



U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

MINUTES OF COMMISSION MEETING

June 25, 1986

5401 Westbard Avenue, Room 456
Bethesda, Maryland

The June 25, 1986, meeting of the U.S. Consumer Product Safety Commission was convened in open session by Acting Chairman Anne Graham. Commissioners Sandra Brown Armstrong and Carol G. Dawson were present. Commissioner Terrence Scanlon participated in the meeting by telephone.

Ballot Vote Decisions. The following decisions made by ballot vote of the Commissioners were placed in the record.

1. Federal Register Notice - Statement of Enforcement Policy on Substantial Product Hazard Reports - Response to Comments and Amended Policy

The Commission voted to approve a Federal Register notice responding to comments regarding its Statement of Enforcement Policy on Substantial Product Hazard Reports and republishing an amended version of that document. Voting to approve were Acting Chairman Graham and Commissioners Armstrong and Dawson. Commissioner Scanlon voted to approve the FR notice with amendments (see attached) that were not agreed to by the Commission.

2. Request for Commission Comments on Amendments No. 1953 to S. 1848, a Bill to Establish Uniform Export Notification Procedures

The Commission voted unanimously (4-0) to approve a response without change to a request for comments on Amendment No. 1953 to S. 1848, a bill introduced in the Senate on May 13, 1986, to establish uniform procedures for notifying other countries about the proposed exportation of banned or severely restricted products from the United States.

3. Civil Penalty Settlement, Electro-Plastics, Inc.

The Commission voted 3-1 to provisionally accept a settlement agreement of a civil penalty settlement with Electro-Plastics, Inc., in accordance with 16 CFR Part 1118.20(e). Voting to accept were Acting Chairman Graham and Commissioners Armstrong and Scanlon. Commissioner Dawson voted to reject the settlement agreement and will file a dissenting opinion with the Office of the Secretary.

4. Request from NSPI for Inclusion of Statement Concerning Commission Review of Safety Information on Two Pamphlets

The Commission voted 3-1 to grant the request from the National Spa and Pool Institute (NSPI) for permission to use the following statement on the covers of two consumer publications: "The safety information contained in this booklet has been reviewed by the U.S. Consumer Product Safety Commission." Acting Chairman Graham and Commissioners Dawson and Scanlon voted to grant the request. Commissioner Armstrong voted not to authorize the request.

Agenda Matter.

Fiscal Year 1988 Budget Format, Planning Issues, and Priority Projects

The Commission considered three basic aspects of CPSC's budget planning for fiscal year 1988: (1) how the budget is structured; (2) planning issues affecting the budget; and (3) priority projects for full funding.

Budget Format. By unanimous vote (4-0), the Commission approved reducing the number of budget categories from 15 to 5. The five categories are Hazard Identification and Analysis; Hazard Assessment and Reduction; Compliance and Enforcement; Consumer Information; and Agency Management.

Planning Issues.

1. Import Surveillance. By unanimous vote (4-0), the Commission approved conducting a narrowed-focus program (11-15 FTE's-\$50,000 to \$100,000) of import surveillance involving inspections or samples of identified problem products at ports or warehouses, focusing on a set of specific products, specific firms, and specific countries of origin each year. Additionally, by a vote of 3-1, the Commission approved undertaking a two-part information/education-oriented approach to dispense advice to importers or to foreign firms about how to comply with rules, what areas the Commission is interested in, and who to contact for additional information. The two parts of this approach would be (a) conduct a systematic series of embassy seminars and importer seminars for interested trade representatives on specific products, and (b) send CPSC emissaries to visit importers, exporters, and foreign manufacturers at the request and expense of foreign governments or trade organizations, explain technical areas of rules, and advise firms of U.S. importers' responsibilities. Commissioners Armstrong, Dawson, and Scanlon approved the two-part information/education approach, emphasizing that these activities are not to be resource

intensive, that is not to involve CPSC travel funds or added staff. Acting Chairman Graham voted against.

2. Communication Functions. In separate votes, the Commission addressed five areas relating to the Commission's "active" communications efforts to inform and educate the public about hazards associated with consumer products and the "reactive" functions that respond to written and oral requests for information.
 - (1) By vote of 3-1, the Commission decided that it should recognize the budgetary problems faced by offices charged with performing reactive communication functions and should consider designating certain reactive communications as "core functions" of the agency, with sufficient resources allocated for adequate performance of the functions. Acting Chairman Graham and Commissioners Dawson and Scanlon voted to approve. Commissioner Armstrong voted against.
 - (2) By vote of 3-1, the Commission decided that priority project status should not be a dominant criterion in the allocation of resources for active information and education (I&E) projects, recognizing that I&E resources may be spent to greater benefit of consumers in addressing hazards that are not the subjects of current priority projects, depending on frequency and severity of the hazards, the potential for I&E activities to reach appropriate audiences effectively and costs. Acting Chairman Graham and Commissioners Dawson and Scanlon voted to approve. Commissioner Armstrong voted against.
 - (3) By unanimous vote (4-0), the Commission decided that operational changes should be considered for the Hotline toward the objective of increased productivity, with the staff to conduct a feasibility study and report back to the Commission on possible changes and the resources involved.
 - (4) By unanimous vote (4-0), the Commission directed the staff to explore what increases in Freedom of Information Act fees for information would be appropriate and what steps can be taken to reimburse the Commission.

