev.*, v 49 (1987) 283. "A physician's duty to warn in prescription drug cases flows from his general duty to inform patients of the risks involved in proposed treatment . . . This duty, [is] known as the doctrine of informed consent." at 290-91. "The overwhelming majority of recent cases have held that pharmacists have no duty to warn consumers of possible adverse reactions inherent in the use of prescription drug under either a negligence or a strict liability theory."at 294.

special measures can be taken by the FDA on an individual drug basis, such as those it has devised for Accutane, to promote desired responses (e.g., avoid use during pregnancy).

Calling for a return to a generic and mandatory PPI rule may be sailing once again into a storm of protest. But all agree that patients need drug information, and evidence now indicates that present voluntary efforts are inadequate and probably very inefficient. A careful reconsideration and re-issuance of a generic PPI rule now seems appropriate.

V. Conclusions

The availability of industrial risk information to members of the public is a necessary feature of our democratic society. Without this information, persons are deprived of the ability to take self-protective measures against the latent hazards of products, workplaces and industrial facilities. Without this information, the public is denied the right to participate on an informed and effective basis in decisions which affect their health, environment and well-being.

Thus, many legal doctrines have been developed which guarantee that industrial risk information will be provided to the American public. The Freedom of Information and National Environmental Policy Acts assure public access to industrial risk information held by federal agencies, including information reported by firms to the agencies under various environmental and health protection laws. Duty to warn principles of tort law are now vigorously applied to industry in state courts. Most recently, "right to know" laws and regulations have been enacted to afford public access to additional industrial information on technological hazards, with appropriate accommodation for protection of trade secrets and other legally-protectible interests of private firms.

Despite initial misgivings, larger firms now routinely comply with the disclosure requirements of right to know laws, and trade associations and professional societies have developed principles affirming industrial risk communication. International organizations and other industrial nations are developing similar doctrines. The corporate duty to disclose and the public right of access to industrial risk information are therefore widely accepted and practiced.

But implementation of industrial risk communication programs raises special problems and needs which must be carefully addressed if performance is to measure up to promise. This study has therefore evaluated three federal programs to illuminate the problems and their causes, to define the special

needs, and to develop recommendations for improving use of industrial risk communication as an instrument of regulatory policy.

This evaluation has had to contend with several unusual circumstances. For example, the national experience with industrial risk communication in the form of "right to know" programs has been very brief and there is little data on the actual effectiveness of the programs for reducing risk. In addition, each program has been beset by significant uncertainties: whether its true objective is to educate the designated recipients of risk information, or to do more, namely to shape their attitudes and behavior; and whether the program is to serve as a supplement to traditional regulation, or as a "new federalism" or budget deficit-necessitated substitute for more expensive standard-setting.

Nevertheless, the evaluation has led to several findings which can be used to improve the design and administration of existing programs and to guide future use of this policy instrument. These findings are now discussed with reference to the three programs, which have been summarily outlined in the following flowcharts to depict the parties involved and their responsibilities (Figure 1).

