Banning Of Two Toys And Certain Aerosol Spray Adhesives

Consumer Product Safety Commission

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

MWD-75-65

APRIL 7,1975

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-139310

The Honorable John Tower
United States Senate

Dear Senator Tower:

In response to your April 29, 1974, request, this is our report on the Consumer Product Safety Commission's actions in the banning of two toys and certain aerosol spray adhesives.

Although given an opportunity to provide written comments on the contents of this report, the Commission did not do so. In interpreting its Freedom of Information Act policy, the Commission said it could not accept GAO draft reports for review and comment when we require that the drafts be safeguarded from premature public disclosure. After discussing the policy with the Commission Chairman, I informed him that we would issue the report without the Commission's written comments. However, we did discuss the matters presented in this report with Commission representatives, and their views have been incorporated where appropriate.

As discussed with your office, the Department of Justice requested that the report not be released because of an unsettled claim the manufacturer of the two toys filed against the Commission in the U.S. Court of Claims. We suggested that the Department of Justice contact your office concerning its request.

Sincerely yours,

Comptroller General
of the United States

Contents

ABBREVIATIONS

BBS	Bureau of Biomedical Science
CPS Act	Consumer Product Safety Act
FDA	Food and Drug Administration
FHS Act	Federal Hazardous Substances Act
GAO	General Accounting Office
NIH	National Institutes of Health
OMD	Office of the Medical Director
3M	Minnesota Mining and Manufacturing Company

GLOSSARY 1/

Chromosome	A pair of rod-shaped bodies in the cell nucleus bearing genes that carry hereditary characteristics.
Chromosome break	A chromosome deletion, displacement, separation, or other disturbance to the alignment of a rod-shaped body which is as wide as or wider than the rod-shaped body.
Chromosome damage	A term that refers to chromosome abnormalities but has no generally accepted specific meaning. Recognizing that there are other types of chromosome damage, we use the term to refer to chromosomes with a disfigured structure expressed as chromosome breaks and gaps.
Chromosome gap	A chromosome separation or other disturbance to the alignment of a rod-shaped body which is less than the width of the rod-shaped body.
Genetics	The study of heredity--the branch of science that deals with natural development.
Mutagenic	Having the power to cause changes or alterations in the character of a gene.

1/ These definitions were established by GAO on the basis of information from Consumer Product Safety Commission representatives and should be used only in connection with this report.

COMPTROLLER GENERAL'S REPORT
TO THE HONORABLE JOHN TOWER
UNITED STATES SENATE

BANNING OF TWO TOYS AND CERTAIN AEROSOL SPRAY ADHESIVES
Consumer Product Safety Commission

D I G E S T

WHY THE REVIEW WAS MADE

GAO was asked to review the Consumer Product Safety Commission's actions in the banning of (1) two plastic toy balls, which were erroneously described in a Commission publication, and (2) certain aerosol spray adhesives, for which the ban was later withdrawn.

As requested, GAO reviewed

--specific actions taken to protect consumers from these products,

--the legal basis for the actions,

--whether "due process" requirements were met before such actions were taken, and

--whether the retraction of the error and the withdrawal of the ban were timely and fair.

FINDINGS AND CONCLUSIONS

The two plastic toy balls were banned as hazardous substances under the Federal Hazardous Substances Act because they posed a danger of children inhaling, swallowing, or choking on plastic pellets.

Banning the plastic balls was appropriate in view of pertinent legal requirements, and adequate due process was afforded the affected manufacturer. However, the Commission inaccurately described the two balls in publishing a list of banned products. The Commission's retraction of the erroneous listing was not timely. (See p. 11.)

The aerosol spray adhesives were banned as an imminent hazard under the Federal Hazardous Substances Act because research results suggested that inhaling the spray mist could cause chromosome damage which could in turn lead to birth defects. The law provides for such a ban to protect consumers from products believed to be imminently hazardous. Such action can be taken immediately.

Although the ban on the adhesives was based on limited data and was lifted after additional data was obtained, GAO does not question either the Commission's decision to ban the products or the time taken to withdraw the ban, in view of the seriousness of the potential hazard.

GAO does question, however, (1) the methods employed by the Commission in reaching the decision to ban the sprays and (2) the contents of its public announcement of the ban

in view of the limited supporting evidence. (See pp. 29 and 30.)

Background

The Commission was established by the Consumer Product Safety Act and began operating in May 1973. This act provides for the Commission to protect the public from unreasonable risks associated with consumer products by establishing safety standards, coordinating safety investigations, and evaluating consumer product safety.

The Commission had transferred to it certain functional responsibilities contained in existing laws, including the Federal Hazardous Substances Act, previously administered by the Food and Drug Administration.

The Federal Hazardous Substances Act authorizes the Commission to ban hazardous toys and other household articles from interstate commerce. If a hazardous product is not already covered by a regulation established through formal rulemaking proceedings, banning must include advance notice and an opportunity for hearings.

There is one exception: if the Commission believes the product poses an imminent hazard, it can immediately ban the product pending completion of formal rulemaking proceedings. (See p. 3.)

Marlin toy case

In November and December 1972, the Food and Drug Administration banned two plastic balls manufactured by Marlin Toy Products, Inc. The Food and Drug Administration's tests showed that the balls violated its regulations because they could be easily broken, creating the danger of children inhaling, swallowing, or choking on the plastic pellets the balls contained. The Food and Drug Administration included the balls on its published lists of banned products. (See p. 6.)

Marlin agreed to recall defective balls that had been distributed and to use stronger plastic and exclude the pellets in future production. The Food and Drug Administration and Marlin agreed, therefore, that future published lists of banned products would identify the two balls as those with plastic pellets. The Food and Drug Administration put a note to this effect on its next published list. (See p. 6.)

On October 1, 1973, the Commission published a list of products banned since December 1970. It erroneously listed one Marlin ball with the notation "without plastic pellets" and the other with no reference to plastic pellets.

In response to a telephone

call from Marlin in mid-October, the Commission acknowledged the error and said a correction would appear in the next banned products list.

The Commission, however, did not issue the next list until June 1, 1974, 8 months after the error. The Commission could not economically justify issuing a separate retraction. (See p. 8.)

Marlin complained that the Commission's actions were inadequate and too late. It claimed to have suffered financial loss and to have been forced out of the toy business because of the Commission's actions. (See pp. 8 and 9.)

Although only the Consumer Product Safety Act explicitly requires that inaccurate or misleading information publicly disclosed by the Commission be retracted in a manner similar to that in which such disclosure was made, GAO believes that, in fairness and in keeping with the spirit of the congressional intent of section 6(b) of the act, the Commission should promptly retract any inaccurate or misleading statements that could cause undue financial hardship on affected parties. (See p. 10.)

Although the Commission has established procedures to improve the accuracy of future banned products lists, it has not established a policy, regulations, or procedures to insure that retractions are made promptly. (See p. 9.)

On October 11, 1974, Marlin filed a petition for a claim in the U.S. Court of Claims after a congressional resolution referred the matter to that court. When GAO completed its review in February 1975, that claim was pending. The Commission, although not admitting liability, believed Marlin should be given the opportunity to prove its claimed losses in that forum. (See pp. 10 and 11.)