- (5) By unanimous vote (4-0), the Commission directed the staff to develop a comprehensive plan that sets forth the agency's public affairs/communications strategy, in a manner that maximizes the use of resources at the present operating level and includes a strategy to obtain optimal use of sources/resources outside the agency, with the understanding that the Commission would review the strategy plan and, upon acceptance, would have the option to modify it on an annual basis.
3. Research. By unanimous vote (4-0), the Commission decided that research and development activities conducted in support of defined hazard project needs should continue to be presented and managed as an integral part of hazard projects.

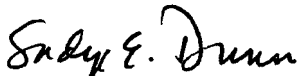
In response to the suggestion that a standing committee of CPSC managers be established to oversee the research program, the Commission agreed that it would like to receive a more developed plan on this idea, including resource requirements, at a later date, following the budget exercise.

Priority Projects. The Commission selected three projects it would give priority attention to and fully fund in fiscal year 1988. Two of the projects, all-terrain vehicles and riding lawn mowers, were approved for priority status by unanimous vote (4-0). The third project, concerning child drownings in residential swimming pools, was approved for priority status by vote of 3-1, with Acting Chairman Graham and Commissioners Dawson and Scanlon voting in favor and Commissioner Armstrong voting against. Project proposals for the three priorities are attached.

The Commission also considered a motion to designate bicycles as a priority project for FY 1988. This motion failed for lack of a majority, with Acting Chairman Graham and Commissioner Armstrong voting to approve, and Commissioners Dawson and Scanlon voting not to approve. Commissioner Scanlon also moved that PPPA and playground equipment be made priorities in FY'88, but both motions died for lack of a second.

There being no further business, Acting Chairman Graham adjourned the meeting.

For the Commission:



Sadye E. Dunn
Secretary

Proposed Priority Project

Office/Directorate: OPM

Priority Project Candidate: All-Terrain Vehicles (ATVs)

Hazard/Health Effects:

As of January 31, 1986, the Commission has reports of 415 ATV-related fatalities which occurred between 1982 and 1985; 174 occurred in 1985. A review of the 415 ATV-related fatalities indicated that 191 victims were under 16 years of age (46 percent) and 91 victims were under 12 years of age (22 percent).

The Commission estimates from its National Electronic Injury Surveillance System (NEISS) that the adjusted number of hospital emergency room treated injuries associated with ATVs in 1985 was 85,900.

A preliminary report on the Survey of All-Terrain Vehicle Related Injuries treated in NEISS hospital emergency rooms between May 1 and July 15, 1985 gave profiles of ATVs, persons using the vehicles and the accident scenarios. Results of the survey included: (1) 18 percent of the persons treated at emergency rooms were hospitalized; and (2) 19 percent of the injured persons were under 12 years of age; 46 percent were under 16 years of age.

Reason for Priority Status:

This is a contingent priority project. The technical work of the ATV Task Force will be completed in Fiscal Year 1986 and a regulatory options package developed for Commission consideration. If the Commission decides to pursue prospective and/or retrospective regulatory options for ATVs in Fiscal Year 1987, the priority status is warranted in Fiscal Year 1988.

Previous CPSC Work on Subject:

The Consumer Product Safety Commission has preliminarily determined that there may be an unreasonable risk of injury associated with the use of All-Terrain Vehicles. On April 3, 1985, the Commission voted to commence a rulemaking proceeding by issuing an ANPR. At that time, the Commission also adopted a number of measures intended to assist it in obtaining further information on the hazards associated with ATVs. These measures which have been or are being undertaken by the Commission staff are:

1. Conducting surveys on ATV injuries, and consumer exposure to obtain detailed information on ATVs and prepare a hazard analysis.
2. Conducting engineering, human factors, and medical analysis of the hazards associated with ATVs and their use.
3. Monitoring the development of any voluntary standards for ATVs, pending review of the future data and industry activity.

4. Sharing information with user groups and state, local, and federal officials.

5. Monitoring the ATV industry's education and training effort, reserving the right to assist or strengthen the industry effort.

The Commission also held six public hearings to obtain safety-related information on ATVs.

Description of Proposed 1988 Work

Conduct the staff work needed to implement a Commission decision on prospective and/or retrospective regulatory options for ATVs.

Anticipated Work in Future Years/"Sunset" Date

This will depend on the Commission decision.

Estimated Cost:

This will depend on the Commission decision. Resources equivalent to FY 87 funding may be in order.

FTEs 8.0 Contract Amount - \$250,000

FY 1988

Proposed Priority Project

Office/Directorate: OPM

Priority Project Candidate: Riding Mowers

Health/Health Effects

Injuries and fatalities from a variety of patterns such as blade contact, stability related patterns, victim falls under or is run over by mower. For 1985 20,300 emergency room treated injuries (50,000 medically attended) 27 fatalities from death certificate file-incomplete for 1985-approximately 100 estimated deaths per year).

Reason for Priority Status

The needed baseline epidemiology, human factors, and engineering work is currently scheduled for completion during FY88. Application of this work will continue into the 1990 sunset. High effectiveness (70-80%) is anticipated in eliminating the estimated 100 deaths per year at a low cost to society.

\$300,000 in contract funds were deferred from the FY87 to meet the demands of G-R-H cutbacks on the agency.

Previous CPSC Work on Subject

During FY 85 & 86 collected and analyzed injury, human factors and engineering data to support Commission recommendations; participated with industry to upgrade voluntary standard.