A. Program Administration and Compliance

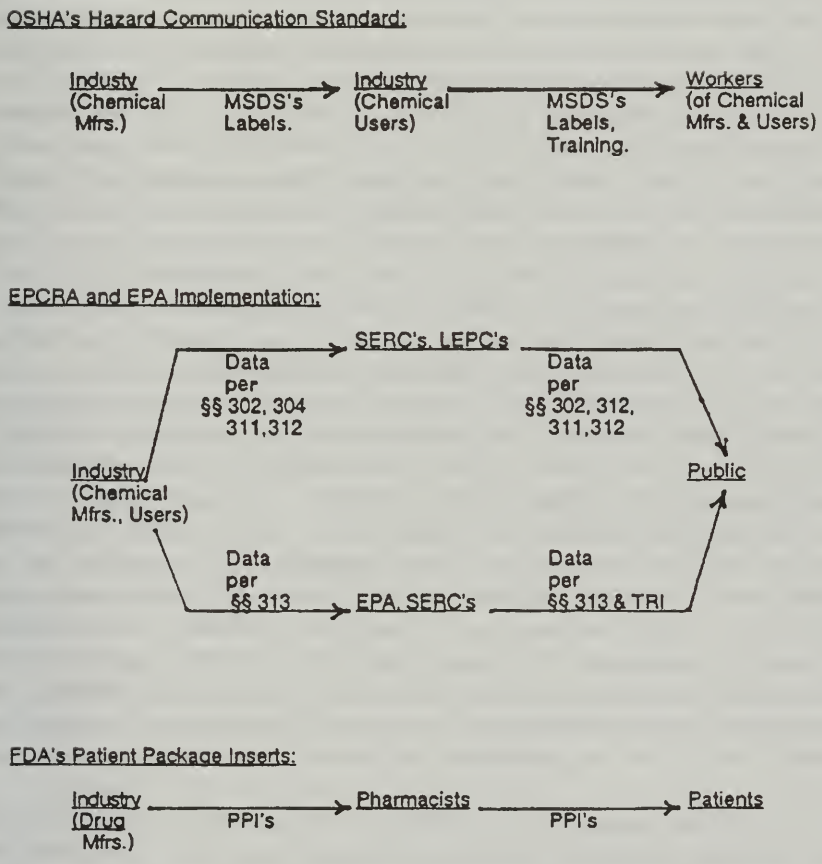
At the core of each risk communication program are important requirements for the production and distribution of risk information materials by designated parties (as depicted in Figure 1). Thus --

- Under HCS, chemical manufacturers must produce MSDS's and labels and provide them to their downstream industrial customers, who must then distribute the materials to workers on request and provide worker training programs;
- Under EPCRA, chemical manufacturers and users must produce several reports for SERC's, LEPC's and EPA, who must then distribute the materials to the public on request and develop emergency plans and data inventories for public use;
- Under PPI, drug manufacturer's were required to produce PPI's for ten drugs and provide them to pharmacists, who were required to distribute the PPI's to patients buying the drugs.

Under the HCS and PPI programs, production function requirements were clearly established for chemical and drug manufacturers, respectively. These relatively large firms have adequately complied by producing MSDS's and PPI's.

However, under EPCRA, breakdowns have occurred in the production function. The statute requires chemical manufacturers and a large universe of

Figure 1: Three Federal Programs
for Industrial Risk Communication



firms which use chemicals to produce at least five types of reports in accordance with multiple lists of subject chemicals and threshold quantities. Compliance involves considerable expertise in certain instances (e.g., Section 313 Chemical Release Reporting) and requires meeting a veritable calendar of deadlines and responding to continuing modification of the lists by EPA. As a result, many smaller firms, particularly those which are end users of chemicals and who do not consider themselves to be "chemical firms," have not produced the reports and are in noncompliance.

The distribution function has proven to be an even greater problem in that it has broken down in certain respects in each risk communication program. OSHA has found widespread noncompliance by smaller firms with its HCS requirements to provide MSDS's and training to workers. Under EPCRA, EPA has found that many LEPC's and SERC's have failed to develop emergency response plans for public use, and some have inadequately responded to public requests for the industrial information submitted to them. FDA found that pharmacists had persistently low levels of performance when requested or even required to distribute PPI's or similar leaflets to purchasers of prescription drugs, even though all they had to do was store the PPI's they received from manufacturers and dispense them to purchasers.

At least two explanations can be provided for these breakdowns. The first involves conventional reasons for regulatory noncompliance. For example, under both the HCS and EPCRA programs, smaller firms have been found to be insufficiently aware of their production and distribution responsibilities, and lacking in the technical expertise and financial resources needed for compliance. Further, both OSHA and EPA enforcement policies have contributed to the breakdowns. OSHA's HCS is a performance-oriented standard which leaves much of its interpretation to company discretion, but its enforcement policy has used narrow and inflexible criteria for evaluating compliance. EPA, at the other extreme, has generously and repeatedly deferred enforcement until firms are "aware" of EPCRA requirements, thereby inadvertantly justifying their persistent noncompliance. In addition, the agency lacks statutory authority to enforce the development of emergency response plans and the distribution of risk information by SERC's and LEPC's.