Aerosol spray adhesive case

The Commission banned certain aerosol spray adhesives as an imminent hazard in August 1973. The spray adhesives were believed to cause chromosome damage in people, and research suggested a relationship with birth defects.

Preliminary findings of a study by a University of Oklahoma Medical Center researcher suggesting this link were the basis for the Commission's ban. (See p. 13.)

After issuing the ban, the Commission coordinated several research studies that did not substantiate the researcher's conclusion. (See p. 26.)

The Commission also requested several medical specialists to review and comment on both the researcher's and the other

study results. These specialists did not believe the studies adequately demonstrated that aerosol spray adhesives caused chromosome damage or suggested that they were responsible for birth defects. They recommended withdrawing the ban. (See pp. 27 and 28.)

On January 18, 1974, the Commission voted to announce its intent to withdraw the ban on March 1, 1974. On January 25, 1974, the proposed withdrawal was discussed in a press conference and announced in a press release. The necessary Federal Register notice was published on January 28, 1974, giving interested parties the opportunity to submit any evidence regarding the banned products. No new information was submitted, and the ban was withdrawn as proposed. (See pp. 28 and 29.)

The Federal Hazardous Substances Act allows the banning of products as an imminent hazard until the Commission can evaluate the extent of the possible hazard (see p. 3) but does not establish the criteria for such evaluations. GAO does not question the Commission's decision, even though it was based on the preliminary findings and conclusions of one researcher's study. (See p. 29.)

Commission press announcements created considerable controversy with the medical community and the public because of their straightforward references to potential birth defects in children born to parents that had used aerosol spray adhesives. The basis for the decision could have been strengthened and the controversy surrounding the public announcements minimized if the Commission had

--coordinated its evaluation of the preliminary research with its Medical Director and other medical specialists before imposing the ban and

--relied less on undocumented verbal evidence and more on documented evaluations of the preliminary findings and conclusions.

If the Commission had procedures to evaluate potential imminent hazards, it could have released information to the public in a manner that would have indicated the limited evidence available and placed the decision in proper perspective. (See p. 30.)

The Commission has no policy, regulations, or procedures for reviewing potential imminently hazardous products and documenting the basis for its decisions. In view of the scope of the Commission's authority, such policy, regulations, and procedures should be established. (See p. 30.)

RECOMMENDATIONS

GAO recommends that the Commission develop a formal policy,

regulations, and procedures for retracting inaccurate or misleading information that may be publicly disclosed under any of the acts it administers. Such policy, regulations, and procedures should be designed to insure appropriate and timely retractions. (See p. 12.)

GAO also recommends that the Commission establish a policy, regulations, and procedures to evaluate potential imminent hazards and document the basis for its decisions on the results of such evaluations. Such policy, regulations, and procedures should require that hazard evaluations be coordinated with appropriate specialists and interested parties. (See p. 30.)

AGENCY ACTIONS AND UNRESOLVED ISSUES

GAO did not obtain the Commission's written comments on the contents of this report because the Commission's interpretation of its Freedom of Information Act policy prevents it from accepting GAO draft reports for review when the draft must be safeguarded from premature public disclosure.

After discussing this policy with the Commission Chairman, GAO informed him it would issue the report without Commission written comments. GAO did, however, discuss the matters in this report with Commission representatives and considered their views in preparing it.

CHAPTER 1

INTRODUCTION

On April 29, 1974, Senator John Tower requested that we review the Consumer Product Safety Commission's actions in the banning of (1) two toys made by Marlin Toy Products, Inc., Horicon, Wisconsin, and (2) certain aerosol spray adhesives as hazardous substances. We were to determine:

> "* * * (1) the specific actions taken by the Commission in the interest of protecting consumers from the products, (2) the basis for such actions in view of pertinent legal requirements, (3) whether the Commission, prior to taking such actions, properly applied the legal provisions and requirements relating to due process, and (4) whether the Commission's subsequent actions, once it determined the dangers originally attributed to the products were not present, were timely and fair under the circumstances."

LEGISLATIVE BACKGROUND

The Commission was established by the Consumer Product Safety Act (CPS Act) (15 U.S.C. 2051) and became operational on May 14, 1973. The Commission consists of five Commissioners appointed by the President with the advice and consent of the Senate. The President designates one of the Commissioners as Chairman.

The Commission, headquartered in Washington, D.C., conducts most of its day-to-day activities through its Product Safety Operations Center in Bethesda, Maryland, and field offices in 14 cities. Its fiscal year 1974 appropriations were $34.8 million.

The purposes of the CPS Act are to

--protect the public from unreasonable risks of injury associated with consumer products;

--assist consumers in evaluating the comparative safety of consumer products;

--develop uniform safety standards for consumer products;

--minimize conflicting State and local government regulations; and

--promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

The CPS Act transferred to the Commission certain responsibilities under existing laws previously administered by other agencies, including the Federal Hazardous Substances Act, as amended (FHS Act) (15 U.S.C. 1261), which the Food and Drug Administration (FDA) had administered. 1/ The Commission assumed responsibility for specific cases involving FDA under the FHS Act. FDA banned the two Marlin toys under the FHS Act before enactment of the CPS Act. The Commission banned the aerosol spray adhesives under the FHS Act.

FHS ACT PROVISIONS FOR BANNING PRODUCTS

Under section 2 of the FHS Act, the Commission may determine that a toy or other article is a "hazardous substance," "banned hazardous substance," or "imminent hazard," depending on the nature of the potential hazard.

Hazardous substance

The definition of a "hazardous substance" includes:

--Any substance or mixture of substances which is toxic, corrosive, an irritant, a strong sensitizer, flammable, or combustible or which generates pressure through decomposition, heat, or other means, if it may cause substantial personal injury or illness during or as a proximate result of any customary or reasonably foreseeable use, including reasonably foreseeable ingestion by children.

--Any toy or other article intended for use by children, which by regulation is determined to present an electrical, mechanical, or thermal hazard.

Banned hazardous substance

A "banned hazardous substance" is:

1/ The other laws the Commission administers are the Flammable Fabrics Act, as amended (15 U.S.C. 1191); the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471); and the act of August 2, 1956 (Refrigerator Safety Act) (15 U.S.C. 1211).

--Any toy or other article intended for use by children which is or contains a hazardous substance.

--Any hazardous substance which is intended or packaged in a form suitable for use in the household and which, by regulation, cannot be made safe with precautionary labeling.

Banned hazardous substances are not to be introduced or delivered into interstate commerce and may be seized if offered for sale. The act also provides for the manufacturer to repurchase banned substances already sold. The rules and regulations under section 2(q) of the FHS Act are established in accordance with general due process provisions--including public hearings and public notice before actions take effect.

Imminent hazard

Section 2(q) contains a provision for the interim banning of potential hazardous substances if they are found to pose an imminent hazard to the public's health. The Commission may ban such a substance immediately and then complete the formal proceedings to prove or disprove the hazard. After the formal proceedings the product can be permanently banned or the ban can be withdrawn.