Description of Proposed 1988 Work

Continue tests at Engineering Laboratory to evaluate and refine the Field Test methods and verify the simulation model. Begin development of specific engineering test procedures and human factors recommendations for the standard. Complete currently contracted work on simulation model. Initiate contract to upgrade the simulation by developing standardized terrain inputs, conducting additional tire tests for the tire-terrain section of the model, and investigating incorporation of bumps and holes into the model. Continue work with industry to apply the data developed to improve the voluntary standard.

Anticipated Work in Future Years/"Sunset" Date

It is estimated that 1989 would be a substantially funded non-priority project with 1990 anticipated as sunset with new provisions being incorporated into the standard.

Estimated Cost: FTEs 6.3
FY88

Contract Amount ES-\$300,000

Proposed Priority Project

Office/Directorate: Household Structural Products Program/OPM

Priority Project Candidate: Child Drownings

Hazard/Health Effects: Each year over 600 people drown in backyard swimming pools in the United States. Of these, almost 300 children are less than five years old and 200 are children under two years of age. Additionally, over 3,000 children under five are treated in hospital emergency rooms for submersion injuries. These incidents frequently leave a child permanently incapacitated. The economic and social costs of these incidents are tremendous.

Reason for Priority Status: Work will be initiated on the problem as a priority project in FY'87. The 1987 effort will concentrate on identifying measures that can be taken (i.e., four-sided fencing, pool alarms, self-closing and self-locking gates, safety covers, etc.) that can be effective in reducing the risk of child drowning in residential swimming pools.

Previous CPSC Work on Subject

- 1985 - Commission cosponsored a national conference to focus attention on the problem
- Late 1985 - Ad Hoc Steering Committee formed from government, industry, and aquatic safety organizations. Commissioner Dawson chairs this committee
- 1986 - Initiate epidemiology study to gather better data on circumstances surrounding child drowning. Data clearinghouse created at CPSC. Areas of needed research explored by subcommittees

Description of Proposed 1988 Work

- Implement recommendations resulting from Epidemiology study
- Implement recommendations resulting from laboratory evaluation of pool alarms and other sensing devices
- Work with code organizations and State/Local Governments on improving barrier requirements for residential swimming pools
- Regional conferences to improve community awareness of the problem and recommend action to reduce the drowning risk

Anticipated Work in Future Years/"Sunset" Date

None (Sunset--1988)

Estimated Cost: FTEs 4

Contract Amount \$55,000



U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

OPINION OF COMMISSIONER CAROL G. DAWSON
REGARDING CIVIL PENALTY AGREEMENT
WITH ELECTRO-PLASTICS, INC.
JUNE 18, 1986

I have voted to reject the \$10,000 settlement agreement between the Commission and Electro-plastics, Inc. This agreement was negotiated to settle a staff allegation that the firm knowingly failed to report a product defect that could constitute a substantial product hazard, in violation of Section 15(b)(2) of the Consumer Product Safety Act.

I do not vote against this consent agreement lightly. It involves a death, which automatically causes me great concern and which under our regulations creates a heightened reporting responsibility for a firm. But whenever we use the potentially coercive power of the federal government to impose a penalty on the private sector, we have a duty to make sure we wield that power with great care. I am not convinced we did so in this instance.

This vote is not several things. It does not indicate that I have changed my views on the importance of the Section 15 reporting requirement. I still believe we should take aggressive action against firms that do not report as required, and so stated as recently as the Commission's April 9 decision meeting on the Section 15 policy statement. Nor does my vote excuse a firm for conducting a "silent" recall, one done without reporting it. And my vote is not really about the size of the penalty, which I realize is small in comparison with penalties paid by other firms and which, in this instance, the company has agreed to pay.

My decision is instead based on my concern about an important principle that goes directly to the heart of Section 15(b) of the CPSA. The purpose of that section's reporting requirement is to permit timely remedial action to be taken. In this case, the remedial action -- a recall -- was taken when the firm recalled its product within weeks of learning of a fatality associated with the product. It seems to me that the intent of the statute was met: the potentially dangerous product was removed from the market in a timely manner. Had the firm reported the incident, would the outcome have been any different? I think not.

Had the company not engaged in a timely corrective action, of course, a fine of the magnitude imposed or greater might have been appropriate. But given the fact that an effective, timely recall did take place, the fine seems inordinate.

Any time the power of the federal government is used against our citizens, we have an obligation to look carefully at the reasons for using that power and the availability of adequate alternatives. Although reasonable people may differ on the merits of this case, based on the facts before me at this time I cannot in good conscience support this settlement agreement.

attachment

COMMISSIONER SCANLON'S SUGGESTED
AMENDMENTS TO FEDERAL REGISTER NOTICE REVISING
1984 SECTION 15 ENFORCEMENT POLICY

#1 (See Page 13822 Federal Register, Vol. 49, No. 68, April 6, 1984)

The 1984 Enforcement Policy Statement contained language on effect of recalls as follows:

(4) Adverse publicity Or Adverse Effects On
Marketing Or Competitive Positions -

Some firms may not file a report based on a belief that a report, or any corrective action arising from it, may result in adverse publicity or may have an adverse effect on the firm's marketing or competitive position. The Commission is not aware of evidence showing these effects to be true. To the contrary, there are indications that corrective action voluntarily taken by a firm has the beneficial effect of showing the firm is responsible and concerned about high standards of product quality.

Subsequently, information has come to the Commission's attention since the Enforcement Policy was published in April 1984 that renders that statement inaccurate.* Accordingly, the Commission also deletes that language from the 1984 guidelines.