But a second explanation may be more useful in several respects. When a risk communication function imposed by federal law, such as production or distribution of information, is not consistent with a duty to warn imposed by common law liability doctrines, the regulatory requirement lacks essential reinforcement and noncompliance is more likely to follow (unless a comprehensive and vigorous agency enforcement program is operative). This rationale, discussed earlier (e.g., Part IV-F of this report) is based on

correlations between compliance experience and the applicability of common law liability doctrines.

For example, under the HCS, firms responsible for producing MSDS's have complied because, as chemical manufacturers, they may be liable under products liability law for injuries to users of their products, such as their customer's employees, if they have failed to provide warnings about chemical risks. However, many of these customer firms responsible for distributing MSDS's and providing training to workers have not complied. One reason may be that they are exempt from tort liability for workplace injuries to their own employees arising from lack of warning because worker's compensation law in each state bars employee tort actions against employers. Similarly, under EPCRA, units of government such as SERC's and LEPC's may fail to act and thereby cause injuries to the community with impunity, because they are shielded from tort liability by immunity doctrines in many states. Finally, under PPI, pharmacists are not subject to tort liability for failure to warn customers of drug risks (since physician's have this duty under the common law), and this may account for their failure to distribute PPI's.

The basic "clockwork" of a risk communication program consists of its mechanisms for the production and distribution of information. Brief federal experience with three programs indicates that special attention must be given to the allocation of responsibilities for production and distribution in order to assure that these important mechanisms will function properly. Thus, in the design of a program, responsibilities should be allocated to the fullest extent to those parties already subject to duty to warn doctrines of liability in the common law, in order to capitalize on these doctrines as incentives for the production and distribution of information under the regulatory program.

In subsequent administration of the program by a federal agency, compliance should be sought through parallel programs of regulatory enforcement and technical assistance. The supervisory agency should first establish the credibility and importance of production and distribution responsibilities by making a clear commitment to an enforcement policy, and formulate compliance criteria which are consistent with the discretion given to the parties responsible for production and distribution.

The agency should then develop and use publicity and technical assistance programs to provide guidance to the parties on how to structure their discretion for interpreting and discharging their production and distribution mandates. Publicity and technical assistance should be targeted in particular at those parties with limited resources (e.g., small businesses) in order to lessen their financial and management burdens, and at parties for whom the agency lacks enforcement authority (e.g., state and local units of government). Finally, in developing and applying the technical assistance strategy, the agency should work in collaboration with pertinent industrial and trade associations.

B. Program Efficacy

Risk communication programs, like other regulatory policies, should be effective and achieve their objectives. Therefore, program design and administration should assure that the materials produced and distributed are useful for program purposes. Agencies responsible for program administration should also be provided with sufficient discretion and resources to cure problems and improve the usefulness of the materials.

Assuring the efficacy of any regulatory program requires that its purposes be clearly understood. However, as discussed earlier, the purposes of risk communication programs have been ambiguous. Thus, it is necessary to clarify whether each risk communication program is intended to educate the intended recipients of the information, or to do more, namely, to shape their attitudes and produce certain behavioral outcomes.