SCOPE OF REVIEW

We made our review at Commission headquarters in Washington, D.C., and at its Product Safety Operations Center in Bethesda. We reviewed applicable legislation, regulations, procedures, and practices; interviewed Commission representatives; and examined pertinent records. We also interviewed several medical researchers as well as representatives from Marlin and one of the companies that manufactured the aerosol spray adhesives.

CHAPTER 2

MARLIN TOY CASE

In 1972 FDA banned two Marlin toys as hazardous substances and included them in published banned products lists. After taking over administration of the FHS Act, the Commission continued FDA's practice of periodically publishing such lists. In a list published on October 1, 1973, the Commission inaccurately listed the toys. Marlin claimed to have lost many thousands of dollars in sales because of the Commission's actions. The Commission acknowledged its mistake to Marlin in October 1973 and stated it would include a retraction on its next published list. But it did not publish another banned products list--which contained a retraction--until June 1, 1974, 8 months after the error.

BANNING OF MARLIN TOYS

As part of an October 1972 toy safety survey, FDA representatives in St. Louis identified Marlin's "flutter ball" toy as a possible mechanical hazard under the FHS Act and acquired a sample for testing. Flutter ball was a transparent plastic ball with toy butterflies mounted on a rod and small plastic pellets; both the rod and the pellets moved freely inside the ball.

FDA's Bureau of Product Safety tested the flutter ball on October 30, 1972, and found that the toy presented an unreasonable risk of injury or illness to children because it could be easily broken or shattered, creating the danger of children inhaling, swallowing, or choking on the pellets. On November 1, 1972, FDA banned the toy as a mechanical hazardous substance.

The FHS Act states that an article may be determined to present a mechanical hazard

> "* * * if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness (1) from fracture, fragmentation, or disassembly of the article, (2) from propulsion of the article (or any part or accessory thereof), (3) from points or other protrusions, surfaces, edges, openings, or closures, * * * (7) because the article (or any part or accessory thereof) may be aspirated or ingested, (8) because of instability, or (9) because of any other aspect of the article's design or manufacture."

The FHS Act prohibits banned hazardous substances from being delivered in interstate commerce and authorizes several methods, including seizure, fines, and imprisonment, for removing them from the marketplace. Through formal rule-making procedures (including such due process provisions as public hearings and public notice), FDA issued regulations for manufacturers, distributors, and retailers to follow in complying with the act (21 C.F.R. 191). Because such regulations had been issued, the toys were banned immediately after FDA determined that they did not conform to those regulations. 1/ Such immediate actions are authorized under the act.

On November 1, 1972, FDA notified Marlin that its flutter ball and any similar toys with like hazards were banned from interstate commerce and that any banned toys remaining in the market were subject to regulatory action--including seizure. In a subsequent meeting at Marlin's plant, FDA representatives learned that a similar Marlin toy--"birdie ball"--could also be hazardous. Birdie ball was basically the same as flutter ball, except it contained plastic birds instead of butterflies.

Late in November 1972, FDA obtained three samples of each ball to test before possibly seizing the balls as banned toys. Both types failed FDA's tests. On December 5, 1972, FDA notified Marlin (1) that birdie ball had failed the test and (2) that both balls were banned under the FHS Act.

After expressing displeasure and resistance to FDA's decision, Marlin agreed to modify the balls in stock and production, but hesitated to recall those already distributed. Marlin stated it would be an extreme financial hardship to recall those balls already distributed because it reportedly manufactured an estimated 5 million flutter and birdie balls during the previous 12 years. After Marlin's continued resistance to recalling the toys, FDA initiated seizure action and seized 88 balls from the marketplace.

Early in January 1973--shortly after the seizure--Marlin informed FDA that the two toys had failed the FDA

1/ FDA did not have formal regulations for testing toys for compliance with its regulations. In January 1975 the Commission issued regulations for specific testing methods to be followed in identifying toys posing potential hazards (16 C.F.R. 1500).

tests because a supplier substituted an inferior grade of transparent plastic that Marlin had used to make the balls. Marlin subsequently informed FDA that it was recalling defective balls it had distributed and excluding plastic pellets from future balls produced. Marlin said that flutter and birdie balls made with the higher grade transparent plastic and without plastic pellets would pass FDA tests.

Since Marlin planned to continue marketing balls similar to but not the same as the ones banned, Marlin and FDA agreed that the banned toys would be listed as those with plastic pellets to distinguish them from those that were not banned (those without plastic pellets). The record did not show whether FDA tested the balls with the higher grade transparent plastic. A Commission official told us he was uncertain whether the modified balls had been tested.

INACCURATE LISTING OF MARLIN TOYS

To inform manufacturers, distributors, retailers, and consumers of banned products, FDA periodically published lists of products banned under the FHS Act. These lists include the products' names, the manufacturers' names and addresses, the reasons for banning, and the dates banned. FDA intended to publish monthly lists of all products banned the previous month and semiannual lists of all products banned during the preceeding 6 months. Although this plan was not followed precisely, FDA published six banned products lists before the transfer of FHS Act functions to the Commission in May 1973.

The Marlin balls appeared on FDA monthly lists issued in November 1972 (flutter ball) and January 1973 (birdie ball)--those issued after the banning of each ball. These lists properly labeled the toys as flutter ball and birdie ball, without any reference to plastic pellets. Both lists were issued before Marlin and FDA agreed that future lists would specify that the ban pertained only to those balls with plastic pellets.

FDA added a note to the February 1, 1973, banned products list stating that the only versions of flutter and birdie balls classified as banned hazardous substances were "those containing pellets." Future lists including flutter and birdie ball entries were to list the two banned balls as those with plastic pellets.

On October 1, 1973, the Commission published a cumulative list of products banned since FDA began its

toy safety program under the FHS Act in December 1970, including Marlin's flutter and birdie balls. Both balls were inaccurately described. Flutter ball was listed without any notation concerning plastic pellets, and birdie ball was listed as "'Birdie Ball' (without plastic pellets)," the opposite of what was intended.

On October 17, 1973, Marlin representatives informed the Commission of the errors in the October 1 list. It was Marlin's understanding that after 6 months a banned toy would no longer appear on the list. Further, Marlin claimed to have lost many thousands of dollars in business because of the Commission's actions and believed it was entitled to some form of compensation.

The Commission acknowledged its inaccurate listing of birdie ball, agreeing that the toy should have been described as those with plastic pellets. It did not specifically acknowledge the inaccurate listing of flutter ball until the retraction was published. The Commission said it would include a retraction in the next list; however, it did not have an anticipated publication date. The next list, published on June 1, 1974, included a retraction stating that the only versions of birdie and flutter balls which had been banned were those with plastic pellets.

The Commission informed Marlin that the inaccurate listing was "an editorial error." Commission representatives told us the inaccurate listing resulted from the following factors.

--The manually prepared note in FDA's February 1, 1973, banned products list was not picked up in the Commission's computer-prepared October 1, 1973, list.

--There was a major change in personnel responsible for preparing the list.

--Commission representatives did not discover the error when proofreading the October list before printing.

