3. That the disposal of VC containing liquid organic and solid wastes in open pits be prohibited if the VC content of said wastes exceeds 10 ppm by weight.

4. That the VC content of polymer leaving the stripping section of suspension, bulk and solution PVC plants be limited to 40 ppm by weight.

5. That the EPA VC standard, as modified by the above recommendations, be extended to apply to all chemical manufacturing facilities in Texas which emit VC into the atmosphere.

If the above recommendations are implemented, all VC emissions in the state will be subject to a single broad based regulation. The emissions of VC in Texas will be reduced to approximately 438 tons/year or about 3% of the 1974 total. Furthermore, the EPA's VC standard will be significantly improved in that public exposure to airborne VC will be restricted to a fixed maximum.

The costs to achieve the level of control recommended in this report have been estimated. The capital costs required are about $10,950,000. The annual operating costs that would be incurred total about $1,670,000.

Jim Tapp
March 14, 1977

2151

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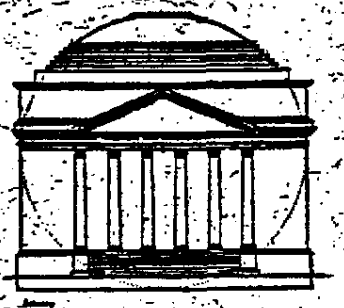

CPSC REGULATION OF CANCER RISKS IN CONSUMER PRODUCTS: 1972-1981

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CPSC REGULATION OF CANCER RISKS IN CONSUMER PRODUCTS: 1972-1981*

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After this article was set in type, Congress passed the Consumer Product Safety Amendments of 1981, which authorize the Consumer Product Safety Commission to operate through fiscal year 1983. The Amendments also effect important substantive and procedural changes in the laws that the Commission administers. These changes, which are summarized briefly at the end of the article, render some of Part II unreliable as a description of current CPSC statutory authority, but they do not undermine its historical accuracy. Furthermore, some of Congress's amendments are consistent with recommendations set forth in this article. In addition, and also after work on the article was completed, the Commission itself made changes in its internal structure that respond to criticisms advanced here and thus date some of the discussion at notes 30-39 infra. These changes, too, are discussed briefly in the epilogue.

THE U.S. Consumer Product Safety Commission (CPSC) administers several statutes designed to ensure that products

 This article is adapted from a chapter of a study on federal regulation of chemical carcinogens that Professor Merrill is preparing under the auspices of the Administrative Conference of the United States. The Conference has provided research support for the study but has neither reviewed nor adopted Professor Merrill's full report of this article.

** Daniel Caplin Professor of Law and Dean, University of Virginia School of Law. The author wishes to thank Mark Colley of the University of Virginia Law School Class of 1980, who assisted on the article from its inception, and Carolyn Flury of the Class of 1983, who helped prepare the manuscript for publication. Several individuals, including current or former employees of the Consumer Product Safety Commission, provided guidance at the research stage and commented on earlier drafts, and Peter Barton Hutt provided essential advice throughout. The help of these individuals is gratefully acknowledged, but they are not in any way responsible for errors in the final product.

marketed for consumer use do not cause injury or illness. The five-member Commission is authorized to disseminate information to the media and to consumers, and to prescribe labeling for, and ban the commercial distribution of, specific products and product formulations. On seven occasions in its nine-year history, the Commission has attempted to regulate products containing substances that it believed posed risks of human cancer.[1] As one of the four founding members of the Interagency Regulatory Liaison Group (IRLG),[2] the agency assumed a visible role in federal efforts to reduce human exposure to cancer-causing chemicals in the late 1970's. The Commission's role in regulation, however, has been subordinate and reactive; most of its actions against carcinogens have followed and relied upon regulatory initiatives by other agencies.

This article examines the CPSC's performance in regulating carcinogens. Part I describes the origins, primary functions, and jurisdiction of the Commission and outlines some of the problems it has faced. Part II reviews the statutes that provide the Commission authority to regulate carcinogens and identifies the important regulatory tools available to the agency. Part III analyzes the CPSC's chronic hazards program as a continuing agency activity, including its development of a system for identifying chemicals that merit regulation. Part IV examines the CPSC's various attempts to regulate chemicals posing risks of human cancer. These case studies identify significant and recurrent problems in the agency's approach to carcinogens. Part V summarizes the deficien-

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[1] As of June 30, 1981, the Commission had initiated regulatory actions against the following: aerosolized products containing vinyl chloride (1974), consumer products containing chlorofluorocarbon propellants (1977-1978), TRIS-treated children's garments (1977), patching compounds and emberizing materials containing asbestos (1977), consumer products containing benzene (1977), hairdryers containing asbestos (1979), and urea formaldehyde foam insulation (1981).

[2] The IRLG was established in August 1977, by the CPSC, the Food and Drug Administration, the Occupational Safety and Health Administration, and the Environmental Protection Agency. These agencies joined together with the announced purpose of sharing information and coordinating their regulation of toxic chemicals, thereby avoiding duplication and achieving consistency. Groups of officials from all four agencies were formed to work in eight areas of common concern, such as test standards, inspections, and enforcement. The purpose of these groups is to amass data on concepts and methodologies and to develop common criteria, but individual agencies retain the responsibility for making judgments concerning appropriate regulation. In 1979, the Food Safety and Quality Service of the Department of Agriculture joined the IRLG. 44 Fed. Reg. 39,858 (1979).

cies in the Commission's statutory authority, organization, internal procedures, and formal public processes.

I. The Institutional Context

A. Origins of the CPSC

The Consumer Product Safety Commission had its genesis in a 1970 report issued by the National Commission on Product Safety.[3] The National Commission determined that over twenty million Americans were injured at home each year as a result of incidents connected with consumer products. Of these, 110,000 were permanently disabled and 30,000 were killed. Moreover, the report concluded that no existing mechanisms—industry self-regulation, common law remedies, or current federal, state, and local regulatory efforts—were adequate to deal with the problem.[4] Remedial legislation, according to the report, was too often delayed until after the occurrence of a widely publicized tragedy.[5]

The National Commission recommended legislation to consolidate authority for consumer product safety within a new, independent federal agency. Although this proposal received bipartisan support in Congress,[6] there were major disagreements over the structure and jurisdiction of the proposed agency. Both the Senate and House versions of the bill would have created a new independent agency. The Senate bill would have transferred to it all functions then performed by the Food and Drug Administration (FDA);[7] the House version would have likewise established an independent agency to deal with consumer product hazards, but would have left FDA intact.[8] The Conference Committee compromise, which more closely resembled the House bill, reallocated many fewer authorities than originally suggested by the National

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[3] Congress authorized The National Commission on Product Safety to "conduct a comprehensive study and investigation of the scope and adequacy of measures now employed to protect consumers against unreasonable risk of injuries which may be caused by hazardous household products." S.J. Res. 33, Pub. L. No. 90-146, 81 Stat. 466, 467 (1967).

[4] U.S. Nat'l Comm'n on Prod. Safety, Final Report to the President and Congress 2-3, 89 (1970).

[5] *Id.*

[6] *See* S. Rep. No. 835, 92d Cong., 2d Sess. 22, *reprinted in* [1972] U.S. Code Cong. & Ad. News 4573, 4594; H.R. Rep. No. 1153, 92d Cong., 2d Sess. 1 (1972).

[7] S. Rep. No. 835, *supra* note 6, at 1, [1972] U.S. Code Cong. & Ad. News at 4574.

[8] H.R. Rep. No. 1153, *supra* note 6, at 24-25.

Commission.[9] Even so, the Consumer Product Safety Act of 1972 (CPS Act)[10] created and conferred upon the CPSC "unprecedented powers to deal with consumer product safety."[11]

The CPS Act was intended "to protect the public against unreasonable risks of injury associated with consumer products."[12] The Act gave the Commission two main responsibilities: (1) the collection and dissemination of information about injuries from consumer products,[13] and (2) the promulgation and enforcement of regulations designed to eliminate or reduce "unreasonable risks" presented by such products.[14]

B. The CPSC's Authority to Regulate Chronic Hazards

All of the product defects that excited congressional concern in 1972 caused, or threatened, immediate injury. For years, the CPSC remained uncertain, and reportedly divided, about whether its mandate extended to longer-term or chronic hazards such as chemically induced cancer. The Commission's current, broad view of its role developed gradually.

The contours of the CPSC's regulatory jurisdiction are established by its organic statute, the CPS Act, and by the Federal Hazardous Substances Act (FHSA).[15] The CPS Act empowers the Commission to regulate all unreasonable risks of injury presented by the large universe of products marketed for consumer use, with several enumerated exceptions.[16] The FHSA authorizes the Commission to regulate various hazards, such as toxicity, flammability, and danger of electric shock, associated with a less clearly defined

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[9] H.R. Rep. No. 1593, 92d Cong., 2d Sess. 36, *reprinted in* [1972] U.S. Code Cong. & Ad. News 4598, 4628-29.

[10] 15 U.S.C. §§ 2051-2082 (1976 & Supp. III 1979).

[11] BNA, ABC's of the Consumer Product Safety Act 3 (1973), *quoted in* J. Trauberman, Regulatory Approaches Under the Consumer Product Safety Act 2 (August 24, 1978) (unpublished paper) (copy on file with the Virginia Law Review Association).

[12] 15 U.S.C. § 2051(b)(1) (1976 & Supp. III 1979).

[13] *Id.* § 2054 (1976).

[14] *Id.* § 2056 (Supp. III 1979).

[15] *Id.* §§ 1261-1275 (1976 & Supp. III 1979). Enforcement of the FHSA was reassigned to the CPSC in 1972. *Id.* § 2079 (1976).

[16] Products under the jurisdiction of FDA, with the exception of medical devices, are excluded from the scope of the CPSC, as are specifically exempted products such as tobacco. *Id.* § 2052(a)(1).

universe of household products.[17] Although the jurisdictional language of the two statutes differs, for purposes of this article it may be assumed that the two laws cover essentially the same products.[18]

Neither the CPS Act nor the FHSA describes a readily identifiable category of products over which the agency has jurisdiction.[19] Together, however, the two statutes confer authority to regulate an enormous variety of products and activities. Both statutes authorize the CPSC to regulate technological hazards in the household, and the CPS Act gives the agency regulatory authority over hazards encountered in school and in recreational settings as well.[20] Furthermore, the Commission's jurisdiction continues to grow unpredictably because it expands with the introduction of new consumer products.[21]

The Commission's broad but nebulous mandate inhibited its regulation of chronic hazards for many years. Many CPSC officials doubted whether the agency should devote significant resources to regulation of long-term hazards.[22] This view may in part have reflected a belief that few consumer products were likely to present such risks. In addition, there was concern that the agency lacked the technical capability to evaluate chronic hazards. Finally, it was argued that regulation of chronic hazards lay beyond the agency's central responsibility of regulating products capable of causing acute injuries.[23]

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[17] *Id.* § 1261(f)-(m).

[18] This is confirmed both by the agency's use of both statutes to regulate carcinogens and by its recognition that the FHSA could apply to hazards it has regulated under the CPS Act. *See* notes 567-71 *infra* and accompanying text.

[19] Nor does either statute prescribe any product licensure, as do the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1976), which establishes procedures for the registration of pesticides, and the Food Additives Amendment, 21 U.S.C. § 348 (1976 & Supp. III 1979), to the Federal Food, Drug, and Cosmetic Act, (FD&C Act), *id.* §§ 301-392, which simultaneously generates and defines the class of products within the agency's jurisdiction.

[20] 15 U.S.C. § 1261(f)-(m) (1976 & Supp. III 1979); *id.* § 348.

[21] *See, e.g.*, Cellulose Insulation, 16 C.F.R. § 1404 (1980); Electric Toys, 16 C.F.R. § 1505 (1980); [1979] U.S. CONSUMER PROD. SAFETY COMM'N ANN. REP. (pt. 2), app. L, at 129 (listing products regulated by the CPSC).

[22] Interview with Janne Gallagher, Assistant to Commissioner R. David Pittle, in Washington, D.C. (August 14, 1979) [hereinafter cited as Gallagher Interview] (copy of notes from interview on file with the Virginia Law Review Association).

[23] *Id.*

The CPSC's first attempts to regulate carcinogens, which were directed at vinyl chloride, asbestos, and chlorofluorocarbons, did not represent either a redirection of its mission or a major expenditure of resources. In attacking vinyl chloride and asbestos, the agency relied almost exclusively on evidence already assembled and evaluated by other agencies.[24] Similarly, the joint actions of the Environmental Protection Agency (EPA), FDA, and the CPSC against chlorofluorocarbon propellants relied on experimental and theoretical work conducted by nongovernment researchers, which was confirmed by the National Academy of Sciences and an interagency task force.[25] But the Commission's participation in this successful, coordinated regulatory effort reportedly helped convince internal skeptics that the agency should give greater emphasis to chronic health hazards.[26]

More recently, the CPSC has made clear its conviction that regulation of long-term hazards comports with its historic mission. In 1978, the agency published a "cancer policy" describing the scientific premises that would guide its evaluation of substances posing a risk of cancer.[27] The agency has allocated a substantial portion of its current budget to chronic hazards regulation. In 1979, it employed a new Deputy Associate Executive Director (DAED) for Health Sciences, who was experienced in toxic chemical control, and it created more positions for scientists trained in toxicology, pharmacology, and other disciplines needed to evaluate potential carcinogens.[28] The five proceedings the agency has initiated to reg-

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[24] *See* text accompanying notes 268 & 385 *infra*.

[25] *See* text accompanying notes 310-12 *infra*.

[26] Gallagher Interview, *supra* note 22.

[27] *See* notes 182-231 *infra* and accompanying text.

[28] This commitment may be in question, however, as indeed may the Commission's continued existence as an agency. The CPSC's proposed budget for fiscal year 1982 is 30% less than the agency's original "current operating level" request. The decrease was demanded by the Office of Management and Budget. The projected total is $32,983,000, of which the chronic hazards program would receive $2,428,000. This represents only 7.4% of the agency's budget (up from 6.8% in fiscal year 1981), even though the CPSC considers the program of major importance. Agency spokesmen assert that work on several identified health hazards—perchloroethylene, benzidine dyes, and asbestos—would have to be curtailed under this allocation, as would the Commission's participation in IRLG activities. *See, e.g.*, [1981] 4 CHEM. REG. REP. (BNA) 1621-22; Agency Talk Sheet: "Impact of the Proposed Budget Cuts on the Consumer Product Safety Commission" (1981) (copy on file with the Virginia Law Review Association). For an outline of the Commission's plans before the contraction of its budget, see *Hearings before the Consumer Subcomm. of the Senate*

ulate carcinogens since 1977, its internal review of suspected carcinogens (designed to develop priorities for regulatory action), and its active participation in the IRLG provide further evidence of the Commission's commitment to regulating chronic hazards.

Whether the agency is capable of playing an important role in chronic hazards regulation remains to be seen, however. The unpredictable dimensions of the Commission's jurisdiction have impeded the creation of an efficient organization and a responsive decisionmaking process. Furthermore, the agency's large potential caseload and small budget have reinforced its predominantly reactive posture; it responds primarily to hazards brought to its attention by outside parties and, in the case of most carcinogens, ones that have been addressed previously by other agencies.

C. Structure and Administration of the CPSC

A general familiarity with the CPSC's structure will aid in evaluating its performance in regulating toxic chemicals. The agency consists of five Commissioners, who are appointed by the President with the concurrence of the Senate for fixed terms of seven years.[19] As a multi-member agency, the CPSC is subject to the Government in the Sunshine Act.[20] The advance notice and open meeting requirements of this statute, coupled with the agency's historic commitment to a liberal disclosure policy under the Freedom of Information Act,[21] have often forced the Commissioners to discuss regulatory strategy in public. The Sunshine Act requirements likewise have impeded communications between the Com-

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Comm. on Commerce, Science & Transportation, 97th Cong., 1st Sess. (Apr. 3, 1981) (statement of Peter W. Preuss, Ph.D., Assoc. Exec. Director for Health Sciences, CPSC).

[19] 15 U.S.C. § 2053(a), (b)(1) (1976 & Supp. III 1979). As an independent regulatory commission, the CPSC theoretically is less vulnerable to presidential control than are most federal regulatory agencies. For example, the President may replace Commissioners only when their terms expire or they resign, or for neglect of duty or malfeasance in office. *Id.* § 2053(a). Both President Carter and President Reagan have refrained from testing the limits of direct presidential oversight of agencies outside the Executive Branch, but the extent of these agencies' legal immunity from presidential oversight remains a matter of dispute.

[20] 5 U.S.C. § 552b (1976). The Sunshine Act applies to any agency "headed by a collegial body." *Id.* § 552b(a)(1).

[21] *See* 16 C.F.R. § 1015 (1980). The regulation announces that "[t]he Commission's policy with respect to requests for records is that disclosure is the rule and withholding is the exception." *Id.* § 1015.1(b). *See generally* Freedom of Information Act, 5 U.S.C. § 552 (1976 & Supp. III 1979).

missioners and the agency's technical staff.[22]

Sandwiched between the Commissioners and the agency's working staff are the two offices that have primary responsibility for the development of regulatory actions. The Office of the Executive Director manages most of the agency's staff. Its personnel are divided into six function- or expertise-oriented "directorates."[23] The Directorate for Engineering and Sciences, which employs most of the Commission's biological scientists, has two components. The science component works under the direction of a DAED for Health Sciences and consists of approximately fifty employees, fewer than half of whom are trained scientists. This group provides the technical support for the Commission's internal evaluation of toxicological and epidemiological studies and assessment of risks. At the time of this study, however, the DAED for Health Sciences did not have formal responsibility for directing the evaluation of individual chemicals or for preparing documents supporting regulatory actions. That authority then lay with the Commission's Office of Program Management (OPM). On the agency's organization chart, the OPM is parallel to the Executive Director, although the OPM apparently reports to the Commissioners through the Executive Director. Of the thirty professionals who compose the OPM, few have technical training. These professionals are responsible for defining the work necessary to outline regulatory options for the Commissioners, for developing project schedules, and for coordinating the work of technical experts made available by the several directorates.

The OPM consists of eight sections, each of which has responsibility for a category of product hazards.[24] On each project, the Pro-

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[22] Information concerning the CPSC's internal organization and operations came from interviews with Peter W. Preuss, Ph.D., Associate Executive Director for Engineering and Science, in Washington, D.C. (August 3, 1979) [hereinafter cited as Preuss Interview]; Richard Heller, Assistant to CPSC Chairman Susan King, in Washington, D.C. (August 3, 1979) [hereinafter cited as Heller Interview]; and Rory Fausett, Project Manager in the CPSC Chronic Hazards Program, in Washington, D.C. (August 23, 1979) [hereinafter cited as Fausett Interview] (copy of notes from interviews on file with the Virginia Law Review Association).

[23] The Directorate for Hazard Identification, for example, is responsible for identifying materials used in consumer products, assessing the prevalence, level, and manner of their use, assessing the number of injuries potentially attributable to them, and providing critical information about economic effects of potential regulatory actions.

[24] Coordination of staff work on a proposal to consider regulating a potentially carcinogenic chemical, for example, historically has been performed by the Program Manager for

gram Manager or an assistant assumes the role of "team leader" to outline, schedule, and coordinate the work of the specialists assigned by the various directorates. The team's product—typically a "briefing" or "action" memorandum—must be approved by all of the Associate Executive Directors (AEDs) before it is submitted to the Commissioners. Until recently, the CPSC staff assumed that team members would keep the individual AEDs abreast of the work being done on individual projects. Accordingly, it was expected that when the team completed its work, the AEDs would approve it routinely. There was no system for careful, senior-level review after the team assembled the document for the Commissioners. The problems resulting from this lack of review were aggravated by the agency's practice of making the staff's documents public at the same time they were forwarded to the Commission's Secretary. In an attempt to combat these problems, several AEDs and the General Counsel have begun meeting informally to review these documents before they are sent to the Commissioners and released to the public.

Three features of the Commission's structure and operations should be noted. First, the Commission is not organized either by product lines or by the kinds of activities it attempts to regulate (*e.g.*, foods, pesticides, water pollution).[35] Furthermore, the staff as a whole is not structured according to the kinds of hazards about which the agency is concerned. When the Project Manager for Chronic Hazards was responsible for coordinating work on regulatory actions dealing with carcinogens, most of the personnel involved were assigned temporarily by other components of the agency. This arrangement weakened continuity in staffing. Moreover, the person responsible for scheduling staff work was not a regular supervisor of the individuals who were responsible for doing the work. This "matrix" organization may have afforded flexibility in staffing individual actions, but it also impeded program continuity and inhibited the development within the agency of the technical expertise required to identify and evaluate toxic chemicals.[36]

Chronic Hazards.

[35] In this respect, the Commission differs from EPA and FDA.

[36] Interview with Andrew S. Krulwich, CPSC General Counsel, in Washington, D.C. (October 1979) [hereinafter cited as Krulwich Interview]; Heller Interview, *supra* note 32;

Second, the separation of personnel possessing substantive expertise from those performing regulatory management functions, coupled with the absence of regular opportunities for discussion between the Commissioners and the staff, has often produced weak and incomplete documents. The most common problem has been failure to consider the full range of pertinent scientific issues or to explore all regulatory options. The intermittent character of communications between the staff and the Commissioners has often delayed identification of these deficiencies.[37]

Finally, the staff members who determine which issues to raise for agency consideration are remote from those ultimately responsible for regulatory decisions, the Commissioners. Once a petition for regulatory action is logged by the Secretary and its filing status is confirmed by the Office of General Counsel, it is sent directly to the OPM for the preparation of a briefing package for the Commissioners. The Commissioners may not actually see the petitions, and often they do not discuss them until near the end of the 120-day period prescribed by statute for a response to a petition.[38] This delay makes it difficult for the Commissioners to identify alternatives not considered by the staff; when a new issue arises during the Commissioners' review, the agency usually must delay action until the matter is investigated.[39] Thus, the Commissioners generally have been confined to the framework outlined by the staff.

D. Special Problems of the CPSC

The CPSC has been slow in determining its proper role in the regulation of chronic hazards and clumsy in implementing actions. The Commission's actions against TRIS-treated childrens' garments and vinyl chloride were invalidated for violations of statutory procedural requirements.[40] Its published cancer policy was overturned on the ground that it failed to comply with the Admin-

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Preuss Interview, *supra* note 32. *See* notes 349-52 *infra* and accompanying text.

[37] Krulwich Interview, *supra* note 36; Preuss Interview, *supra* note 32.

[38] Krulwich Interview, *supra* note 36.

[39] *Id.*

[40] *See* notes 298-300 *infra* and accompanying text (vinyl chloride discussion); notes 368-74 *infra* and accompanying text (TRIS discussion). The agency escaped challenge to its regulation of hairdryers containing asbestos because the prospect of adverse publicity probably influenced manufacturers and retailers not to insist upon the procedural safeguards the CPS Act affords.

istrative Procedure Act (APA).[41] In addition, the agency has never articulated criteria for selecting among the remedies that its two basic statutes provide.[42] It was slow to establish a system for identifying consumer products that present a risk of cancer, although in the last two years it has attempted to develop such a program. The agency's miscalculations, however, have not ultimately impeded its primary objective of eliminating targeted materials from consumer products; none of the products that the agency attempted to regulate before 1981 is currently being marketed for consumer use. This is true even though in three instances the Commission never actually banned the substances.[43] There are several explanations for the Commission's "success" in the face of serious obstacles.

1. Consumer Sensitivity

Many products over which the CPSC has jurisdiction enjoy wide recognition among consumers. Although most consumer products are not used in as intimate a fashion as foods, drugs, and cosmetics, they nonetheless play prominent roles in the lives of many individuals. For example, most members of households with hairdryers are aware of their daily use, and many users handle them two or even three times a day. Consumers are similarly conscious of the use of many aerosolized products. Although not all of the products

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[41] Dow Chem., USA v. CPSC, 459 F. Supp. 378, 383 (W.D. La. 1978).

[42] Section 30(d) of the CPS Act, which governs the CPSC's choice between using the CPS Act or the FHSA, provides:

> (d) Regulation by Commission of consumer products in accordance with other provisions of law.
>
> A risk of injury which is associated with a consumer product and which could be eliminated or reduced to a sufficient extent by action under the Federal Hazardous Substances Act [15 U.S.C. 1261 et seq.], the Poison Prevention Packaging Act of 1970 [15 U.S.C. 1471 et seq.], or the Flammable Fabrics Act [15 U.S.C. 1191 et seq.] may be regulated under this chapter only if the Commission by rule finds that it is in the public interest to regulate such risk of injury under this chapter. Such a rule shall identify the risk of injury proposed to be regulated under this chapter and shall be promulgated in accordance with section 553 of title 5; except that the period to be provided by the Commission pursuant to subsection (c) of such section for the submission of data, views, and arguments respecting the rule shall not exceed thirty days from the date of publication pursuant to subsection (b) of such section of a notice respecting the rule.

15 U.S.C. § 2079(d) (1976).

[43] The Commission never issued formal bans on chlorofluorocarbon propellants, benzene, and hairdryers containing asbestos.

within the Commission's jurisdiction are as familiar to consumers as these examples,[44] most are more readily recognized than the substances regulated by other agencies. Furthermore, consumer product hazards often involve convenience items and luxuries, which buyers may dispense with quickly in response to reports of a cancer risk.

Awareness of this potential market volatility influences the CPSC's performance in two ways. First, it sometimes enables the agency to "ban" a product without resorting to formal regulatory proceedings.[45] Manufacturers often have been willing to accede to the agency's demands rather than endure the public attention that would accompany a formal CPSC action. Second, the CPSC's concern about consumer overreaction to publicity about potential product hazards may inhibit it from taking initiatives in close cases.

2. *Uncertainty of Exposure*

The variety of human exposures to consumer products impedes the CPSC's efforts to assess the risks associated with these products. The agency must ascertain the amount of carcinogenic material present in each product, its form, whether and how it is shielded from release, and the frequency and duration of the product's use. The agency also must consider whether exposure varies with the age and design of the product. These questions usually can be answered, but the research necessary to obtain answers typically requires major expenditures. Moreover, tests performed on one kind of product may yield little information that is helpful in assessing human exposure to another product.[46]

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[44] For instance, wallboard patching compounds are used less frequently, by fewer consumers, and probably without much sense of attachment. Nonetheless, a higher degree of consumer awareness characterizes the products within the CPSC's jurisdiction than, for example, the air and water pollutants and pesticides that compose EPA's caseload.

[45] This power of publicity is not unique to the CPSC. For years, FDA has been aware of the regulatory impact of its public warnings and other efforts to disseminate information. *See* R. Merrill & P. Hutt, Food and Drug Law: Cases and Materials 793-804 (1980).

[46] In this respect, FDA may have some advantages over the CPSC. Both agencies often must rely on scanty evidence in evaluating the toxicity of a chemical. But in assessing human exposure to a chemical in food, FDA usually can proceed more efficiently. The same sample of food often can be used to measure concentrations of several contaminants, and information about dietary consumption of one kind of food typically is obtained through surveys that also yield data about the consumption of other foods.

The CPSC is responsible for a diverse universe of products, and the kinds of exposures to potential toxins are correspondingly diverse. Individuals wear, breathe, handle, sit on, swallow, fondle, and cook with consumer products.[47] Furthermore, the forms of materials in consumer products vary. A material may or may not be absorbable through the skin or able to be inhaled, depending on how it is incorporated in a product.

The difficulty of determining levels of exposure to chemicals in consumer products can slow agency decisionmaking, although the CPSC has sometimes initiated regulatory action before obtaining detailed information about human exposure.[48] The problem of measuring exposure also limits the Commission's ability to assess the risks posed by the materials it regulates. Even if the agency can determine the carcinogenic potency of a chemical, it cannot quantify the associated risk of cancer without also learning the levels at which humans are exposed. This difficulty in assessing risks may be one explanation for the Commission's reluctance, until recently, to perform, or rely on, quantitative risk assessments.[49]

3. The Petition Process

Section 10 of the CPS Act permits any interested member of the public to petition the Commission to initiate regulatory action against a product that presents an unreasonable risk of injury or

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[47] The CPS Act's definition of "consumer product" has been construed broadly. An individual may even *ride* in a consumer product. *See, e.g., CPSC v. Chance Mfg. Co.*, 441 F. Supp. 228 (D.D.C. 1977), which holds that an amusement park ride is a consumer product because it fulfills the two statutory criteria, which require a product to be "produced or distributed (i) . . . for sale to a consumer for use in . . . [a] residence, a school, in recreation, or otherwise . . . or (ii) for the personal use, consumption or enjoyment of a consumer." *Id.* at 230 (quoting 15 U.S.C. § 2052(a)(1) (1976)). The forms of potential human uptake are limited biologically, but they are still more varied than those with which other agencies must deal. Moreover, the CPSC's small size has prevented the specialization possible in programs at FDA and EPA, which may deal exclusively with one kind of hazard or form of exposure.

[48] One example is asbestos in hairdryers, discussed in notes 473-79 *infra* and accompanying text.

[49] *Compare* 42 Fed. Reg. 38,783 (1977) (proposal to ban asbestos) *with* 45 Fed. Reg. 39,434 (1980) (to be codified in 16 C.F.R. § 1405) (urea formaldehyde proposal). *See* notes 494-507 *infra* and accompanying text (discussing the CPSC's actions against asbestos); notes 508-32 *infra* and accompanying text (discussing the CPSC's actions against urea formaldehyde).

illness.[50] The statute requires the agency to respond to petitions within 120 days,[51] and permits a disappointed or unanswered petitioner to seek judicial review of the Commission's action or inaction.[52] Although the Commission usually misses the statutory deadline, it gives petitions priority over projects generated internally and makes a serious effort to respond with reasonable promptness.[53]

The petition mechanism appears to have played an important role in the Commission's efforts to regulate carcinogens. With one exception, all of the agency's proceedings to control consumer exposure to carcinogens have followed filings of public petitions.[54] CPSC officials insist that the petitions were not the primary impetus for any of the agency's actions, asserting that its staff was evaluating each of the substances when the petitions were filed.[55] Most of the petitions relied on published scientific reports and actions by other agencies, either of which probably would have prompted the Commission to act in any case. But petitions clearly have influenced the timing and, in some instances, the content of the Commission's actions against carcinogens. This public petition process reinforces the Commission's reactive posture by making the agency's regulatory agenda dependent on demands for action by outside groups.