#2

Strike from draft on page 10 in second paragraph, sentence beginning with "For example" to end of paragraph. These two sentences set forth examples which could create additional confusion and which may needlessly require the Commission to again address the question of whether such examples do or do not require the filing of a Section 15(b) report.

*The Impact of Product Recalls on the Wealth of Sellers by Gregg Jarrell and Sam Peltzman, Journal of Political Economy, (1985, Vol. 93, No. 3)

**CONSUMER PRODUCT SAFETY
COMMISSION**

16 CFR Part 1115

**Statement of Enforcement Policy on
Substantial Product Hazard Reports**

AGENCY: Consumer Product Safety
Commission.

ACTION: Response to Comments on
Statement of Enforcement Policy on
Substantial Product Hazard Reports.

SUMMARY: In this document, the Consumer Product Safety Commission responds to comments regarding its Statement of Enforcement Policy on Substantial Product Hazard Reports, and republishes an amended version of that document. The comments were submitted in response to a December 28, 1984 request for public comment on the April 6, 1984 enforcement policy on reporting substantial product hazards. That policy statement was issued to provide guidance to firms that are subject to the reporting requirements of section 15(b) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2064(b). Section 15(b) requires every manufacturer, distributor or retailer of a consumer product distributed in commerce who obtains information which reasonably supports the conclusion that the product either fails to comply with an applicable consumer product safety rule or contains a defect which could create a substantial product hazard immediately to inform the Commission, unless the manufacturer, distributor, or retailer has actual knowledge that the Commission has been adequately informed of the defect or of the failure to comply.

In this document, the Commission clarifies certain aspects of the 1984 policy statement which were of concern to commenters, by a 4-1 vote withdraws examples given in the policy statement,¹ and by a 5-0 vote re-emphasizes the importance of the section 15(b) reporting requirements.

EFFECTIVE DATE: June 27, 1986.

FOR FURTHER INFORMATION CONTACT: Philip E. Bechtel, Director, Division of Administrative Litigation (301) 492-8628, or David W. Thome, Director, Division of Corrective Actions (301) 492-8608, Consumer Product Safety Commission, Washington, DC 20207.

SUPPLEMENTARY INFORMATION: Section 15 of the CPSA authorizes the Consumer Product Safety Commission to initiate administrative proceedings to obtain remedial action for products which present a substantial product hazard. Among the remedies available to the Commission are administrative orders requiring manufacturers to give public notice of the hazards and requiring the

repair, the replacement or refund of the purchase price of products which present a substantial product hazard.

Section 15(b) of the Consumer Product Safety Act establishes an "early warning system" which enables the Commission to become aware of products which may present substantial product hazards. This section requires every manufacturer, distributor, and retailer of a consumer product distributed in commerce, who obtains information which reasonably supports the conclusion that the product either fails to comply with an applicable product safety rule or contains a defect which could create a substantial product hazard, immediately to inform the Commission, unless the firm has actual knowledge that the Commission has been adequately informed. After being notified of a potential hazard, the Commission assesses the degree and severity of the risk of injury associated with the product and determines what corrective action, if any, is necessary to protect the public. It is a prohibited act for a firm that obtains reportable information to fail to make a section 15(b) report. 15 U.S.C. 2068(a)(4). If the failure to report is done knowingly, a civil penalty may be assessed against the firm. 15 U.S.C. 2069.

On August 7, 1978, the Commission issued regulations interpreting the reporting obligation under section 15(b), 16 CFR Part 1115 "Substantial Product Hazard Reports" (43 FR 34988). These interpretative rules, which remain in effect today, identify the type of information that is reportable under section 15(b) or which should be studied and evaluated to determine whether a report is required.

The regulations state that in deciding whether to report, a firm should first consider whether the information available reasonably supports the conclusion that the product contains a defect. If it does, the firm must then consider whether that defect could create a substantial product hazard. (§ 1115.4). The regulations explain the factors that the Commission and staff consider in determining whether a risk of injury associated with a product is the type of risk that will render the product defective as well as the factors to be assessed in determining whether a substantial product hazard could exist. (§ 1115.4 and § 1115.12(f)).

The regulations state that a firm should not wait until it obtains a complete product evaluation or accurate risk estimate before reporting under section 15(b) of the CPSA. (§ 1115.14(c)). However, the regulations recognize that a reasonable time for investigation and

evaluation might be necessary to determine whether the Commission should be notified when the initial information is not clearly reportable on its face. (§ 1115.14(c)).

On April 6, 1984, the Commission published a Statement of Enforcement Policy on Substantial Product Hazard Reports (49 FR 13820). That statement supplemented, rather than replaced, the August 1978 interpretative rule. The 1984 statement was published because of the Commission's serious concern about the level of compliance with the reporting requirement of section 15(b) of the CPSA. The Commission provided an analysis of the frequency with which corrective actions were initiated as a result of section 15 reports as opposed to independent investigation by the Commission. Based on this analysis, the Commission concluded that there was a substantial amount of under-reporting the most serious hazards as well as undue delay in filing reports.