The Commission told Marlin that the October 1, 1973, cumulative banned products list was issued because some previously banned toys were still on the market. The Commission pointed out that (1) although banned products are removed from production, they might still be in retail stores, (2) the originally designed version of a banned product is banned permanently, and (3) a redesigned product would not be banned unless found to be hazardous through further testing.

The Commission informed Marlin that confusion might have arisen about a product appearing on the list for only 6 months. To help clarify the matter, the Commission told Marlin that FDA had planned to publish banned products lists each month and a cumulative list semiannually. Thereafter, items would remain banned but would not appear on new published lists. Marlin representatives may have interpreted this as meaning that the banned products would be listed for only 6 months.

The Commission gave Marlin no explanation for its delay in publishing a banned products list containing a retraction or for not publishing a separate retraction. Commission representatives told us that the major reason for the delay was that, knowing of other errors, the Commission wanted to scrutinize and purify the list to improve its accuracy and usefulness. Banned products were to be more clearly identified, and reasons for their banning more fully explained.

The Commission wrote Marlin two letters--one in November 1973 and another in March 1974--acknowledging its error and explaining its intention to publish a retraction in the next banned products list. A Commission representative told us that publishing a separate retraction was not considered economical because of the wide distribution of the October 1, 1973, banned product list--about 240,000 copies--and the Commission's belief that a retraction in the next issue would be sufficient. Commission representatives also told us Marlin could have used the Commission's letters to Marlin to inform its customers of the Commission's error and intention to publish a retraction. Although it did not tell Marlin, the Commission believed that Marlin was responsible for informing its customers of the error and the planned retraction.

Although it did not know the extent of any financial loss Marlin may have incurred because of the inaccurate listing of the two balls, the Commission rejected Marlin's request for reimbursement. The Commission told us that it did not have the authority to compensate Marlin and that Marlin's recourse was to file a claim in the U.S. Court of Claims.

In a letter to the Commission dated May 6, 1974, Marlin said it was forced out of the toy business because the two balls were inaccurately listed. According to Marlin, 40 percent of its business was from flutter and birdie ball sales and the Commission's November 1973 letter acknowledging the error and planning a retraction was "too little and too late." Marlin requested that the Commission permit it to

sue and let the courts determine whether and to what extent the Commission was liable.

LACK OF POLICY, REGULATIONS, AND PROCEDURES FOR RETRACTING INACCURATE INFORMATION

The Commission's Bureau of Compliance has installed procedures to upgrade the banned products list through controls and other verification practices. Commission officials believe these prepublication controls should eliminate inaccurate lists. The Commission, however, has not established any policy, regulations, or procedures for insuring prompt retractions.

Recognizing that the Commission may err in attempting to promptly advise the public of its activities to protect consumers from hazardous products, section 6(b) of the CPS Act requires it to retract erroneously published data. Section 6(b) states:

> "If the Commission finds that, in the administration of this Act, it has made public disclosure of inaccurate or misleading information which reflects adversely upon the safety of any consumer product, or the practices of any manufacturer, private labeler, distributor, or retailer of consumer products, it shall, in a manner similar to that in which such disclosure was made, publish a retraction of such inaccurate or misleading information."

The FHS Act does not contain a similar provision.

Commission officials said that, although the June 1, 1974, banned products list included a retraction, the Commission was not legally bound to issue retractions of information published under the FHS Act. According to the Commission's General Counsel, because the two balls were banned under the FHS Act, the Commission was not legally bound by section 6(b) of the CPS Act in that case. However, he said the Commission planned to follow the "spirit and intent" of section 6(b) in retracting any inaccurate or misleading information published under any of the acts it administers.

We reviewed the provisions of the CPS Act, its legislative history, and the Commission's implementation of FHS Act responsibilities transferred to it to determine

the appropriateness of the Commission's interpretation of section 6(b) of the CPS Act. We believe that, in fairness and in keeping with the spirit of the congressional intent of section 6(b), the Commission should retract inaccurate or misleading statements it may make, and such retractions should be made within a reasonable time from the date the Commission learns that it has made an error.

Commission officials said (1) publishing separate retractions in most cases would not be economically justified, (2) publishing a retraction in the next issue of the list would be sufficient, and (3) unsatisfied manufacturers could go to the courts for relief.

A Commission official stated also that the Commission would be willing to send any manufacturer or other concerned party a retraction letter explaining an inaccurate listing and expressing the Commission's intent to publish a retraction in the next list. The manufacturer could use such a letter to inform its customers of the error and planned retraction. Commission representatives believed it would be the manufacturer's, and not the Commission's, responsibility to disseminate the letter to the customers.

Although a letter written to a manufacturer might be beneficial, this retraction method is not consistent with section 6(b) of the CPS Act. Such a retraction would not be issued in "the same manner" as the original inaccurate statement.

PENDING LITIGATION

In June 1974 two bills (S. 3666 and H.R. 15403) were introduced in the 93d Congress which would provide for the payment of an unstated amount to Marlin in settlement of its claim for the erroneous description of its toys in the banned products list. Senate and House resolutions (S. Res. 344 and H. Res. 1181) referred the two bills to the Chief Commissioner of the U.S. Court of Claims to determine the facts in this matter. Marlin filed a petition for its claim in the Court of Claims on October 11, 1974.

The Commission was given an opportunity to comment on the bills and resolutions and, in July 19, 1974, letters to the House and Senate Committees on the Judiciary, said the two balls were inaccurately listed in the October 1, 1973, list. The Commission believed that Marlin should be given an opportunity to prove its reported financial losses in the Court of Claims. The Commission's recommendation, however, included a three-part qualification.

1. The Commission's general support of the bills was not to be interpreted to mean that it generally favored relief for any company claiming to have been damaged by a Commission action.

2. By supporting the bills, the Commission did not admit its liability but felt that Marlin should have the opportunity to prove such liability in the Court of Claims because of the particular circumstances of this case.

3. The Commission suggested that the wording of the bills be revised to more correctly explain the nature of Marlin's claim--that the two balls were inaccurately described, not that they were erroneously included, on the list.

When our review was completed in February 1975, Marlin's claim was pending in the Court of Claims.

CONCLUSIONS

The FHS Act was appropriately applied in banning Marlin's flutter and birdie balls as hazardous substances because (1) FDA's interpretation of its test results showed that the two Marlin balls should be banned and (2) due process was served with the publication and application of formal regulations before the banning.

The Commission's description of the two balls in the October 1, 1973, list was an error that took 8 months to retract. The Commission acknowledged to Marlin its mistake and expressed its intentions to publish a retraction in the next list; however, it did not publish a retraction until June 1, 1974. Alternative retraction methods were discounted as being uneconomical even though Marlin informed the Commission that the inaccurate listing resulted in substantial financial loss.

The Commission's actions to strengthen its controls over the publication of banned products lists should better insure the accuracy of future lists and thus reduce the potential for inflicting undue financial hardship on manufacturers.

The Commission, in administering the CPS Act and the transferred acts, should retract within a reasonable time all inaccurate or misleading statements it may make.

However, the Commission had not established a policy, regulations, or procedures to guide it in making timely and appropriate retractions of inaccurate or misleading information. Such procedures could reduce the hardships on manufacturers, the Government's possible financial liability, and court actions that might arise from publicly disclosing erroneous or misleading information.