Choosing education as the purpose means that the program and its materials should be evaluated by educational criteria: is the information sufficiently clear and understandable to the recipient; objective and reasonably accurate as to what is known; candid as to what is uncertain and what is not known; and truly informative in that it provides what a reasonable recipient would want to know about hazards in an abstract sense and risks in a personal sense. Overall, do the materials and their manner of presentation enable the recipient to more wisely evaluate risks and remedial options? Broad support has been expressed for the proposition that education is the true purpose of risk communication, because it is most consistent with personal freedom and "new federalism" policies, and establishes the necessary social framework for addressing technological advances.[443]

Choosing to do more through risk communication, namely shaping attitudes and behavioral outcomes (as in the PPI program), necessitates the use

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[443] *See*, for example, S. Krimsky, A. Plough, *Report to EPA on Improving Risk Communication*, Tufts University (Feb. 1988): "Do not assume that good risk communication correlates directly with change in behavior. The best presentation of risk information will be used differently in diverse socioeconomic contexts. In evaluating most risk communication programs, structure, process and educational outcomes should be emphasized, not behavioral change." at p. 55. *Also see* R. Katz, *Protecting the Consumer Interest*, Ballinger Publ. Co. (1976): "Providing consumers with more information . . . leaves both the number of choices and the quality of the alternatives unchanged. It is therefore the means most compatible with freedom of choice . . . to what extent do we wish to influence, and by what right do we try to change, the values consumers use in making their decisions? Are the sanctity of the environment, the welfare of our fellow citizens, and the rights of future generations more important values than our . . . maximization of individual, short-term self-interest? It is not the American tradition to legislate morality, but perhaps we can try to make consumers . . . more aware of the ethical and social dimensions of consumption activity by providing information . . . at pp. 65, 66.

of advertising and public relations techniques. Many have objected to this role for risk communication as being dishonest, manipulative and authoritorian.[444] Nevertheless, for risks which are significant and imminent, and have irreversible consequences, manipulative communications may be justifiable[445] (as in the Accutane drug case discussed in Part IV).

In light of these considerations, the more widely supported educational purpose of communication should govern any evaluation of program efficacy, and special cases where manipulation of certain outcomes is socially justifiable should be disclosed and dealt with by traditional regulatory means such as standard-setting (e.g., FDA's use of "packaging solutions" to supplement PPI's).

Thus, in evaluating the efficacy of risk communication under the HCS and EPCRA on educational grounds, one must focus on the MSDS's used in both programs to educate workers, community residents and LEPC's, and also address the use of worker training under the HCS and the additional information required by EPCRA.

The MSDS prepared by manufacturers and importers for each of many chemicals is the basic risk communication document under both programs, and must therefore serve multiple purposes in several contexts. Many criticisms of the MSDS have been expressed by workers, unions and employers as being too abstract, technical and uninformative for worker education under the HCS. Parallel criticisms have been expressed by community residents, public interest groups and LEPC's under EPCRA. Specific deficiencies have also been identified including its lack of information about chronic health hazards, its failure to provide comparisons with common risks (e.g., smoking) which would provide "perspective," and its failure to provide useful guidance on safe handling of hazardous chemicals and effective response to chemical accidents.[446]

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[444]H. Otway, B. Wynne, "Risk Communication and the Paradigm of Paradox" (unpublished, 1988): "we should give up notions of 'communication' taken from fields such as advertising... ."

[445]R. Keeny, D. von Winterfeldt, "Improving Risk Communication: Insights from Decision Analysis," paper presented at EPA Workshop on "Risk Perception and Communication," Long Beach, Calif. (1984): "Risk communicators should . . . encourage the public to take personal risk reduction measures . . . they may have to borrow communications strategies and tools from advertising and marketing." at p. 23.

[446]*See* discussion of the importance of communicating risk information to workers on a "need to know" or response promoting basis, "taking into account the level of education, knowledge and training" in order to assure that the information is understood and "action-oriented." For example, European chemical industry officials have suggested use of a series of questions which would clarify what the worker should know, such as "what could happen if . . . ?" L. Jourdan, *Information on Hazards of Substances at the Individual Workplace*, CEFIC,

In addition, since each manufacturer and importer of a subject chemical produces its own MSDS and transmits it downstream in commerce, where it is subsequently distributed to workers, LEPC's, fire departments, and the public, many diverse MSDS's on the same chemical often converge on these designated recipients. Upon receiving diverse MSDS's, for the same chemical, these recipients then have the burden of determining which MSDS's have superior information to rely on for their own needs. This circumstance also indicates that industrial resources are being wasted on duplicative efforts.