The policy statement was also designed to provide guidelines and clarification to help firms meet the section 15(b) reporting obligations. The following guidelines were offered: (1) Know the requirements set out at Section 15 of the CPSA, as interpreted by the Commission's regulations; (2) Seek informal guidance from the CPSC as to the need to report; (3) Report if at all in doubt; (4) The term "defect," as used in the reporting requirements, has a broad meaning and includes design defects, manufacturing and production errors, as well as defects in warnings or instructions; (5) The test for reporting is based on a reasonableness standard and does not require certainty that a defect or hazard exists; (6) Report immediately, not weeks or months later; (7) Report even if an insurance carrier is handling the matter; (8) Report any death or grievous injury that may have been caused by a product defect or non-compliance with a consumer product safety rule; (9) Don't wait for incidents, complaints, and lawsuits to accumulate before reporting; (10) Remember that Section 15 reporting is a high CPSC priority.

Six months after publication of the 1984 guidelines, four trade associations representing manufacturers of consumer products requested that the Commission solicit public comment on the 1984 Policy Statement. The Commission has not done so at the time of the original publication because, as an interpretative policy statement, public notice was not required by the Administrative Procedure Act, 5 U.S.C. 553. The requesting organizations, however, believed that public comment was

¹ Acting Chairman Anne Graham and Commissioners Sandra Brown Armstrong, and Carol Dawson voted to approve this Federal Register notice which deletes the examples. Commissioner Terrence M. Scanlon voted to issue this notice which deletes the examples, and would have adopted other changes that were not agreed to by the majority. Former Commissioner Stuart M. Stalter voted to issue a notice that included the examples. A separate statement of Commissioner Stalter is available from the Commission's Office of the Secretary.

appropriate, given the importance of the requirements of section 15(b). The organizations also asserted that public comment would alleviate some misunderstandings which the commenters thought the 1984 statement of policy may have generated. In response to the request, on December 28, 1984 the Commission published in the Federal Register a notice soliciting written comments on the April 6, 1984 statement of enforcement policy on substantial product hazard reports. Comments were received from ten manufacturers, eleven trade associations, one consumer organization and two individuals. The comments and the Commission's responses are as follows:

A. Purpose of the 1984 policy statement

Although the consumer organization and the two individuals who commented generally supported the 1984 policy statement, a majority of the commenters expressed general opposition to the 1984 policy statement. Most took the position that the provisions of that policy statement exceeded the statutory requirements of section 15(b) and thus were beyond the power of the Commission to enact. Others indicated that the policy statement appeared to conflict with the provisions of the Commission's 1978 interpretative rule. Many of these commenters also expressed specific reservations about the general impact of the 1984 policy statement. Some contended that, if followed to the letter, the 1984 guidelines would require manufacturers to report any safety related information, regardless of whether that information reasonably supported the conclusion that a product contained a defect which could create a substantial product hazard. These commenters pointed to the Commission's admonition to file a report if in doubt as an indication that the Commission encourages indiscriminate reporting. Others objected to the policy statement on the grounds that firms would have to report even if consumer misuse were the cause of an injury rather than a defect. Most of the commenters claimed that the specific examples set forth in the 1984 policy statement reinforced the impression that the Commission was attempting to encourage reports where the statutory criteria of section 15 are not met.

The guidelines for reporting pursuant to section 15(b) appear in the Commission's interpretative regulations, 16 CFR Part 1115. Those guidelines were published in 1978 and republished without change for the convenience of readers, in the Federal Register notice of

April 6, 1984. These guidelines set forth criteria for reporting which the Commission believes will aid a firm in satisfying its obligations under section 15(b) of the CPSA. The 1984 policy statement does not supersede the 1978 interpretative rule; rather, the policy statement apprises the public of the concerns of the agency about inadequate reporting, and gives additional guidance to industry concerning section 15(b) reporting.

The guidance in the 1984 policy statement was intended to prevent the recurrence of certain kinds of reporting problems which the Commission staff discovered through its investigations. Many of these investigations resulted in corrective actions and some in the payment of civil penalties for failure to report pursuant to section 15(b).

The policy statement was not an attempt to revise the Commission's 1978 rule governing substantial hazard reports. The 1978 interpretative rule remains in effect.

B. The Examples

The 1984 policy statement contained a section entitled *Guidance to Industry on Reporting Under Section 15 CPSA*. That section contained the Commission's views on when and what types of information should be reported. In order to help firms apply the guidance as to when to file a section 15(b) report, the Commission included, in the policy statement, examples of situations where there might be a question of the need to file a report. In the Commission's opinion, these examples illustrated the more difficult situations that can confront firms trying to meet the responsibilities of section 15(b).

A great number of commenters took issue with the Commission's conclusions about whether the facts set forth in these examples created an obligation to report. While the scope of the comments varied, the common thread was that the information contained in each example was not *per se* reportable under section 15(b). Rather the commenters contended that the information laid out in the examples would only be sufficient to trigger further investigation of the facts to determine whether a report was in fact required. Some commenters, therefore, advocated deleting the examples from the 1984 policy statement while others suggested that the Commission clarify the purpose for which they were placed in the statement. Some commenters suggested that the examples needed additional information to make the reporting obligation more easily understood, and several commenters suggested that the Commission include examples of

situations in which a report is not required.

Some of the examples in the policy statement were intended to alert firms to the existence of evidence of design defects. In the past, many firms have viewed injury reports within the narrow frame of reference of their product liability defenses. An injury or incident attributed to "misuse" or "abuse" of a product often receives little further scrutiny, even though it has been the Commission's experience that such incidents or injuries—particularly when they are cumulative—sometimes reflect a misjudgment by the original designer and may be indicative of a design defect. Firms should analyze such incidents with that perspective in mind and not merely ignore such incidents for section 15(b) purposes.