II. The CPSC's Governing Statutes

The CPSC is responsible for administering five federal safety laws. The agency's principal statute is the CPS Act,[56] which created the agency and transferred to it the authority[57] for administering four other statutes: the FHSA,[58] the Poison Prevention Packaging Act of 1970,[59] the Flammable Fabrics Act,[60] and the Re-

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[50] 15 U.S.C. § 2059(a) (1976).
[51] *Id.* § 2059(d).
[52] *Id.* § 2059(e).
[53] Preuss Interview, *supra* note 32.
[54] *See* note 544 *infra* and accompanying text.
[55] Gallagher Interview, *supra* note 22; Heller Interview, *supra* note 32.
[56] 15 U.S.C. §§ 2051-2082 (1976 & Supp. III 1979).
[57] The transfers are effected by *id.* § 2079 (1976).
[58] *Id.* §§ 1261-1274 (1976 & Supp. III 1979).
[59] *Id.* §§ 1471-1476.
[60] *Id.* §§ 1191-1204.

frigerator Safety Act.[81] The Commission has relied on both the CPS Act and the FHSA to regulate carcinogens and has displayed versatility in choosing among the remedies provided by these two laws, invoking four different remedies in the seven proceedings it has initiated.

A. The Consumer Product Safety Act

1. Coverage of the Act

The CPS Act is the Commission's organic statute and has largely displaced the FHSA as its primary legal basis for regulating carcinogens. The Act gives the Commission broad powers to regulate consumer products that pose unreasonable risks of injury or illness.[82] It defines "consumer product" as follows:

> [a]ny article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but such term does not include—
>
> (A) any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer . . . .[83]

This definition excludes several classes of products regulated by other agencies.[84] In addition, the statute precludes the CPSC from regulating any risk of injury associated with a substance that is, or is contained by, a consumer product "if such risk could be eliminated or reduced to a sufficient extent by actions taken under the Occupational Safety and Health Act of 1970 (OSH Act)."[85] Neither the CPS Act's limitation of the Commission's jurisdiction to "consumer products"[86] nor its requirement that the OSH Act be found

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[81] *Id.* §§ 1211-1214 (1976).

[82] *Id.* § 2051 (1976 & Supp. III 1979).

[83] *Id.* § 2052(a)(1), (a)(1)(A) (1976).

[84] For example, foods and drugs regulated by FDA, and pesticides regulated by EPA, are excluded from the coverage of the CPS Act. *Id.* § 2052(a)(1)(D), (H), (I).

[85] *Id.* § 2080 (1976 & Supp. III 1979) (citation omitted).

[86] Fausett Interview, *supra* note 32; Interview with David Melnick, Office of the General Counsel, in Washington, D.C. (August 14, 1979) [hereinafter cited as Melnick Interview]

inadequate to deal with a risk, however, has seriously impeded the agency's regulation of any toxic chemical.[67]

2. *Product Safety Standards and Bans*

Section 7(a) of the CPS Act authorizes the CPSC to promulgate a consumer product safety standard whenever "reasonably necessary to prevent or reduce an unreasonable risk of injury" associated with a consumer product.[68] A product safety standard may prescribe requirements for product performance, composition, or design; it may specify warnings or instructions that must be supplied with a product; or it may combine both requirements.[69] If "no feasible consumer product safety standard . . . would adequately protect the public from the unreasonable risk of injury" posed by a consumer product, section 8 empowers the Commission to ban the product from commerce.[70] The finding necessary to invoke this authority may be made at the outset of proceedings to effect a ban, or it may be made during proceedings initially begun to establish a product safety standard, after further study convinces the agency that no feasible standard would prevent the risk posed by the product.

These two sections of the CPS Act theoretically provide the Commission quite different methods of regulating consumer products that pose an unreasonable risk of injury or illness. The agency may devise a standard to reduce human exposure to the dangerous substance, *e.g.*, by prescribing the formulation, use, or performance of a product, or it may ban the product from commercial distribution altogether.[71] When the risk from a product results from a

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(copy of notes from interview on file with the Virginia Law Review Association), revealed that the limitation of the Commission's jurisdiction to "consumer products" has sometimes occasioned or changed internal debate over the approach the agency should take.

[67] Doubts about the coverage of the CPS Act, *see* Melnick Interview, *supra* note 66, may have influenced the agency's choice between that statute and the FHSA as the basis for regulating products and materials.

[68] 15 U.S.C. § 2056(a)(1) (1976).

[69] *Id.* As noted earlier, *see* note 45 *supra* and accompanying text, manufacturers of consumer products may choose to avoid adverse consumer reaction by changing products before any regulation takes place. Thus, the threat of regulation may be as important as its occurrence. *See* notes 485-93 *infra* and accompanying text (discussing asbestos in hairdryers).

[70] 15 U.S.C. § 2057 (1976).

[71] For example, Safety Standards for Matchbooks, 16 C.F.R. § 1202 (1980), prescribes such features as "[t]he cover shall remain closed without external force," *id.* § 1202.4(b),

toxic constituent, however, the distinction between a safety standard and a product ban can be elusive.[73] In practice, the Commission rarely has banned a product genus or type; instead, it has usually banned only products made in a specific way or containing a specific material. For example, the agency banned only those caulking compounds that contained asbestos. A "safety standard" for caulking compounds listing permitted ingredients and excluding asbestos would have the same effect as the ban that the agency imposed.[74] Furthermore, both kinds of regulatory action result in the issuance of a "consumer product safety rule." In regulating potential carcinogens under sections 7 and 8 of the CPS Act, the Commission thus far has contemplated only the promulgation of product bans.[74]

3. *Rulemaking Procedures*

The CPSC follows the same administrative procedure for establishing a consumer product safety standard as for banning a product; both are variants of informal rulemaking. Section 9(a)(2) of the CPS Act specifies that proceedings to adopt a consumer product safety rule shall be conducted "pursuant to section 553 of Title 5 [of the APA], except that the Commission shall give interested persons an opportunity for oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions."[75] The Commission has succeeded in keeping these proceedings both informal and brief. The legislative-style hearings are conducted before the entire five-member Commission.[76] Witnesses

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and "no friction material shall be located on the inside of the cover," *id.* § 1202.4(c). An example of a ban under the CPS Act is Ban of Unstable Refuse Bins, 16 C.F.R. § 1301 (1980), which forbids marketing of refuse bins that fail to meet tests for stability enunciated in *id.* §§ 1301.6-.7. Such a ban may be difficult to differentiate from a standard because it proscribes only products with specific characteristics rather than banning all products of a class or type.

[73] For a discussion of the elusive distinction, see Scalia & Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 U.C.L.A. L. Rev. 899 (1973).

[74] This is also true with respect to nontoxic consumer products. *See* Ban of Unstable Refuse Bins, 16 C.F.R. § 1301 (1980). Presumably, a performance standard could specify a maximum permissible level of risk of chronic disease from exposure to a product. The Commission, however, has not openly considered this possibility for any carcinogen.

[75] This may be because such action is simply faster in light of the statutory alternatives and the substances involved. Melnick Interview, *supra* note 66.

[76] 15 U.S.C. § 2058(a)(2) (1976 & Supp. III 1979).

[77] Gallagher Interview, *supra* note 22.

present prepared statements and may then be questioned by the individual Commissioners, though the interrogation is not ordinarily vigorous. Occasionally, another participant may be allowed to question a witness, but no opportunity for traditional cross-examination is provided. Hearings rarely last more than two days.[77]

Section 7 of the CPS Act[78] prescribes a unique procedure for the development of proposed consumer product safety standards. Once the Commission publishes its determination that a product safety standard is necessary, consumer or industry groups and other government agencies may submit an existing standard or offer to develop a new standard for agency consideration.[79] Congress included this "offeror provision" in the statute because it believed that the CPSC would require the assistance of outside experts to develop requirements for the enormous range of products within its jurisdiction.[80]

4. Petitions

Section 10 of the CPS Act[81] explicitly invites members of the public to initiate actions against unsafe consumer products by petitioning the Commission to establish a consumer product safety rule. If the agency fails to act on such a petition within 120 days, or if it denies the petition, the petitioner may sue in federal district court to compel the agency to initiate the action requested.[82] A petitioner in such a suit must prove by a preponderance of the evidence that the consumer product presents an "unreasonable

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[77] The Commission completed its entire rulemaking process for banning asbestos in patching compounds and emberizing materials within approximately six months. *See* notes 384-430 *infra* and accompanying text.

[78] 15 U.S.C. § 2056 (1976 & Supp. III 1979).

[79] *Id.* § 2056(b), (d).

[80] H.R. Rep. No. 1153, *supra* note 6, at 33. As originally enacted, the statute required the Commission ordinarily to accept any reasonable offer by an outside party to develop a proposed standard. The complications caused by this arrangement, primarily delay, prompted Congress to amend the CPS Act to permit the agency greater discretion in developing proposed standards internally. *See* Act of Nov. 10, 1978, Pub. L. No. 95-631, 92 Stat. 3742; H.R. Rep. No. 1184, 95th Cong., 2d Sess. 5-6, *reprinted in* [1978] U.S. Code Cong. & Ad. News 9434, 9434-35. In either form, however, this "offeror provision" has never impeded CPSC regulation of chronic hazards. To date, no Commission action against a carcinogen has involved the setting of product safety standards, so the offeror provisions of § 7 have never been triggered.

[81] 15 U.S.C. § 2059(a) (1976).

[82] *Id.* § 2059(a).

risk" and that the Commission's failure to act "unreasonably exposes . . . consumers to a risk of injury."[82] The court may compel the agency to commence rulemaking; it may not prescribe a rule or require the Commission to do so.

5. Criteria for Banning

Before the Commission may ban consumer products containing a hazardous substance, it must find that "(1) a consumer product is being, or will be, distributed in commerce and such consumer product presents an unreasonable risk of injury; and (2) no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury associated with such product."[84] The Act explicitly states that "risk of injury" includes "the risk of death, personal injury, or serious or frequent illness,"[85] but it does not define "unreasonable risk."[86] Nor does the Act prescribe the analysis the Commission should perform in determining whether the risk posed by a product is "unreasonable." When the agency has relied on section 8 to regulate a carcinogen, it appears to have considered both risks and offsetting benefits.[87] But agency representatives insist that the Act does not require a formal balancing of risks and benefits, and its actions indicate that no such analysis is done.[88] Section 9(c) of the Act, which requires the Commission to make findings on a series of pertinent factual issues and to incorporate these findings in its rule, provides:

> (1) Prior to promulgating a consumer product safety rule, the

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[82] *Id.*

[84] *Id.* § 2057.

[85] *Id.* § 2052(a)(3).

[86] The Senate-passed version of the legislation that became the CPS Act contained a definition of "unreasonable risk," but this provision was eliminated in conference without explanation. *See* H.R. REP. No. 1593, *supra* note 9, at 42-43, [1972] U.S. CODE CONG. & AD. NEWS at 4634-35. The House had already decided, in its version of the bill, not to define "unreasonable risk." The committee report explained that "[p]rotection against unreasonable risks is central to many federal and state safety statutes, and the courts have had broad experience in interpreting the term's meaning and application." H.R. REP. No. 1153, *supra* note 6, at 33 (1972).

[87] *See* notes 392-408 *infra* and accompanying text (patching compounds and emberizing compounds containing asbestos action); notes 441-49 *infra* and accompanying text (benzene action); notes 522-29 *infra* and accompanying text (urea formaldehyde action).

[88] *See, e.g.*, Heller Interview, *supra* note 32.

> Commission shall consider, and shall make appropriate findings for inclusion in such rule with respect to—
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> (A) the degree and nature of the risk of injury the rule is designed to eliminate or reduce;
>
> (B) the approximate number of consumer products, or types of classes thereof, subject to such rule;
>
> (C) the need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need; and
>
> (D) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety.
>
> (2) The Commission shall not promulgate a consumer product safety rule unless it finds (and includes such finding in the rule)—
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> (A) that the rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product;
>
> (B) that the promulgation of the rule is in the public interest; and
>
> (C) in the case of a rule declaring the product a banned hazardous product, that no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury associated with such products.[89]

The statute does not purport to assign specific decisional weight to these elements, and the legislative history is unhelpful. The Senate Report indicates that the Commission is to balance the probability that the risk posed by a consumer product will result in harm and the gravity of such harm against the effect of reducing or eliminating the harm on the product's utility, cost, and availability to consumers.[90] The House Report states that a complete cost-benefit analysis is not required before the Commission promulgates a safety standard or ban.[91] The report then asserts, however, that

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[89] 15 U.S.C. § 2058(c) (1976).

[90] H.R. Rep. No. 1153, *supra* note 6, at 33.

[91] *Id.* In 1976, the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce produced a report on "regulatory reform," which included a chapter on the CPSC. The report concludes that formal cost-benefit analysis is not required under the CPS Act. Subcomm. on Oversight and Investigations, House Comm. on Interstate and Foreign Commerce, 94th Cong., 2d Sess., Federal Regulation and Regulatory Reform 193 (Subcomm. Print 1976) [hereinafter cited as Moss Report].

"no standard would be expected to impose added costs or inconvenience to the consumer unless there is reasonable assurance that the frequency or severity of injuries or illnesses will be reduced."[92] These delphic instructions have left the agency a wide range of discretion.

The case law provides clearer guidance. The central case — the first to consider the CPSC's authority to prescribe consumer product safety rules under section 8 — is *Aqua Slide 'N' Dive Corp. v. CPSC*,[93] decided by the United States Court of Appeals for the Fifth Circuit in 1978. *Aqua Slide* involved a challenge to the Commission's standard for swimming pool slides. The court overturned the standard on the ground that the agency had failed to show, by substantial evidence, that it would curtail admittedly severe but infrequent swimming pool accidents.[94] The majority opinion, written by Judge Roney, focuses on the language in section 9(c)(2) of the Act, which requires the agency to find that a consumer product safety rule is "reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with" a product.[95] The opinion explains: "The Commission does not have to conduct an elaborate cost-benefit analysis . . . . It does, however, have to shoulder the burden of examining the relevant factors and producing substantial evidence to support its conclusion that they weigh in favor of the standard."[96] With respect to the mandated warning signs, the court contended that the "crucial question . . . is whether the benefit has a reasonable relationship to the disadvantages the sign requirements pose."[97] The court also suggested that the degree of consumer awareness about the products' risk and the extent to which that risk may be avoided are important considerations.[98]

Judge Roney's opinion recognizes that the CPS Act itself provides the Commission little guidance in applying the "unreasonable risk" and "reasonably necessary" criteria, which it characterizes as interrelated.[99] Relying on the legislative history, the opinion

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[92] H.R. Rep. No. 1153, *supra* note 6, at 33.
[93] 569 F.2d 831 (5th Cir. 1978).
[94] *Id.* at 844.
[95] *Id.* at 838-44.
[96] *Id.* at 840.
[97] *Id.* at 842.
[98] *Id.* at 839, quoted at text accompanying note 101 *infra*.
[99] *Id.*

states: "The necessity for the standard depends upon the nature of the risk, and the reasonableness of the risk is a function of the burden a standard would impose on a user of the product."[100] Judge Roney went on to describe in general terms the kind of analysis the agency is expected to perform:

> [T]he legislative history specifies the costs to consumers that are to be considered: increases in price, decreased availability of a product, and also reductions in product usefulness. . . . Implicit in this analysis is an understanding that the regulation is a feasible method of reducing the risk. . . . Also, an important predicate to Commission action is that consumers be unaware of either the severity, frequency, or ways of avoiding the risk. If consumers have accurate information, and still choose to incur the risk then their judgment may well be reasonable . . . .[101]

As noted above, the majority opinion in *Aqua Slide* disclaims any requirement that the Commission perform a cost-benefit analysis of proposed product safety rules. But Judge Roney did make clear that the agency must weigh the different consequences of its actions to determine "whether the benefit has a reasonable relationship to the disadvantages . . . ."[102] Judge Wisdom's concurring opinion is more explicit:

> [T]he Commission is required to do more than determine whether there are any benefits to its regulation. Congress required it to consider the economic costs. In this case those costs are the effects on the manufacturers, and the effects on consumers who will be frightened away from purchasing pool slides. The Commission's determination that benefits exist is not the only conclusion that must be supported by substantial evidence. Most importantly, the balance the Commission draws between the benefits and the costs must have such support. This is the argument pressed by Aqua Slide. The benefits from these signs have no reasonable relationship to the costs they will impose. . . . I agree that the cost analysis done by the Commission is not entitled to consideration. These signs are not so innocuous as to be presumed "inexpensive." With no evidence on the cost side of the ledger, the Commission's cost-benefit analysis is without substantial evidence for support.[103]

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[100] *Id.*
[101] *Id.*
[102] *Id.* at 842.
[103] *Id.* at 845 (Wisdom, J., concurring).

Aqua Slide would have proved influential on its own terms, but it has gained weight by virtue of the Supreme Court's ruling on the Occupational Safety and Health Administration's (OSHA) occupational standard for benzene. In *Industrial Union Department, AFL-CIO v. American Petroleum Institute*,[104] the Supreme Court upheld another Fifth Circuit decision[105] — which had in turn relied on *Aqua Slide*[106] — and overturned OSHA's benzene standard on the grounds that the agency had failed to demonstrate either that the health risk at prevailing exposure levels was "significant" or that the costs of achieving the new standards bore a reasonable relationship to the benefits.[107] Although the Supreme Court declined to reach the cost-benefit issue,[108] its ruling, coupled with its implicit endorsement of *Aqua Slide*, has raised doubts about the CPSC's authority to regulate speculative risks under section 8.[109]

In the same year that *Aqua Slide* was decided, the CPSC received an equivocal boost from the United States Court of Appeals for the District of Columbia Circuit. In *ASG Industries, Inc. v. CPSC*,[110] the court upheld in substantial part a CPSC standard to ensure the safety of architectural glassing materials, but ordered a remand to permit the agency to consider the appropriateness of including wired glass within the standard.[111] Although Judge Leventhal expressed doubt about the wisdom of this choice, he acknowledged the possibility that it could be sustained even if it meant elimination of a type of product from the market: "[A]pplication of a safety rule is not dependent on technological advance; the sale of a hazardous article may be prohibited even if attainment of the required standard is not feasible because technology will not yield a safe product."[112] Judge Leventhal's opinion

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[104] 448 U.S. 607 (1980).

[105] American Petroleum Inst. v. OSHA, 581 F.2d 493 (5th Cir. 1978).

[106] *Id.* at 501-05.

[107] *Id.* at 510.

[108] 448 U.S. at 614-15.

[109] The Fifth Circuit overturned the CPSC swimming pool slide standard because it did not consider it an effective response to a risk that was severe but statistically remote. In regulating a carcinogen, it ordinarily should be easy for the CPSC to demonstrate that its remedy would avert the risk; showing that the risk is "significant" in quantitative terms or "unreasonable" in light of the costs of preventing it should be more difficult.

[110] 593 F.2d 1323 (D.C. Cir. 1979).

[111] *Id.* at 1337.

[112] *Id.* at 1333-34 (citation omitted).

concludes with the following general observations about the purpose of the CPS Act:

> One of the principal functions of CPSA is to promulgate safety rules that have the effect of compelling the internalization of these costs to the extent required to meet performance and other safety standards. Internalization of costs previously disregarded by manufacturers will likely result in a rise in cost and price, and may constrict or eliminate the demand for a particular product as consumers substitute products that offer the desired utility at the lowest price. Such an outcome would not be contrary to the intent of Congress so long as the agency has given reasoned consideration to all the pertinent factors and has made the requisite findings supported by substantial evidence. A severe economic impact on an industry, or on a significant segment of an industry, would be a material factor in appraising the reasonableness of a rule, but it cannot, in and of itself, be held to render a safety rule unreasonable.[113]

6. *Suit to Condemn an "Imminent Hazard"*

The CPS Act contains no provision allowing the Commission to suspend administratively the marketing of a hazardous product prior to the completion of proceedings to promulgate a safety standard or ban. Section 12 of the Act,[114] however, empowers the agency to initiate suit in federal district court seeking the seizure of "an imminently hazardous consumer product" or injunctive relief against a distributor. Such a suit may be accompanied by administrative proceedings to establish a product safety standard or ban.[115]

The CPSC has never invoked this emergency authority against a product containing a suspected carcinogen.[116] When the Commission has sought speedier relief than is possible through banning under section 8, it has resorted to other mechanisms available

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[113] *Id.* at 1337.

[114] 15 U.S.C. § 2061(a) (1976).

[115] *Id.* § 2061(c).

[116] On four occasions, the CPSC has attempted to persuade a court to declare a product an "imminent hazard" under § 12 of the CPS Act. One action has failed. *See* CPSC v. Anaconda Co., 593 F.2d 1314 (D.C. Cir. 1979) (rejecting the agency's action on the ground that the challenged electrical wiring was not a "consumer product"). The other three suits were settled without decision. *See, e.g.*, CPSC v. Advance Machine Co., Civ. No. 77-1323 (D.D.C. May 8, 1978); CPSC v. AK Elec. Corp., Civ. No. 74-1206 (D.D.C. Sept. 9, 1974).

under the CPS Act or the FHSA. It may seem anomalous to characterize as an "imminent hazard" a product that poses a risk of cancer that will eventuate, if ever, only many years after humans are exposed to it. But judicial opinions construing identical language in the Federal Insecticide, Fungicide, and Rodenticide Act suggest that section 12 would support a suit to restrict a chemical in consumer products if the evidence of carcinogenicity were strong and the potential for human intake apparent.[117] The Commission would have the burden of proving these facts by a preponderance of evidence[118] rather than enjoy the deference accorded administrative findings that would accompany a ban under section 8.[119]

7. Suit to Prevent a "Substantial Product Hazard"

Section 15 of the CPS Act authorizes the Commission to order a variety of remedial actions respecting any product that presents a "substantial product hazard."[120] Paragraph (a) of the section defines "substantial product hazard":

> (1) a failure to comply with an applicable consumer product safety rule which creates a substantial risk of injury to the public, or
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> (2) a product defect which (because of the pattern of defect, the

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[117] *See* Environmental Defense Fund, Inc. v. EPA, 510 F.2d 1292 (D.C. Cir. 1975) (construing § 6(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136d(c) (1976)); Environmental Defense Fund, Inc. v. EPA, 465 F.2d 528 (D.C. Cir. 1972) (same), both of which upheld EPA orders summarily suspending registration of pesticides shown through experiments to be carcinogenic in animals.

[118] In this sort of suit, where the agency is the plaintiff, the usual civil rules apply. The party bringing the suit has the burden of proving its allegations by a preponderance of evidence. The rationale for imposing this burden of proof, as explained in the Senate Report recommending passage of the CPS Act, is that "[a]gency action affecting interests in life and health should be subject to the most searching judicial examination. . . . [It] justifies a departure from the normal standard of review." S. REP. No. 335, *supra* note 6, at 15, [1972] U.S. CODE CONG. & AD. NEWS at 4587.

[119] Because the CPSC must bring an "imminent hazard" proceeding in court in the first instance, its findings are likely to receive less deference than on review of a standard or ban. In the former, the court will evaluate the evidence de novo. Where the agency has conducted rulemaking, its findings and conclusions will be reviewed under the more deferential "substantial evidence" standard. CPS Act, § 11(c), 15 U.S.C. § 2060(c) (1976).

[120] *Id.* § 2064. These actions may be taken only after an opportunity for an adjudicatory hearing has been afforded to interested parties in accordance with § 554 of the APA. *Id.* § 2065(f) (1976). For a comprehensive discussion of the CPSC's powers under — and use of — § 15 of the CPS Act, see Madden, *Consumer Product Safety Act Section 15 and Substantial Product Hazards*, 30 CATH. U.L. REV. 195 (1981).

> number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.[121]

This definition apparently focuses on the seriousness of the risk to consumers in terms either of the severity of the potential harm or of the number of consumers exposed.[122] To use this provision to regulate a product containing a carcinogen, the CPSC would have to characterize the hazard as resulting from a product "defect," because it has established no applicable safety standards. Despite the awkwardness of this language, the agency has used section 15 in one such case.

Section 15 affords the Commission a range of remedies to deal with a product presenting a "substantial hazard." The agency may require any manufacturer, distributor, or retailer that is a party to the proceeding to provide written notice of the defect to any other person in the distribution chain or "to every person to whom the person required to give notice knows such product was delivered or sold."[123] Furthermore, the Commission may order the manufacturer or any distributor or retailer to repair the defect in all products distributed, replace the product without cost to the consumer, or refund the consumer's purchase price.[124]

The CPSC has devised an informal enforcement system that ordinarily avoids formal public proceedings under section 15. The Commissioners, either explicitly or informally, customarily authorize the agency's compliance staff to invite the manufacturers or distributors of the investigated product to an informal conference. At that conference, the staff explains its preliminary conclusion that the product presents a "substantial hazard."[125] Because manufacturers and distributors of consumer products generally desire to avoid the adverse publicity associated with a formal charge that

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[121] *Id.* § 2064(a). The House Report adds little to this definition, stating only that "[t]his definition looks to the extent of the public exposure to the hazard. A few defective products normally will not provide a proper basis for compelling notification under this section." H.R. Rep. No. 1153, *supra* note 6, at 42.

[122] *See* H.R. Rep. No. 1153, *supra* note 6, at 42. By contrast, § 5 requires a finding that the risk of a product is unreasonable. 15 U.S.C. § 2057 (1976). *See also* 16 C.F.R. § 1115.4 (1981).

[123] 15 U.S.C. § 2064(c)(3) (1976).

[124] *Id.* § 2064(d).

[125] *See* 16 C.F.R. § 1115.20(a) (1980), which describes voluntary corrective action plans. Other descriptions were derived from interviews with CPSC staff members.

the product presents a "substantial hazard," a voluntary recall, typically accompanied by joint public announcement, usually follows such a conference.[126] In the rare case where invited firms decline to take corrective action voluntarily, the Commission authorizes issuance of a formal complaint, which may result in a formal evidentiary hearing.[127]

Section 15 is not always a practical option for the Commission. That authority is most effective when the suspect product is readily identified by consumers and when relatively few manufacturers are capable of effecting a recall. Furthermore, a remedial order under section 15 can be issued only against a company that is a party to the agency proceeding; this necessitates personal service of process and an opportunity to participate.[128]

Section 15 now also provides the Commission an interim remedy, which can be invoked pending resolution of any contested charges. Once the agency has initiated a formal proceeding for the issuance of a remedial order under section 15(d), it may apply to a district court for a preliminary injunction to restrain distribution of the product pending completion of the administrative process.[129] The injunction will issue if the agency can show that it has "reason to believe" the product "presents a substantial product hazard"[130] and if the customary criteria for the issuance of a civil preliminary injunction are met.[131] The Commission has never had occasion to seek such preliminary relief, because the informal threat of adverse publicity implied by the staff's recommendation that a product be considered a "substantial hazard" is the CPSC's real regulatory

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[126] The agency used this informal mechanism to stop the distribution of hairdryers containing asbestos. *See* notes 465-93 *infra* and accompanying text.

[127] *See* 16 C.F.R. § 1115.21 (1980), which describes compulsory corrective action plans. Section 15 mandates an opportunity for an evidentiary hearing before official remedial orders may be issued, 15 U.S.C. § 2064(f) (1976), but most parties prefer the informal enforcement system.

[128] Krulwich Interview, *supra* note 36. Section 15(f) of the CPS Act provides that such a remedial order "may be issued only after an opportunity for a hearing in accordance with section 554 of title 5, United States Code." 15 U.S.C. § 2064(f) (1976). Section 554 requires personal notice of the time, place, and nature of the hearing, as well as the legal authority for the proceeding and the matters of law and fact asserted. 5 U.S.C. § 554(b), (c) (1976 & Supp. III 1979).

[129] 15 U.S.C. § 2064(g)(1) (1976).

[130] *Id.*

[131] The federal amount in controversy requirement, 28 U.S.C. § 1331 (1976), however, is waived. 15 U.S.C. § 2064(g)(3) (1976 & Supp. III 1979).

weapon.

8. *Special and General Orders*

The Commission has authority to obtain formulation data and to demand the results of safety tests that manufacturers have conducted independently. Section 27 of the CPS Act authorizes the agency to "require, by special or general orders, any person to submit in writing such reports and answers to questions as the Commission may prescribe."[132] In addition, section 27(e) provides: "The Commission may by rule require any manufacturer of consumer products to provide to the Commission such performance and technical data related to performance and safety as may be required to carry out the purposes of this chapter . . . ."[133] Relying on section 27, the Commission has required a large number of manufacturers to disclose information about the quantitative formulations of their products. The agency has used this authority to discover the composition of products whose use involves significant human exposure, as well as to obtain information about the dosage of known constituents.[134]

It is less clear whether under section 27 the agency can require product manufacturers or users of a specific ingredient to conduct tests in the first instance. Commission officials have argued that section 27(e) provides authority to require such testing,[135] but the agency has not ordered testing of any product or ingredient to date. It apparently is inclined to delay any legal test of its power to require testing until an appealing case arises. In evaluating the health effects of carcinogens in consumer products, therefore, the Commission has relied largely on data generated or obtained by other government agencies or available in the scientific literature. Sometimes the agency conducts its own tests to determine human exposure to a product or it contracts with another organization to do so. In the future, the Commission will continue to depend on outside sources for health effects data, but it hopes to improve its own capability to measure human exposure to hazardous sub-

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[132] 15 U.S.C. § 2076(b)(1) (1976).
[133] *Id.* § 2076(e).
[134] Fausett Interview, *supra* note 32.
[135] Krulwich Interview, *supra* note 38.

stances in consumer products.[136]

9. *Criteria for Preferring the CPS Act*

Section 30(d) of the CPS Act implies a preference for regulating product hazards under the other statutes transferred to the Commission in 1972.[137] This provision requires the Commission to promulgate a rule[138] determining that the public interest will be served better by regulating a product under the CPS Act than under the FHSA.[139] Because most toxic materials in consumer products could be regulated under the FHSA, the Commission must issue a section 30(d) ruling when it concludes that the CPS Act is the preferable statutory basis for regulating a carcinogen.[140] This step has become almost routine.