Thus, OSHA and EPA, as the supervisory agencies, must work together to cure both types of problems: first to improve the information content and style of the MSDS so that it better serves the educational purposes of both programs, and second, to promote MSDS uniformity and clarity of message either by developing model MSDS's for priority chemicals or by delegating this task to manufacturers or their trade associations (as the FDA intended to do under PPI). Several firms have already acted to voluntarily "improve" their MSDS's beyond current HCS requirements to better educate LEPC's and community residents under EPCRA, and to better warn customers and their employees in order to reduce "downstream" risks and potential liability. These initiatives indicate that industry would cooperate with OSHA and EPA in improving MSDS's.

OSHA and EPA should also jointly address two other issues which impair the efficacy of their programs, but which transcend the content and style of MSDS's. The first of these issues is growing recognition that even the best emergency response plans cannot be put to use with sufficient rapidity by workers and community officials to prevent major harms in many instances (e.g., sudden toxic gas release with rapid dispersion characteristics). One remedy suggested by New York state officials and others has been the identification and mapping of "vulnerable zones" and the development of more stringent accident reduction measures and more rapid emergency response plans for these zones, similar to the flood plain mapping and special standards developed under the National Flood Insurance Program by the Federal Emergency Management Agency (FEMA).

The second issue relates to a serious omission in EPCRA, namely that firefighters and other emergency responders and community residents are endangered by the toxic by-products of nontoxic chemicals (not subject to EPCRA reporting) when these chemicals burn or decompose during a facility accident. (e.g., lethal release of hydrochloric acid when nontoxic polyvinyl chloride burns). This omission should be addressed by both agencies in

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Brussels (1987). *Also see* discussion in M. Baram, *Corporate Risk Management*, note 20 *supra* at pp. 38-40.

collaboration with LEPC's and their fire departments, which are responsible for emergency plans and response actions.

C. Implications for Regulatory Policy

Federal agencies essentially serve as supervisors of the numerous parties responsible for producing, distributing and using risk information. This supervisory role differs in many respects from more familiar regulatory roles in that it requires the agency to 'manage' or orchestrate the designated parties into coordinated compliance. Since agency authority to enforce compliance in risk communication programs is usually limited, and where available, has been shown to be of limited practical value, the supervisory agency must develop other methods of 'managing' coordinated compliance. The most suitable method is the development of partnerships or constructive working relationships with designated parties such as private firms and state and local officials.

The need to develop these constructive working relationships is apparent in the HCS and EPCRA programs. As discussed earlier, EPA and OSHA should work jointly on industrial risk communication, and together work with chemical manufacturers and their trade associations to improve the information content and educational value of the MSDS so that it better serves both programs, and provide regulatory guidance and technical assistance to smaller downstream firms which receive the MSDS's but fail to discharge their duties under the HCS and EPCRA programs.

This collaborative effort can produce a very useful form of 'technology transfer,' useful to both programs, namely the dissemination throughout all 'downstream' industrial sectors of the superior knowledge of chemical risks and safe management methods possessed by 'upstream' chemical manufacturers. Several large manufacturers have already acted voluntarily to transfer this useful information and provide risk management expertise (e.g., safety audits) to their downstream customers. Therefore, the two supervisory agencies should now join and structure these collaborative efforts through formation of a joint OSHA-EPA-Industry Council on Chemical Risk Management which would work on improving MSDS's and fostering technology transfer.

Given the design of the EPCRA program, EPA needs to work in similar close collaboration with state and local officials on their development of emergency response plans, and their use of inspections, safety audits and regulations (e.g., new standards and permit requirements) to prevent accidents in the first instance. EPA's regional offices should be assigned the task of

developing relationships with the SERC's and LEPC's in each region on a formal and continuing basis. This would enable the sharing of technical expertise among these government officials, their development of safety audit and inspection programs, and their mapping of vulnerable zones for special attention. Overall, it would motivate the state and local officials to use their considerable state 'police power' authority to regulate safety and prevent accidents at industrial facilities. EPA should also develop public support in each region for SERC and LEPC activities.