RECOMMENDATION

We recommend that the Commission establish a formal policy, regulations, and procedures for retracting inaccurate or misleading information that may be publicly disclosed under any of the acts it administers. Such policy, regulations, and procedures should be designed to insure appropriate and timely retractions.

CHAPTER 3

AEROSOL SPRAY ADHESIVE CASE

On August 20, 1973, the Commission banned certain brands of aerosol spray adhesives as an imminent hazard. The Commission's decision was based primarily on its review and evaluation of the preliminary findings and conclusions of Dr. J. Rodman Seely's chromosome research study. Dr. Seely identified possible links between the use of certain brands of aerosol spray adhesives and chromosome damage and between chromosome damage and birth defects. After more extensive research and review and a medical panel's evaluation of this research, the Commission determined that the ban should not continue and withdrew it on March 1, 1974.

STUDY BACKGROUND

Dr. Seely is a clinical researcher, genetic counselor, and associate professor of pediatrics, biochemistry and molecular biology, and cytotechnology at the University of Oklahoma Medical Center. He began his research in March 1973 after being asked to examine a child with multiple birth defects consisting of uncommon or nontypical abnormality patterns. After preliminary examination, Dr. Seely performed a chromosome analysis and found what he considered to be significant numbers of damaged chromosomes, which he defined as chromosome breaks and gaps. Attempting to identify the source of the child's chromosome damage and birth defects, Dr. Seely examined the parents and found that their blood cells had damaged chromosome patterns similar to their child's.

To determine a possible association between an environmental or chemical agent and this condition, Dr. Seely questioned the parents about their life styles, physical habits, health, and other background characteristics. One thing that interested Dr. Seely was the parents' participation in a hobby called "foiling" or "foil art"--attaching various designs of multicolored foil paper to posters and other objects, usually with aerosol spray adhesives. The exhibits were usually finished with spray paint.

Dr. Seely was unfamiliar with foil art and directed his investigation to determine whether a possible link existed between foilers' use of aerosol spray adhesives and chromosome damage. He discounted the foilers' use of spray paint as a cause-factor because they used it for only a short period of time and chemical agents in spray adhesives were generally more subject to question by the medical community. Aerosol spray adhesives of various formulas have been commercially marketed since 1961.

Dr. Seely examined four other foilers who had been exposed to aerosol spray adhesives and found that their blood cells had chromosome damage similar to that found in the deformed child and its parents. Also, in mid-July 1973 Dr. Seely examined another child with uncommon or unusual birth defect characteristics and found that it and both of its parents had a high percentage of cells with damaged chromosomes. Both parents were foilers.

In total, Dr. Seely had examined 10 persons with what he considered to be a high percentage (about 9 percent) of damaged chromosomes--2 deformed children, their 4 parents, and 4 other persons. (This 10-person group will be referred to as "exposed persons.")

Chromosome damage is a condition known to the medical profession, but research on its causes and effects has been limited. Medical researchers are not sure what percentage of damaged chromosomes is normal, acceptable, or harmful and have not satisfactorily tied chromosome damage to birth defects.

Dr. Seely expressed chromosome damage as the percentage of damaged chromosomes found in the total cells examined. Although he found what he considered to be high percentages of damaged chromosomes in the 10 exposed persons, he did not know how the percentages compared with those in persons who had not been exposed to aerosol spray adhesives.

He examined 12 persons who were not spray adhesive users (referred to herein as "nonexposed persons") for possible chromosome damage. He found that 1.65 percent of the cells sampled showed chromosome damage, compared to 8.99 percent for exposed persons. He considered this 7.34-percent difference--a five-to-one relative difference--statistically significant. These findings reinforced his belief in a possible relationship between aerosol spray adhesives and chromosome damage and suggested a relationship between chromosome damage and birth defects.

Other factors leading Dr. Seely to suspect the foilers' use of spray adhesives as a possible cause of the chromosome damage included the following:

--Chemical agents used in various aerosol sprays concern researchers because of the sprays' recent appearance in consumer products and the absence of what is generally considered adequate research on these products' safety.

--Some of the exposed persons used the products for several hours in closed areas without adequate ventilation (contrary to directions on the containers) and with their faces near the spray mist. Aerosol spray mist consists of small particles that may be inhaled into the lungs and enter the blood stream, causing researchers to consider the sprays a potential health hazard.

Dr. Seely attempted to identify a chemical agent he thought may have been responsible for the chromosome damage. He contacted the major manufacturer of the sprays the foilers used and obtained its formula. The products did not contain the chemical agent he thought was responsible.

Dr. Seely was uncertain of the action to take but believed a responsible Federal agency should look at his preliminary findings and conclusions. On July 25, 1973, he contacted FDA, who referred him to the Commission's Bureau of Biomedical Science (BBS), which is responsible for the Commission's laboratory reviews, evaluations, and analyses to help reduce hazards from chemical consumer products.

After the Commission was given some preliminary information on the telephone, BBS and FDA representatives (an FDA researcher assisted the Commission in reviewing Dr. Seely's study) went to Oklahoma City on August 5, 1973, to meet Dr. Seely, establish his credibility, and review his research findings. At the meeting, the two representatives found Dr. Seely's data to be legitimate and adequately prepared and documented, and they concluded that he was a responsible researcher.

One aspect of the study that they found particularly troubling was the fact that the second child's parents had stopped using aerosol spray adhesives several months before conception, yet both parents and the child had a high percentage of damaged chromosomes. This indicated that aerosol spray adhesives could be a hazard resulting in long-lasting chromosome damage that might (1) remain in a person even after discontinuing the product's use and (2) adversely affect future generations through heredity. BBS representatives considered this condition critical and believed Dr. Seely's research had identified a link between aerosol spray adhesive use and chromosome damage.

On August 7, 1973, BBS and FDA representatives briefed the Commission Chairman and verbally recommended that three brands of aerosol spray adhesives be declared an imminent hazard. Dr. Seely's data had been verbally provided to the Commission because he had neither completed his research

nor prepared a report. Attempting to obtain documentation, the Commission requested him to submit his study results and other data.

The Commission requested the two manufacturers Dr. Seely identified in his research--Minnesota Mining and Manufacturing Company (3M) and Borden Inc.--to submit studies, research, and other information on their spray adhesives, including formulas, sales data, and consumer complaints. Both companies complied.

FACTORS CONSIDERED BEFORE THE BAN

The Commissioners were concerned about Dr. Seely's preliminary research findings. His was the first study suggesting a link between aerosol spray adhesives and genetic problems, and the potential severity of this hazard motivated the Commission to act quickly.

In separate meetings held in Washington, D.C., on August 15, 1973, the Commission apprised 3M and Borden of its concern about the connection between their aerosol spray adhesives and potential health problems and the possible need for quick regulatory action. Although the companies knew of the Commission's interest in spray adhesives, this was the first indication they had of the Commission's serious concern and the possibility of the products being banned as an "imminent hazard" under the FHS Act.