In its last four actions against carcinogens, the Commission offered two main justifications, both procedural, for its conclusion that regulation under the CPS Act was "in the public interest,"[141] and thus preferred. It emphasized that the FHSA, unlike the CPS Act, requires that any rule declaring a material a "banned hazardous substance" must be promulgated through formal rulemaking.[142] Because the CPS Act permits informal rulemaking, the

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[136] Krulwich Interview, *supra* note 36; Preuss Interview, *supra* note 32.

[137] A risk of injury which is associated with a consumer product and which could be eliminated or reduced to a sufficient extent by action under the Federal Hazardous Substances Act . . . may be regulated under this chapter only if the Commission by rule finds that it is in the public interest to regulate such risk of injury under this chapter. 15 U.S.C. § 2079(d) (1976).

[138] Such a rule must comport with the procedures specified by § 553 of the APA. *See* note 231 *infra*.

[139] 15 U.S.C. §§ 2061-2075 (1976 & Supp. III 1979). For a discussion of the FHSA's scope, see notes 143-51 *infra* and accompanying text.

[140] Although the CPS Act specifies that the period for public comment on the proposed rule shall not exceed 30 days, this provision could conceivably delay action by the Commission against a product hazard that could be regulated under either statute.

[141] The agency relied on the CPS Act in regulating chlorofluorocarbon propellants, 42 Fed. Reg. 21,807 (1977); benzene, 42 Fed. Reg. 22,516 (1977); patching and emberizing compounds containing asbestos, 42 Fed. Reg. 38,782 (1977), 42 Fed. Reg. 63,354 (1977), 43 Fed. Reg. 21,838 (1978); hairdryers containing asbestos, 44 Fed. Reg. 28,829 (1979) (to be codified at 16 C.F.R. § 1145); and urea formaldehyde foam insulation, 46 Fed. Reg. 11,183 (1981) (to be codified at 16 C.F.R. § 1306).

[142] 15 U.S.C. § 1261(q)(2) (1976). Under the applicable provisions of the FD&C Act, formal rulemaking requires both an opportunity for the submission of written comments and a formal evidentiary hearing on material factual disputes raised in objections to a "first" rule. *See* Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 Tex. L.

agency believed it could act more readily under the CPS Act.[143] In addition, the Commission asserted that the less formal procedures of the CPS Act would better facilitate participation by diverse interests.[144] The agency also mentioned that persons who violated a CPS ban would be subject to civil penalties.[145]

10. Judicial Review

The CPS Act provides for a court of appeals review of any consumer product safety rule (including a ban) upon a petition filed within sixty days by "any person adversely affected."[146] The reviewing court may order that new evidentiary presentations be made to the Commission. The court may grant any relief appropriate under chapter 7 of the APA, including suspension of Commission action pending review. A product safety rule is to be affirmed if it is supported by substantial evidence on the record taken as a whole. The CPS Act contains its own definition of the rulemaking "record," which includes the rule, the proposal, the transcripts of any oral hearing and all written submissions, and "any other information which the Commission considers relevant to such rule."[147]

B. The Federal Hazardous Substances Act

The FHSA[148] is the other statute on which the CPSC has relied to regulate carcinogens. The FHSA contains detailed definitions of "hazardous substance" and "banned hazardous substance," prescribes mandatory warning labeling for products in the former category, and authorizes the CPSC to initiate enforcement action

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Rev. 1132 (1972).

[143] 43 Fed. Reg. 21,838 (1978).

[144] *Id.*

[145] *Id.*

[146] 15 U.S.C. § 2060 (1976).

[147] *Id.*

[148] *Id.* §§ 1261-1275 (1976 & Supp. III 1979). The FHSA was enacted initially as a labeling statute. Federal Hazardous Substances Labeling Act, Pub. L. No. 86-613, 74 Stat. 372 (1960). It originally was adopted to fill gaps in other federal statutes (*e.g.*, the FD&C Act, 21 U.S.C. §§ 301-392 (1976 & Supp. III 1979); the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1976 & Supp. III 1979)), and to provide for labeling of poisons and hazardous materials brought into the home. Enacted in 1960, the FHSA was administered originally by FDA, and its draftsmen employed several of the legal concepts used in the FD&C Act. *See* H.R. Rep. No. 1861, 86th Cong., 2d Sess., *reprinted in* [1960] U.S. Code Cong. & Ad. News 2833.

against the latter as misbranded. As originally enacted, the FHSA was simply a labeling statute. Most of the warnings and cautionary information that appear on household products are prescribed by this law. The Act was later revised, however, to authorize more drastic action to control product hazards.[149] The CPSC has relied on this authority to regulate carcinogens twice.

1. Coverage of the FHSA

Section 2(f)(1)(A) of the FHSA defines a "hazardous substance" as

> [a]ny substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer [or] (v) is flammable or combustible . . . *if* such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.[150]

Section 2(g) of the Act defines "toxic" as "any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface."[151] Sections 2(i), 2(j), and 2(k) define "corrosive," "irritant," and "strong sensitizer."[152] Supplementing the FHSA definitions, CPSC regulations[153] describe toxicity tests to be performed on white rats and rabbits.[154] The regulations also state that the term "hazardous substance" applies to any substance shown to be toxic on the basis of human experience. A substance that meets either a supplementary definition or

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[149] The scope of the FHSA has been expanded to cover hazardous substances in general use in the home, and particularly to protect children from hazardous toys and products. Poison Prevention Packaging Act of 1970, Pub. L. No. 91-601, 84 Stat. 1670 (1970); Child Protection and Toy Safety Act of 1969, Pub. L. No. 91-113, 83 Stat. 187 (1969); Child Protection Act of 1966, Pub. L. No. 89-756, 80 Stat. 1303 (1966).

[150] 15 U.S.C. § 1261(f)(1)(A) (1976) (emphasis added). Congress suggested certain criteria for determining whether a particular substance is "hazardous." The basic test was the standard applied in common law civil liability cases, in which a seller must warn potential purchasers of the inherent dangers of his product. S. Rep. No. 1153, 86th Cong., 2d Sess. 2 (1960).

[151] 15 U.S.C. § 1261(g) (1976).

[152] *Id.* § 1261(i), (j), (k) (1976).

[153] Federal Hazardous Substances Act Regulations, 16 C.F.R. § 1500 (1980).

[154] *Id.* § 1500.40.

the Act's own definition of "toxic" is a "hazardous substance" under the FHSA *if* it also "may cause substantial personal injury or substantial illness."[155]

A determination that a material is a "hazardous substance" has immediate regulatory consequences. A product containing a hazardous substance must bear prescribed label warnings to avoid being deemed misbranded. If no label warnings will protect consumers from the hazard adequately, the CPSC is empowered to declare the product a banned hazardous substance.

2. *Alternative Banning Approaches*

The FHSA provides a comprehensive scheme for banning hazardous substances that are "intended, or packaged in a form suitable for use in the household."[156] Indeed, the statute probably could have been relied on to support all of the actions that the CPSC has taken to date against products containing carcinogens.

Section 2(q)(1)(B) of the FHSA empowers the Commission to issue a regulation declaring a product banned if the agency finds that "notwithstanding such cautionary labeling as is or may be required . . . the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance . . . out of the channels of interstate commerce."[157] Formal rulemaking[158] is required before a product may be banned as a hazardous substance under the FHSA. The agency first conducts what amounts to an informal rulemaking proceeding: it issues a proposed rule, entertains comment, and publishes a "final order." If persons adversely affected by such an order file legally sufficient objections, the Commission must then conduct an evidentiary hearing before an

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[155] *Id.* § 1500.3(a)(4)(i)(A). The CPSC has never considered amending its regulations to define all carcinogens, *e.g.*, all substances listed by EPA or OSHA, as "toxic." It could also prescribe tests for determining such toxicity. *See* Comments on a Preliminary Draft of this article by Peter Barton Hutt (Oct. 11, 1980) [hereinafter cited as Hutt Comments] (copy on file with the Virginia Law Review Association).

[156] 15 U.S.C. § 1261(q)(1)(B) (1976).

[157] *Id.*

[158] The procedure for declaring a product a banned hazardous substance under § 2(q)(1)(B) must conform to the FD&C Act, 21 U.S.C. § 371(e) (1976). 15 U.S.C. § 1261(q)(2) (1976). The FD&C Act requires formal, or on-the-record, rulemaking. *See* note 142 *supra*.

administrative law judge. If the Commission must undertake formal rulemaking to determine that a material is "toxic" under section 3(a) and thus is a hazardous substance, it uses the same proceeding to declare that products containing that material are banned hazardous substances.[160]

During the rulemaking period, the Commission has emergency authority to order its proposed ban effective immediately. Such an order must be based on a finding that "the distribution for household use of the hazardous substance involved presents an imminent hazard to the public health."[161] This authority was intended by Congress to enable the agency to prevent very dangerous articles from remaining on the market during the rulemaking process.[162] The CPSC has exercised this emergency power only once and not to regulate a carcinogen.[163]

Section 2(q)(1)(A) of the FHSA provides a narrower but speedier basis for banning carcinogens.[164] This section contains a special statutory definition of "banned hazardous substance." The definition applies to "any toy, or other article intended for use by children . . . which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted."[165] Section 2(q)(1)(A) does not set forth a general standard for the agency to apply to specific products by administrative action; instead it classifies a category of products as "banned hazardous substances." It thus constitutes a self-executing congressional ban, which the CPSC is empowered to enforce.[166]

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[160] The Commission combined these two steps, for example, in its regulation of fireworks, 41 Fed. Reg. 22,931 (1976), and vinyl chloride, 39 Fed. Reg. 18,115 (1974).

[161] 15 U.S.C. § 1261(q)(2) (1976).

[162] The House Report on § 2(q)(1)(B) states that "[w]here the procedural delay involved in plenary hearings would otherwise result in injury to the public, the [Commission] would be authorized to suspend the article from the market, pending the completion of hearing and review." H.R. Rep. No. 2166, 89th Cong., 2d Sess. 3, *reprinted in* [1966] U.S. Code Cong. & An. News 4095, 4096.

[163] The agency issued an administrative order declaring spray adhesives "imminent hazards" under the FHSA. 38 Fed. Reg. 22,569, 23,355, 25,216 (1973). It later rescinded this order. 39 Fed. Reg. 3582 (1974).

[164] 15 U.S.C. § 1261(q)(1)(A) (1976). *See* notes 336-82 *infra* and accompanying text (discussion of TRIS in children's garments).

[165] 15 U.S.C. § 1261(q)(1)(A) (1976).

[166] "Toys or other articles intended for use by children which bear or contain a hazardous substance are banned by the language of the bill itself . . . ." H.R. Rep. No. 2166, *supra*

Although the section requires no administrative action or formal announcement prior to commencing enforcement, some antecedent administrative procedure is permitted and, in some instances, is necessary. For section 2(q)(1)(A) to apply, a material must be "toxic" within the meaning of the definition in section 2(g).[166] When there is doubt on this point, the Act's remedies are not triggered until the CPSC conducts a rulemaking proceeding to establish the material's toxicity. Section 3(a) reinforces this requirement by calling for rulemaking to "[avoid or resolve] uncertainty" as to whether a product is a hazardous substance.[167]

3. *Remedies Against Banned Hazardous Substances*

Section 4 of the FHSA[168] bars banned hazardous substances from interstate commerce and defines "interstate commerce" broadly.[169] Section 6 authorizes the seizure of banned hazardous substances.[170] Sections 5 and 8 authorize the Commission to seek injunctions[171] or criminal penalties[172] against persons who violate any of the forgoing prohibitions.

Section 15 requires the automatic repurchase of banned hazardous substances, whether banned by statute or by Commission rule under section 2(q)(1).[173] Manufacturers (including importers for resale), distributors, and retail dealers must repurchase these products from their customers. Any customer is entitled to a refund of the purchase price and to payment of certain expenses incurred in returning the items. A CPSC regulation, however, gives sellers the option of replacing or repairing banned items instead of repurchas-

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note 161, at 3, [1966] U.S. Code Cong. & Ad. News at 4096.

[166] 15 U.S.C. § 1261(g) (1976), *quoted at* text accompanying note 151 *supra*.

[167] *Id.* § 1262(a)(1) (1976).

[168] Section 4 prohibits the introduction or delivery for introduction into interstate commerce of a banned hazardous substance; the doing of any action with respect to a hazardous substance while it is in interstate commerce that results in its being a banned hazardous substance; and delivery or proffered delivery for pay or otherwise of a banned hazardous substance. *Id.* § 1263 (1976 & Supp. III 1979).

[169] *Id.* § 1261(b) (1976).

[170] *Id.* § 1265.

[171] *Id.* § 1267.

[172] *Id.* § 1264 (1976 & Supp. III 1979).

[173] *Id.* § 1274 (1976). This requirement has been changed by the Consumer Product Safety Amendments of 1981, Pub. L. No. ___, § 1211, ___ Stat. ___ (amending 15 U.S.C. § 1274 (1976)).

ing them.[174] The Commission also requires that retailers place signs in their establishments informing customers of their repurchase obligation.[175] Although the FHSA provides no criminal or civil penalties for violations of repurchase requirements, violations can be enjoined.[176]

Section 15 is one of the most potent, and controversial, weapons in the CPSC's arsenal. Although this statutory repurchase obligation appears to cover products anywhere in the distribution chain, the CPSC has sometimes used the FHSA's banning provisions to reach only articles that are introduced into interstate commerce after a specified date.[177] Despite precedents to the contrary,[178] the agency apparently possesses legal authority to issue regulations defining products as "banned hazardous substance[s]" without requiring the repurchase of articles at various stages of distribution and articles already in the hands of consumers.[179]

4. *Judicial Review*

Any party adversely affected by a rule banning a hazardous substance under the FHSA may petition a court of appeals within sixty days for review.[180] The reviewing court may order the agency to take additional evidence, or it may grant other appropriate relief. The FHSA requires the Commission's order to be affirmed if it is based on a fair evaluation of the hearing record. A determination by the CPSC that section 2(q)(1)(A) of the FHSA defines a product as "banned," even though not reached following rulemaking, can also be challenged in court.[181]

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[174] 16 C.F.R. § 1500.203 (1980).

[175] *Id.* § 1500.202.

[176] 15 U.S.C. § 1267(a) (1976).

[177] Krulwich Interview, *supra* note 36.

[178] The agency did not follow this approach in its regulation of vinyl chloride and TRIS, the two carcinogens it has attempted to regulate on the basis of the FHSA. It was the impact of mandatory repurchase on manufacturers that precipitated the ultimately successful judicial challenges to the Commission's actions against these two substances.

[179] Krulwich Interview, *supra* note 36.

[180] In 15 U.S.C. § 1262(e)(3) (1976), such review is provided specifically with respect to children's toys. For actions against other hazardous substances, § 1262(a)(2)(B) provides the same review mechanism through incorporation of 21 U.S.C. § 348(g) (1976).

[181] For example, such a contest may occur when U.S. Attorneys initiate enforcement proceedings, or the Commission's interpretation may be challenged directly by a suit seeking injunctive and declaratory relief. *See, e.g.*, United States v. Articles of Hazardous Substance, 588 F.2d 39 (4th Cir. 1978); Springs Mills, Inc. v. CPSC, 434 F. Supp. 416 (D.S.C. 1977).

C. *Summary of Statutory Authorities*

The forgoing discussion of the CPSC's main authorities illustrates the range of options open to the agency in its regulation of consumer products that pose cancer risks. The Commission has experimented with most of the remedies afforded by the two statutes. It relied on section 8 of the CPS Act to ban caulking and emberizing compounds containing asbestos and in proposing to ban benzene in consumer products. It secured the recall of hairdryers containing asbestos by commencing the initial steps to correct a "substantial product hazard" under section 15 of the CPS Act. In regulating vinyl chloride, the agency relied on section 2(q)(1)(B) of the FHSA. Its clumsy attack on TRIS in children's sleepwear relied on an "interpretation" of section 2(q)(1)(A)'s statutory ban of toxic substances exposed to children. Although the Commission has developed a general preference for the CPS Act, its most recent actions provide little guidance as to which of the remedies provided by that law it will use customarily.

The diversity of products for which the CPSC is responsible may require a variety of regulatory weapons, although it is not clear that the statutes it now administers afford the optimum selection. The Commission has picked and chosen among statutory authorities partly because none of the laws seems ideally suited. The procedures mandated for specific remedies influence strongly, and may sometimes distort, the agency's choice. The statutory procedures, moreover, often do not mirror accurately the processes by which the Commission actually makes and implements decisions.

III. The Commission's Chronic Hazards Program

This section describes generally the CPSC's efforts to develop criteria for regulating consumer products that pose cancer risks, and it traces the agency's attempts to establish a system for identifying and evaluating substances that are candidates for regulation. The discussion reveals that only in the past four years has the Commission seriously begun to evaluate its role in controlling exposure to toxic chemicals. Its current efforts reveal an agency still uncertain about its mission, one that is attempting to move from a posture of reaction to external reports of hazards toward one of responsibility for its own agenda.

A. The 1978 Cancer Policy

1. Background and Content

Demands that the federal government develop a uniform "cancer policy" began to receive congressional and media attention during 1975 and 1976. Members of the CPSC, frustrated by their own experience with TRIS, used this interest as an opportunity for the agency to develop its own cancer policy.[182] The policy was to be a statement of the scientific principles the Commission would use in evaluating suspected carcinogens. When published in 1978, however, the CPSC policy went beyond a mere statement of scientific principles; it also outlined a framework for evaluation and forecast the regulatory consequences that would flow from different levels of evidence of carcinogenicity.[183]

The Commission published its policy in the Federal Register without allowing prior opportunity for public comment, although drafts had been in public circulation for several weeks. The published document invited comment on the agency's scientific principles, its framework for evaluation, and its suggested regulatory responses, but the agency also stated that the policy was effective immediately on an "interim basis," pending consideration of comments.[184]

In this policy, the CPSC announced its intention to prevent known carcinogens from being added to consumer products intentionally if such substances could be absorbed, inhaled, or ingested by humans. Use of any carcinogenic substance would be phased out unless "no reasonable substitute" were available and elimination of the substance would result in "unacceptable economic and social costs."[185] In the latter case, the agency would require that use of the substance be reduced to the "lowest attainable level" until a substitute could be identified.[186] The Commission stated

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[182] Former CPSC Commissioner Barbara Franklin and former Commission Chairman John Byington were strong proponents of a government-wide cancer policy. Commissioner R. David Pittle, who urged greater CPSC involvement in the regulation of chronic hazards, was instrumental in persuading the Commission to focus on the creation of its own policy. Gallagher Interview, *supra* note 22.

[183] 43 Fed. Reg. 25,658 (1978).

[184] Heller Interview, *supra* note 32. The decision to make the policy immediately effective reportedly was reached on the eve of publication. Melnick Interview, *supra* note 68.

[185] 43 Fed. Reg. 25,658, 25,659 (1978).

[186] *Id.*

that it would consider a variety of factors, including the extent to which products containing a carcinogen were used, and by whom; the potency of the substance; the potential for human uptake; the probable effect of regulation; the extent of human exposure to the substance and the availability and adequacy of substitutes; the environmental impact; and the potential economic and social effects of regulation.[187]

The CPSC's cancer policy described a system for categorizing individual substances based upon the weight of the evidence of their carcinogenicity[188] and forecast the regulatory action that would be likely to follow a substance's classification in each category.[189] Specifically, the policy provided that, once questions about a substance's carcinogenicity were raised, the CPSC staff would determine (1) whether the substance was present in products within the agency's jurisdiction, and (2) whether the agency should refrain from action because another agency was dealing adequately with the potential hazard.[190] A substance that survived this preliminary review would be classified into one of four categories.[191] Category A would consist of substances for which there was "strong" or "compelling" evidence of carcinogenicity.[192] This category would automatically include substances that the National Cancer Institute had found to be animal or human carcinogens. Category A also would cover substances that were determined to increase significantly the incidence or reduce the onset time of benign or malignant neoplasms in humans or in soundly conducted experiments on animals.[193] Other "compelling evidence," such as dramatic positive findings in a single animal study, could warrant a substance's classification in Category A.[194] The CPSC thus endorsed the prin-

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[187] *Id.* at 25,661, 25,664.

[188] This system resembled the one subsequently adopted by OSHA in its generic cancer policy, 29 C.F.R. § 1990 (1980), and followed by EPA in its announced criteria for evaluation of chemical carcinogens, 40 C.F.R. § 61 (1979).

[189] *In this respect, the CPSC policy was dissimilar to OSHA's.*

[190] 43 Fed. Reg. 25,658, 25,661 (1978).

[191] *Id.* at 25,663.

[192] *Id.*

[193] To support such a finding, animal data would have to consist of test results in (1) two species of animals, (2) one species of animal if replicated in a second experiment, or (3) one species of animal if the result were supported by a battery of sound short-term tests. *Id.*

[194] *Id.*

ciple, adopted by other agencies and sustained in the courts,[195] that a substance demonstrated to be capable of causing cancer in animal tests should be assumed carcinogenic to humans.[196] Similarly, the agency would regard positive human epidemiological evidence as a reliable indicator of carcinogenic risk, but it would view negative findings with skepticism.[197] The CPSC stated that it would act to ban or reduce to the lowest possible level the intentional addition of a Category A substance to any consumer product.[198]

Category B was to include substances for which evidence of carcinogenicity was "suggestive" of a risk to humans.[199] Such evidence could consist of indicative animal or human data, positive results in a single short-term test not yet confirmed in human or long-term animal tests, or positive results in an animal study that were not conclusive enough for Category A classification.[200] Category C would include substances that were members of a chemical class containing many known carcinogens, or for which limited experimental evidence of carcinogenicity existed.[201] Category D would include substances that exhibited no evidence of carcinogenicity.[202] Substances initially classified in Category A, B, or C would be reclassified into Category D if further evaluation did not indicate carcinogenic potential.[203]

The policy announced that the CPSC would seek further testing of substances placed into Categories B and C. The agency asserted

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[195] *See* Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks, 44 Fed. Reg. 39,858 (1979) (hereinafter cited as IRLG Document). *See also* Environmental Defense Fund, Inc. v. EPA, 510 F.2d 1292 (D.C. Cir. 1975); Environmental Defense Fund, Inc. v. EPA, 465 F.2d 528 (D.C. Cir. 1972).

[196] The CPSC policy declared that, in evaluating the results of animal tests to determine a substance's possible carcinogenicity, the agency generally would follow the "General Criteria for Assessing the Evidence for Carcinogenicity for Chemical Substances," proposed by the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board for the National Cancer Institute. 58 J. NAT'L CANCER INST. 461 (Feb. 1977), *cited at* 43 Fed. Reg. 25,658, 25,662 (1978).

[197] 43 Fed. Reg. 25,658, 25,662 (1978).

[198] *Id.* at 25,664-65.

[199] *Id.* at 25,663.

[200] *Id.*

[201] *Id.*

[202] *Id.* at 25,665.

[203] *Id.* at 25,663.

that it could either[204] require manufacturers of products containing the substances to conduct and report tests under section 27(e) of CPS Act,[205] or request EPA to require such testing pursuant to its authority under the Toxic Substances Control Act (TSCA).[206] The policy contemplated interim regulatory action requiring warnings and special labeling on consumer products containing Category B or Category C substances, as well as mandatory recordkeeping on production and distribution of such products.[207]

The Commission declared that the evaluation, testing, and regulation of substances in all four categories would be geared to the agency's overall priorities. Classification in Category A, for example, usually would result in high priority. Apparent potency, extent of consumer exposure, and potential for human uptake, however, could lead the agency to allocate resources for the investigation of a Category B or C substance ahead of a low-priority Category A substance.[208]

2. *Judicial Reversal*

The first substance that the CPSC considered for provisional categorization under its new policy was perchloroethylene (PERC), a chemical used in commercial and coin-operated dry cleaning establishments. The agency staff had been evaluating data on PERC prior to issuance of the cancer policy, and the Commissioners had given preliminary indications that they would ultimately classify PERC in Category A.[209] Concerned that the material would be indicted publicly as a cause of cancer, Dow Chemical and the other principal manufacturers of PERC sued to enjoin the Commission from taking any action to categorize suspected carcinogens under its published policy.[210] The manufacturers contended that the Commission's failure to provide prior notice and opportunity to comment pursuant to the APA[211] rendered the policy invalid.[212]

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[204] *Id.* at 25,665 & n.8.
[205] 15 U.S.C. §§ 2051-2082 (1976 & Supp. III 1979).
[206] *See* Toxic Substances Control Act, 15 U.S.C. §§ 2601, 2603 (1976).
[207] 43 Fed. Reg. 25,658, 25,666 (1978).
[208] *See id.* at 25,664.
[209] Heller Interview, *supra* note 32.
[210] Dow Chem., USA v. CPSC, 459 F. Supp. 378 (W.D. La. 1978).
[211] 5 U.S.C. § 553(b), (c) (1976).
[212] Dow Chem., USA v. CPSC, 459 F. Supp. 378, 383 (W.D. La. 1978).

The CPSC responded[213] that its cancer policy was merely a "statement of policy" and thus exempt from the informal rulemaking requirements of the APA.[214]

In rejecting the Commission's position, Judge Veron identified several features that belied the agency's description of the policy and required compliance with the APA. First, the policy stated clearly that its provisions, which resembled regulations, would be followed in subsequent proceedings.[215] The court expressed concern that proceedings involving individual substances would focus simply on whether the criteria set forth in the policy were met. The court stressed the value of prior public comment, observing that many principles endorsed by the policy were still being debated within the scientific community. It would be improper, in the court's view, to implement regulations that appeared to settle those uncertainties without airing the alternatives that would be raised in public comments. The court expressed concern that the Commission's attempt to categorize PERC pursuant to the policy would cause immediate harm to the plaintiffs.[216] Accordingly, it declared that "the interim rules should have been announced only after the informed reflection and genuine dialogue contemplated by the APA,"[217] and entered a preliminary injunction ordering the CPSC to refrain from classifying any substance under the policy.[218]

In an effort to salvage its cancer policy, the CPSC published an

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[213] As a preliminary matter, the agency contended that the challenge to its policy was premature. The court rejected this claim, finding the matter ripe for review because the manufacturers faced immediate economic hardship if PERC were publicly declared a cancer hazard. The court stressed that the regulations had been issued in a formal fashion and contained unequivocal language, indicating that they represented a final decision by the agency. *Id.* at 385-87. Thus, whether the agency had complied with the APA was a legal question ripe for judicial determination. *Id.* at 387.

[214] *Id.* at 390. The exceptions to the informal rulemaking requirements of the APA, including the exception for "general statements of policy," are set forth in 5 U.S.C. § 553(b) (1976).

[215] Dow Chem., USA v. CPSC, 459 F. Supp. 378, 383 (W.D. La. 1978).

[216] *Id.*

[217] *Id.* at 394 (footnote omitted).

[218] *Id.* at 395. The court's determination that the plaintiffs were likely to prevail on the merits was crucial to its selection of injunctive remedy. *Id.* at 390. The court also found that (1) plaintiffs would suffer irreparable injury if PERC provisionally were listed in Category A; (2) because the policy had taken so long to develop, further delay would harm the Commission less than the plaintiffs; and (3) the public interest called for protecting the integrity of the APA rulemaking procedures. *Id.* at 394-95.

ostensibly clarifying notice in the Federal Register.[219] This notice attempted to bulwark the agency's contention that its classification scheme was merely a statement of policy and not a legislative rule, *i.e.*, that it was intended only to advise the agency staff and inform the public of the Commissioners' current approach toward carcinogens. The CPSC emphasized that the policy would not foreclose evidence or argument on any issues raised by its attempts to regulate specific substances. It also stressed that the provisional classification of any chemical would be subject to notice and public comment. Furthermore, the only action triggered by final classification would be further testing or the commencement of regulatory action that would itself be subject to the full procedural requirements prescribed by the CPS Act or the FHSA.[220] The explanatory notice also reopened the comment period on the Commission's cancer policy for an additional sixty days.[221]

Based on this notice, the CPSC unsuccessfully sought reconsideration of the district court's injunction.[222] Judge Veron declared that because the agency's clarifying statement did not modify the original policy, the policy must continue to be interpreted as written.[223] He asserted that the clarification did not respond to his original conclusion that public rulemaking was essential for such policymaking.[224]

Rather than seek appellate review, the Commission withdrew the policy.[225] It offered two reasons for this retreat. First, a nonbinding policy was not worth the effort of protracted litigation, particularly because its publication was not essential to the agency's ability to regulate carcinogens.[226] Second, the IRLG planned to publish a similar set of scientific principles for evaluating potential carcinogens; these would be supported by the collective expertise of the four agencies.[227]

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[219] 43 Fed. Reg. 60,436 (1978).
[220] *Id.* at 60,437.
[221] *Id.* at 60,438.
[222] Dow Chem., USA v. CPSC, 464 F. Supp. 904 (W.D. La. 1979).
[223] *Id.* at 908.
[224] *Id.* at 909-10.
[225] 44 Fed. Reg. 23,821 (1979).
[226] *Id.* at 23,822.
[227] *Id.* The four contributing agencies were the CPSC, EPA, FDA, and OSHA. Also, the Food Safety and Quality Service of the Department of Agriculture had joined the IRLG shortly before the CPSC withdrew its policy. *Id.*

Judge Veron's ruling is questionable on two grounds. First, its reasoning does not respond adequately to the Commission's legal position. The APA exempts agency "statements of policy" from informal rulemaking requirements. Although the court cited several decisions supporting a nonliteral reading of the APA's exception,[218] it did not explain why such a reading was appropriate in this case. The CPSC's published policy neither foreclosed the contest of any scientific or economic issue in proceedings to establish safety standards, nor banned any product or substance—including PERC.