Since industrial accident risk factors (e.g., industrial process, chemicals used, facility site, demographics, local response capability, etc.) differ at each facility site and are therefore too diverse for uniform national regulation, this regional approach drawing on state and local authority and public support seems more promising as a means of ultimately reducing facility accident risks and improving community preparedness for emergencies.

EPA must also develop a similar regional collaboration with state air and water quality officials to stimulate actions to reduce the routine release of toxic materials by industry. Toxic Release Inventory (TRI) data on routine releases is now AVAILABLE for regions, states and localities, and can immediately be put to use by state officials to set priorities and to use their considerable authority (under federal Clean Air and Water Acts and state laws) to reduce toxic releases. EPA has recently structured a prototype for such an approach on a national scale to deal with 900 industrial and municipal dischargers of toxic materials nil surface waters under the Clean Water Act, as discussed earlier. This promising start should now be adapted for use on a regional basis, and be used as a model for another set of regional programs to reduce the release of toxic pollutants into the atmosphere, consistent with the Clean Air Act and state air quality law.

In New Jersey, Massachusetts, California and several other states, legislative and regulatory initiatives for the reduction of routine releases have been promoted by public interest groups and are now being implemented. EPA should therefore use its regional offices, TRI data, technical expertise and educational programs to further these state and local initiatives.

The effectiveness of risk communication programs ultimately depends on the ability of the recipients of risk information to understand it and act on the basis of what they have learned. This circumstance creates another major implication for regulatory policy, namely, the need for the supervisory agency to facilitate understanding and responsible action by various sectors of the general public (e.g., workers under HCS, community residents under EPCRA). OSHA and EPA should recognize by now that many persons reviewing MSDS's and EPCRA Reports are confused by the technical information, uncertainties and probabilistic nature of the information in these

documents, have developed anxieties about their health status, and are uncertain as to their options for reducing risk.

To meet these special needs, supervisory agencies (e.g., OSHA and EPA) should collaborate with state and local environmental and health officials to provide these public sectors with special services for interpretation of the hazard information disclosed by industry (e.g., the MSDS's and EPCRA reports), and for counseling persons (workers, community residents) on how they should evaluate their risk status and the measures they can take to reduce disease and accident outcomes. State public health agencies and occupational medicine officials should be particularly useful, if mobilized for these purposes.

Another major implication for regulatory policy arises from the condition that risk communication programs must coexist with traditional regulatory programs for standard-setting, but that these distinctly different approaches to risk reduction will often intersect and influence each other.

Thus, supervisory agencies must define this coexistence and address potential intersections so that each approach reinforces, rather than impairs, the other.

For example, risk communication programs may provide industrial data which would support new preventive standards and special monitoring' and reporting requirements, or which indicates that reliance on disclosure alone is inadequate and that prescriptive standards are needed. Conversely, standards alone may prove to be impractical in certain circumstances and require reinforcement in the form of risk communication.

Supervisory agencies such as OSHA and EPA should therefore structure their discretion to address how the coexistence of their risk communication and standard-setting programs should be managed, keeping in mind that risk communication should not serve as a low-cost substitute for traditional standard-setting. For OSHA, this translates into the need to structure a mutually-supportive relationship between the HCS and its standards program for toxic substances in the workplace (as well as its use of the 'general duty clause' and 'emergency temporary standards.') For EPA, the task is to define relationships between the EPCRA program and its regulatory functions under several other statutes which authorize standard-setting to prevent environmental harms (e.g., TSCA, Clean Air and Water Acts).

In some instances, industrial risk communication may generate new perspectives which challenge the agency's basic assumptions and existing approach to regulating chemical risks. These cases which require full scale reconsideration of regulatory programs should be openly deliberated and may require Congressional support in the form of statutory amendments authorizing new regulatory approaches.