The Commission requested the two firms to provide any additional information on their products' safety to possibly refute Dr. Seely's findings and to discuss any action they planned to take as a result of the anticipated ban. The companies said they had not received Dr. Seely's written report (neither had the Commission at that time) and asked for the opportunity to discuss his findings with him. Commission representatives agreed to accompany 3M and Borden representatives to Oklahoma City on the following day (August 16, 1973) to meet with Dr. Seely.

At that meeting, the Commission received Dr. Seely's report containing his preliminary research findings and conclusions. Although the companies did not receive copies of the report, Dr. Seely read it aloud at the meeting. Company representatives discussed the study's preliminary conclusions and the research methods and laboratory techniques used with Dr. Seely.

The Commission's minutes of the meeting indicate that the company representatives questioned Dr. Seely on the possibility that other foiling materials may have contributed

to the high damaged chromosome readings. Company representatives expressed their concern about the organization of Dr. Seely's information and did not agree that the findings supported his conclusions. Neither company provided the Commission with information substantiating their comments or otherwise refuting the findings. At the completion of these meetings, a BBS representative told the companies that the Commission might ban the products until the study was corroborated or disproved.

Representatives of 3M told us they had expressed some reservations to the Commission about Dr. Seely's research and conclusions and the time they were allotted to reply to allegations that their products were an imminent hazard. Some 3M comments to us follow.

--The 3M representatives told Dr. Seely and Commission representatives that 3M was concerned about possible subjective bias; that is, when analyzing blood samples for chromosome damage, Dr. Seely knew which samples were from exposed and nonexposed persons. They also said Dr. Seely was not fully objective in selecting and analyzing the nonexposed people. They did not believe these methods were consistent with good research techniques.

--3M did not question Dr. Seely's data; however, it believed other factors, such as foilers' use of spray paint, could cause or contribute to chromosome damage. Also, 3M did not believe the data adequately supported identifying its aerosol spray adhesives as the primary cause of chromosome damage and birth defects. It believed that Dr. Seely and the Commission should have contacted medical specialists in mutagenics, genetics, and other related fields to discuss the research results and obtain comments on the preliminary findings and conclusions before taking regulatory action. A 3M toxicologist told us several such specialists he contacted said damaged chromosomes in the 4- to 8-percent range were common.

--3M requested that the Commission wait 1 to 2 weeks before deciding whether to ban the products because Dr. Seely admitted his data was preliminary. This would have permitted the Commission and 3M--working together, as they did after the ban--to look deeper into Dr. Seely's work and obtain the opinions of specialists before taking regulatory action.

Both companies recognized that a significant potential public health problem had been raised and that the Commission

had the authority to immediately ban the products as an imminent hazard. They also knew about the general lack of information linking aerosol spray adhesives and chromosome damage and recognized the seriousness of such problem to future generations.

Therefore, knowing of the Commission's intent to declare the products an imminent hazard, both manufacturers voluntarily stopped production and distribution of the aerosol spray adhesives in question on August 17, 1973--the date the Commission announced its intention to ban the sprays--until further study could be completed.

The Commission banned the aerosol spray adhesives on August 20, 1973, recognizing that certain aspects of Dr. Seely's research justified banning the products and other aspects raised questions about the necessity of a ban. The Commission did not have documentation showing whether and how it had considered all such factors before the ban. We obtained the following information primarily by interviewing Commission representatives.

Factors supporting the ban

The Commission (1) considered Dr. Seely as credible because of his credentials--he held M.D. and Ph.D. degrees, was a National Institutes of Health (NIH) grant recipient, and was widely published in the medical field and (2) believed his research and test techniques showed good organization and investigative methods.

Dr. Seely's study identified two deformed children whose parents had used aerosol spray adhesives. The fact that this association did not have to be extrapolated from animal data added credibility to the research. Also, the fact that the second deformed child's parents had stopped using the products several months before conception illustrated potential long-lasting and hereditary effects of the hazard. The five-to-one ratio between damaged chromosomes in exposed persons and those in nonexposed persons was statistically significant.

Although the Commission knew that little mutagenic testing had been previously performed, its representatives believed Dr. Seely's research demonstrated an adverse relationship between aerosol spray adhesive use and chromosome damage and between chromosome damage and birth defects. Neither the Commission nor the manufacturers were able to produce any data assuring the products' safety or refuting Dr. Seely's research.

The Commission's biomedical staff recommended, on the basis of discussions with Dr. Seely and its review of his preliminary research, that certain aerosol spray adhesives be declared an imminent hazard.

The Commission also believed that enough alternative glue products were being marketed so consumers would not be overly inconvenienced by the ban.

Factors raising questions

Because of the research procedures Dr. Seely used, he knew which blood samples came from exposed and nonexposed persons as he analyzed them. Such analyses are usually made without such knowledge to avoid subjective bias. Commission representatives told us they were aware of such bias in Dr. Seely's research and of the need for additional study and review. However, the Commission considered the percentage difference between damaged chromosomes in the two groups so significant that it did not want to take the time necessary to verify Dr. Seely's research before taking regulatory action.

Although researchers had studied the cause and effect of chromosome damage, its relationship to birth defects was relatively unresearched and little factual data existed. The Commission recognized that Dr. Seely's preliminary research findings were unique and that they addressed a subject not adequately explored by previous research. However, the Commission, relying partly on BBS's review of Dr. Seely's research and laboratory practices, decided that the severity of the potential chromosome damage problem was overriding.

Dr. Seely's contacts with BBS were verbal. No written report was provided the Commission until August 16, 1973--the day before it publicly announced its intention to ban the products.

No peer group evaluation of Dr. Seely's research was conducted. Peer group evaluation is a corroboration tool researchers use to help build confidence and credibility in research findings--especially studies in previously unresearched areas. Commission representatives said that, although peer group evaluations are desirable, their use depends on the research area and the nature of the findings. The Commission Chairman told us it is not uncommon for regulatory action to be based on the research results of one researcher.

The unavailability of data linking aerosol spray adhesives to chromosome damage and chromosome damage to birth defects tended to both support and contradict the Commission's decision. As discussed on page 16, the Commission believed

Dr. Seely's research illustrated a potentially serious problem. On the other hand, it recognized that some members of the medical community could argue that insufficient evidence existed to ban the products on the basis of one researcher's limited and unevaluated work. The Commission believed, however, that it had adequate data to justify banning certain spray adhesives.

COORDINATING THE REVIEW OF DR. SEELY'S STUDY BEFORE IMPOSING THE BAN

The Commission has no policy, regulations, or procedures that provide guidance for coordinating its review of potential hazardous products.

A Commission representative said that, before the banning of aerosol spray adhesives, he telephoned the National Library of Medicine and the Environmental Mutagen Information Center to determine if any chromosome damage studies had been performed on selected chemical formulations or aerosol spray adhesives. He was told that there were none.

Also, before the ban the Commission contacted a pediatrician-epidemiologist at NIH to obtain his opinion of Dr. Seely's preliminary findings. A BBS representative told us the NIH doctor did not believe Dr. Seely's preliminary research and findings were correct or that they could be adequately documented and supported. The BBS representative told us he discounted these comments because the doctor did not have a report to review and could not be expected to comment on the research's fine points.