Furthermore, the court's ruling induced the CPSC to submerge rather than clarify its policy concerning carcinogens. Although the agency out of prudence will avoid formal categorization, the decision left it free to follow the same criteria in regulating individual substances and to dispense with the opportunity, promised in its published policy, for public comment on the staff's preliminary assessments.

The district court's primary concern appeared to be the adverse publicity that manufacturers of PERC might suffer if the Commission were to classify preliminarily the chemical in Category A. The decision solved that problem by forbidding the agency from taking any action against the chemical until its procedural mistake had been corrected. The injury caused by such an announcement, however, probably would carry less stigma than would accompany publication of a proposed ban under section 8 of the CPS Act, which would be the CPSC's next logical step if it decided to regulate PERC. Furthermore, the Commission's provisional classification system would have provided an additional opportunity to vindicate the chemical, one that is not afforded by section 8 itself.[219]

See IRLG Document, *supra* note 195. Although it did not purport to be a proposed rule or otherwise have decisional weight in individual substance-specific regulatory proceedings, the IRLG agencies invited public comment on their statement of principles. *See* T. McGarity, The Occupational Safety and Health Administration's Generic Carcinogen Policy: Rulemaking Under Scientific and Legal Uncertainty 10 (unpublished paper on file with the Virginia Law Review Association).

[218] These cases included Continental Air Lines, Inc. v. CAB, 522 F.2d 107 (D.C. Cir. 1974), *rehearing en banc*, 522 F.2d 122 (1975); Pickus v. United States Board of Parole, 507 F.2d 1107 (D.C. Cir. 1974); Pacific Gas & Elec. Co. v. FPC, 506 F.2d 33 (D.C. Cir. 1974); Texaco, Inc. v. FPC, 412 F.2d 740 (3d Cir. 1969); St. Francis Memorial Hosp. v. Weinberger, 413 F. Supp. 323 (N.D. Cal. 1975).

[219] Although PERC remains on the government's agenda as a candidate for regulation, no formal action has been initiated to ban or limit its use.

This is not to suggest that the CPSC was sure-footed in publishing the policy without prior public comment. It would have been prudent for the agency to have invited comment on a proposal before issuing its policy in final form.[230] Alternatively, the agency might have been successful in announcing its scientific criteria without prior comment had it given the "policy" a less formal appearance.[231] Nonetheless, one can understand why the agency thought its approach appropriate. The published principles were to be treated simply as guidelines. The Commission staff needed *some* criteria for evaluating chemicals that might pose a risk of cancer. Postponing evaluation of, or action on, any chemicals until a final policy could be promulgated seemed unnecessary.

B. Determinants of the CPSC's Agenda

The projects to which the CPSC devotes resources generally are identified through one of two procedures: (a) the public petition process, and (b) staff identification and evaluation of product hazards that merit the agency's attention.

1. The Petition Process

The CPS Act authorizes interested persons to petition the CPSC to initiate proceedings to establish a consumer product safety rule

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[230] Such an approach would have been indispensible if the agency had desired to make the scientific principles binding in subsequent proceedings, as some Commissioners reportedly urged.

[231] The CPSC cancer policy bore some resemblance to the EPA announcement, discussed at note 188 *supra*, with two differences. First, EPA promised explicitly to evaluate the costs of regulation once a substance was classified as a presumptive cancer risk. The CPSC has avoided such a commitment. Perhaps more important, EPA consciously refrained from giving its policy the appearance of a regulation. No C.F.R. section numbers appeared in the document and much of the supporting narrative appeared in smaller, appendix-style type.

To adopt a substantive rule, an agency must follow the procedures prescribed by section 553 of the APA, which requires publication of a "general notice of proposed rulemaking" and "an opportunity [for those affected] to participate in the rulemaking." 5 U.S.C. § 553 (b), (c) (1976). Although general statements of policy are excepted from this procedure, courts have construed this exception narrowly: "The basic policy of Section [553] at least requires that when a proposed regulation of general applicability has a substantial impact on the regulated industry . . . notice and opportunity for comment should first be provided." Pharmaceutical Mfrs. Assoc. v. Finch, 307 F. Supp. 858, 863 (D. Del. 1970). EPA's description of the criteria it intended to follow in evaluating potential carcinogens, however, was never challenged for failure to comply with the APA, perhaps because the document did not convey the impression that these criteria were not open to dispute in specific cases.

(standard or ban) and mandates a response by the agency within 120 days.[223] This process has influenced the CPSC's general agenda, and most of the agency's actions against carcinogens have followed the filing of petitions by public interest groups.[224]

Cognizant of the 120-day statutory time limit for response,[225] the CPSC accords petitions priority over projects identified through internal evaluation.[226] So long as the statute or the agency's view of its requirements remains unchanged, the petition process will continue to play a major role in determining which substances the Commission selects for regulatory action. Members of the Commission have always disagreed on whether the agency could legitimately decline to act on a petition on the ground that the agency's resources were already fully committed to other projects, some of which might have been stimulated by petitions.[227] The view that such refusal is proper seems convincing, but it has not been tested in court. In 1976, the Subcommittee on Oversight and Investigation of the House Committee on Interstate and Foreign Commerce issued a report indicating that the Commission could and often should refuse to act on public petitions.[228] The legality of such a refusal might depend on the Commission's adherence to a rational priority-setting system. For example, candidate chemicals could be selected for regulation based upon such criteria as degree of toxicity, prevalence of use, or level of potential exposure. Using such a system, the Commission could develop an agenda that is less vulnerable to outside pressures and that concentrates resources on substances that pose the greatest risk.

Such an approach, however, has limitations. The CPSC has established a system for determining which chemicals should receive attention, but this internal review process has not yet produced candidates for regulatory action.[229] Evaluation has been hampered

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[223] 15 U.S.C. § 2059(a), (d) (1976).

[224] Its actions against vinyl chloride, chlorofluorocarbons, TRIS, benzene, patching compounds and emberizing materials containing respirable asbestos, and hand-held hairdryers containing asbestos all followed the filing of petitions by public interest groups.

[225] *See* 15 U.S.C. § 2059(d) (1976).

[226] One agency official remarked that petitions "go to the top of the pile." Preuss Interview, *supra* note 32.

[227] Decision of the CPSC Regarding Agency Priorities for 1980; Dissenting Opinion of Commissioner Stuart M. Statler, Dec. 20, 1979, at 5 [hereinafter cited as CPSC Priorities].

[228] Moss Report, *supra* note 91, at 193, 242.

[229] Asbestos has been a long-standing CPSC concern, and the Commission's 1980 Advance

both by ignorance about product composition and by the difficulty of determining levels of human exposure to chemicals in many consumer products. Furthermore, staffing the review process requires scarce human and monetary resources.

Prudential considerations may also dictate departures from a formal priority system. The CPSC desires flexibility in responding to two sources of unanticipated problems.[239] First, some petitions are likely to be the product of new scientific evidence that should place a chemical high on the Commission's agenda. Second, the agency may value the ability to respond to demands for action against hazards that have a high profile. Still, it will always be difficult to know how much such a response reflects concern about public relations and how much it represents a desire to meet more serious hazards.

2. *Internal Review of Candidates for Regulation*

The CPSC's internal "system" for evaluating chemicals that might be candidates for regulation was carried out initially through the project management system.[240] The Program Manager for Chronic Hazards in effect served as the "team leader" of a group of professionals, drawn primarily from the Office of Health Sciences and the Directorate for Hazard Identification. Now under the direction of the new Directorate for Health Sciences, the group is responsible for identifying and preliminarily evaluating potential chronic hazards. The group prepares briefing packages on chemicals identified as deserving high priority; these packages outline criteria to assist the Commissioners in deciding whether to seek more data, initiate regulation, or defer action. A chemical selected for regulation is dealt with through the usual team or project system.

In its initial efforts to identify possible chronic hazards in consumer products, the review group concentrated on existing lists of

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Notice of Proposed Rulemaking reflects its own initiative, but this action was not precipitated by any systematic study of chronic hazards in consumer products.

[239] The CPSC is taking this approach with its current budget and operating plan. This is based on the necessary assumption that the agency's efforts to rank regulatory targets on an internal agenda will withstand challenges from nonpriority petitioners who demand action, pursuant to the statute, regardless of the Commission's budgetary reserves or priorities.

[240] The CPSC had no internal "system" for identifying and evaluating chemicals that might be candidates for regulatory action until 1978. Preuss Interview, *supra* note 32.

chemicals identified as potential human carcinogens.[241] The review group then attempted to answer a series of questions about each of the chemicals on these overlapping lists, including: (1) Has the substance been shown to be carcinogenic in humans, or in animals as a result of well-designed studies?[242] (2) Is the substance present in consumer products? (3) Are products in which the substance is used subject to CPSC jurisdiction? (4) What is the extent of human exposure to the substance in such products? In answering the first of these questions, the staff has relied heavily on the findings of other bodies, including other regulatory agencies.[243] In answering the other questions, the staff has relied primarily on existing information. The CPSC has not conducted, or contracted with others to conduct, additional testing of any chemical, nor has it authorized major new investigations of product formulations or assessments of likely human exposure. Such inquiries apparently await an initial determination by the Commissioners that a substance warrants regulation or further study. Until recently, the review group has not performed quantitative risk assessments in identifying chemicals as potential targets for regulation.[244]

In 1980, the Commission accepted an outside proposal to broaden the approach of its chronic hazards review group.[245] It

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[241] These included the approximately 20 chemicals characterized by the International Agency for Research on Cancer as human or animal carcinogens; the more than 100 chemicals on which the National Cancer Institute has completed bioassays, with specific attention to those with positive results in the studies; the chemicals nominated for testing priority by the Interagency Testing Committee; and the several chemicals being regulated by the other agencies who are members of the IRLG. There are sufficient external sources of candidates for evaluation that the Commission staff should not need to identify new targets of its own.

[242] The extent to which the Commission staff has undertaken to reach an independent judgment on this threshold issue is unclear. Given the agency's lack of expertise in this area, the staff should rely primarily on other bodies for this judgment. The Commission's approach to the evaluation of formaldehyde's carcinogenicity is a healthy sign that it appreciates its limitations.

[243] *See* Hutt Comments, *supra* note 155. For example, the agency relied on data provided to OSHA in banning vinyl chloride, on the National Academy of Sciences and the Interagency Task Force on Inadvertent Modification of the Stratosphere for evidence of the risk of chlorofluorocarbons, and on information already accepted by the other three IRLG agencies to regulate asbestos in patching and emberizing compounds. In the case of hand-held hairdryers, the CPSC did arrange for its own testing to determine the extent asbestos was available for human uptake, but it relied on the common body of information to find that asbestos posed a health risk.

[244] Preuss Interview, *supra* note 32.

[245] *Id.*

granted in principle an Environmental Defense Fund (EDF) petition recommending that the agency identify products whose use entails exposures of a kind that could present serious health hazards if the products released carcinogenic materials.[246] One current agency project, suggested by EDF, involves evaluation of room deodorizers to identify their constituents, determine their potential carcinogenicity and teratogenicity, and verify the premise for their selection to be regulated, namely, that room deodorizers are a significant source of inhaled materials.[247] The staff contemplates that the Commission may issue special orders under section 27(b) of the CPS Act requiring major manufacturers to reveal the composition of their products and to submit currently available data on toxicity.

The agency has found this internal review process difficult to manage. One impediment to a systematic review function has been the agency's "matrix" organization, which stresses flexibility at the expense of continuity. This structure does not lend itself readily to the formation of a staff-level group with continuing responsibility for reviewing substances that may never become regulatory projects. The absence of a fixed timetable governing review of, and actions on, substances identified by the review group also has impeded the CPSC's efforts to formulate its own regulatory agenda.[248] Although several chemicals have been identified preliminarily as candidates for potential regulation, the Commission has initiated action against only one.[249] Furthermore, before the recent changes in the Commission's organization, the ill-defined arrangements between the Office of Health Sciences and the OPM Chron-

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[246] *Id.*

[247] Heller Interview, *supra* note 32. The Commission also has established a project to evaluate aerosolized products that contain hydrocarbon propellants. *Id.* This project, too, reflects a preliminary judgment that consumers are exposed to hydrocarbon propellants in increasing quantities and may suffer serious adverse health effects if these materials are chronically toxic. Both projects contemplate that the Commission may issue special orders under § 27(b) of the CPS Act requiring major manufacturers to reveal the composition of their products and to submit data on toxicity.

[248] This flexibility is in contrast to the 120-day statutory deadline for answering public petitions demanding agency action under § 8 of the CPS Act. 15 U.S.C. § 2059(d) (1976).

[249] This exception is urea formaldehyde foam insulation, which the agency has proposed to ban. 46 Fed. Reg. 11,183 (1981) (to be codified in 16 C.F.R. § 1306). *See* notes 508-32 *infra* and accompanying text. Among the substances still under review are a large number of dyes and asbestos, which still appears in many consumer products. [1981] 5 CHEM. REG. REP. (BNA) 129.

ic Hazards Program left unclear which component had responsibility for determining the priorities for work on specific chemicals and scheduling that work's completion.

C. Internally Generated Regulatory Actions

To date, the CPSC has not regulated a carcinogen identified through its internal review of chemicals or product exposures.[250] In fact, even before recent cutbacks in its budget,[251] the Commission may have lacked the capability to mount a major program to regulate toxic chemicals. Its relatively modest resources[252] have always had to be spread across a wide range of consumer product hazards. The agency has never possessed the scientific staff or facilities to undertake substantial testing on its own, and unlike EPA and FDA, it has no licensing programs that routinely generate test data from the private sector.[253] Furthermore, the CPSC's authority to mandate product safety testing remains unconfirmed.[254] Finally, the Commission's preoccupation with public petitions has forced it to neglect other regulatory priorities.[255]

Despite these difficulties, the CPSC has several chronic hazards projects on its agenda that were identified through the petition process or staff recommendations. The CPSC has published an advance notice of proposed rulemaking addressing the use of asbestos in consumer products.[256] It contemplates a series of actions pursuant to this notice, including the issuance of special orders under

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[250] The agency's ill-fated evaluation of PERC under its 1978 cancer policy, *see* notes 209-31 *supra* and accompanying text, was its first such attempt. The Commission's proposal to ban urea formaldehyde foam insulation is its only other initiative against a chemical that has not been regulated by another agency. *See* notes 516-19 *infra* and accompanying text.

[251] *See* note 28 *supra*.

[252] The CPSC budget is minuscule in comparison with those of other agencies responsible for regulating health hazards. EPA's proposed budget for fiscal year 1982 is $1.39 billion; FDA's proposed budget totals $336 million. By contrast, the Office of Management and Budget has recommended a $33 million budget for the CPSC, which itself is a concession, for the Reagan administration has announced its desire to abolish the Commission as a separate agency and merge its functions into the Department of Commerce. Because the CPSC budget has always been small, the cuts demanded by the Reagan administration may be felt more sharply than those inflicted upon its sister agencies. [1981] 4 CHEM. REG. REP. (BNA) 1577-80, 1621.

[253] *See* note 538 *infra* and accompanying text.

[254] *See* notes 135-36 *supra* and accompanying text.

[255] *See* notes 543-48 *infra* and accompanying text.

[256] 44 Fed. Reg. 60,057 (1979).

section 27(b)(1) to obtain formulation and safety data;[357] this may lead ultimately to the banning of some uses or products. The agency has proposed to ban urea formaldehyde as a component of foam insulation.[358] It continues to regard PERC as a candidate for regulation.[359] Its staff has been considering recommended regulatory actions on n-Hexane, a substitute for benzene in adhesives, and on benzidine dyes,[360] both of which are the subjects of public petitions. Other projects on the Commission's agenda include hydrocarbon propellants and solvents. Given the CPSC's continued interest in chronic hazards regulation, it is appropriate to evaluate its past performance in greater detail.

IV. CPSC Regulatory Actions Against Carcinogens

The administrative proceedings examined in this section constitute virtually all of the CPSC's attempts to regulate substances that pose a risk of human cancer.[361] This survey highlights recurrent issues in the agency's decisionmaking and compares its approaches to different substances.

Certain common threads run through all of the regulatory actions discussed in this section. Each administrative action was undertaken following, although not necessarily as a result of, the submission of petitions by public interest groups. With the exception of TRIS, each substance that the CPSC attempted to regulate had already been regulated by at least one other agency; as a result, in no case was the underlying issue of carcinogenicity seriously disputed. The central questions for the CPSC revolved around the issue of human exposure. Manufacturers of the products targeted for regulation usually acquiesced in the agency's insistence that use of the subject material be halted; where litigation ensued, it centered on the disposition of products already in commerce. The CPSC's actions display no systematic approach toward balancing risks and benefits, nor do they reveal a clear view about the impor-

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[357] *Id.* at 60,055.

[358] 46 Fed. Reg. 11,188 (1981).

[359] Heller Interview, *supra* note 32.

[360] *See* 44 Fed. Reg. 76,387, 76,388 (1979).

[361] The agency also devotes resources to the evaluation of other chronic hazards and to joint activities with other regulatory agencies.

tance of economic effects in decisionmaking under the CPS Act or the FHSA.

A. Aerosolized Vinyl Chloride

Vinyl chloride was the first carcinogen that the CPSC attempted to regulate. The Commission joined a multi-agency response to petitions filed by the Health Research Group (HRG) before the CPSC, FDA, and EPA requesting that each agency ban the use of the chemical in products within its jurisdiction.[263] The HRG petitions relied on recently reported findings[264] of a rare form of liver cancer, angiosarcoma, in workers exposed to vinyl chloride. The CPSC was the last of the three agencies to respond.[264]

On May 6, 1974, the CPSC announced its preliminary determination that consumer products containing vinyl chloride created a "substantial product hazard" under the CPS Act, and it ordered the manufacturers of consumer products suspected of containing vinyl chloride to submit formulation information.[265] Two weeks later, the Commission proposed to declare household products containing vinyl chloride "banned hazardous substances" under section 2(q)(1)(B) of the FHSA.[266] Its proposal cited data from both human experience and animal studies reported previously to OSHA,[267] and relied on actions of sister agencies.[268] It reported that OSHA had published an Emergency Temporary Standard for

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[263] The FDA proposal appears at 39 Fed. Reg. 14,215 (1974), EPA's emergency order suspending registrations for pesticide spray products containing vinyl chloride at 39 Fed. Reg. 14,753 (1974), and the CPSC's initial notice at 39 Fed. Reg. 18,115 (1974).

[264] Most of the studies cited in the CPSC notice were animal experiments, although epidemiological data from B.F. Goodrich employees exposed to vinyl chloride provided convincing support for the extrapolation to humans. The major laboratory experiment relied upon was performed by Dr. Cesare Maltoni, of the Institute di Oncologia, Bologna, Italy. It indicated carcinogenesis in laboratory animals exposed to vinyl chloride concentrations as low as 250 parts per million (ppm). 39 Fed. Reg. 18,115 (1974).

[265] The agencies proposed actions in the following sequence: OSHA on April 5, 1974; FDA on April 22, 1974; EPA on April 26, 1974; and the CPSC on May 23, 1974.

[266] 39 Fed. Reg. 18,511 (1974).

[267] 39 Fed. Reg. 18,115 (1974).

[268] This data came from two sources: (1) reports of an increased incidence of liver cancer among occupationally exposed workers at B.F. Goodrich, Union Carbide, and Goodyear factories, and (2) studies conducted on three rodent species by Dr. Cesare Maltoni, a well-known Italian toxicologist, which demonstrated that vinyl chloride could induce liver tumors at concentrations as low as 250 ppm. *Id.*

[269] *See id.* at 18,116.

vinyl chloride, setting an occupational exposure limit of 50 ppm in air.[268] The Commission noted that OSHA had later proposed a permanent exposure standard of no detectable level,[269] and that the FDA had proposed to forbid the use of vinyl chloride as an ingredient in aerosolized drug and cosmetic products.[270] EPA had published an emergency order suspending the registrations of pesticide products that contained vinyl chloride as a propellant and announced its intent to cancel the registrations of such products.[271] The EPA proposal received special attention because it reported the preliminary results of a new experiment that observed angiosarcoma in mice that had been exposed to vinyl chloride concentrations as low as 50 ppm. According to the Commission, EPA had calculated that under "reasonable conditions of use of self-pressurized products" the level of human exposure to vinyl chloride might be as high as 400 ppm.[272]

The Commission's rationale for banning vinyl chloride appeared in a single paragraph:

> Ample evidence in the form of scientific studies and chemical reports is available to establish the carcinogenicity of vinyl chloride monomer by inhalation and to demonstrate that human exposure to vinyl chloride monomer can result in angiosarcoma of the liver, a highly malignant, irreversible neoplasm. Because no safe level of human exposure to vinyl chloride monomer has been established, the Commission finds that adequate cautionary labeling cannot be written under the Federal Hazardous Substances Act for self-pressurized household products containing vinyl chloride monomer. The formulation of proper labeling under that act requires consideration of the possibility of latent injury from overexposure to a single dose, from frequent exposure to small doses, and infrequent exposure to small doses. The Commission has determined that the degree and nature of the hazard presented by the use of self-pressurized household products containing vinyl chloride monomer is such that the public health and safety can be adequately served only by keeping those products out of channels of interstate commerce, and takes this action to classify all such products as banned hazardous substances without regard to the date on which those

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[268] *See* 39 Fed. Reg. 12,342 (1974).
[269] *See* 39 Fed. Reg. 16,896 (1974).
[270] *See* 39 Fed. Reg. 14,215 (1974).
[271] *See* 39 Fed. Reg. 14,753 (1974).
[272] 39 Fed. Reg. 18,115, 18,116 (1974).

products were introduced into interstate commerce . . . .[274]

The Commission thus concluded that inhalation of vinyl chloride could be hazardous. The agency found "that any use of a self-pressurized product exposes the consumer to inhalation of some of its contents," and therefore it determined that "precautionary labeling would be insufficient to protect the public health."[275] Accordingly, it proposed to ban vinyl chloride from all self-pressurized products in interstate commerce.[276] This would have required manufacturers to repurchase such products from consumers.[277]

By the time the CPSC published its proposed ban,[278] the vast majority of manufacturers of household products had ceased using vinyl chloride as an ingredient or propellant. Thus, the Commission's proposal focused on those completed products that had not yet been sold or consumed. The few comments received—two from manufacturers and one from a trade association—did not oppose the agency's ultimate objective.[279] Rather, they urged that the ban apply only to products introduced into interstate commerce after its effective date. This modification would have relieved manufacturers of any obligation under section 15 of the FHSA to repurchase products already in commercial distribution or in consumer hands.[280]

The Commission rejected these suggestions to make the ban only prospective.[281] It reiterated EPA's finding that vinyl chloride may be present in the air in concentrations as high as 400 ppm after use of self-pressurized containers, and it observed that liver tumors had been induced in mice after exposure to concentrations as low as 250 ppm.[282] Furthermore, since publication of the CPSC proposal, OSHA had received information that liver tumors had been observed in rats exposed to vinyl chloride monomer at 50 ppm. The Commission cited OSHA's computation that the incidence of

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[274] 39 Fed. Reg. 30,112, 30,113-14 (1974).
[275] 39 Fed. Reg. 18,115, 18,116 (1974).
[276] *Id.*
[277] *See* notes 173-79 *supra* and accompanying text.
[278] *See* 39 Fed. Reg. 30,112, 30,112 (1974).
[279] Additional comments on the proposal were received from two consumer groups and four individuals. These generally favored the proposed ban. *Id.* at 30,112-13.
[280] *Id.*
[281] *Id.* at 30,113-14.
[282] *Id.* at 36,113.

angiosarcoma among workers exposed at the workplace to vinyl chloride was approximately 1 per 1,000, compared with a rate of approximately 1 per 10,000,000 in the unexposed population.[283] It observed that neither the manufacturer nor the trade association commenting on the proposal had submitted information that would permit establishment of a safe level of exposure to vinyl chloride. The Commission therefore concluded that the risk posed by products already in commerce was not speculative or minimal, and it refused to make its ban prospective only.[284] "[T]he potential hazard of exposure to vinyl chloride monomer from self-pressurized products used in households is sufficiently serious and immediate to warrant repurchase under provisions of section 15 . . . ."[285] The Commission also disputed comments suggesting that the repurchase provisions of section 15 were designed to assure reimbursement of consumers and to provide a means for retailers and distributors to recover economic losses rather than to effect the recall of hazardous products.[286]

The Commission's "final order" provided that persons adversely affected by the ban could submit objections and request a formal evidentiary hearing.[287] Reciting current FDA regulations,[288] the agency noted that "[i]f a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought."[289] Apart from this language, the agency did not suggest that facially adequate objections would be scrutinized to determine whether they justified a hearing.

The CPSC received only four requests for hearings on its ban of vinyl chloride,[290] all asserting that the repurchase requirement would work "financial hardship" upon them.[291] It concluded that

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[283] *Id.*

[284] *Id.*

[285] *Id.*

[286] *Id.*

[287] This is mandated by § 701(e) of the FD&C Act. 21 U.S.C. § 371(e) (1976).

[288] 39 Fed. Reg. 30,112, 30,114 (1974). The Commission inherited the FDA's regulations implementing the procedural requirements of the FHSA when it was given authority to administer that statute in 1972.

[289] *Id.*

[290] 39 Fed. Reg. 36,576, 36,577 (1974).

[291] The parties submitting objections will not be affected by the ban, and did not object to it, insofar as it prohibits the future sale of self-pressurized household products

none of the following principal objections justified a hearing:

(1) The Commission characterized the claim that its action represented an abuse of discretion as "a legal question which cannot be resolved in an evidentiary hearing."[202]

(2) It characterized the claim that it should have acted under the CPS Act as a legal objection. Furthermore, the agency stressed that it could not conscientiously find, as section 30(d) of the CPS Act then required, that the hazard of vinyl chloride could not be eliminated or reduced sufficiently under the FHSA.[203]

(3) The agency at once avoided and disputed the objectors' claim that it had failed to consider economic hardships:

> Although the Commission is not required by the Federal Hazardous Substances Act to consider the economic consequences of its actions, as a matter of policy the Commission has weighed economic factors in deciding upon courses of action. Such was the case with the vinyl chloride ban, for the Commission had before it and did consider the economic repercussions of its order. Since the objection is predicated upon an incorrect statutory interpretation . . . and since the contention is factually incorrect on its face, the Commission considered the objection frivolous and legally insufficient to warrant a section 701(e) hearing.[204]

(4) The agency rejected the claim that it had failed to make available the scientific data on which it relied.[205]

(5) The Commission insisted that it had found specifically that cautionary labeling would be inadequate to avert the hazard of vinyl chloride, and it asserted that an objection that this finding lacked substantial evidence was, "without more, insufficient to require a section 701(e) hearing."[206]

The Commission concluded with the following paragraphs, which clearly contributed to the subsequent judicial reversal of its decision that no hearing was required:

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containing vinyl chloride monomer. The objections focused on the fact that the ban applies to products already in the hands of consumers and suppliers and requires that such products be repurchased by the manufacturer. The objectors claim that the repurchase requirement will work financial hardship upon them.

Id.

[202] *Id.*
[203] *Id.*
[204] *Id.*
[205] *Id.*
[206] *Id.*

> All of the statements filed regarding the order raise objections dealing with the facts upon which the order is based. The Commission has carefully examined the objections and finds that none of them disputes the truth of the data relied upon by the Commission. The vast majority of these objections merely say that the Commission's data are not enough, that more is needed to support the Commission's action or that the data do not apply to the products being banned. The section 701(e) hearing was not placed in the statute so that parties regulated by agency action can require the agency to present evidence, more evidence, and still more evidence until the affected parties are finally satisfied that enough evidence has been presented. Whether the Commission's conclusions are reasonable cannot be resolved by an evidentiary hearing. The hearing is directed to receiving factual evidence and expert opinion testimony, not arguments regarding conclusions drawn from the evidence.
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> The objections are practically void of any references to, or offers to present, factual information which the Commission believes would lead to a conclusion contrary to that reached by it. Such information as has been referred to, even if true, is not legally sufficient to invalidate the ban order.
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> . . . .
>
> Whether the Commission's conclusion that this and other information before it necessitated the ban order was a reasonable conclusion is not a matter which can be resolved by an evidentiary hearing. The facts on which the ban order are based can be disputed, or other facts necessitating a contrary decision can be presented in an evidentiary hearing, but an evidentiary hearing for any other purpose would serve no valid function.
>
> In the present instance the Commission is concerned with protecting the public from a hazard which is highly severe. Angiosarcoma of the liver is a highly malignant, lethal neoplasm. To delay the effectiveness of the ban and leave products which have known dangers in the hands of dealers and consumers while an evidentiary hearing is being conducted to test the reasonableness of the Commission's decision on the basis of the information it had before it can serve no valid purpose and would be a mockery of the Commission's congressional mandate to protect the public from hazardous substances.[207]

The frustrated objectors, motivated primarily by the require-

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[207] *Id.* at 36,577-78.

ment to repurchase all outstanding products containing vinyl chloride, challenged the CPSC's "final order" review in the United States Court of Appeals for the Ninth Circuit.[396] The court held that the Commission had acted unlawfully in refusing to conduct the evidentiary hearing required by section 701(e) of the FD&C Act.[397] The objectors had filed timely objections that took issue with certain scientific studies the CPSC had relied upon to support its ruling. They also had sought a hearing to explore the potential health effects of the expected exposure levels of vinyl chloride in household products, which were expected to be much lower than those encountered by exposed industrial workers who developed liver cancer. The court concluded:

> Our examination of the legislative history of section [701(e)] convinces us that the Commission's regulations and procedures, insofar as they allow the Commission to deny a hearing when the objections adduced in good faith raise material issues that are not frivolous or inconsequential, are contrary to the statutory scheme established by Congress.
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> . . . .
>
> We hold that section [701(e)] leaves the agency no discretion to rule on the quality and validity of the objections prior to the formal hearing, so long as they are made in good faith and draw in question in a material way the underpinnings of the regulation at issue. It is inconsistent with the statutory scheme to require the objecting party to allege anything more.[398]

The Ninth Circuit's decision returned the issue of vinyl chloride regulation to the CPSC, although use of the chemical in consumer products had long since ceased. Thus, the court's ruling meant only that the agency could not assure the recall of products already

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[396] Pactra Indus., Inc. v. CPSC, 555 F.2d 677, 678 (9th Cir. 1977).