For example, OSHA and EPA have acquired sufficient evidence to establish that each hazardous chemical has a commercial life cycle which includes upstream manufacturers and downstream processors, distributors and end user firms; and that the manufacturers in each life cycle usually possess superior KNOWLEDGE of the chemical's hazardous attributes and techniques for safely managing its use.

Given this life cycle perspective and the readiness of manufacturers to use the MSDS and other means to transfer their expertise to downstream firms, OSHA and EPA should now use this knowledge to develop life cycle approaches to the reduction of chemical risks under the OSH Act, TSCA and their other statutes. By taking a holistic view of where a chemical creates risks throughout its commercial life cycle, OSHA and EPA can identify where risk reduction for that chemical is most needed, and work with all firms in the life cycle to transfer superior knowledge from firms which possess it to firms which lack it. Thus, the agencies can stimulate the diffusion of the best methods of corporate risk management throughout the entire life cycle. This approach could be tested first on chlorine, ammonia, and other well-known, high-volume, high-risk chemicals and gradually be extended to lesser-known specialty chemicals, and could provide a useful basis for revising traditional regulatory approaches.

These examples demonstrate that risk communication has several implications for regulatory policy which should be dealt with by supervisory agencies. Therefore, OSHA and EPA should conduct internal studies and subsequently hold public hearings to begin the process of addressing these implications.

D. Transparency and Industrial Democracy

Industrial democracies value technological advance and a citizenry which is capable and active in promoting and protecting its diverse interests. For several decades, the federal government has sought to accommodate both values in its deliberations and decision-making on risk and other determinants of technological advance. When citizen involvement was found to be impaired by lack of information, Freedom of Information and other laws were enacted to provide public access to agency-held information. Thus, citizen capabilities were enhanced by making government activities more transparent.

However, many hazardous technologies continued to be advanced without the awareness or involvement of the public because critical information was held by private firms and remained unavailable to workers, product users and residents of communities hosting industrial activity. Recognition of this

circumstance and other factors led to the enactment of new doctrines of industrial risk communication which afford citizen access to certain corporate information on risk. Citizen capabilities were thereby enhanced further by making corporate activities more transparent.

Thus, transparency is now a basic principle for social control of technology in the United States, and holds similar status in the European Community. Transparency empowers the public and enables it to effectively express its diverse interests, thereby providing industrial democracy with the most effective mode of promoting the accountability of government and industrial decision-makers to the full social context in which they operate.[447] But transparency can also produce a spiral of conflicts and adversarial proceedings in agencies and courts. In response to this potential, government and industry are now beginning to recognize the necessity for making changes in their treatment of the risk issues and public concerns which determine technological advance. Probably the most fundamental change is the need to structure truly collaborative relationships in which agencies, industry and the public share information and opinion and jointly resolve technological risk issues.[448]

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[447]M. Baram "Technology Assessment and Social Control," *Science*, v. 180 (May 4, 1973) 465.

[448]*See Communicating with the Public About Major Accident Hazards,* Conference Proceedings, Commission of the European Communities, D.G. XI and JRC Ispra Site (June 1989) for similar views expressed by Conference Director H. Otway, "Risk Communication is not just about the narrow issue of providing accurate technical information, it is about relationships. If we are to enjoy the full benefits of technology wisely selected and applied, new relationships amongst government, industry and society must be established. Communication is the foundation on which these relationships can be built." at 10. Also see, B. Wynne, "Observations of the Conference Rapporteur-General," (unpublished, June 11, 1989): "It is therefore inescapable that once started, risk communication has to face up to change and development in the social relationships between the industry and its community ... In any case, there is now no turning back. Public information, accountability and institutional transparency are a rising tide ... If the public is treated as incapable and immature, the truth of that prejudice is encouraged; and conversely, if they are treated as trustworthy and capable partners, the truth of that more positive faith is encouraged." at 11, 13.