During the discussion, the NIH doctor gave the BBS representative the names of several specialists the Commission could contact for views on Dr. Seely's preliminary findings. The Commission did not contact any of these specialists before imposing the ban. Commission representatives said they did not believe they had time to contact other specialists before taking regulatory action.

The NIH doctor told us he provided the Commission the names of several doctors and made the following comments about Dr. Seely's preliminary research to a BBS representative.

--The two deformed children had dissimilar abnormality characteristics, suggesting that the association with aerosol spray adhesives should not be considered seriously without further evaluations. Because of the dissimilarity, there was a good probability that (1) the malformations were not caused by the same chemical agent and (2) aerosol spray adhesives were not the cause.

--It is difficult to interpret the meaning of chromosome damage because little is known about its causes and effects. For instance, an LSD (lysergic acid diethylamide) study several years ago tied chromosome damage to birth defects but was later proven inaccurate.

--Because this was the first potential problem identified with aerosol spray adhesives, independent specialists should confirm Dr. Seely's findings by drawing and analyzing new blood samples before any regulatory action. It would take about a month to get a better understanding of Dr. Seely's research.

--The Commission should perform chromosome analyses for persons exposed to high concentrations of aerosol spray adhesives--such as industrial users--to ascertain if a problem exists. Industrial users would be affected if the products were hazardous.

Commission representatives told us they did not contact other mutagenic, genetic, or medical specialists before banning the adhesives because:

--The Commission could not expect others to comment on Dr. Seely's research without a report summarizing his research methods, findings, and conclusions.

--They believed they did not have sufficient time--the Commissioners wanted prompt action--for any detailed analysis, evaluation, or specialists' review of findings before imposing the ban.

The Commission's Office of the Medical Director (OMD)--established to provide Commission offices and bureaus with medical review, knowledge, and assistance in establishing medically sound findings supporting product safety decisions--did not review Dr. Seely's research, nor provide any input into the Commission's decision before adhesives were banned. The Medical Director first learned of the ban from the August 17, 1973, press announcement.

The Chairman explained that OMD did not participate in the review mainly because (1) BBS was better staffed to review Dr. Seely's research because OMD was a one-man office at the time and (2) laboratory staffs generally support medical decisions. Therefore, the Chairman believed that BBS could perform this analysis and make the evaluation.

ACTIONS IN BANNING THE ADHESIVES

The FHS Act permits the immediate banning of a product considered to be an imminent hazard by publishing a notice in the Federal Register. An imminent hazard determination does not require the same due process proceedings as standard regulations, which generally require public hearings and advance notice before their effective date. However, normal regulation proceedings continue after the product is banned as an imminent hazard and a manufacturer has the right to challenge the Commission's determination in court. Neither 3M nor Borden did.

Alerting the public

The Commission wanted to immediately alert the public to the adhesives' potential danger, but was not prepared to ban the products by publishing the required Federal Register notice. Therefore, on the basis of its intention to ban certain aerosol spray adhesives as an imminent hazard under the FHS Act, the Commission issued a press release on Friday, August 17, 1973.

The press release stated that the Commission was going to use all appropriate means to halt the production, distribution, and sale of certain aerosol spray adhesives and was conducting a nationwide investigation to determine the extent of the problem. No timeframe was given for completing this investigation. The Commission believed the seriousness of the potential problem justified warning consumers before the ban. Three days later, on August 20, 1973, the Commission banned the three aerosol spray adhesive brands as an imminent hazard with the appropriate notice in the Federal Register.

Additional brands of aerosol spray adhesives with "the same or similar chemical formulations" were banned when identified. In all, 13 brands were banned--11 manufactured by 3M and 2 by Borden. When these additional brands were banned, the Commission issued a press release adding them to the list, reiterating the names of the previously banned adhesives, and reaffirming its reasons for the ban.

The Commission drew criticism from the medical community because of the contents of the press releases. The Commission's August 17, 1973, press release stated "* * * there is concern about the genetic damage which may cause problems in subsequent offspring * * *." In an August 27, 1973, announcement, the Commission recommended that adults concerned about aerosol spray adhesive exposure "* * * should consider delaying pregnancies * * *" until further information was available. This announcement also warned pregnant women that

the risk for the infant is not known and concern may be increased if both parents have been exposed to aerosol spray adhesives.

Practicing and laboratory medical professionals were concerned about the mental anguish these announcements inflicted on the public, especially pregnant women. One doctor wrote the Commission that Dr. Seely's findings were based on limited knowledge and were prematurely announced to the public and that more extensive study should have been performed before publishing such information. According to another doctor, the Commission's news releases were unduly frightening and caused some pregnant women to seek advice about abortions. A third doctor wrote the Commission stating its actions were based on inconclusive and limited information.

One doctor stated: "It's easy to find chromosome breaks, but hard to say what they mean. The warning is a little premature to say the least * * *." A medical center published its own news release:

> "There has been some concern expressed about potential harmful effects of spray adhesives. In our opinion, the actual evidence of harmful effects is inconclusive and based on limited information. It is difficult to know whether there is any risk at all. We feel that the expression of concern to the public was premature and that the evidence of a harmful effect on chromosomes or on the developing baby is inconclusive."

The Commission's Medical Director told us that:

--Because the aerosol spray adhesives case was a medical problem, medical opinions and comments should have been obtained before imposing the ban to supplement its technical evaluation and to help keep Dr. Seely's preliminary findings in proper perspective.

--The Commission should have given more consideration to the public's mental well-being when reviewing and evaluating Dr. Seely's research, in proposing a ban, and especially in preparing press announcements.

COMMISSION ANALYSIS OF DR. SEELY'S RESEARCH AFTER THE BAN

After banning the adhesives, the Commission called on mutagenic and genetic specialists to assist it in evaluating Dr. Seely's research data by providing impartial, professional, third party opinions.

Research studies

The Commission coordinated several studies to evaluate Dr. Seely's research. Most were funded by the Commission--several from existing research projects. Two were sponsored by 3M. The studies were generally completed in about 2 months and reports transmitted to the Commission in mid-November 1973. A brief discussion of five of these studies follows.

Study A

This study was to confirm the chromosome damage rates for persons included in Dr. Seely's research by having other researchers review blood samples Dr. Seely had taken from the patients in the original study. Dr. Seely had made several laboratory slides from each blood sample. Two medical researchers analyzed different slides than Dr. Seely had analyzed for 12 (6 exposed and 6 nonexposed) of the original 22 persons. Approximately half the blood cells selected for analysis were studied independently in each doctor's laboratory. The doctors jointly reviewed those cells containing abnormalities.

These two researchers did not find the same statistical difference between exposed and nonexposed persons that Dr. Seely had found and did not confirm his findings that aerosol spray adhesives adversely affected chromosomes.

Study B

In this study, the doctors that performed Study A reviewed the same slides Dr. Seely had analyzed for 6 of the 12 persons examined in their initial study. With minor deviations, this study's research techniques were similar to those of Study A.

The analysis reaffirmed the results of Study A--there was no statistically significant difference in damaged chromosomes between exposed and nonexposed persons--and did not substantiate a relationship between aerosol spray adhesives and chromosome damage. The study did not confirm Dr. Seely's original observations, and both doctors believed no further study was needed.