[397] *Id.* at 684.

[398] *Id.* The court stated further:

> This is not a case where the objections simply raise legal challenges to well-settled principles of law. Pactra's objections raise material issues that should not be dispelled at the outset without a hearing. The objections are neither frivolous nor inconsequential, and by raising the issue whether the products are hazardous within the statutory definition and whether the protection of the public could be served as well by means other than by classifying the products as banned hazardous substances, the company has expressed legitimate doubts as to the factual and legal premises of the Commission's order.

Id.

introduced in interstate commerce at the time of its original decision.

In early 1978, the CPSC concluded this episode by publishing a new "final" regulation declaring vinyl chloride a banned hazardous substance when used in self-pressurized household products.[361] The purpose of this action was simply to prevent future use of vinyl chloride in household products,[362] and the Commission's reasons paralleled those set forth in its original ban.[363] The agency made no attempt to correlate the human exposure to vinyl chloride resulting from the use of household products with the exposures of workers or test animals. It merely recited that "no safe level of human exposure to vinyl chloride monomer has been established . . . ."[364]

The Commission's 1978 "final order," like its predecessor, invited persons adversely affected to submit objections and requests for a formal evidentiary hearing.[365] None were filed, and thus the renewed ban became effective.

B. Chlorofluorocarbon Propellants

In 1977, the CPSC contemplated banning, and ultimately proposed to require warning labels on, products containing chlorofluorocarbon propellants.[366] The announced basis for the proposal was that the propellants increased the risk of human skin cancer by depleting atmospheric ozone.[367] Thus, unlike other carcinogens the CPSC has attempted to regulate, chlorofluorocarbons do not directly damage the DNA of vulnerable cells; rather, they increase the risk of human cancer, if at all, *indirectly*, by increas-

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[361] 43 Fed. Reg. 12,308 (1978).

[362] *Id.*

[363] The agency reiterated its conclusions that vinyl chloride had been shown capable of causing liver cancer in humans exposed by inhalation, that tumors had been induced in mice after exposure to concentrations as low as 250 ppm, and that concentrations as high as 400 ppm may remain in the air after household use of self-pressurized products. *Id.* at 12,309.

[364] *Id.* at 12,310.

[365] *Id.* The 1978 ban ostensibly applied to all products containing vinyl chloride as a propellant and thus apparently required repurchase by manufacturers. Manufacturers, however, had no reason to demand a hearing on this issue because product supplies had been exhausted in the intervening years.

[366] The CPSC's regulation of chlorofluorocarbon propellants was undertaken in conjunction with EPA and FDA.

[367] 43 Fed. Reg. 21,807, 21,808 (1978).

ing human exposure to the ultraviolet radiation filtered through the ozone layer.[208] Furthermore, the Commission did not have to confront the problem of measuring human exposure because the anticipated damage to the ozone layer, and thus the increased risk of cancer, is believed to be a function of the total quantity of chlorofluorocarbon propellants released into the atmosphere. In a rough sense, therefore, the level of usage could be taken as a measure of the level of human risk.

In the early 1970's, scientists first suggested that the release of chlorofluorocarbons into the atmosphere might deplete atmospheric ozone.[209] In June 1975, the Federal Interagency Task Force on Inadvertent Modification of the Stratosphere (IMOS)[210] recommended federal regulatory action to ban the use of certain fluorocarbons unless a contemporaneous National Academy of Sciences (NAS) study concluded that such action was not necessary.[211] The NAS study questioned the need for immediate regulatory action, but it confirmed IMOS's scientific hypothesis.[212] EPA, FDA, and the CPSC interpreted this conclusion as justifying prompt action to terminate most uses of chlorofluorocarbon propellants.[213]

The Natural Resources Defense Council (NRDC) had previously petitioned the CPSC to ban chlorofluorocarbon propellants in products within its jurisdiction. The agency had denied the petition on the ground that it lacked adequate supporting data and because the NAS report was expected soon.[214] In November 1976, however, following renewed petitions from NRDC citing the IMOS Task Force recommendation and anticipating the NAS conclusions, the Commission announced its preliminary conclusion that chlorofluorocarbon propellants presented an unreasonable risk of injury to consumers and that the risk could not be corrected by a product safety standard.[215] This announcement was not accompa-

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[208] 42 Fed. Reg. 21,807 (1977).

[209] *See id.* for a description of the early studies, which demonstrated the plausibility of their theory through computer models and other simulation techniques. This showing, coupled with the seriousness of the consequences if their theory were valid, prompted the two major scientific reviews, discussed at notes 310-12 *infra* and accompanying text.

[210] 42 Fed. Reg. 21,807 (1977).

[211] *Id.*

[212] *Id.*

[213] *Id.*

[214] 40 Fed. Reg. 36,419, 36,420-21 (1975).

[215] 42 Fed. Reg. 21,807 (1977).

nied by a formal proposal to ban, because contemplated EPA action under the TSCA would terminate production of the propellants for all nonessential uses, and thus render CPSC action unnecessary.[316]

In January 1977, the Chemical Specialties Manufacturers Association petitioned the CPSC to require consumer products containing chlorofluorocarbon propellants to bear labels stating their ingredients.[317] Although the Commission declined to act under the FHSA, it concluded that some form of labeling might be required under the CPS Act.[318] The Commission published a proposal to require products to bear warning labels and to require manufacturers of products in self-pressurized containers to report their composition.[319] This proposal relied on section 27(e) of the CPS Act.[320] The agency explained that the warning was an interim measure designed to "decrease the sale of such products by allowing consumers to choose between products that contain chlorofluorocarbons and products that are either non-aerosols or that contain another propellant."[321] The Commission did not attempt to document the hazard associated with the use of chlorofluorocarbon propellants; it simply recited the findings of the IMOS Task Force

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[316] *Id.*
[317] *Id.*
[318] *Id.*
[319] *Id.* at 21,808.
[320] Section 27(e) of the Act authorizes the agency by rule to

> require any manufacturer of consumer products to provide to the Commission such performance and technical data related to performance and safety as may be required to carry out the purposes of this [Act], and to give such notification of such performance and technical data at the time of original purchase to prospective purchasers and to the first purchaser of such product for purposes other than resale, as it determines necessary to carry out the purpose of this [Act].

15 U.S.C. § 2076(e) (1976), *cited at* 42 Fed. Reg. 21,807, 21,808 (1977). In support of its proposal, the Commission offered the following explanation:

> While it is anticipated that the use of chlorofluorocarbons will ultimately be halted, such regulatory action may take one year or longer to become effective. In the meantime, however, labels on the containers of aerosol consumer products propelled by chlorofluorocarbons informing consumers of the presence of the propellant and warning them of the possible hazard of ozone depletion would decrease the sale of such products by allowing consumers to choose between products that contain chlorofluorocarbons and products that are either non-aerosols or that contain another propellant. Thus, by reducing the use of chlorofluorocarbons during this interim period, the amount of ozone ultimately depleted could be reduced.

Id. at 21,808.
[321] 42 Fed. Reg. 21,807, 21,808 (1977).

and the NAS. Nor did it attempt to quantify the risk associated with the propellants or to assess the economic effects of its proposals, even though it acknowledged that one of its objectives was to discourage use of products containing chlorofluorocarbon propellants prior to EPA's anticipated ban.[323]

On May 13, 1977, EPA and FDA proposed to ban the production and use of chlorofluorocarbon propellants in all but certain "essential" consumer and drug products.[324] The CPSC announced contemporaneously that the proposed EPA ban rendered any ban of its own unnecessary.[325] The Commission also reminded observers that its own warning label proposal remained outstanding.[326]

On August 24, 1977, the CPSC adopted a final rule requiring this warning and requiring manufacturers of self-pressurized products to report their formulations to the agency:[327]

> [S]ince the proposed EPA ban will not apply to every consumer product containing these propellants, and since the EPA proposal would not prohibit the sale of products subject to the ban that are sold and introduced into commerce by the processor by April 15, 1979, the Commission has decided to require that the aerosol consumer products within its jurisdiction that contain chlorofluorocarbon propellants shall bear a label stating that the product contains a chlorofluorocarbon and that such compounds may harm the public health and environment by reducing ozone in the upper atmosphere.[328]

The Commission's label rule required consumer products shipped after February 20, 1978, but prior to the effective date of EPA's proposed ban, to bear the following statement: "WARNING—Contains a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere."[329] The rule's preamble dealt mainly with the twenty-one comments received on the proposal. Most comments had favored the proposed warning or more aggressive action by the agency to

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[323] *Id.* at 21,807-08.
[324] 42 Fed. Reg. 24,536 (1977) (FDA Proposal); 42 Fed. Reg. 24,542 (1977) (EPA Proposal).
[325] 42 Fed. Reg. 24,550 (1977).
[326] *Id.*
[327] 42 Fed. Reg. 42,780 (1977) (codified at 16 C.F.R. § 1401 (1980)).
[328] *Id.*
[329] *Id.*

ban chlorofluorocarbon propellants.[329] To those commentators who viewed the hazard as unconfirmed or as not serious enough to warrant a warning, the agency responded:

> [T]he great weight of current scientific opinion is that continued use of these compounds will result in a depletion of the ozone layer.
>
> Although there is some controversy as to the exact degree of ozone depletion, the Commission concludes that at any level within the range that is currently estimated by National Academy of Sciences' committees and other current researchers, the risk of harm is substantial.
>
> The Commission also believes that providing the identification and warning statement on the containers of these products will substantially reduce the demand for them during the period that these products are available before the proposed EPA ban becomes effective. In addition, a number of products subject to Part 1041 are not affected by the initial phase of EPA regulation.[330]

Most manufacturers of products subject to the CPSC's warning label requirement had complied voluntarily before the rule became effective.[331] On March 17, 1978, EPA banned production of chlorofluorocarbon propellants under the TSCA for all but "essential" uses,[332] and the CPSC announced contemporaneously that there was no need for it to take similar action under its statutory authority.[333]

The CPSC played only a minor role in the combined federal efforts to regulate chlorofluorocarbon propellants. Consumer products other than foods, drugs, and cosmetics constituted a very small percentage of the market,[334] and the Commisson's staff

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[329] *Id.* at 42,781-82.

[330] *Id.* at 42,783 (footnote omitted).

[331] Fox, *Atmospheric Ozone Issue Looms Again*, Chemical & Engineering News, Oct. 16, 1978, at 25.

[332] 43 Fed. Reg. 11,318, 11,318-19 (1978).

[333] 43 Fed. Reg. 11,326 (1978).

[334] At the time, American production of fluorocarbons amounted to approximately 1 billion pounds annually, for which the principal uses were as aerosol propellants (50%) and refrigerants (28%). FDA had jurisdiction over nearly 80% of the fluorocarbons used in the United States as propellants in self-pressurized containers, primarily for cosmetics and drugs; the CPSC was responsible for only a small part of the market, because most household products even then contained propellants other than fluorocarbons. *See* Council on Environmental Quality, Fluorocarbons and the Environment, Report of Federal Task Force on Inadvertent Modification of the Stratosphere 4 (June 1975), *cited at* 41 Fed.

played a subordinate role in the evaluation of the hazard. After its initial labeling proposal, the agency deferred to EPA and FDA.[335]

C. TRIS-treated Children's Garments

On April 8, 1977, the CPSC announced that it considered TRIS-treated garments for children to be "banned hazardous substances" within the meaning of section 2(q)(1)(A) of the FHSA.[336] The events leading to this announcement are not atypical of governmental responses to discoveries that a substance poses a risk of human cancer. Unhappily, they depict Commission decisionmaking at its most inept.

Long before the Commission's 1977 announcement CPSC scientists, aware that a Commerce Department standard for flame retardant fabrics would increase the use of new chemicals in the production of clothing, had urged unsuccessfully that the agency establish a program to evaluate new flame retardants in consumer garments.[337] Meanwhile, the National Cancer Institute's (NCI) Chemical Selection Work Group had nominated TRIS for carcinogenicity testing based on its chemical structure and on its growing use as a flame retardant.[338] Chronic feeding studies in rats and mice were commenced within a year.[339]

Evidence incriminating TRIS as a potential carcinogen slowly began to accumulate. On October 29, 1975, EPA advised the CPSC that TRIS had been found mutagenic in short-term testing.[340] On March 19, 1976, the Director of the CPSC's Bureau of Biomedical Sciences received a telephone call from Dr. Bruce Ames,[341] a renowned microbiologist and developer of a well-known test for mutagens. Ames said that on the basis of extensive testing, he considered TRIS to be a mutagen and probably a carcinogen, and he

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Reg. 52,070, 52,072 (1976) (copy on file with the Virginia Law Review Association).

[335] 42 Fed. Reg. 42,780 (1977).

[336] 42 Fed. Reg. 18,849, 18,853 (1977).

[337] Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce, 95th Cong., 2d Sess., Report on the Consumer Product Safety Commission's Regulation of TRIS: The Need for An Effective Chronic Hazards Program 5 (Comm. Print 1978) [hereinafter cited as TRIS Report].

[338] *Id.*

[339] *Id.* at 9.

[340] *Id.*

[341] *Id.* at 10.

urged the Commission to ban the use of TRIS in consumer products.

Less than a week later, the EDF petitioned the Commission to promulgate a rule "[r]equiring a label on sleepwear [containing TRIS] warning consumers of the potential hazard and recommending that sleepwear be pre-washed three times prior to use, a practice which would reduce, although not eliminate, the exposure."[342] The EDF petition cited studies that concluded that rats absorbed significant amounts of TRIS through their skin and pointed out that large amounts of TRIS could be found on the surface of treated garments. The petition contended that children could easily take up significant levels of the chemical through skin absorption or by mouthing of treated garments.[343] Although the agency staff reviewing the petition dismissed a memorandum from the principal domestic manufacturer of TRIS that challenged the EDF's characterization of TRIS as a potential hazard,[344] it forwarded no recommendation to the Commissioners. The EDF was informed that the agency would not act on its petition until the results of the ongoing NCI rat and mouse studies[345] were available. In the same month, the staff received a report from FDA about the results of three new short-term tests that demonstrated that TRIS was capable of causing mutagenic effects.[346]

The problem facing the Commission changed when production of new TRIS-treated fabrics ceased—at least temporarily. For a ban to have reduced exposure immediately, it would have had to apply to articles in the manufacturing pipeline. The business community would have opposed this, but would not have opposed a ban on future use of TRIS, because that would not have required any recall of outstanding stocks.[347] Such a delayed ban would have exposed the Commission to sharp criticism by consumer groups, however, and probably to suit by the EDF.

On February 4, 1977, the NCI provided the CPSC with preliminary reports of the recently concluded rodent bioassays.[348] The

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[342] *Id.* (quoting EDF petition).
[343] *Id.*
[344] *Id.* at 10-11.
[345] *Id.* at 11.
[346] *Id.* at 11 n.193.
[347] Krulwich Interview, *supra* note 38.
[348] 42 Fed. Reg. 18,849, 18,850 (1977).

EDF also obtained the NCI data, and within two weeks it submitted a second petition, demanding that the Commission ban TRIS-treated garments as an "imminent hazard to the public health" under the FHSA.[349] Sometime later, the EDF also filed suit against the agency "seeking an immediate Commission ban on the sale of TRIS-treated garments."[350] This suit's contribution to the public perception of bureaucratic foot-dragging led to frantic discussions within the agency.

Several weeks prior to the filing of the lawsuit, Commission staff members held a public meeting with EDF representatives to discuss the scientific basis for the request for action and to examine the regulatory options available to the agency.[351] The Commissioners held separate public meetings with NCI biostatistician Marvin Schneiderman[352] and with both EDF and industry representatives.[353] On March 25, 1977, the NCI's data evaluation group verified the results of the rodent bioassays.[354] As press and congressional interest mounted, the Commission undertook its own studies on the extent of human exposure to TRIS from treated garments. The agency also authorized the staff to develop estimates of the risk.[355]

On April 7, 1977, the CPSC announced its response to the EDF petition and its actions on TRIS. Though it was entitled "Interpretation," the agency's decision was published in the Rules and Regulations section of the next day's Federal Register.[356] The agency construed section 2(q)(1)(A) of the FHSA as automatically rendering TRIS-treated garments "banned hazardous substances":[357]

> Section 2(f)(1)(A) . . . defines "hazardous substance" as "any substance or mixture of substances which is toxic * * * if such substance or mixture of substances may cause substantial personal in-

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[349] TRIS Report, *supra* note 337, at 13 (quoting EDF petition).

[350] *Id.* (quoting Environmental Defense Fund v. CPSC, Civ. No. 77-517 (D.D.C., filed March 23, 1977)).

[351] Interview with Alan Shakin, Attorney in the CPSC General Counsel's Office, in Washington, D.C. (August 14, 1979) [hereinafter cited as Shakin Interview] (copy of notes from interview on file with the Virginia Law Review Association).

[352] *Id.*

[353] *Id.*

[354] 42 Fed. Reg. 18,849, 18,850 (1977).

[355] Shakin Interview, *supra* note 351.

[356] 42 Fed. Reg. 18,849 (1977).

[357] *Id.* at 18,853.

> jury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children." Section 2(g) of the FHSA . . . states that "[t]he term 'toxic' shall apply to any substance * * * which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface."
>
> Section 2(q)(1)(A) of the FHSA . . . defines "banned hazardous substance" as "any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted." . . .
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> . . . .
>
> The Commission finds that children's wearing apparel containing TRIS that is currently in interstate commerce or will be introduced into interstate commerce in the future is a banned hazardous substance according to these applicable provisions of the FHSA. In addition, any children's wearing apparel containing TRIS that has not been washed, even if it has already been sold, is also banned as hazardous. Such wearing apparel is toxic and presents a substantial risk of cancer as a result of its foreseeable absorption through the skin and ingestion by mouthing. It is also of course intended for use by children.[348]

Anticipating legal challenges to its failure to afford any opportunity for public comment, the CPSC emphasized that it was simply interpreting the self-executing language of section 2(q)(1)(A). The agency observed that the APA's rulemaking requirements do not apply to statements of agency policy or to interpretative rules, and contended further that even if the APA's rulemaking requirements were formally applicable, the hazard posed by TRIS-treated garments provided good cause to dispense with notice and opportunity for comment.[349]

The Commission's cryptic explanation of its legal theory ultimately proved unconvincing. Its discussion of the health risk associated with TRIS in children's garments was more careful, if no less controversial. The agency cited the NCI animal data and observed that any compound capable of inducing cancer in laboratory animals must be considered a risk to humans.[350] It identified expo-

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[348] *Id.* at 18,852-53.
[349] *Id.* at 18,853.
[350] *Id.* at 18,850.

sure data assembled by three different sources, including the EDF, and referred to three quantitative estimates of the human cancer risk which projected increases in the incidence of cancer among exposed children ranging from 25 to 17,000 per million population.[361] The CPSC acknowledged that TRIS-treated fabrics provided a health benefit by reducing the risk that children would be seriously burned if their clothing caught fire, but it concluded that the standard requiring children's garments to be flame retardant could be met by other materials.[362]

The Commission's "ban" on children's garments did not extend to unfinished TRIS-treated fabric supplied by mills to garment manufacturers, although it was intended to reach uncut fabric intended for sale directly to consumers. The agency also specifically excepted TRIS-treated children's garments that had already been washed, on the theory that the process of washing reduced substantially the amount of TRIS to which children were likely to be exposed.[363]

The CPSC's April 7 announcement sparked a whirlwind of legal

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[361] The proposal stated:

> The Commission has considered risk assessments that are based on the estimates of exposure . . . . The methods used to prepare the estimates are described in a March 1977 paper entitled, *Estimates of Human Lifetime Carcinogenic Risk From Exposure* to TRIS, prepared by Drs. Charles Brown, Marvin Schneiderman, and Kenneth Chu of the National Cancer Institute. The statistical extrapolations are based on the use of two mathematical models: The single-hit model (linear no threshold) and the log-probit model (Mantel-Bryan). . . .
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> (1) *Bureau of Biomedical Science.* BBS has projected cancer incidence rates based on its exposure estimates and on data from the NCI study. These projected rates show the kidney to be the primary target organ. The best estimates [sic] of BBS is approximately 300 kidney cancers per million male population. For females the projected rate is about one-fifth that of males.
>
> Based on the single hit model the BBS estimates for lifetime risk of cancer of the kidney is between 60 and 1,800 cases per million male population. For the log probit model the estimates range from 25 to 5,100 cases per million males. All of these estimates are lifetime risk or lifetime incidence estimates.
>
> (2) *Environmental Defense Fund.* EDF also provided its estimates on human exposure to NCI which used the same models, and these data provided estimates of a lifetime incidence of cancer of as high as 6,000 per million male population, based on maximum exposure, the rat kidney and the log probit model.
>
> (3) *Hooper and Ames.* Hooper and Ames estimate that for one year of exposure, 1.7 percent of the children would develop cancer (17,000 cases/million). An exposure throughout childhood would give a higher risk . . . .

Id. at 18,851 (document numbers omitted).

[362] *Id.* at 18,851-52.

[363] *Id.* at 18,853.

and political controversy. An association of garmentmakers quickly sued the Commission, seeking expansion of the ban to include fabrics they had already purchased from the mills but had not yet incorporated into finished garments.[364] Such an expansion would have required repurchase by the fabric mills. Anticipating a judicial ruling that its action had been too limited, the Commission extended its ban to include uncut TRIS-treated fabric and other component products.[365] The agency's original decision to limit its ban to finished children's garments had been designed to comport with its legal theory, namely that the Act defined as a "banned hazardous substance" any product that was (a) toxic and (b) therefore hazardous and (c) capable of absorption or ingestion by children.[366] Its later expansion of the ban rested on the theory that the FHSA authorized regulation of components, as well as finished products sold at retail.[367]

The Commission's decision to extend the FHSA's repurchase requirement to the fabric mills precipitated immediate legal challenges from producers of TRIS-treated fabric, one of which resulted in a decision that undercut the agency's legal theory. In *Springs Mills, Inc. v. CPSC*,[368] the district court held that the agency's failure to engage in rulemaking before declaring TRIS-treated fabrics and garments "banned hazardous substances" amounted to a denial of due process.[369] It was not sufficient for the Commission simply to announce its interpretation of section 2(q)(1)(A). Because of the "continuous reference to 'regulation' in the applicable parts of the statute and in the legislative history," the court concluded that Congress intended to require rulemaking for any ban under the statute.[370] In rejecting the CPSC's reliance

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[364] American Textile Mfrs. Inst. v. CPSC, No. 77-482 (D.D.C., filed April 20, 1977), *cited at* 42 Fed. Reg. 28,059 (1977).

[365] 42 Fed. Reg. 28,059, 28,064 (1977).

[366] *See* Memorandum to the Commission from Alan C. Shakin, Office of the General Counsel, Options for Commission Action as to Wearing Apparel Containing TRIS 3 (Feb. 25, 1977) (copy on file with the Virginia Law Review Association).

[367] *See* 42 Fed. Reg. 28,059, 28,063 (1977).

[368] 434 F. Supp. 418 (D.S.C. 1977).

[369] *Id.* at 418, 435.

[370] *Id.* at 430. The court observed:

> The continuous reference to "regulation" in the applicable parts of the statute and in the legislative history clearly indicate the congressional intent that the Commission proceed with rule-making procedures, as set forth in the Food, Drug and Cosmetic Act, and not attempt to make final decisions having nationwide impact without af-

on the APA exemption for "interpretative rules and statements of policy,"[372] the court emphasized the disruptive impact of the Commission's announcement. Noting that the ban set in motion the repurchase requirements of section 15, which it termed "one of the most drastic procedures known to law,"[373] the court observed:

> [Defendants'] position is not supported by the language of the statute or by the legislative history. This history . . . shows clearly that Congress intended the Secretary to act "by regulation" which would mean under the rule-making process. Congress also indicated its concern for the powers given CPSC by requiring rule making under the Federal Food, Drug and Cosmetic Act rather than the Administrative Procedure Act in matters relating to hazardous substances. . . . Obviously, Congress did not intend for matters under the Federal Hazardous Substances Act to be handled or decided on the basis of ex parte communications with members of the Commission or without effective notice so that objecting parties could appear, present evidence and test the validity of the information presented. . . .
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> . . . The fact that children may be involved does not obviate the necessity that CPSC by proper rule-making procedure determine that an article is a "hazardous substance," before it may go on to find that it is a "banned hazardous substance."[374]

The court set aside the Commission's revised June 1 ruling and enjoined the agency "from attempting to apply or enforce against any party, any article, fabric, yarn, or fiber any of its previously adopted TRIS regulations . . . ."[375]

This ruling caused the CPSC to revise its regulatory posture. First, it settled several enforcement proceedings[376] on terms that effectively precluded requiring manufacturers of TRIS-treated fabric to repurchase material from their customers.[377] Second, the

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fording affected parties the basic requirements of due process.

Id.

[372] 5 U.S.C. § 553(d)(2) (1976).

[373] 434 F. Supp. at 430.

[374] *Id.* at 431-32.

[375] *Id.* at 435.

[376] The Commission originally brought suit in New York against several other fabric mills in addition to Springs Mills. That action was later transferred to the District of South Carolina, where it was assigned to the same district judge who presided in the *Springs Mills* case.

[377] Krulwich Interview, *supra* note 38; Shakin Interview, *supra* note 351.

agency tried to salvage its original legal theory. It formally withdrew its April 8 "interpretation" that the FHSA automatically defined TRIS-treated garments as "banned hazardous substances,"[377] and simultaneously substituted a statement of policy that reiterated its original legal position.[378] The agency made clear that it did not regard *Springs Mills* as precluding initiation of court proceedings to enforce its original interpretation of the FHSA, and noted that it had undertaken a number of suits against manufacturers and sellers of finished children's garments.

The Commission explained its earlier action in the following terms:

> The interpretations were intended to state the Commission's enforcement policy and forewarn that individual enforcement actions would be filed in Federal District court whenever the Commission found a violation of the FHSA to be associated with any TRIS products that are banned hazardous substances. As interpretations, however, the April 8 and June 1 documents could not be relied on by the Commission to prove that any TRIS products are banned hazardous substances under the FHSA.[379]

It then proceeded to reiterate a disclaimer that had never been explicit in its earlier announcements:

> Similarly, the Commission cannot and will not rely on its new statement of policy to prove that any hazards are associated with TRIS products. In any enforcement action the Commission files, it is prepared to prove that the TRIS products are banned hazardous substances and that judicial relief is therefore necessary. In these enforcement actions, then, any affected party will be provided an opportunity to litigate the merits of the Commission's claim and thus will be afforded due process.[380]

The CPSC brought several cases during 1977 and 1978. In one, *United States v. Articles of Hazardous Substance*,[381] the owner of seized garments challenged the agency's enforcement action on grounds similar to those accepted by the *Springs Mills* court. But the United States Court of Appeals for the Fourth Circuit ac-

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[377] 42 Fed. Reg. 61,593 (1977).
[378] 42 Fed. Reg. 61,621 (1977).
[379] *Id.*
[380] *Id.*
[381] 588 F.2d 39 (4th Cir. 1978).

knowledged that the FHSA provides the Commission alternative ways of regulating some hazardous substances:

> Under FHSA a substance may be a "banned hazardous substance" either by meeting the statutory definition in Section 1261(q)(1)(A), or by being so defined by regulation after formal rule-making under Sections 1261(q)(1)(B) and (q)(2). Similarly, a substance may be a "hazardous substance" if it meets the statutory definition contained in Section 1261(f)(1)(A) or has been so defined by regulation under 15 U.S.C. § 1262(a). From our examination of the statutory structure, it appears that the Commission may proceed against a substance by regulation pursuant to its rule-making authority, or may go directly to court upon its allegation that the goods or substances meet the statutory definition under Section 1261(q)(1)(A). We agree with the district court that *where the Commission elects to follow the latter course in a Section 1265 proceeding, the issue of whether TRIS-treated children's sleepwear is, in fact, a "banned hazardous substance" is a question to be later determined in a hearing on the merits in the condemnation proceeding.*[325]

The CPSC continues to enforce the FHSA's "ban" against TRIS-treated garments, but it has not engaged in rulemaking to extend that "ban" to unfinished fabric. The agency thus has never confronted squarely the scientific issue raised by its May 1, 1977 announcement; the extent of the risk posed by TRIS in children's garments remains a matter of conjecture.[326] The different, and pre-

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[325] *Id.* at 42 (emphasis added). This statement both acknowledges the Commission's primary jurisdiction to declare a substance or product banned through a formal administrative proceeding and confirms that if the agency instead proceeds to enforce the statutory prohibition of section 2(q)(1)(A), the issue of whether several articles pose a hazard will be for the court to decide in the first instance. *Cf.* United States v. Tutag Pharmaceuticals, Inc., 602 F.2d 1387 (10th Cir. 1979) (FDA may find that a new drug requires a new drug application with or without an administrative record).