Other examples were designed to encourage firms to examine information relating to potential hazards expeditiously to determine whether a reportable defect existed. The Commission believes that it is important to re-emphasize a critical concern raised in the 1984 policy statement that, when in doubt, firms should report. The 1984 policy statement encourages firms to err on the side of surfacing rather than burying potential problems.

The Commission has determined that the examples themselves had become the focus of unnecessary debate and confusion. Since, as brief descriptions of situations, they were by necessity incomplete and imprecise, they were subject to a wide range of interpretation. Furthermore, the basic guidance provided in the examples as to when to report appears elsewhere in the policy statement and in the Commission's interpretative rules at 16 CFR Part 1115. For these reasons, the Commission has decided to withdraw the examples. At the conclusion of this document, the Commission republishes the Section of the 1984 Statement of Enforcement Policy entitled "Guidance to Industry on Reporting Under Section 15 CPSA" without the examples.

Withdrawal of the examples should not be viewed as a modification of the Commission's position on section 15(b) reporting. In fact, the Commission places an even stronger emphasis on compliance with the reporting requirement in section 15(b), and 16 CFR Part 1115. The Commission re-emphasizes that the 1978 interpretative rule remains in effect without change.

Firms subject to the section 15(b) requirements should pay careful attention to the 1978 interpretative rule, especially the sections concerning the reportability of a death or grievous

bodily injury, at § 1115.12(c) and the meaning of "defect," at § 1115.4. The Commission reaffirms the importance of section 15(b) reporting and urges firms to resolve close questions in favor of notifying the Commission of potential substantial product hazards.

The section 15(b) reporting requirements are critical to the Commission in administering its statutory responsibilities. Section 15 reports enable the Commission to obtain information at an early stage from knowledgeable sources and provide a key basis for evaluating a potential hazard and the need, if any, for corrective action. Where firms do not report, the Commission must rely on other sources of information as well as its own independent investigations to find out about potential problems. This in turn often is detrimental to the safety of the public because needed remedial measures can be significantly delayed during the course of the investigation.

Because of the importance of section 15(b) reporting, the Commission directs the staff to investigate aggressively and thoroughly product defects which may present substantial product hazards and to prepare routinely to consider the imposition of civil penalties when the staff learns that information which reasonably supports the conclusion that a product contains a defect which could create a substantial product hazard has not been reported. The Commission will make the resources available to accomplish this objective.

C. Time for Reporting

Many of the commenters expressed concern—particularly in response to the examples—over the timing of section 15(b) reports. The Commission's substantial product hazard rules at 18 CFR Part 1115 provide basic guidance. If a firm receives information indicating that a non-compliance with a consumer product safety rule, or a defect in its product has caused, may have caused, or could have caused or contributed to the causing of a death or grievous bodily injury, it should report immediately or conduct a reasonably expeditious investigation as provided for at 18 CFR 1115.12(c) and 1115.14. Other information which tends to indicate the existence of a non-compliance or a defect which could create a substantial product hazard should be reported or studied and evaluated pursuant to 18 CFR 1115.12(e) and 1115.14. The regulations advise that the time for investigating and evaluating the reportability of a death or grievous bodily injury or other information should not exceed ten days unless the firm can demonstrate that a longer

period is reasonable. If the firm determines after a reasonably expeditious investigation that a reportable noncompliance or defect exists, then it must report immediately (within 24 hours).

The Commission realizes that conducting such investigations is often difficult, and the firm initially may be able to obtain only sketchy information concerning the possible product defect. The Commission urges firms to inform the Commission of such information even if they are not entirely certain that a formal report is required. The Commission is willing to adapt to such circumstances and work with the company to develop the information needed to fully determine the level of the problem. The staff is also willing to establish with the firm a reasonable timetable for completing its investigation.

In addition to assuring compliance with the statutory intent that companies immediately report, prompt reporting within these guidelines provides firms with other benefits. A firm that unilaterally performs an investigation of a potential defect without reporting to the Commission and settles on a corrective action plan runs the real risk that the Commission staff may not concur with the firm's assessment of the problem and may disagree with the course of the corrective action selected by the manufacturer. As a result of such disagreement, the firm may need to reevaluate its approach to the problem, often creating further expense and delay in remedying the problem. This is not in the firm's or the Commission's, or the public's interest.

By reporting early, the firm is able to receive the benefit of the views and technical expertise of the Commission's staff in analyzing the potential problem. As a result, if a serious problem does exist, the firm and the Commission have already established a dialogue and can develop a corrective action plan in an orderly, cost-effective fashion. The firm does not run the risk of expending substantial amounts of time and money on corrective action which is subsequently not accepted by the staff or the Commission. If the firm initially presents information which demonstrates that a substantial product hazard is not present or if such information is developed in the subsequent investigation, the Commission staff will close its file.

D. Over-reporting

A number of commenters contented that if the guidance contained in the 1984 policy statement were followed literally, the Commission would be

inundated with thousands of unnecessary reports. This concern was often based on an extremely literal reading of the policy statement's examples. The commenters expressed concern about the burden that such reporting would place on industry and also pointed out that, given scarce resources, the Commission staff might be unable to handle the volume of reports. Accordingly, the commenters feared that adequate attention might not be given to serious hazards which deserve immediate corrective action.