[326] On June 4, 1981, the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce released a study prepared by the Commission on the risk posed by TRIS-treated children's pajamas. The study found, first, that TRIS can be absorbed through the skin, and, second, that rewashing of treated garments does not remove all of the chemical. According to press accounts, the study concluded that "the risk of contracting cancer from wearing children's pajamas treated with TRIS is seven times greater than previously thought." [1981] 5 CHEM. REG. REP. (BNA) 300. This estimate has not been subjected to challenge in any public proceeding or reviewed by independent scientists.

The primary studies include Nicholson, *Case Study I: Asbestos—The TLV Approach*, 271 N.Y. ACAD. SCI. 152 (1976); Selikoff, Hammond & Churg, *Carcinogenicity of Amosite*

sumably lesser, risk associated with the unfinished fabric that the agency later sought to regulate also remains unexplored. The use of TRIS in producing flame retardant fabric has, however, long since ceased.

D. Patching Compounds and Emberizing Materials Containing Asbestos

Evidence has been accumulating since the 1920's that asbestos can produce serious chronic adverse effects in humans, including lung cancer; most of this evidence has come from studies of workers exposed to asbestos on the job.[384] By 1976, FDA, EPA, and OSHA had initiated regulation of exposures within their respective jurisdictions.[385]

In July of that year, the NRDC[386] petitioned the CPSC to ban wall-board patching compounds containing asbestos as "hazardous" under the FHSA. The next year, the Commission received a consumer complaint[387] about the potential health hazards of asbestos used in artificial emberizing compounds, materials used on artificial logs and fireplace floors to simulate live embers and ashes.[388] The CPSC responded by publishing a proposal to ban both patching compounds and artificial emberizing materials containing respirable asbestos.[389] The Commission relied on section 8 of the CPS Act,[390] and it justified its preference for the CPS Act on two grounds. First, the agency argued that rulemaking under the CPS Act would be more expeditious and less costly than under the FHSA. Second, it contended that the informality of the process

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Asbestos, 25 ARCH. ENV. HEALTH 183 (1972); Selikoff, Hammond & Seidman, *Cancer Risk of Insulation Workers in the United States*, INTERNATIONAL AGENCY FOR RESEARCH ON CANCER 209 (1973). *See generally* M. SHAPO, A NATION OF GUINEA PIGS 191-217 (1979).

[384] The adverse effects attributable to asbestos exposure include (1) asbestosis, a nonmalignant scarring of the lungs; (2) bronchogenic carcinoma, a malignancy of the interior of the lung; (3) mesothelioma, a diffuse malignancy of the lining of the chest cavity or of the lining of the abdomen; and (4) cancer of the stomach, colon, and rectum. 42 Fed. Reg. 38,783, 38,784 (1977).

[385] *See* 38 Fed. Reg. 27,076 (1973) (FDA proposal); 40 Fed. Reg. 1,879 (1974) (EPA proposal); 40 Fed. Reg. 47,652 (1975) (OSHA proposal).

[386] 42 Fed. Reg. 38,781, 38,783 (1977).

[387] *Id.* The EDF later supported the consumer complaint.

[388] *Id.*

[389] *Id.* at 38,783, 38,790-91 (codified at 16 C.F.R. §§ 1304-1305 (1980)).

[390] *Id.* at 38,782.

would facilitate public participation.[391]

The proposal's summary of the evidence of the health hazards of asbestos noted that most available human data concerned exposure in the workplace. The agency added, however, that adverse effects had been observed in individuals—notably families of workers—who did not themselves handle asbestos.[392] Furthermore, it stated that "[a]ll commercially available forms of asbestos which have been tested are carcinogenic in mice, rats, hamsters, and rabbits."[393] The hazard appeared dependent on the likelihood of inhalation and thus was a function of the form of asbestos.

The agency acknowledged that evidence of chronic risk associated with short-term exposure to asbestos was limited,[394] and it conceded that "[q]uantitative dose-response relationships between asbestos inhalation and related disease have not been determined for animals or humans . . . ."[395] Still, the Commission noted that laboratory rats exposed once to respirable asbestos for as short a period as seven hours developed tumors, including mesotheliomas.[396] In addition, studies of industrial employees who did not work with asbestos, but who were exposed intermittently on the job site, revealed a heightened risk of mesothelioma.[397] Moreover, "evidence has indicated that asbestos also acts as a lung carcinogen at levels much below those which will produce asbestosis."[398]

The Commission assessed consumer exposure to asbestos as follows:

> Reports of the hazard, or potential for hazard, from exposure to asbestos resulting from use of asbestos-containing consumer products are very limited. The only known quantitative study of asbestos levels in products regulated by this Commission [concerned] asbestos fiber concentrations measured during the use of consumer spackling patching and taping compounds. This study indicated that airborne fiber concentrations, exceeding the interim OSHA allowable excursion exposure level, were detected during application

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[391] *Id.* at 38,783.
[392] *Id.* at 38,784-85.
[393] *Id.* at 38,784 (citation omitted).
[394] *Id.* at 38,785-86.
[395] *Id.* at 38,784.
[396] *Id.* at 38,785.
[397] *Id.* at 38,785-86.
[398] *Id.* at 38,786.

> and cleanup operations. Fibers were detected in adjacent rooms during mixing operations and it was reported that ["]* * * significant concentrations of asbestos remained suspended and could pervade living quarters for a considerable duration of time * * *" The authors suggest that the use of spackling and other patching compounds (in mixing, and sanding and cleanup operations) may expose the user and other members of the household to "* * * significant concentrations of asbestos."
>
> Asbestos in the household presents a great risk due to the presence in the household of persons, such as children, who may be particularly vulnerable to carcinogens. It is generally observed that, because of the long latency period, exposure to inhalable asbestos in the some [sic] can be life-shortening for children. . . .
>
> The Commission concludes that exposure to asbestos from either patching compounds or artificial emberizing materials presents an unreasonable risk of injury sufficient that either product standing alone should be banned. The Commission also notes that consumers are exposed to asbestos from sources other than the products proposed for banning. . . . Consumers who are exposed to asbestos fibers from artificial embers and ash and patching compounds thus receive additional doses of asbestos and can be presumed to face a greater risk than members of the population who are not so exposed, and a greater cumulative risk than if no asbestos were present in the general environment.[405]

The agency concluded that a "no effect" level for asbestos had not been demonstrated. Although a threshold dose may exist for some individuals, "other individuals may have cancer induced by doses so low as to be effectively zero."[406]

The Commission focused specifically on the risk associated with asbestos in patching compounds:

> In assessing the degree and nature of the risk of injury to consumers, the Commission has reviewed experimental data and human experience information. In addition, on the basis of data by Rohl, et al. . . ., the Commission's Health Sciences staff has calculated an assessment of the risk of consumer exposure which is available at the Office of the Secretary. The calculations are based on the application of a theoretical model . . . to epidemiological data cited in the literature. . . . For purposes of this assessment,

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[405] *Id.* (citation omitted).

[406] *Id.* (citation omitted). The proposition that no dose of a carcinogen can be considered safe does not distinguish asbestos. *See, e.g.*, IRLG document, *supra* note 195.

> the Commission considered the use of patching compounds by a consumer, for six hours a day four times a year, to be a high yet reasonably foreseeable yearly exposure. The increased risk of death from respiratory cancer induced by this yearly exposure is estimated at between 10 and 2,000 per million. For five years of exposure at these levels, the risk increases geometrically and is estimated at between 1,000 and 12,000 per million. Based on current information, the Commission estimates that the lower estimate of 10 per million is closer to the actual risk for a one year exposure. Nevertheless, in view of the seriousness of the injury and the cumulative effects of asbestos exposure, even this minimum figure represents an unacceptable risk. The Commission believes that reducing exposure to respirable free-form asbestos in the home represents a substantial decrease in risk to consumers, since, for many people, the major exposure to inhalable asbestos is in the home.[401]

In addressing the availability of substitute materials, the agency conceded that asbestos possessed unique qualities such as strength, pliability, and temperature resistance. Alternatives had not been found for all products, and the substitution of more costly materials could lead to ten to fifteen percent higher prices.[402] But the Commission noted that "[m]any producers are . . . either presently marketing asbestos-free materials or expect to in the near future."[403] In short, consumers would have asbestos-free patching compounds, but at higher prices.[404]

The Commission purported to consider the commercial impact and the relative health effects of various possible effective dates of a ban—ranging from 30 to 360 days after promulgation. It concluded that the manufacture, sale, importation, and distribution of patching compounds containing asbestos should be prohibited thirty days after publication of a final rule.[405] This choice of date would have forced the recall of some products.

The CPSC's analysis of artificial emberizing materials was more conclusory. The Commission made no attempt to quantify the risk posed by these products.[406] The agency identified three substitutes

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[401] 42 Fed. Reg. 38,781, 38,787 (1977) (citations omitted).
[402] *Id.*
[403] *Id.*
[404] *Id.*
[405] *Id.* at 38,788.
[406] The proposal stated:

> Measurements are not available of the amounts of asbestos in the air from asbes-

for asbestos already in use, but noted that at least one was more expensive and that another was a less realistic mimic of the " 'glowing' look" of real ashes.[407] With this cursory explanation, the agency proposed that its ban take effect immediately upon publication of a final ban.[408] The agency's treatment barely concealed its disdain for the consumer demand satisfied by this group of products.

In the final section of its proposal, the Commission concluded that it could legitimately single out and ban individual ingredients or kinds of products. The agency cited its similar action banning unstable refuse bins,[409] and then explained:

> The Commission believes that not all patching compounds present an unreasonable risk of injury to the public, only patching compounds containing respirable free-form asbestos. The hazard associated with this product is the free form in which the asbestos appears. While a safe patching compound can be manufactured, it is not possible to manufacture a safe patching compound containing respirable free-form asbestos because a safe level of exposure to free-form asbestos is unknown. Therefore, it does not appear that a standard for patching compounds containing respirable free-form asbestos is feasible at this time.[410]

On August 15, 1977, the CPSC conducted the hearing required[411] to afford interested persons an opportunity to express their views. Seven witnesses appeared at the one-day hearing, four of whom represented manufacturing interests and three of whom spoke for consumers. In addition, the Commission received thirty written comments on its proposal, of which ten (including those of five-

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tos-containing emberizing materials in homes. However, it appears that the amount of airborne asbestos in such homes would increase when air currents in the home are created by downdrafts from a fireplace chimney or other activities that stir air in any room. Since emberizing materials may contain up to 50 percent asbestos, which if not permanently bound into artificial fireplace logs would be in respirable form, the risk associated with emberizing materials is considerable since it continues to exist 24 hours a day.

Id.

[407] *Id.*

[408] *Id.*

[409] *Id.* at 38,789 (citing 42 Fed. Reg. 30,296 (1977)).

[410] *Id.*

[411] Section 9(a)(2) of the CPS Act, 15 U.S.C. § 2058(a)(2) (Supp. III 1979), requires the Commission to give interested persons an opportunity to present their views before it promulgates a rule.

manufacturers) supported the agency's contemplated ban.[413] The low level of interest in the agency's proposal probably reflected the slight importance of the products and the relative ease with which manufacturers of patching compounds found adequate substitutes.

The Commission published its final banning regulation and its response to comments on December 15, 1977.[414] In a separate document, the agency determined formally, in accordance with section 30(d) of the CPS Act,[415] that it was in the public interest for the agency to regulate the two products under the CPS Act rather than the FHSA.[416] It noted that "several persons in the marketing chain commented approvingly on the decision to regulate under the [CPS Act] because the [CPS Act] does not require repurchase of banned hazardous products."[417] For the same reason, unidentified "consumer-oriented interests" disputed the agency's failure to invoke the mandatory repurchase requirement of the FHSA. The Commission held to its initial view, concluding that prompt issuance of a final ban outweighed any need for repurchase.[418]

The preamble to the final rule addressed several comments that focused on the scope and implementation of the ban.[419] Opposition to the agency's decision focused primarily on deficiencies in its risk analysis and on its rather perfunctory assessment of economic effects. The agency adhered to its conclusion that the emberizing materials should be banned immediately,[420] but it set two effective dates for consumer patching compounds in an attempt to soften the economic effects of its ban.[421] Several comments questioned whether exposure to the levels of asbestos found in the banned products presented a serious health risk. The Commission acknowledged its reliance on the occupational evidence,[422] but insisted that it was relevant to the consumer context. The agency again cited one report that documented significant levels of respirable asbestos in rooms adjacent to those in which patching com-

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[413] 42 Fed. Reg. 63,354, 63,355 (1977) (document no. 2).
[414] *Id.*
[415] 15 U.S.C. § 2079(d) (1976).
[416] 42 Fed. Reg. 63,354 (1977) (document no. 1).
[417] *Id.*
[418] *Id.*
[419] 42 Fed. Reg. 63,354, 63,355-60 (1977) (document no. 2).
[420] *Id.* at 63,358.
[421] *Id.* at 63,357-58.
[422] *Id.* at 63,358.

pounds were being used,[423] and it speculated—without providing supporting data—that where background levels of asbestos were low, "exposure in the home to asbestos fibers released from consumer products could represent the major exposure."[424]

Comments specifically challenged the Commission's risk estimate for the patching compounds. One commentor submitted a study involving an actual product that contained much less asbestos than those hypothesized in the agency's risk assessment. The accompanying analysis estimated the risk associated with five year's exposure to be as low as one lifetime excess cancer death per million population. The agency responded that "while asbestos levels may vary, they do not change the fact that there is no known level below which inhalable asbestos may be considered safe."[425] It discounted any differences in asbestos exposure between compounds mixed by the consumer and those sold in premixed form,[426] and argued that "no data were submitted" to show that its own exposure estimate was inflated.[427] The Commission did not stand squarely behind its original risk assessment, but it did decline to conclude that the risk from patching compounds was insignificant.[427] Although the Commission agreed that further study of the many possible substitutes for asbestos was needed, it insisted that "the known risk from inhalable asbestos requires the banning of these products at this time."[428]

The CPSC also answered criticisms of its original estimate of the

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[423] *Id.*

[424] *Id.*

[425] *Id.* at 63,359.

[426] *Id.*

[427] *Id.* The Commission's estimate assumed exposure for four days, eight hours a day. *Id.*

[427] *Id.* at 63,360-61. The Commission used the statutory characterization "unreasonable" to describe the risk. The implication was that, in the context, any risk of cancer was "unreasonable." In light of the recent Supreme Court ruling on benzene, requiring that a risk of cancer be "significant" before OSHA can restrict worker exposure, *see* Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980), any concession that the risk was remote could have undermined the CPSC's regulatory authority.

[428] 42 Fed. Reg. 63,354, 63,359 (1977) (document no. 2). The Commission stated:

> For the fibrous clay minerals which may be used as asbestos substitutes such as wollastonite, kaolinite, sepiolite and bentonite, the Commission is aware that there is a lack of conclusive data on the hazard potential associated with these minerals. Additional study is needed to evaluate the risk of inhalation exposure to such small mineral fibers. Nevertheless, the Commission believes that the known risk from inhalable asbestos requires the banning of these products at this time.

Id.

ban's economic effects. The agency acknowledged that some small manufacturers might be unable to afford to reformulate, that the initial expense of reformulation could add as much as twenty-five percent to the product costs, and that the reformulated products would not perform as well as those made with asbestos.[429] The Commission again provided no detailed discussion of economic effects, however, and made no quantitative comparison of the economic costs and the health benefits.[430]

The CPSC's ban became effective as scheduled. No petition for judicial review was filed. Because the agency scheduled the ban to minimize its effect on current inventories, no manufacturer of patching compounds or emberizing materials remained interested in using asbestos as an ingredient in these products..

E. Consumer Products Containing Benzene

Concern about the health effects of benzene, which has led EPA and OSHA, as well as the CPSC, to regulate human exposure within their jurisdictions, has likewise been triggered by occupational evidence.[431] The CPSC relied heavily on the work of these other agencies in its efforts to eliminate the use of benzene as an ingredient in consumer products, such as paints, paint removers,

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[429] *Id.*

[430] The report observed:

> As is indicated in the proposal, the Commission is aware that economic impacts of varying degrees will occur as a result of the ban on inhalable asbestos containing [sic] patching compounds and emberizing materials containing respirable free-form asbestos. Also, the Commission is aware that technology for producing asbestos-free patching-compound formulations is becoming more generally available. The economic impact will tend to be reduced over time as non-asbestos formulation technology becomes more widespread and as existing recent formulations are improved by manufacturers.

Id. at 63,360. The Commission concluded its report with the finding required by the statute: "In determining that the risk of cancers is unreasonable, the Commission concludes that the degree and nature of the risk of injury and the probability that the risk will result in harm outweighs the rules' effect on the products' utility, cost and availability to the consumer." *Id.* at 63,361.

[431] Concern about the health effects of benzene has focused primarily on occupational exposures. Even before the enactment of the OSH Act in 1970, 29 U.S.C. §§ 651-658 (1976 & Supp. III 1979), most producers and industrial users of benzene observed a voluntary standard designed to limit employee exposure. In late 1976, a study of two Ohio industrial plants revealed that workers exposed to benzene exhibited a dramatically increased risk of death from leukemia. The study rekindled efforts to persuade OSHA to revise the prevailing standard. 42 Fed. Reg. 22,518 (1977).

and rubber cements.[432]

Prompted by the findings of an epidemiological study on which OSHA based an Emergency Temporary Standard sharply decreasing worker exposure to benzene,[433] the HRG filed a petition in May 1977, requesting that the CPSC declare benzene a banned hazardous substance under the FHSA. The petition sought to require removal of "all products containing benzene from the marketplace."[434] In granting the petition, the CPSC relied primarily on information assembled in hearings on OSHA's proposed permanent standard for benzene and on exposure data assembled by its staff from the scientific literature.[435] The agency chose to act under section 8 of the CPS Act rather than under the FHSA,[436] again observing that the newer law provided for informal rulemaking that permitted speedier action and facilitated public participation. The agency also noted that a ban under the CPS Act would not automatically require manufacturers to repurchase products already distributed.[437]

The Commission proposed a rule that would (1) ban benzene as an intentional ingredient in all consumer products except gasoline and laboratory chemicals and (2) ban all consumer products containing benzene as a contaminant at levels of 0.1% or higher.[438] The agency's preamble underscored OSHA's earlier actions,[439] and EPA's recent decision to list benzene as a hazardous air pollutant.[440] Although acknowledging that benzene produced acute health effects, the agency made clear that its proposal was a response to the chemical's chronic effects, particularly evidence that occupational exposure to benzene caused leukemia.[441]

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[432] 43 Fed. Reg. 21,839, 21,847 (1978) (appendix). Benzene is now used primarily as an intermediate in the production of other chemicals. It is also used as a component of unleaded gasoline, as a solvent and reaction agent in chemical laboratories, and in the manufacture of detergents and pesticides. *Id.* at 21,840; 42 Fed. Reg. 22,516, 22,517 (1977).

[433] *See* 42 Fed. Reg. 22,516, 22,517 (1977).

[434] 43 Fed. Reg. 21,839, 21,839 (1978).

[435] *Id.* at 21,840-41.

[436] *Id.* at 21,838-39.

[437] *Id.* at 21,838.

[438] *Id.* at 21,841-42.

[439] *Id.* at 21,840.

[440] *Id.* EPA acted under § 112 of the Clean Air Act, 42 U.S.C. § 7412 (Supp. III 1979).

[441] Although the Commission noted that "[t]he acute effects of benzene exposure include drowsiness and loss of consciousness at high doses," 43 Fed. Reg. 21,839, 21,840 (1978), the chemical's chronic health effects prompted its proposal. The Commission appended a tech-

The CPSC recognized that levels of consumer exposure to benzene were likely to be much lower than those experienced by workers exposed occupationally. Still, it noted that blood disorders had been observed in workers exposed "at levels reported to be as low as 10-15 ppm," and concluded "that a serious health hazard to consumers may be presented by the use of benzene-containing consumer products."[442] The CPSC attempted to translate this occupational evidence into an estimate of the risk for consumers:

> [T]he Commission's Health Sciences staff has calculated an assessment of the leukemia risk from consumer exposure to benzene-containing paint strippers. . . . For purposes of this assessment, the Commission considered the use of a paint stripper containing 52 percent benzene by a consumer, for 5 hours a day ten times in his life, to be a reasonably foreseeable lifetime exposure. The increased lifetime risk of death from myelogenous and monocytic leukemia induced by this exposure is estimated by the assessment at be-

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nical report prepared under contract by Dr. Michael L. Freedman of New York University Medical Center, which listed the chronic effects of benzene under three general headings: "(1) pancytopenia (a decrease of all the formed elements of the blood—red cells, white cells, and platelets); (2) chromosomal abnormalities; and (3) leukemia, particularly acute myelogenous (produced in the bone marrow) leukemia." *Id.* at 21,840.

The Commission's proposal stated:

> In a recent study of workers exposed to benzene from 1940-1949 in two Ohio plants manufacturing the product "Pliofilm," Infante . . . demonstrated a five-fold excessive risk of death from all leukemias and a ten-fold excess of deaths from myeloid and monocytic leukemias in the study population compared with the number expected in a non-exposed cohort. Infante stated that benzene concentrations at the two plants ranged from 0 to 10 or 15 parts per million. This study as well as other occupational studies noted in the Freedman report argue convincingly that benzene is a human leukemogen.
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> The Commission recognizes that much of the documentation in the consultant's report concerns benzene exposure in an industrial setting. However, as the [Freedman] report indicates, in 1977 the National Institute for Occupational Safety and Health conducted an experiment to measure the amount of benzene exposure to a person using a paint remover containing 52 percent benzene by volume . . . . An end table was stripped in a home garage having essentially no air circulation. Five sequential, five minute air samples from the worker's breathing zone were taken. The benzene concentration ranged from 73 to 225 ppm with a mean of 130 ppm. In addition, the Commission notes that values from 1971 exist for exposure levels in one man or husband-wife combination commercial paint stripping operations utilizing paint strippers containing approximately 40 percent benzene. The breathing zone average atmospheric concentration of benzene ranged from 24 to 1216 ppm in 8 such establishments.

Id. at 21,841 (reference numbers omitted).

[442] *Id.*

> tween 142 and 346 per million exposed.
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> This is equivalent to a benzene-induced increased risk of between 15.2 percent and 37.1 percent due to the use of such paint strippers. While the Commission is not relying upon a specified percentage of increased risk in issuing this ban, the Commission believes that in view of the seriousness of the risks of injury from benzene exposure, any increased risk is unacceptable.[443]

The Commission thus disclaimed reliance on any quantitative assessment of the risk of benzene exposure; its position essentially was that no exposure should be accepted. It acknowledged that no more than one percent of paint strippers then in use contained benzene as an ingredient,[444] but emphasized "that once the carcinogenicity of a substance has been established qualitatively, any exposure must be considered to be attended by risk when considering any given population, because individual susceptibility to a carcinogen varies widely."[445] Because "there is no known safe level of exposure to a carcinogen, . . . it is appropriate that exposure to benzene be reduced to the lowest feasible level."[446]

The Commission's proposed ban exempted gasoline, however, because it concluded that the economic consequences of banning that use would be substantial:

> [T]he Commission believes that any attempt to eliminate benzene from gasoline would have a major economic impact, necessitating thorough feasibility studies which are beyond the scope of this proposal. In this regard the Commission notes that benzene is present in gasoline as a contaminant and in unleaded gasoline, as an intentional ingredient used to increase the octane rating. The use of benzene and its closely related aromatic distillates, xylene and toluene, has increased in the past few years because the distillates are the principal substitutes for tetraethyl lead. The Commission has information indicating that the removal of benzene from gasoline motor fuel would entail major adjustments in the petroleum refining industry in terms of capital equipment and performance and price and availability of gasoline as well as other petrochemicals

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[443] *Id.*

[444] *Id.* at 21,843.

[445] *Id.* at 21,841. This conclusion may not suffice to support regulation under the CPS Act after the Supreme Court's decision in Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980). *See* notes 482-84 *infra* and accompanying text.

[446] 43 Fed. Reg. 21,839, 21,841 (1978) (footnote omitted).

> and has, therefore, concluded that the use of benzene in consumer product gasoline should not be restricted at this time.[447]

The Commission's proposal also exempted benzene sold for use as a laboratory solvent and reagent. This decision reflected the Commission's awareness of the chemical's unique qualities, coupled with the belief that in the laboratory setting, cautionary labeling would induce the care necessary to minimize human exposure.[448] The agency selected 0.1% as the maximum permissible level for benzene as a contaminant because this limit was achievable by most manufacturers of petroleum products. The agency emphasized that "benzene cannot be eliminated entirely from all products . . . because of the physical properties of petrochemical refining process. . . . [W]ithout resorting to extremely expensive special techniques, these refining processes do not result in chemically pure products."[449]

The Commission's analysis of the proposed ban's impact on products containing benzene as an ingredient is illuminating. The agency identified only two such products: paint removers and rubber cement.[450] It reported that only two of the forty-nine firms manufacturing paint removers were then using benzene, and it estimated that "less than 1 percent of the paint removers currently on the market contain benzene as an intentional ingredient."[451] The Commission suggested that several chemicals might be substituted for benzene in paint removers, although it acknowledged that the most effective was also more expensive and perhaps even

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[447] *Id.* at 21,842. The proposal also stated:

> While most gasoline is specifically for use with motor vehicles and would appear to be considered "motor vehicle equipment" excluded from Commission authority under the [CPS Act] . . ., the Commission notes that some gasoline is used by consumers "in or around a permanent or temporary household or residence, a school, in recreation, or otherwise." . . . However, since this gasoline generally comes from the same source (i.e. the retail pumps) as motor vehicle gasoline and may be subject to regulation by OSHA, EPA, and/or the National Highway Traffic Safety Administration (NHTSA), the Commission is of the opinion that exposure to benzene from gasoline is a complex interagency problem which would probably best be resolved on an interagency basis.

Id. (citation omitted).

[448] *Id.*

[449] *Id.*

[450] *Id.* at 21,843.

[451] *Id.*

more hazardous,[452] and therefore invited comment on the health hazards of possible substitutes. Similarly, the agency determined that only one of fifty-two rubber cement producers was still using benzene as an ingredient and estimated that less than 0.1% of the rubber cements on the market contained benzene.[453] The agency also noted that sales of rubber cements had dropped sharply between 1963 and 1973 as the product was displaced by other adhesives.[454]

The CPSC thus found that only a very small percentage of two classes of products would be affected by its proposed ban on benzene. Although the agency speculated generally about the consequences of a ban, there is no evidence that it attempted to quantify the economic effects or to compare those effects with the risks associated with exposure to benzene in the two groups of products.

The agency proposed that the portion of the ban directed at benzene as a contaminant should apply only to products manufactured or imported 120 days after publication of a final order.[455] This timing obviated any repurchase of products already in commercial channels. The Commission explained that any exposure from these products would not be high and that extending the ban "might result in a chaotic situation."[456] It proposed alternative effective dates for products containing benzene as an ingredient. Under the first, the ban would apply to products manufactured or imported sixty or more days after publication; no recall or repurchase would be required. Perhaps concerned that this schedule might appear to trivialize the risk, the agency offered an alternative that would ban products initially introduced into commerce fifteen days after publication of its final order and that would ban the sale of the products thirty days after publication, no matter when they were introduced into commerce. The agency stressed that this alternative would not have "major economic impact," because so few companies were using benzene as an ingredient,[457] but it did not advert to the relationship between the extent of use and the degree of human risk.

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[452] *Id.* at 21,843-44. The substitute was methylene chloride.
[453] *Id.* at 21,843.
[454] *Id.*
[455] *Id.* at 21,844.
[456] *Id.*
[457] *Id.*

Three years after publishing the proposed ban, the CPSC proposed to withdraw it.[456] After its initial proposal, the agency on several occasions extended the time for completing the rulemaking process.[457] Few products would have been affected by the ban as originally proposed. By 1980, the agency believed that no products were being manufactured containing benzene as an intentional ingredient and that only four classes of products—stove and lantern fuels, brush cleaners, lacquer thinners, and rubber cements—contained benzene as an impurity at a level higher than 0.1%. None of these contained over 0.25% benzene.[458] Agency staff members accordingly questioned the need for a final ban.[459] Their reservations were strengthened by the Supreme Court's decision in *Industrial Union Department, AFL-CIO v. American Petroleum Institute*,[460] overturning OSHA's permanent standard for benzene on the ground that OSHA had failed to show that worker exposure to ten ppm benzene posed a "significant" risk. CPSC staff members understandably questioned whether the agency could legally sustain a ban on even lower exposures, particularly when its own proposal had relied almost entirely on the epidemiological evidence assembled by OSHA.

The plurality opinion in *American Petroleum Institute* faulted OSHA's failure to document the probable adverse health effects of benzene exposure at ten ppm, the prevailing Labor Department standard. One estimate of the risk, submitted on behalf of the American Petroleum Institute during OSHA's rulemaking proceeding, predicted a maximum of two cases of cancer among exposed workers each six years.[461] It was partially OSHA's failure to respond to this submission on the merits—by demonstrating its inaccuracies or by characterizing the estimated risk as "significant"—that led the Court to set aside its standard.

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[456] 46 Fed. Reg. 3,034 (1981).

[457] *See, e.g.*, 44 Fed. Reg. 22,499 (1979); 43 Fed. Reg. 47,197 (1978); 43 Fed. Reg. 21,838 (1978).

[458] 46 Fed. Reg. 3,034, 3,035 (1981).

[459] The agency has considered staff proposals that it contract for a study of human exposure to benzene from current and former uses, as well as suggestions that it adopt a rule, under section 27(b) of the CPS Act, that would require manufacturers to notify the agency if they subsequently decided to add benzene to consumer products. Krulwich Interview, *supra* note 36.

[460] 448 U.S. 607 (1980).

[461] *Id.* at 653-54.

In insisting that OSHA can regulate only "significant" risks, Justice Stevens's plurality opinion relied on language in the OSH Act defining an occupational health standard as one "*reasonably necessary* or appropriate to provide safe or healthful employment . . . ."[464] The similarity of this language to section 9(c) of the CPS Act, a provision that expressly limits the Commission's authority rather than defines other terms in the law, suggests that the CPSC likewise is obligated to demonstrate the "significance" of any risk it attempts to regulate.

F. Hairdryers Containing Asbestos

The CPSC successfully effected the removal of hairdryers containing asbestos from the consumer market without any formal administrative proceedings or any systematic assessment of the health risks or economic costs. As in other cases, the Commission acted under heavy public pressure generated by press reports of a health hazard.

In July 1978, representatives of WRC, a Washington, D.C., television station, sought information from the CPSC about the prevalence of asbestos insulation in hand-held hairdryers. The agency responded by making available a consultant's study that estimated the levels of asbestos in all consumer products.[465] This "Kearney Report" stated that although asbestos had once been used in several brands of hand-held hairdryers, only one manufacturer was currently using the material.[466] The Report further surmised that the asbestos in hairdryers could present a consumer health hazard only if the products malfunctioned.

In January 1979, a CPSC scientist circulated within the agency a memorandum confirming the presence of asbestos in a number of current brands of hand-held hairdryers and posed questions about potential human exposure.[467] The memorandum recommended that the agency undertake tests to determine whether the asbestos was discharged when the hairdryers were used. Apparently, no for-

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[464] 29 U.S.C. § 652(8) (1976) (emphasis added).

[465] A.T. Kearney, Inc., Review of Asbestos Use in Consumer Products (April 1978) (unpublished report cited at 44 Fed. Reg. 60,057, 60,058 (1979)).

[466] CPSC Office of Budget, Program Planning & Evaluation, Review of Commission Actions on Asbestos in Hair Dryers 3 (June 27, 1979) [hereinafter cited as Walton Report] (copy on file with the Virginia Law Review Association).

[467] Fausett Interview, *supra* note 32.

mal action was taken in response to this memorandum, although CPSC Chairman King later testified before Congress that the delay was attributable partly to government contracting procedures.[468] As late as March 1979, the public record revealed no evidence that the Commission was concerned about the problem.

On March 28, 1979, WRC ran a news story describing its earlier inquiry and reporting the results of laboratory tests for which it had contracted.[469] The tests found that after two hours of continuous use, all six models of hairdryers tested released some quantity of asbestos. The older models released considerably more asbestos than newer products.[470] WRC had provided the Commission with a copy of the laboratory's report four days earlier.[471] Very soon thereafter, the agency arranged with the National Bureau of Standards to perform tests on at least two models of hairdryers to verify whether those containing asbestos could discharge the material in normal use.[472]

On March 29, 1979, the EDF petitioned the agency to act under section 15 of the CPS Act to declare hairdryers containing asbestos a "substantial product hazard" and to order repurchase of hairdryers already in consumer hands.[473] Acting under sections 5 and 27(b)(1) of the CPS Act, the agency ordered nine manufacturers and four retailers to provide information about the use of asbestos in their products.[474] These special orders required responses within ten days; they also requested that the companies submit information respecting any testing they had performed to determine the potential for asbestos discharge or the health hazard of discharged asbestos. The Commission accompanied these special orders with requests that representatives of each of the firms attend a meeting with the agency's staff on April 5, 1979.[475] Fearing adverse publicity, J.C. Penney and Montgomery Ward promptly announced that

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[468] *Possible Threat to the Consumer Posed by Emission of Asbestos from Certain Hand-Held Electric Hair Dryers: Hearings Before the Subcomm. for Consumers of the Senate Comm. on Commerce, Science and Transportation*, 96th Cong., 1st Sess. 30 (1979) (statement of Susan King).

[469] *Id.* at 25.

[470] *Id.* at 3-14.

[471] *Id.* at 26.

[472] *Id.*

[473] *Id.* at 6 (statement of Lee Thompson).

[474] *Id.* at 26 (statement of Susan King).

[475] *Id.* at 26-27.

they were voluntarily removing hairdryers containing asbestos from their stores and expressed a willingness to reimburse customers who returned hairdryers containing the material. Both E.J. Korvette and Sears also expressed their willingness to repurchase hairdryers that contained asbestos from consumers who desired to return them, but at that point declined to withdraw these hairdryers from their stores.[476]

Hours after the issuance of the special orders, the CPSC arranged with the National Institute for Occupational Safety and Health (NIOSH) to test fifty models of hand-held hairdryers to determine whether they could discharge asbestos and to estimate the quantity of asbestos discharged into the atmosphere by each use.[477] The agency expected to have results from those tests within thirty days,[478] but it was not until several months later that NIOSH reported its test results to the Commission.[479]

On April 2, CPSC Chairman King and General Counsel Krulwich appeared before the Senate Subcommittee for Consumers. They testified that they regarded section 15 of the CPS Act as the most likely basis for any CPSC regulatory action.[480] Krulwich emphasized the Commission's need to identify all of the manufacturers currently marketing hairdryers containing asbestos before publicizing brand and model information to consumers.[481] Their testimony implied that if large numbers of hairdryers were found to contain asbestos, the Commission would order use of the material stopped and would recall outstanding products if manufacturers and retailers did not voluntarily agree to a corrective action plan.[482]

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[476] *Id.* at 6-7 (statement of Lee Thompson).

[477] *Id.* at 27 (statement of Susan King).

[478] *Id.*

[479] This delay was caused by difficulties in developing an appropriate test protocol. WALTON REPORT, *supra* note 466.

[480] *Id.*

[481] Section 6 of the CPS Act restrains the Commission from publicizing product hazard information before it has verified its accuracy and afforded affected manufacturers an opportunity to comment on it. *See* CPSC v. GTE Sylvania, 447 U.S. 102 (1980), holding that § 6 applies to responses to Freedom of Information Act requests as well as to affirmative disclosures by the agency, thus limiting its ability to provide information to the public. Congress very recently amended the CPS Act to restrict even further the Commission's authority to release product-related data. Consumer Product Safety Amendments of 1981, Pub. L. No. ___, § 1204, ___ Stat. ___ (amending 15 U.S.C. § 2055 (1976)).

[482] Krulwich Interview, *supra* note 36.

At a public meeting with the agency's compliance staff, the hairdryer manufacturers and retailers made clear their general willingness to effect a marketplace recall of hairdryers containing asbestos and to repurchase hairdryers from consumers. The representatives seemed eager to achieve a voluntary resolution of the problem, rather than face formal proceedings under the CPS Act.[483] In conformity with agreements negotiated following this meeting, the CPSC's Directorate of Compliance and Enforcement issued preliminary determinations of substantial product hazard under section 15 of the CPS Act to all eleven manufacturers and retailers that had attended the meeting.[484] The agency received formal, voluntary agreements for corrective action from all eleven firms, which reportedly accounted for ninety percent of the hairdryers containing asbestos then in consumer hands or in commercial channels.[485] The Commission also issued a list of brands of hairdryers containing asbestos, based upon information supplied at the meeting with the manufacturers and retailers.[486]

It is unclear whether the CPSC ever systematically considered whether the risk posed by hairdryers in consumer hands was great enough to warrant the cost of recall and repurchase. The agency certainly did not then conduct, nor arrange for anyone else to conduct, a quantitative assessment of the risk posed by continued use of hairdryers already purchased. The alacrity with which the manufacturers and retailers agreed to repurchase deflated interest in such an assessment. The agency also did not disclose whether it had considered the possibility that manufacturers might resort to substitutes for asbestos that might pose health hazards themselves, including an increased risk of fire. The Commission appears simply to have concluded that asbestos, a known human carcinogen, was present in, and likely to be discharged in some quantities by, the hairdryers.

By late summer 1979, the CPSC had concluded recall agreements with all major distributors of hairdryers containing asbestos. The agency was thus able effectively to "ban" such products from commerce without initiating formal proceedings, but it was not en-

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[483] *Id.*
[484] *Id.*
[485] *Id.*
[486] Press releases were issued April 6, April 17, and May 3, 1979. *See id.*

tirely successful in terminating human exposure to the products. A recent evaluation of recalls as a regulatory device reported that, notwithstanding the public awareness of the hairdryer episode and the Commission's efforts to notify users, only twenty percent of all units covered by recall agreements were ever returned by consumers.[487]

The hairdryer episode convinced many CPSC staff members that the agency could regulate products effectively without protracted administrative proceedings or procedural missteps. The agency's success strengthened the position of officials who believed that regulation of chronic hazards should play a larger role.[488] The episode also caused the Commissioners to order a staff study evaluating and recommending changes in its internal procedures.[489]

The resulting study concluded that the Commission had acted only after WRC had broadcast the results of its own investigative reporting.[490] Staff members were chagrined that the agency had missed an opportunity to act *before* events made it appear that once again it was responding only under pressure. The staff study found a need to improve communication between agency components and criticized the CPSC's difficulty in arranging tests to determine the kinds and quantities of asbestos emitted from the hairdryers.[491] The study also stressed the importance of early evaluation of regulatory options by the Commissioners. Apparently, agency staff members had considered using section 15 long before the television reports galvanized the agency into action, but this approach had not been discussed at the Commission level.[492] Thus, there was considerable uncertainty about what facts were important as well as what procedures the agency should follow:

> [T]he existing procedures do not provide an adequate framework for reaching a decision relative to what further information is necessary, obtaining the information and bringing it before the Commission for a quick decision. The question of which regulatory

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[487] Product Recalls: Do They Work, CFA News, February, 1980.

[488] One result of this experience has been the establishment by the Commission of a small asbestos testing laboratory at NIOSH's facilities in Cincinnati. Krulwich Interview, *supra* note 36.

[489] *See* WALTON REPORT, *supra* note 468.

[490] *Id.* at 4.

[491] *Id.* at 5-6.

[492] *Id.* at 7-9.

option to pursue is a recurring one, with significant policy implications. General guidelines would not be helpful because each case usually has a unique set of circumstances. Procedures are needed to assure that in important cases this issue is raised to the AED's and Executive Director for a full assessment by the staff and General Counsel, and presented quickly to the Commission for decision.[482]

G. Pending CPSC Actions

1. Asbestos

In October 1979, the CPSC announced a cooperative effort with EPA to reduce public exposure to asbestos. In concurrent Advance Notices of Proposed Rulemakings (ANPRs), the two agencies stated their intentions to regulate sources of asbestos exposure within their respective jurisdictions. Their announced objectives were to exchange information and to avoid duplicative regulations.[484]

The CPSC's notice asserted three reasons why consumer products that release asbestos pose unique problems. First, products used in a household setting subject young children and infants to exposure. Second, asbestos fibers released into living quarters can pose a continuing risk by remaining in a confined space and settling and resuspending in the air, rather than dispersing into the general environment. Finally, unlike most workers exposed on the job, household members have little protection from asbestos fibers released from consumer products.[485]

In this notice, the Commission set a huge task for itself. Drawing primarily on the Kearney Report, the agency listed ninety-six categories of consumer products containing asbestos.[486] Even though many of these categories may be found to pose no health risk or to fall outside the Commission's jurisdiction, the investigation necessary to make these judgments may prove difficult. To assemble the data needed to determine whether regulatory action may be necessary, the CPSC intends to require that manufacturers submit in-

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[482] *Id.* at 8-9.
[484] 44 Fed. Reg. 60,058 (1979).
[485] 44 Fed. Reg. 60,057, 60,057 (1979).
[486] *Id.* at 60,060-61.

formation on the use of asbestos in specified consumer products.[497] The ANPR sets forth six criteria for ranking the products to be investigated:

> (1) the number of units of the product estimated to be in use by consumers; (2) the form and location of the asbestos in the product; (3) the frequency, duration, manner, and location in the consumer's environment of product use, including such factors as the expected useful life of the product and the presence of heat and/or moisture and the likelihood of abrasion during use or forseeable misuse; (4) the likely availability and feasibility of substitutes for asbestos in the product; (5) the relative ease of data collection and analysis by the Commission and the reporting burden on industry; and (6) the degree of potential overlap of CPSC reporting requirements with the information gathering efforts of other regulatory agencies, particularly the Environmental Protection Agency.[498]

In describing the possible regulatory responses to the discovery that a consumer product poses a risk of asbestos exposure, the ANPR lists virtually every weapon in the agency's regulatory arsenal.[499]

The CPSC's current approach to asbestos has two distinctive features. First, the Commission proposes initially to focus on, and ban, all "nonessential" uses of asbestos in consumer products. The agency stated that any action to eliminate nonessential uses would rely simply on the *fact* of asbestos fiber emission rather than on any quantitative assessment of risk.[500] The Commission noted that in prior cases, after considering the effects on the utility, availability, and cost of products, it had approved regulatory action when there was an "absence of compelling evidence of unacceptable social or economic costs associated with removal of asbestos from the

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[497] This would be done pursuant to § 27 of the CPS Act. 15 U.S.C. § 2076 (1976 & Supp. III 1979).

[498] 44 Fed. Reg. 60,057, 60,058 (1979).

[499] *Id.* at 60,059. Although the Commission referred to its powers under both the CPS Act and the FHSA, it did not mention the possibility of a ban against products posing a risk of exposure to children pursuant to § 2(q)(1)(A) of the FHSA—the weapon it attempted to use against TRIS-treated garments.

[500] *Id.* at 60,058-59. There is considerable doubt, after the Supreme Court's benzene ruling, whether this approach is sustainable. *See* notes 462-64 *supra* and accompanying text. Moreover, it conflicts directly with the regulatory approach announced the same day by EPA, which contemplates the use of quantitative risk assessment. 44 Fed. Reg. 60,061, 60,063 (1979).

product."[501] Accordingly, it concluded that the extent of risk would be sufficient to justify action once any release of asbestos is found during reasonably foreseeable use or misuse of a consumer product. Only unacceptable social or economic costs would justify a different response.[502] The Commission said that it would consider a number of factors when deciding whether a particular use of asbestos is subject to its proposed "generic ban": "the function performed by the asbestos in the product, the benefit derived from the use of asbestos in the product; and the availability and cost of substitutes for the asbestos; and the safety of such substitutes."[503] The second novel feature of the CPSC's asbestos notice is the agency's announced intention to regulate categories of products that share a similar use of asbestos as a component. The agency's regulatory options include action to reduce consumer exposure against any product at the site where asbestos is released or regulation of a category of products that releases asbestos, in addition to the more traditional product-by-product approach.[504]

The ANPR reveals several unresolved issues in the CPSC's current approach to asbestos. The agency requested comment on whether its list of consumer products possibly containing asbestos was complete. It also invited comment on whether its focus on nonessential uses of asbestos was sound; on what constitutes an essential use of asbestos in consumer products; on whether the emission of asbestos, without more, should be sufficient to trigger action against a nonessential use; and on whether "generic" regulation is legally supportable or advantageous.

The CPSC has taken additional steps related to regulation of asbestos exposure since publication of the ANPR. First, it cosponsored with EPA a public "Workshop on Substitutes for Asbestos" to gather information on the potential health hazards of products containing asbestos and of substitutes for asbestos.[505] Second, the CPSC approved a general order requiring 1,200 manufacturers to

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[501] 44 Fed. Reg. 60,057, 60,058 (1979).

[502] *Id.* at 60,058-59.

[503] *Id.* at 60,059.

[504] *Id.*

[505] 45 Fed. Reg. 35,414 (1980). The workshops were to include talks on technical, economic, and regulatory aspects of asbestos substitutes and the difficulty of substitution, a review of approximately 10 categories of asbestos products, and meetings on the health implications of potential alternatives to asbestos. *Id.*

submit information concerning the use of asbestos in certain consumer products.[506] Commissioner Zagoria dissented from the order, arguing that the request was too broad and that demands for information should be limited to matters "demonstrably necessary" for the CPSC to carry out its responsibilities.[507]

2. *Formaldehyde*

In its evaluation of the carcinogenicity of formaldehyde, the CPSC experimented with a novel procedure for assessing the risk of a substance in consumer products. The agency drew explicitly on the scientific expertise of other components of the federal government, perhaps setting a useful precedent.

Formaldehyde[508] is an ingredient in urea formaldehyde foam insulation, which has been installed in many private homes. In 1979, the Formaldehyde Institute, an industry trade association, reported to the CPSC that the preliminary results from tests conducted by the Chemical Industry Institute for Toxicology (CIIT)[509] indicated that formaldehyde had caused nasal cancer in rats exposed to 15 ppm of the substance.[510] Six government pathologists representing the CPSC and other federal agencies visited the CIIT laboratory and confirmed these interim findings.[511] Several other long-term animal studies conducted to determine the teratogenic and carcinogenic potential of formaldehyde have yielded negative

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[506] The manufacturers will be asked to

> [d]escribe the usual marketing and use patterns of each product identified, including: prices (e.g., price lists or schedules); promotional materials (to the extent they relate to potential consumer uses); typical distribution channels (e.g., wholesale only, catalogue sales only, wholesale and retail); regional distribution patterns (e.g., nationwide, Northwest only); and intended uses, functions, and applications.

[1980] 4 CHEM. REG. REP. (BNA) 267-68.

[507] *Id.* at 267.

[508] Formaldehyde has a variety of important industrial uses, *e.g.*, in tanning and textile manufacturing, but it is also found in consumer products.

[509] The CIIT is, as the name implies, a research laboratory funded by private commercial sources, which tests chemicals to determine their health effects and seeks to develop and improve test protocols. It is located in the Research Triangle in North Carolina and enjoys a reputation for high-quality scientific work.

[510] 45 Fed. Reg. 34,031, 34,031 (1980). The CIIT study was to be completed by mid-1980. More recent CIIT data reveals that rats exposed to 6 ppm of formaldehyde contract tumors. *See* Comments on a Preliminary Draft of this article by Janne Gallagher (Oct. 1, 1981) [hereinafter cited as Gallagher Comments] (copy on file with the Virginia Law Review Association).

[511] 45 Fed. Reg. 34,031, 34,031 (1980).

results, but another recent study suggests that formaldehyde may have co-carcinogenic potential.[812]

Confronting these findings, the CPSC took two preliminary actions. First, it requested that the National Toxicology Program (NTP)[813] empanel a group of government scientists to review the CIIT study and assess the human health implications of exposure to formaldehyde. This group was to evaluate the evidence of formaldehyde's carcinogenicity, mutagenicity, and teratogenicity in animals.[814] The review group's report, originally expected by the end of July, was delayed until November 1980.[815]

The CPSC's effort to obtain the expert views of scientists outside the agency is noteworthy. The agency's decision to seek the help of the NTP in evaluating the CIIT data was joined by other members of the IRLG, some of which are also interested in formaldehyde's hazards. The approach not only enabled the CPSC to gain the support of more distinguished scientists than could be found among its own staff; it enhanced the credibility of the assessment of risks on which the agency ultimately relied. Nor did the decision to go outside the agency for the initial assessment of carcinogenicity delay the CPSC's action. Unlike asbestos, benzene, and vinyl chloride, whose carcinogenicity was well established before the agency acted, formaldehyde presented a new issue, not just for the CPSC, but for the other IRLG agencies as well.

The CPSC's second action was a proposal to require disclosure of the risk posed by urea formaldehyde (UF) foam insulation.[816] Based on demonstrated acute and noncarcinogenic chronic effects

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[812] 45 Fed. Reg. 39,434, 39,438 (1980). In other words, "formaldehyde may increase the incidence of tumors when combined with a different substance that is known to be a carcinogen." *Id.*

[813] The NTP was established in late 1978 by then-Secretary of Health, Education & Welfare Califano. 43 Fed. Reg. 53,060 (1978). The purpose of the program was to centralize and strengthen the Department's toxicological research and testing programs and to provide advice and information to research and regulatory agencies. Four agencies of HEW compose the NTP: the National Center for Toxicological Research (a component of FDA with funding as well from EPA); the NCI; NIOSH (part of the Center for Disease Control); and the National Institute of Environmental Health Sciences (part of the National Institutes of Health). 1 NTP Technical Bulletin 2 (1979) (copy on file with the Virginia Law Review Association).

[814] 45 Fed. Reg. 34,031, 34,031 (1980).

[815] The panel, which consisted of 16 senior government scientists, delivered its report on November 21, 1980. 46 Fed. Reg. 11,183, 11,190 (1981).

[816] 45 Fed. Reg. 39,434 (1980).

in humans exposed to formaldehyde gas, the Commission proposed that manufacturers of UF foam insulation provide specific performance and technical data to prospective purchasers to alert them about the insulation's possible adverse health effects.[517] The agency specifically kept open the possibility that the final rule might require notice of the cancer risk or of other chronic hazards. The preamble called attention to the ongoing scientific review of the CIIT study.[518]

The CPSC's discussion of the economic effect of disclosure was decidedly conclusory. Though the agency conceded that the resulting decrease in demand for UF foam insulation had not been determined, it asserted that the adverse economic consequences probably would not be significant. It did not discuss the economic effects of requiring a cancer warning.[519] More troubling, the proposal made no attempt to explain why notification of consumers might be appropriate in this context when the agency declined to consider it for other cancer hazards, such as hairdryers containing asbestos.

The CPSC's more dramatic initiative began in February 1981, following its evaluation of the NTP work group's assessment of formaldehyde's carcinogenicity. The agency concurred in the NTP

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[517] *Id.* at 39,439.

> [I]n commenting on this proposal, interested persons should take into account the possibility that, based on the assessment of existing information by the panel of federal scientists as well as additional information that is obtained during this rulemaking, the Commission may decide to include information concerning the possible long-term health effects in the notification if the Commission issues a final rule. In this regard the Commission could:
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> . . . .
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> (3) Issue a requirement for a notification that includes a statement concerning the carcinogenic potential to humans of exposure to formaldehyde.
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> The Commission requests interested persons commenting on this proposed regulation to address these possibilities.

Id.

[518] *Id.* at 39,438-39.

[519] The CPSC's proposed notification rule would not apply in all contexts in which consumers are exposed to insulation containing formaldehyde. Manufacturers of UF foam insulation would be required to notify prospective purchasers of the product to be used in private construction. Use of the product in commercial buildings, recreational facilities, schools, and other public buildings would be excluded, however, because "most of the complaints . . . received to date concern homes or residences." The proposed rule also would not extend to insulation sold to builders for installation in homes later sold to consumers or to sellers of homes in which the insulation had already been installed. The Commission believed that section 27(a) of the CPS Act would not extend to those settings. *Id.* at 39,435.

panel's judgment that the material had been shown to cause cancer in rats and probably in mice, and it proposed to ban future installation of UF foam insulation in homes and businesses.

The Commission's preamble represents its most recent discussion of the criteria it follows in regulating carcinogens in consumer products, and therefore merits special attention. The CPSC acknowledged that the health hazards of UF foam insulation were first brought to its attention when the Denver District Attorneys' Consumer Office in 1976 filed a petition asking the agency to set a safety standard for the product. The preamble summarizes the agency's rationale for proposing to ban the material. Unlike its earlier ANPR for asbestos, which suggests that any exposure would pose an unreasonable risk, the CPSC's evaluation of formaldehyde discusses prevailing levels of human exposure and provides a quantitative assessment of the risk of cancer.[220]

Several features of the CPSC's formaldehyde proposal warrant comment. First, the agency made clear that any ban would apply only to future installations, and would not require retrofitting of buildings in which UF foam insulation had been installed previously.[221]

Second, in sharp contrast with its professed skepticism of quantitative risk assessment in the asbestos ANPR, the agency embraced the technique, albeit cautiously, and concluded that as many as twenty-three additional cancers might occur each year among residents of newly insulated buildings if UF foam insulation were not banned.[222] The risk assessment was performed by the CPSC's staff, based upon the NTP panel's analysis of the dose-response relationship displayed by the CIIT data.[223] After estimating the dose-response curve for formaldehyde, the staff projected the incidence of cancer among persons exposed to formaldehyde gas in insulated homes. To determine levels of exposure, the staff relied on actual measurements of formaldehyde obtained in insulated homes whose owners had complained about noxious odors and on laboratory simulations of levels occurring in homes with

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[220] 46 Fed. Reg. 11,188 (1981).
[221] *Id.* at 11,189.
[222] *Id.* at 11,193.
[223] *Id.* at 11,190-92.

lower concentrations.[524] It estimated that the so-called "complaint homes" represented 6.9% of all UF foam-insulated residences, and concluded that of the 120,000 people exposed, as many as thirty-five would contract cancer.[525] The agency did not acknowledge that these "additional" cancers would not be prevented by its ban, which would not apply to insulation already installed. In comparing the health benefits of its proposed action with the economic costs, however, the agency counted only the twenty-three "additional" cases likely to occur among residents of homes yet to be insulated.[526]

The Commission's assessment of the economic effects of a ban of UF foam insulation is at once the most elaborate it has performed for any chronic hazard and the most seriously deficient. The agency identified the groups primarily affected as chemical manufacturers and importers; foam insulation contractors; and consumers, who would forgo energy savings or possibly experience a reduction in real estate values. The agency's analysis of the anticipated costs for those three groups is thoughtful but inconclusive, in that it does not attempt to estimate the aggregate costs of a ban. For the first group, the Commission concluded: "The maximum impact of a ban for manufacturers and distributors of the component materials used to make U.F. foam insulation may be the exodus of 19 firms from the industry, with a loss in employment of approximately 250 to 350 persons."[527] The Commission made no attempt to place a dollar figure on this outcome. Its analysis of the effects on the 600 to 800 installers of insulation, who currently receive up to $120 million each year for sales of UF foam insulation,[528] does not suggest any magnitude. The Commission's discussion of the energy savings that owners would forgo because their buildings could not be insulated effectively with substitutes for UF foam is more convincing. The staff estimated that owners of such residences would forgo energy savings of between $204,000 to $518,000 each year that insulation could not be installed. It assumed that energy prices would rise at the rate of between five and ten percent

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[524] *Id.* at 11,192-93.
[525] *Id.* at 11,194.
[526] *Id.* at 11,195.
[527] *Id.* at 11,200.
[528] *Id.*

a year during a predicted ten-year period before alternative insulating materials became available.[839]

The third notable feature of the proposal is the CPSC's self-conscious attempt to weigh the costs and benefits of the ban. The agency construed the relevant case law as requiring that "the benefits of the regulatory action . . . bear a reasonable relationship to the costs."[840] Although it asserted that it had no obligation to quantify costs and benefits, the agency nonetheless concluded that whether assessed qualitatively or quantitatively, the benefits of a ban would bear a reasonable relationship to the costs.[841] It then attempted to demonstrate that the prevention of an estimated twenty-three additional cases of cancer a year would be worth the economic costs of banning UF foam insulation:

> The principal measure of the direct societal costs of a ban of U.F. foam insulation would be the foregone energy savings (or higher future energy costs) resulting from the buildings that are not insulated because of the absence of U.F. foam insulation from the market. . . .
>
> . . . The foregone energy savings from these homes is estimated to be 35 to 87 billion Btu's, with a value of $204,000 to $516,000, at 1980 energy prices. The staff has evaluated future foregone energy savings by discounting these savings to their present value. Based on these calculations, the present value of foregone energy savings resulting from a ban of U.F. foam insulation would range from approximately $1.6 million to $5.2 million.
>
> If the estimated value of foregone energy savings is compared to the estimated risk of 23 cases of cancer that might eventually result from these installations each year, based on the upper value of the estimated range of risk, the calculated cost per cancer avoided would range from $70,000 to $226,000 per year.
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> This range addresses only the benefits of avoided incidences of cancer in terms of foregone energy savings. Although additional benefits can not be reliably quantified, a ban would also benefit society in the following ways: (1) avoidance of the costs of lives lost and the medical and social costs for treatment of cancer; (2) reducing the costs of adverse acute health effects caused by formaldehyde; (3) avoidance of the costs of remedial measures to attempt to correct problems in future installations, including the costs of re-

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[839] *Id.* at 11,202.
[840] *Id.* at 11,201.
[841] *Id.*

> moving foam from residences; and (4) avoidance of costs incurred due to time lost from work, rental of other residences, and costs of litigation involving installations.
>
> When the benefits of avoided incidences of cancer and the additional benefits described above are considered in relationship to the facts that the ban is likely to result in a relatively minor impact to the economy as a whole, and will result in minimal energy losses because of the ready availability of substitute types of insulation for most applications, the Commission preliminarily concludes that the benefits of the ban do bear a reasonable relationship, and do in fact justify, the costs of the regulatory action.[332]

V. Analysis and Conclusions

The CPSC has not played a decisive role in regulating potential carcinogens. It has assumed a reactive posture, largely responding to hazards identified by other bodies and by public petitions. In all but two instances, the CPSC has acted only after other agencies initiated regulation, and usually after manufacturers ceased using the substances in consumer products. In some cases, the Commission's intervention has amounted to little more than a gesture.

Earlier sections of this article have described difficulties encountered by the CPSC in regulating chronic health hazards. This section speculates about their causes and suggests solutions. Before discussing these problems, however, three preliminary observations are in order. First, certain difficulties are inherent in the Commission's mission and organizational structure. The Commission's jurisdiction over all "consumer products" embraces a boundless array of articles and potential health hazards. Furthermore, a multimember agency inevitably faces unique problems in internal communications and in reaching consensus. These functions are further complicated by the formal requirements of the Sunshine Act.[333]

Second, any agency responsible for regulating potential human carcinogens confronts large scientific uncertainties. Determinations of carcinogenic potency and human exposure often rest on speculative evidence, which may frustrate quantification. The limits of scientific understanding are a continuing impediment to intelligent

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[332] *Id.* at 11,202 (footnote omitted).

[333] Government in the Sunshine Act, 5 U.S.C. § 552b (1977).

regulation. Furthermore, all health regulatory agencies[834] depend on data from outside sources, both in deciding what substances to regulate and in determining what controls to impose.

Third, the current Commissioners are aware of the agency's earlier missteps. They have, for example, improved the agency's internal system for identifying and evaluating substances that warrant regulation.[835] It is not yet clear, however, whether recent agency initiatives, which have yet to be tested in specific regulatory proceedings, will avoid the difficulties experienced in the past.