The Commission believes that its response to the comments concerning the examples and its discussion of the relationship of the 1984 policy statement to the 1978 interpretative rule resolves the concerns expressed by the commenters. In addition, the Commission has conducted a review of reports received after the publication of the 1984 policy statement to determine whether there was an upsurge in unnecessary reporting. The Commission found that while the number of reports increased from 128 in FY1984 to 177 in FY1985, there was no indication that a significant number of reports of marginal information were received. Therefore there is no indication that publication of the policy statement led to over-reporting.

Section 15 is high priority of the Commission. The Commission wishes to encourage increased reporting by informing industry of the nature and scope of the reporting requirements. Should an upsurge in reports require the commitment of additional resources to that area, the agency is prepared to act accordingly.

E. Under-reporting

One of the prime reasons for issuing the 1984 policy statement was the Commission's concern that firms were not reporting potentially serious hazards as required by section 15(b). The policy statement pointed out that of the 25 most serious hazard files opened by the Commission staff in Fiscal Year 1983, only 5 resulted from section 15(b) reports by firms; the others arose from investigations conducted by the Commission's own headquarters and field staff. Based on this information, the Commission concluded that additional guidance was necessary to apprise firms of their obligations under section 15(b) and therefore issued the policy statement.

This trend in under-reporting of the more serious hazards has continued. In 1984, 14 of the 106 recall actions initiated by the Commission staff were classified as Class A or Class B+ (the

highest hazard priorities under the Commission's Classification System). Of these A and B+ cases, only 2 were voluntarily reported by firms and 12 resulted from Commission staff investigations. In 1985, 5 of the 100 Section 15 recall actions initiated by the staff were classified as A's or B+'s. All of these A or B+ cases resulted from staff investigations, although in one case, the firm reported shortly after the staff commenced its investigation.

Many commenters objected to the Commission's conclusion concerning under-reporting. Of major concern to these commenters was their belief that, in response to its perception of under-reporting, the Commission had initiated a policy of requiring firms to report marginal information which, under the 1978 interpretive rule, would not have been reportable. These commenters contended that, if there were a problem with under-reporting, the solution would be to seek civil penalties for failing to file timely reports.

The Commission disagrees with those commenters who challenge the Commission's belief that there is substantial underreporting. In the view of the Commission, the numbers speak for themselves.

Several comments expressed concern that the Commission was attempting in the 1984 policy statement to increase the reporting of less than substantial matters. The Commission intended to encourage prompt reporting of the same types of hazards or potential hazards as it did in its 1978 rules (16 CFR Part 1115). If a firm is unsure of the level of hazard and/or unable to conclude a reasonably expeditious investigation, then it should notify the Commission of the problem and work with the staff to resolve any questions.

The Commission agrees with those commenters who suggested that one way to stimulate reporting is to bring more enforcement actions when violations of the reporting requirements are discovered. Accordingly, the Commission will continue its investigatory efforts to identify products which may present unreported potential substantial product hazards and to seek the imposition of civil penalties against firms who have failed to report. However, the Commission also believes that the 1984 policy statement is itself a useful tool in heightening manufacturers' awareness of the requirements of section 15(b). As a result, the Commission will not revoke the policy statement but has clarified in this document issues that caused concern.

F. Section 23 CPSA

Several commenters referred to the potential impact of the 1984 policy statement on cases arising under section 23 of the Consumer Product Safety Act, 15 U.S.C. 2072. Section 23 provides for a private cause of action by any party injured by the knowing violation of any consumer product safety rule or other rule issued by the Commission. Those commenters pointed to a number of judicial decisions holding that the 1978 interpretative rule was a rule for the purposes of section 23. The commenters argued that, because the 1984 policy statement appeared to broaden the reporting obligations set forth in the 1978 interpretative rule, exposure to product liability suits under section 23 would also increase. In particular, these commenters contended that the examples contained in the 1984 policy statement would become a benchmark by which compliance with the reporting requirements of the interpretative rule would be measured. This result would subject firms to liability for the failure to report information which the commenters contended need not be reported under the statute.

The Commission agrees with the commenter who pointed out that the Commission's primary concern in publishing the 1984 policy statement should be the basis for reporting rather than any collateral hypothetical effect that issuance of the 1984 policy statement might have on section 23 causes of action. Nevertheless, the Commission's clarification of the purpose of the examples and their deletion should alleviate most of these liability concerns.

G. Miscellaneous

1. Generic use of section 15

Two commenters contested what they characterized as the attempt of the Commission to use section 15(b) against generic product classes rather than proceeding to remedy the hazards through rulemaking. This comment goes beyond the scope of the 1984 policy statement and, therefore, is irrelevant to the issues discussed in that statement.

2. Disclaiming reports

Two comments concern reports submitted to the Commission by manufacturers which contain disclaimers stating that the reports are not submitted pursuant to section 15(b) because the manufacturer does not believe that the product in issue is defective. The commenters noted that the Commission staff routinely designates such product safety information as a section 15(b) report,

disregarding the disclaimer. The commenters suggested that the Commission staff treat such a submission as a preliminary notification of a potential safety problem to distinguish it from reports submitted in compliance with the statutory requirements of section 15(b).

The Commission staff has already implemented a policy of not automatically referring to all industry submissions on safety problems with specific products as "Section 15(b) reports". If a company elects to characterize information which it has submitted as something other than a section 15(b) report, the staff will not refer to this submission as a "Section 15(b) report" in written communications. Thus, the staff will conduct any necessary investigation and request any needed information from firms in order to determine if a potential substantial product hazard exists which could warrant corrective action to protect the public. In the process of doing this, the staff may request that the firm file a "full report" under 16 CFR 1115.13(d).

3. Use of actual case histories

Two commenters suggested the Commission should conduct a comprehensive review of its administration of section 15 since 1973. The commenters request that the Commission publish a series of actual case histories summarizing relevant facts in order to provide specific guidance on the criteria for the reasonableness of reporting.

As noted earlier, the examples contained in the 1984 policy statement were based in part on actual case histories. One primary criticism of those examples is that they did not contain enough specific facts to give guidance to manufacturers about the applicability of the reporting requirements to analogous situations. The Commission believes that any attempt to publish a compendium of case histories would suffer similar criticism.

Additionally, section 6 of the Consumer Product Safety Act, especially section 6(b), severely restricts the Commission's ability to disclose to the public information concerning specific products or information which has been reported pursuant to section 15(b).

Further, to date, virtually every case involving an issue of timely reporting has been settled without litigation and without admission of a violation by the defendant. Given the disputes concerning the reportability of information which preceded the great majority of the settlements, it is likely that any attempt by the Commission to

prepare a series of case histories would encounter at least as much controversy as the examples in the 1984 policy statement. The Commission declines to adopt the commenters' suggestion at this time.

Guidance to industry on reporting under section 15 CPSA:

1. *Know the Legal Requirements*—The reporting requirements are set out at section 15 of the CPSA (15 U.S.C. 2064), as interpreted by 16 CFR Part 1115. Substantial penalties exist for non-compliance with these requirements.

2. *Seek Informal Guidance*—Firms can seek informal guidance from the Compliance staff as to the need to report.

3. *Report if in Doubt—When in Doubt, Firms Should Report.* Firms should clearly err on the side of reporting, rather than failing or waiting to report. The obligation to report is created when the firm *first* receives information reasonably supporting the conclusion that the product is non-complying or contains a defect that could create a substantial product hazard. Firms should not wait to determine to a certainty whether these conditions exist. Instead, when a firm first receives information reasonably supporting these conclusions, the firm should report. The firm and the Commission will then be in a position to evaluate this information, even if it is of a preliminary or tentative nature, as well as any additional relevant information that is discovered later. With the Commission staff's expertise in these matters, the firm will be helped in reaching a more expeditious assessment of the nature and severity of the matter and the need, if any, for corrective action. The regulations provide that firms can report without admitting, and can specifically deny, that the information indicates a substantial product hazard (Section 1115.12(a)).

4. *Broad Meaning of "Defect"*—The term "defect" includes design problems, labeling, instruction, and warning problems; as well as unintended faults, flaws, irregularities, and manufacturing and production problems (Section 1115.4).

5. *Reasonableness is the Test—Not Certainty*—The test for reporting is based on a reasonableness standard and does not require certainty that a defect or hazard exists. Instead, a firm must report if available information *reasonably* supports the conclusion that the product either contains a defect which could create a substantial product hazard, or fails to comply with an applicable consumer product safety rule (Section 15(a)(2) of the CPSA; § 1115.12).

6. *Need to Report Immediately*—Time is of the essence in filing reports under Section 15. The statute specifies that firms must "immediately" inform the Commission (Section 15(b)). The regulations provide that the report must be filed within 24 hours after the firm obtains reportable information. While a firm can elect to conduct an expeditious investigation to determine reportability, the regulations provide that this investigation and evaluation should not ordinarily exceed 10 days. If at the end of 10 days, a firm is unable to determine that the matter is not reportable, the Commission expects the firm to immediately file a report (Section 1115.14). Firms that have delayed reporting and have reportable information should not withhold it, even if they realize that the Commission is likely to consider the report to be late. The Commission will seek to invoke the most significant penalties where it discovers a firm that does not file a report. Firms that file a late report can generally anticipate a less serious penalty than those firms that do not report.

7. *Must Report Even if Insurance Carrier is Handling*—Given the requirement to immediately inform the Commission, a firm can not avoid or delay the reporting requirement by turning claims and complaints over to its insurance carrier for follow-up investigation and handling (Section 1115.14).

8. *Must Report Death or Grievous Injury*—A death or grievous bodily injury that may have been caused by a product defect or non-compliance must be reported unless the firm has investigated and is certain that it is not reportable (Section 1115.12(c)).

9. *Don't Wait for Complaints and Lawsuits to Accumulate*—Firms should not wait for consumer complaints, claims and product liability lawsuits to accumulate before deciding whether to report. Firms should develop and implement internal controls to ensure that the information is expeditiously routed to a responsible persons and dealt with promptly. If information reasonably support the conclusion that a defect, or non-compliance is present, firms should immediately report (Section 1115.12).

10. *Remember That Section 15 Reporting is a High CPSC Priority*—Section 15 reporting is among the highest priority matters for CPSC enforcement. Section 15 reports are critical to the rapid, resource efficient evaluation, by the firm involved and the Commission staff, of the potential hazard and the need to take corrective action for a particular product. The

failure of a firm to report, or undue delay in reporting, seriously hinders the Commission's efforts to protect and inform the public with respect to substantial product hazards in a timely and efficient manner. The Commission intends to vigorously pursue civil penalties against firms that violate the reporting requirements of section 15.

Dated: June 24, 1986.

Sadye E. Dunn,

Secretary, U.S. Consumer Product Safety Commission.

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