A. The Commission's Agenda

The CPSC has been frustrated in its efforts to establish and follow priorities for regulating chronic health hazards. Its main difficulty has not been in identifying substances that may pose a risk of cancer if present in consumer products; the Commission has relied largely on outside scientific bodies and published research to identify suspected carcinogens.[836] Instead, the agency has faced its major difficulty in setting and following priorities for investigating and regulating suspected carcinogens. Several circumstances have impeded the Commission's efforts to set and follow these priorities.

1. Agency Jurisdiction

The Commission's statutory jurisdiction encompasses an unusually broad and diverse universe of products. Although FDA and EPA also have broad responsibilities, they have been able to create subunits responsible for such relatively discrete categories as food, drugs, cosmetics, and pesticides.[837] Moreover, unlike the CPSC,

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[834] *I.e.*, FDA, EPA, OSHA, the CPSC, and the Food Safety and Quality Service of the Department of Agriculture.

[835] *See* notes 240-49 *supra* and accompanying text.

[836] *See* note 243 *supra* and accompanying text.

[837] FDA and EPA are both organized around their special areas of responsibility. FDA is divided into six product-specific bureaus (foods, drugs, veterinary medicine, radiological health, biologics, and medical devices) and two functional offices (National Center for Toxicological Research and Executive Director for Regional Operations). Each bureau is further subdivided according to regulatory function. The Bureau of Drugs, for example, comprises the following function-oriented components: Information Systems, Biometrics and Epidemiology, Pharmaceutical Research and Testing, Drug Monographs, New Drug Evaluation, and Compliance.

EPA is organized both by function and statutory responsibility. The first tier of offices

those agencies administer licensing schemes for many classes of products. Required premarket approval permits discovery of many potential problems before public exposure occurs, and forces producers to generate much of the data needed for regulatory decisionmaking.[838] Although manufacturers are formally required to notify the CPSC of "substantial product hazards" presented by marketed products,[839] they have little incentive to test their products for nonobvious hazards. The Commission must discover most of the hazards to which consumers are exposed on its own. This task is complicated by the lack of an accurate inventory of products available for consumer use and by the paucity of ready information about their design and formulation. Ignorance about potential human uptake of materials used in consumer products increases the difficulty of identifying regulatory targets. With the exception of chlorofluorocarbon propellants, each carcinogen that the CPSC has attempted to regulate has presented the agency with unique exposure issues.[840]

2. *Agency Resources*

The CPSC's limited budget and scientific resources have frustrated its attempts to set regulatory priorities within its broad potential jurisdiction. Establishing priorities would be difficult enough if the agency were concerned only with chronic hazards, but it also has the additional, and perhaps primary, responsibility of regulating products posing risks of acute injury or illness.[841]

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consists of the Assistant Administrators for Planning and Management, Research and Development, Water and Hazardous Materials, Air and Waste Management, and Enforcement. The second tier reflects EPA's subject matter responsibilities. For example, the Office of Water and Hazardous Materials encompasses the offices of Pesticide Programs, Toxic Substances, Water Planning and Standards, Water Program Operations, and Water Supply.

These structures contribute to the agencies' continuity, and minimize the risk of ad hoc distractions to which less-specialized organizational structures are susceptible. [1974] FDA Ann. Rep. 997, 1000, 1054; U.S. Envt'l. Protection Agency, *Operating Year Guidance for the Fiscal Year 1981*, in EPA *Manual* (February 1980); U.S. Envt'l. Protection Agency, *Finding Your Way Through EPA*, in EPA Directory (June 1976).

[838] Heller Interview, *supra* note 32.

[839] CPS Act § 15, 15 U.S.C. § 2064 (1976).

[840] Exposure to substances in consumer products can occur through inhalation, dermal contact, and ingestion. Furthermore, the frequency, duration, and manner of use of consumer products vary widely.

[841] *See* discussion at notes 22-28 *supra* and accompanying text regarding the Commission's reticence about entering the chronic hazards regulation area.

Thus, the agency must initially determine what portion of its limited resources it should devote to chronic hazards.[443] Within this more limited universe, it must then set its agenda of specific regulatory targets.

3. *Vulnerability to Petitions*

Public petitions have played an important role in determining the substances that the CPSC has chosen to regulate.[444] All seven of the CPSC's regulatory actions against carcinogens were begun after the agency received petitions from one or more outside organizations.[445] In the instances where the Commission staff had commenced evaluation of the substances before a petition was filed, other agencies already had initiated regulatory proceedings.

Although the petition process may assure CPSC responsiveness to immediate public concerns, the attention given to petitions by both the staff and the media can distort judgments about how the agency should allocate its limited resources. The potential for disruption is substantial, given that a majority of the petitions received by the CPSC have been submitted by industry groups.[446] This workload depletes agency resources because the statutory time limit for response has led the Commission routinely to undertake immediate review of petitions.[447]

The CPSC should explore ways to coordinate its handling of petitions with pursuit of its own priorities. The agency could "accept" petitions and then assign them priorities determined by its own criteria. Alternatively, it might "grant" facially meritorious petitions by publishing ANPRs calling for public comment, thus satisfying the 120-day period for response. Finally, the agency could grant or deny petitions based on the availability of agency

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[443] *See* note 28 *supra* for a discussion of the CPSC budget.

[444] *See* notes 54-55 *supra* and accompanying text for a discussion of the petition process.

[445] *See* notes 262-305 *supra* and accompanying text (vinyl chloride); notes 306-35 *supra* and accompanying text (chlorofluorocarbons); notes 336-83 *supra* and accompanying text (TRIS); notes 384-430 *supra* and accompanying text (asbestos in patching compounds and emberizing materials); notes 431-64 *supra* and accompanying text (benzene); notes 465-93 *supra* and accompanying text (hairdryers containing asbestos); notes 508-32 *supra* and accompanying text (urea formaldehyde foam insulation).

[446] CPSC Priorities, *supra* note 238, at 6 (Statler, Comm'r, dissenting). *But see id.*, Concurring Opinion of Commissioner R. David Pittle, Jan. 29, 1980, at 5-11 (arguing that industry groups have not flooded the agency with petitions).

[447] Preuss Interview, *supra* note 32. *See* notes 232-35 *supra* and accompanying text.

resources.[547] Although these approaches might stretch the statutory language,[548] courts should be persuaded that the CPS Act's requirements are sufficiently flexible to embrace these or other means of responding to petitions instead of allowing them to dictate the agency's agenda.

A more skeptical approach to public petitions would have two advantages. First, it would give the CPSC greater control over the allocation of its limited resources, thereby facilitating more systematic responses to chronic hazards. Second, the agency's adherence to its internal agenda would strengthen its image as an effective regulator.

4. *Internal Review Process*

The Commission established an internal review system for chronic hazards late in 1978.[549] Focusing on lists of suspected carcinogens assembled by outside groups, the review group determines whether such substances are found in products within the agency's jurisdiction and estimates the extent of potential human exposure. The CPSC has not yet regulated any substance identified by this review system, but several substances are current candidates for regulation.[550] The review procedure confronts two internal problems. First, there is no time limit for action on internally developed priorities.[551] The resulting competition for resources and consequent unpredictability impede creation of a coherent system that would allow the agency to control its agenda. Second, it remains unclear which office within the agency will set the priorities among substances found to merit attention. The official in charge of the Commission's chronic hazards program is primarily responsible for the internal review, but until very recently he lacked for-

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[547] CPSC Priorities, *supra* note 238, at 5-6 (Statler, Comm'r, dissenting).

[548] Section 10(c) of the CPS Act provides: "The Commission *may* hold a public hearing or *may* conduct such investigation or proceeding as it deems appropriate in order to determine whether or not such petition should be granted." 15 U.S.C. § 2059(c) (1976) (emphasis added). Section 10(d) states: "Within 120 days after filing of a petition . . . the Commission shall grant or deny the petition." 15 U.S.C. § 2059(d) (1976). Thus, a formal investigation is not required, although surely Congress expected some inquiry.

[549] Gallagher Interview, *supra* note 22; Heller Interview, *supra* note 32; Preuss Interview, *supra* note 32.

[550] These substances include respirable asbestos, hazardous dyes, and perchloroethylene. [1981] 4 CHEM. REG. REP. (BNA) 1621.

[551] Krulwich Interview, *supra* note 36.

mal authority to assign work, allocate resources, or fix deadlines.[563]

B. Criteria for Regulation

1. Risk, Cost, and Benefit Analysis

The CPSC rarely has analyzed carefully the health or economic consequences of its actions involving carcinogens. The agency's formal statements often have been conclusory, sometimes reciting simply that the Commission "carefully considered" pertinent factors.[564] The passages from the documents quoted in Section IV represent the agency's full explanation of its decisions. In three instances, the Commission attempted to quantify a product's risks,[565] but on occasion, it also has spurned such analysis.[566] The agency has not explained the weight accorded such factors as the availability of substitutes for a banned substance, the effect of regulation on product price, performance and availability, and the costs of repurchase. The agency's discussions of exposure levels often have betrayed a lack of both data and investigation.[567]

One explanation for the CPSC's apparent superficiality is technical. Quantification of human risk requires accurate estimates of human exposure. The agency not only faces technological problems in measuring many exposures, but it also possesses limited resources for the necessary tests. Measurement of consumer exposure often requires novel methods that are expensive to develop.[568] The technical difficulties of risk quantification are not the full explanation, however. The CPSC has denied that it is legally required to quantify risks or costs.[569] The CPS Act requires that it weigh cer-

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[563] *Id.*

[564] *See, e.g.*, 39 Fed. Reg. 30,112 (1974) (CPSC ban of aerosolized vinyl chloride); 42 Fed. Reg. 42,780 (1977) (final statement of CPSC on chlorofluorocarbon propellants).

[565] *See* 43 Fed. Reg. 21,839, 21,840-41 (1978) (proposal to regulate benzene); 42 Fed. Reg. 18,850, 18,850-51 (1977) (interpretation of TRIS as a banned hazardous substance); 46 Fed. Reg. 11,188, 11,190-93 (1981) (proposed ban of urea formaldehyde insulation).

[566] *See* Advance Notice of Proposed Rulemaking on Asbestos, 44 Fed. Reg. 60,057, 60,057 (1979).

[567] *See, e.g.*, the agency's proposed rule on benzene, in which it remarked: "While the Commission recognizes that much of the data discussed below concern benzene exposure in an industrial setting, the Commission points out that it does have some information concerning consumer exposure." 43 Fed. Reg. 21,839, 21,839 (1978).

[568] Krulwich Interview, *supra* note 38; Preuss Interview, *supra* note 32.

[569] *See* notes 84-113 *supra* and accompanying text for a description of the criteria used by the CPSC. In its proposed ban of urea formaldehyde insulation, the agency reiterated its

tain risk and cost factors,[459] but the legislative history indicates that a formal cost-benefit analysis is not mandated.[460] Prior to its proposed ban on formaldehyde, the Commission had rejected arguments that the statutory language requiring that product safety rules be "reasonably necessary" to eliminate a risk of injury or illness required quantification of health benefits.[461]

The CPSC has combined two approaches in evaluating consumer exposure. Usually, it has made an informed guess about whether consumers will be exposed significantly to a hazardous material in consumer products. In its proposal to ban benzene, the Commission apparently made a "seat-of-the-pants" judgment about how much benzene a "typical" product user might encounter.[462] Invariably, however, the Commission has gone on to emphasize that safe levels for carcinogens have not been known, and that *any* confirmed exposure warrants regulatory action unless there is a compelling reason to allow continued use of the material. The CPSC used this approach in its action against patching compounds and, again hypothetically, in its ANPR on asbestos.[463] The Commission has not yet confronted the question of what formula it will employ when it finds the use of a carcinogen in a consumer product *important*, but the issue appears inescapable after the Supreme Court's recent decision overturning OSHA's exposure standard for benzene.[464]

2. *Scientific Criteria*

No one has seriously challenged the CPSC's characterization of any chemical as a carcinogen, but the agency has never relied solely on its own scientists to support its judgment. The CPSC's acceptance of other agencies' judgments concerning vinyl chloride,

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position: "The statute does not require the Commission to quantify the potential costs and benefits before taking regulatory action." 46 Fed. Reg. 11,183, 11,201 (1981) (citation omitted). Cautious after the *Industrial Union* decision, however, the CPSC did attempt such an analysis. *Id.* at 11,183-211.

[459] CPS Act § 9(c), 15 U.S.C. § 2058(c) (1976).

[460] *See* note 90 *supra* and accompanying text.

[461] *See* Advance Notice of Proposed Rulemaking on Asbestos, 44 Fed. Reg. 60,057 (1979). *See generally* CPSC Cancer Policy, 43 Fed. Reg. 25,658 (1978).

[462] *See* notes 443-46 *supra* and accompanying text.

[463] *See* notes 399-401 *supra* and accompanying text. *See also* Advance Notice of Proposed Rulemaking on Asbestos, 44 Fed. Reg. 60,057, 60,058 (1979).

[464] *See* notes 462-64 *supra* and accompanying text.

asbestos, benzene, and chlorofluorocarbon propellants demonstrates that it has adhered to the same tenets in identifying carcinogens and in evaluating their risks as have other federal agencies. These precepts include the acceptance of positive results in animal experiments as evidence of potential human risk, a skepticism toward negative epidemiological studies, and the assumption that no level of a carcinogen can be shown to be safe for all exposed individuals. These tenets formed the basis of the Commission's 1978 cancer policy, which was set aside in the *Dow Chemical* case and was replaced subsequently by the IRLG's own statement of principles for evaluating carcinogens.[565] The CPSC's reliance on outside agencies also reflects its shortage of trained scientists. As late as 1978, the agency employed only one toxicologist, who worked in both the acute and chronic hazards programs.[566] The CPSC's overworked staff, shortage of resources for in-house testing and analysis, and general lack of experience also contribute to its reactive posture. Gaps in the agency's scientific analysis often betray deficiencies in the available data. Information about exposure levels and human uptake is typically sparse. In many cases, no methodology has been developed to measure human exposure, or levels may be too low to be measured.

C. *Execution of Regulatory Actions*

1. *Statutory Options*

Section 30(d) of the CPS Act permits the Commission to choose the legal remedy best suited to fulfilling the "public interest."[567] Neither the statutory language nor the legislative history offers guidance in applying this standard beyond suggesting that the agency should have flexibility in selecting its regulatory tools. In the proceedings the agency has begun, it has relied on five different statutory provisions.[568] The Commission's disparate ap-

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[565] See notes 182-231 *supra* and accompanying text for a discussion of the 1978 cancer policy and the *Dow Chemical* case. On the IRLG cancer policy, see T. McGarity, *supra* note 227, at 9-11.

[566] Preuss Interview, *supra* note 32.

[567] Section 30(d) identifies the FHSA, the Poison Prevention Packaging Act, and the Flammable Fabrics Act as statutes under which the CPSC may regulate risks of injury associated with consumer products. 15 U.S.C. § 2079(d) (1976).

[568] The Commission has relied on the "banned hazardous substance" authority of the FHSA (vinyl chloride; TRIS), the labeling requirements of the CPS Act (chlorofluoro-

proaches to vinyl chloride, TRIS, benzene, and asbestos in hairdryers are difficult to reconcile on theoretical grounds; it appears simply to have seized upon the statutory options that have permitted it to act promptly and, when possible, without having to conduct a formal hearing. As a general approach, this is sure to be controversial. The CPSC understandably desires to reduce consumer exposure to carcinogens as promptly as possible, but it should not be able to avoid systematic examination of the risks posed by consumer products and the costs of their control.

The Commission's actions against vinyl chloride and TRIS were awkward, if not inept. They were taken in disregard of obvious legal risks,[569] and both met judicial reversal. The CPSC has displayed greater skill in more recent actions. Its ban of patching compounds and emberizing materials containing respirable asbestos was completed within approximately six months without any loss of opportunity for interested parties to participate, although by the time the agency commenced rulemaking, asbestos use in these products had ceased voluntarily.[570] Where the costs of eliminating or reducing exposure are higher, however, the Commission cannot expect lack of interest to clear its path.

CPSC officials have expressed pride in their handling of regulation of hairdryers containing asbestos, noting the speed with which the effective "ban" was implemented.[571] This result was achieved, however, at the expense of both internal analysis and public understanding. No contemporaneous study was made of the dimensions of the risk associated with those products or of the costs of a comprehensive recall. Nor was any legislative authority formally invoked to effect the recall; it was undertaken voluntarily, because the retailers and manufacturers did not wish to jeopardize their goodwill with consumers.

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carbons; urea formaldehyde insulation), the "substantial product hazard" provision of the CPS Act (hairdryers containing asbestos), and the administrative banning authority of the CPS Act (patching compounds containing asbestos; benzene).

[569] *See* notes 262-305 *supra* and accompanying text (discussion of vinyl chloride action); notes 336-83 *supra* and accompanying text (discussion of TRIS action).

[570] *See* notes 384-430 *supra* and accompanying text (discussion of patching compounds/emberizing materials actions).

[571] Krulwich Interview, *supra* note 36.

2. *Importance of Recall and Repurchase*

A recurrent point of controversy in CPSC actions against carcinogens has been the status of existing product stocks. In no completed CPSC action have manufacturers disputed the ultimate fate of the challenged substance, and in three instances use of the substance was discontinued before the agency commenced regulation. In several cases, however, the disposition of unsold inventory became a major issue. The CPSC's action against vinyl chloride would not have been contested had the agency not insisted on extending its ban to cover products already distributed, thereby triggering the automatic repurchase provisions of the FHSA.[372] Similarly, the agency's assault on TRIS foundered over the scope and incidence of repurchase obligations.[373] By contrast, the ban on patching compounds and emberizing materials containing asbestos, which scarcely touched outstanding products, was not contested.[374]

This does not suggest that the CPSC should ignore products already distributed and focus only on future use of carcinogenic substances. Sometimes human exposure to outstanding stocks may be too significant to neglect, although none of the actions examined here appears to have posed such a case. The case studies, however, do illustrate the practical importance of the repurchase/recall decision. The agency should assess the risks posed by distributed products independently and consider their disposition as an issue separate from the broader question of whether continuing use of a substance poses an unacceptable risk.

D. Program Management

Both the CPSC's organization and some of its policies have repeatedly impeded its performance in regulating carcinogens.

1. *Internal Organization*

Recognizing the wide range of products subject to its jurisdiction, the Commission initially chose an organizational structure that would give it maximum flexibility. Under the agency's matrix

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[372] *See* notes 298-300 *supra* and accompanying text for discussion of the challenge to the recall and repurchase order in the action against vinyl chloride.

[373] *See* notes 368-74 *supra* and accompanying text.

[374] *See* notes 384-430 *supra* and accompanying text.

organization, the persons responsible for preparing briefing materials and regulatory documents often changed with each assignment. For regulatory actions against many product hazards, assembling teams of staff specialists on an ad hoc basis may be a practical approach. For chronic hazards, however, such an approach ultimately is frustrating. Effective regulation of carcinogens requires a staff that is familiar with and understands the scientific principles involved. Only by moving toward a structure of fixed personnel assignments for chronic hazards has the CPSC's staff begun to develop the kind of experience that will permit sophisticated evaluation of carcinogens in consumer products.

2. Openness

The Commission's ritualistic observance of the Government in the Sunshine Act[675] and the Freedom of Information Act[676] (FOIA) also has hampered its effectiveness. The agency's view of the Sunshine Act is that all meetings involving the Commissioners as a group and the agency staff must occur in public. These include preliminary briefings, discussions about regulatory options, and debates over agency priorities. This approach has impeded the Commissioners' ability to provide direction to the staff and has discouraged candid discussion of regulatory strategies, because attorneys representing affected firms attend the critical meetings. All discussions between industry representatives and the Commissioners or agency staff also occur in public. This inhibits candid negotiations and discourages voluntary disclosure of sensitive product information.[677]

The CPSC has adopted an equally generous reading of the FOIA. Staff documents ordinarily can be released to the public as soon as one office—at any level—approves them and passes them along the bureaucratic chain. Thus, staff recommendations are sometimes publicly available before they are discussed with the Commissioners. These documents do not ordinarily reflect official policy, and they may contain misleading information. Further-

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[675] 5 U.S.C. § 552(b) (1976). For general discussions, see Statler, *Let the Sunshine In!*, 67 A.B.A.J. 573, 575 (May 1981); Moss Report, *supra* note 91, at 241.

[676] 5 U.S.C. § 552 (1976). *See also* Statler, *supra* note 675; Moss Report, *supra* note 91, at 241.

[677] Statler, *supra* note 675, at 574.

more, early access to staff documents may provide intelligence to potential regulatory targets that can be used to impede Commission action.[575]

The consequences of the CPSC's historic dedication to "openness" as an agency objective recently provoked the following comments from one member, Commissoner Statler, who recently served as Acting Chairman of the Commission:

> Instead of weighing the competing values of consumer protection and open decision making, the commission simply assumed that total openness could be obtained without detracting from its safety mandate. It was felt that openness could only enhance the quality of decisions affecting consumer health and safety.
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> . . . .
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> . . . [R]egulatory agencies must accord top priority to their substantive mandates, to what Congress originally asked of them, to their *raison d'etre*. Adding other laudable aims to their task—openness, among them—has taken its toll. At times the added burdens have impaired the ability of these agencies to accomplish their primary mandates. Even praiseworthy means, such as open decisions openly arrived at, do not justify poor regulatory results.
>
> When a formal regulatory decision is at hand, openness should be preserved to the extent possible. . . . But when an agency is simply exploring issues devoid of any immediate regulatory impact—and especially at an early or preliminary stage—unfettered discussion should be encouraged. If candid dialogue is inhibited by openness and the overriding public interest does not suffer from any one person's exclusion, then preserving openness in those circumstances may be unwarranted.[576]

E. Conclusion

The CPSC's contribution to the federal effort to regulate exposure to carcinogens defies simple assessment. Perhaps the Commission's role is largely redundant. The statutory authorities and administrative bodies existing prior to adoption of the CPS Act probably could have dealt adequately with the substances that the

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[575] *Id.* at 575.

[576] *Id.* at 573, 575. *But see* Decision of the CPSC Regarding CPSC Meetings Policy, Dissenting Opinion of Commissioner R. David Pittle, Oct. 22, 1980. Commissioner Pittle is the Commission's current Vice Chairman.

CPSC has regulated. Before the Commission began its action against vinyl chloride based on the FHSA, FDA, which originally administered the FHSA, had already regulated other uses of vinyl chloride. Although the agency relied on the CPS Act in regulating chlorofluorocarbon propellants and benzene, it acted against benzene only after other agencies had regulated the more significant uses and after manufacturers of consumer products had ceased using the ingredient. The FDA and EPA actions against chlorofluorocarbon propellants ultimately made a CPSC response unnecessary. Asbestos use in embarizing materials and caulking compounds had ceased by the time the Commission completed its rulemaking.

Still, it would be premature to suggest that the CPSC has no role to play in reducing exposure to carcinogens, or that the CPS Act has been unnecessary. Not all hazardous materials in consumer products fall within the jurisdiction of other agencies or are likely to be affected by the actions they take. Asbestos may be an example. Routine reliance on the FHSA to regulate such substances in consumer products would be unsatisfactory. The CPS Act offers a broader range of regulatory tools, including more authority to mandate disclosure of information, and more expeditious rulemaking procedures.[580]

Despite many past missteps, the CPSC has begun to mount a more sophisticated program for regulating chronic hazards. The agency has several suspected carcinogens on its current list of priorities that are not likely to receive attention from other federal agencies.[581] It has attempted improvements in its internal review and investigatory procedures. There are also signs that the Commission is recognizing its scientific limitations and is relying more heavily on other regulatory agencies and the scientific components of the government. The CPSC precipitated the first government-wide effort to evaluate the carcinogenicity of formaldehyde, a substance potentially of multi-agency interest. CPSC staff members reportedly have been among the most vigorous proponents of coor-

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[580] *See* § 27 of the CPS Act, 15 U.S.C. § 2076 (1976 & Supp. III 1979), for details of what is obtainable.

[581] Of the current CPSC projects, hazardous dyes may be the next target for regulation. If benzidine dyes are not used primarily by consumers, however, OSHA may have primary responsibility. *See* [1980] 4 CHEM. REG. REP. (BNA) 1070.

dinated regulatory proceedings within the IRLG.

There is an irony, and a warning, in the CPSC's current efforts to upgrade its performance in regulating carcinogens. Its past regulatory initiatives have contributed comparatively little to reducing human exposure to harmful agents. The costs it has imposed, although indeterminate, also probably have been modest.[548] To the extent the Commission now begins to tackle more serious problems, its regulatory apparatus will be tested more severely. Its scientific judgments will be contested more sharply. It will be forced to document exposure estimates with greater care and precision, and to perform quantitative assessments of risk. The increased economic stakes will not only require more thoughtful analysis of the costs of regulation; they will also more frequently require the agency to prove its case in a public forum. It is still much too early to judge whether the CPSC, as currently structured and staffed, can meet these challenges.

Epilogue

The Reagan administration's efforts to eliminate the CPSC and transfer its important functions to other bodies, principally the Department of Commerce, stimulated critical examination of the agency's performance during Congress's recent consideration of reauthorization legislation. Ultimately, Congress voted to continue the CPSC for two additional years but with a substantially reduced budget.[549] The reauthorization legislation also made important changes in the laws that the Commission administers. Some of these changes are pertinent to the subject of this article and therefore are described briefly here. Neither time nor space permits thorough analysis of their likely impact on the CPSC's regulation of chronic hazards.

Although Congress focused on the CPS Act, it also enacted

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[548] The costs of some CPSC actions, however, may be neither modest nor reasonable. *See* Linneman, *The Effects of Consumer Safety Standards: The 1973 Mattress Flammability Standard*, 24 J.L. & ECON. 461 (1981).

[549] Consumer Product Safety Amendments of 1981, Pub. L. No. ___, § 1214, ___ Stat. ___ (amending 15 U.S.C. § 2081 (1976 & Supp. III 1979)). Congress authorized $33 million for fiscal year 1982, and $35 million for fiscal year 1983.

changes, largely parallel, in other laws administered by the CPSC.[504] This discussion deals only with the amendments to the CPS Act, which has been changed substantially in three pertinent areas: (1) the Commission's rulemaking authority and procedures; (2) the Commission's duty to respond to public petitions; and (3) the Commission's scientific evaluation of products thought to present cancer hazards.

Rulemaking authority. The CPSC must now commence any proceeding to ban, or establish a standard for, a product by publishing an advance notice of proposed rulemaking that describes the risk of injury to be controlled and invites the development of a voluntary industry standard. Before the agency can establish a mandatory standard or ban, it must conclude that a voluntary standard is unlikely to eliminate or reduce the hazard. In any such proceeding, the agency must perform both a preliminary and a final regulatory analysis, which assess the potential costs and benefits of the action as well as alternatives to it. The amendments supplement the Commission's duties under section 9(c) of the Act, requiring specifically that it find that a voluntary standard is not likely to deal with the hazard, that the benefits of its rule "bear a reasonable relationship to" its costs, and that the rule imposes the least burdensome requirements necessary to address the hazard. These findings are in some sense a synthesis of the teaching of the *Aqua Slide* decision[505] and President Reagan's regulatory reform order.[506] They obviously push the CPSC toward cost-benefit analysis and require more comprehensive evaluation of the economic effects of regulation than the Commission usually has conducted.

Public petitions. Congress has freed the CPSC from the burdens of responding within 120 days to public petitions, imposed by the original section 10 of the CPS Act. That provision has been repealed, leaving the Commission subject simply to the obligations imposed by the APA, which imposes no time limit on responding to petitions.[507] Although a rather blunt response, this change should permit the CPSC greater freedom to set its own agenda, a

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[504] *See, e.g., id.* § 1203 (amending rulemaking procedures for both the CPS Act, 15 U.S.C. § 2058 (1976) and the FHSA, 15 U.S.C. § 1262 (1976)). For a discussion of the CPSC's governing statutes, see notes 56-181 *supra* and accompanying text.

[505] *See* notes 93-109 *supra* and accompanying text.

[506] Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (1981).

[507] *See* 5 U.S.C. §§ 551-75 (1976).

goal urged in this article.

Advisory panels. The amended CPS Act requires the Commission to appoint and consult with a Chronic Hazard Advisory Panel,[886] composed of scientists nominated by the National Academy of Sciences, whenever it contemplates regulating a substance believed to present a risk of cancer, birth defects, or gene mutation. The Commission must ask the panel to report whether the substance is a carcinogen and, where possible, to provide an estimate of its probable harm to human health. Each panel will be established for the purpose of reporting on a particular substance, in the fashion of the NTP committee assembled to review formaldehyde, rather than as a standing advisory committee. Although the panel's report technically will be advisory, it will become part of the agency's rulemaking record and, as a practical matter, probably will be conclusive on the issues it addresses.

It is appropriate here to mention one change made in the CPSC's internal operations since this article was written. In late 1980 the Commission voted to make the Health Sciences division a separate Directorate, elevating both the responsible DAED and the visibility of the chronic hazards program. Responsibility for overseeing staff work on chronic hazards, including the agency's internal review of candidates for regulation, was assigned to the new Directorate, in effect eliminating the intermediary role of the Office of Program Management.[887] These important institutional changes are entirely consistent with the views stated in the article.[888]

There is an irony in this juxtaposition of very recent changes in the CPSC's authority and organization. Although the reforms effected by the Commission on its own initiative were obviously designed to enhance its ability to deal with chronic hazards, the amendments made by Congress are likely, and perhaps intended, to encumber and delay Commission action in this field.

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[886] Consumer Product Safety Amendments of 1981, Pub. L. No. ___, § 1206, ___ Stat. ___ (amending 15 U.S.C. § 2077 (1976)).

[887] *See* Gallagher Comments, *supra* note 510.

[888] *See* notes 29-39, 549-52 *supra* and accompanying text.