Study C

A medical researcher attempted to corroborate Dr. Seely's findings by analyzing new blood samples from several persons, most of whom were included in Dr. Seely's original study. The researcher studied new blood samples from 10 persons--6 exposed and 4 nonexposed.

This study's results conflicted with Dr. Seely's original findings because nonexposed persons showed a higher percentage of damaged chromosomes than did spray adhesive users. The researcher questioned the objectivity of Dr. Seely's selection of nonexposed people because some worked in the medical field and others were his patients.

Study D

This study was directed at industrial and other heavy users of aerosol spray adhesives (although not necessarily the same brands as those banned). The researchers' general criteria for selecting persons for analysis were (1) extended exposure to spray adhesives (generally daily use during the last 6 months to 4 years) and (2) exposure to the products during the 3 weeks before this study.

Blood samples were drawn and analyzed by a three-member investigative team. A comparative analysis of 14 aerosol spray adhesive users and 5 nonexposed persons failed to show the same statistically different percentages of damaged chromosomes that Dr. Seely found. The investigators knew the identity of the 19 persons whose slides they had analyzed. Therefore, they blindly analyzed (i.e., slides were coded so the identity of the person was not known to the researcher when analyzing the slide) slides for another five exposed and five nonexposed persons. This investigation confirmed the previous results and failed to corroborate Dr. Seely's findings.

Study E

In this 3M-sponsored study, 14 3M employees were sent to the Mayo Clinic for analysis. Eight had moderate to heavy industrial exposure to aerosol spray adhesives, two had infrequent exposure (such as office use), and four had no exposure. The researchers did not know to which group the employees belonged. The analysis was to identify and compare damaged chromosomes rates between aerosol spray adhesive users and nonexposed persons.

In a statement accompanying its study results, the Mayo Clinic pointed out that the medical profession does not have good data on the "normal limits" of chromosome breaks and gaps. Although this study showed higher damaged chromosome percentages for nonexposed persons, the Mayo Clinic believed, on the basis of what is known about chromosome damage, that none of the 14 employees had abnormal chromosome breaks and gaps.

In addition to these and other studies, Dr. Seely re-examined his own slides for five exposed and six nonexposed

persons without knowing which slides were which. Through his own reevaluation, Dr. Seely found that the ratio of the percentage of damaged chromosomes in exposed and nonexposed persons had decreased from five to one to two to one. However, Dr. Seely still considered this difference significant.

The results of the research studies used to evaluate Dr. Seely's research did not show similar statistical differences between exposed and nonexposed persons. A Commission representative said these differences were the result of each researcher's individual interpretation and judgment in the (1) definition of chromosome breaks and gaps when following Dr. Seely's research methods and (2) review of cells to identify breaks and gaps.

After reviewing the results of the studies, BBS and OMD representatives believed that continuing the ban was not justified and, in mid-November 1973, recommended that the Commissioners withdraw it.

The Commission Chairman told us the Commissioners did not believe the study results were adequate to support withdrawing the ban. Although the studies did not support Dr. Seely's conclusions and the Commission's staff recommended lifting the ban, the Commissioners believed that questions concerning the studies' conflicting results and spray adhesives' safety needed answering before further action was taken. For instance, the Chairman believed the studies' results were confusing and nondefinitive because

--the studies were done quickly and may not have been comprehensive,

--the researchers got conflicting chromosome damage percentage readings when analyzing Dr. Seely's data,

--the spray adhesive users analyzed in Study D did not all use the same brands of adhesives as those persons Dr. Seely had examined, and

--the results of Dr. Seely's reevaluation demonstrated to the Commissioners that his credibility was still intact.

To better understand the chromosome studies, the Commissioners (1) prepared a series of questions about the relationships between aerosol spray adhesives and chromosome damage and between chromosome damage and birth defects and (2) established an ad hoc committee to review and

comment on Dr. Seely's and the other studies. Committee members were also asked to comment on the Commissioners' questions. The Chairman told us that, although establishing the committee was time consuming, it was appropriate under the circumstances.

Commissioners' questions

The Commissioners developed a list of about 50 questions on the relationships between aerosol spray adhesives and chromosome damage and between chromosome damage and birth defects; the laboratory research techniques used in the analyses; and the adequacy of the various studies' test methods. Although the Commissioners did not get answers to all their questions, the Chairman told us that they were generally satisfied with the responses.

Ad hoc committee

The Commission requested 11 medical researchers in genetics, pediatrics, epidemiology, and toxicology to give their professional opinions on (1) the validity and significance of Dr. Seely's study and the other research performed and (2) the Commissioners' questions. The Commission sent this material to each committee member and asked several questions, including:

1. Was there a relationship between aerosol spray adhesive use and chromosome damage?

2. Was there an association between the spray adhesives and birth defects?

3. Should the Commission withdraw its ban on the aerosol spray adhesives in question and, if not, what course of action was recommended?

The committee members generally responded to each Commission question. Overall, they believed that Dr. Seely's original conclusions were not corroborated and that the research data failed to establish a relationship between spray adhesive use and chromosome damage.

Most committee members did not believe the relationship between adhesive use and birth defects was adequately documented. One member believed that one of the research studies was not very persuasive in documenting the association between adhesives and birth defects; another believed that the questions concerning this relationship could not be answered with available data. The committee's consensus was the Commission should withdraw the ban because Dr. Seely's conclusions were

not adequately supported by data. Two members commented that adhesives had not been adequately tested for mutagenicity. Most members suggested performing additional research after withdrawing the ban.

In spite of this suggestion, the Commission is not sponsoring any new aerosol spray adhesive research. The Commission does have a contract with Dr. Seely to finish his research and submit his final report.

According to a Commission representative, the Commission is studying household aerosol sprays in general, rather than directing its research to only aerosol spray adhesives. The Commission has one contract for studying the effects of long-term, low-level exposure to household aerosol sprays. Commission representatives said the aerosol spray adhesive case has reemphasized the need for better coordination between Federal agencies in studying aerosol sprays. The Commission's participation in the Interagency Panel on Environmental Mutagenesis is one effort to improve this coordination.

WITHDRAWING THE BAN

After reviewing Commission- and 3M-sponsored research studies, analyzing the ad hoc committee comments, and considering staff recommendations, the Commissioners voted on January 18, 1974, to announce their intent to withdraw the aerosol spray adhesive ban on March 1, 1974. The Chairman told us the Commissioners wanted to wait until March to withdraw the ban to give any interested parties time to make other information available or comment on the proposed action. The Commission was also aware of a study in the New York City area and believed the additional time would give that study group an opportunity to add any relevant information it might develop.

In a January 25, 1974, news conference, the Chairman discussed the Commission's plan to withdraw the ban. In a press release issued on that date, the Commission explained that subsequent research did not substantiate Dr. Seely's findings and alerted the public to the Commission's intent to withdraw the aerosol spray adhesives ban on March 1, 1974, unless other information was presented affecting the case. The required Federal Register notice was published on January 28, 1974.

The Commission received three written responses to its proposed ban withdrawal. A retail store chain said it planned to resume selling aerosol spray adhesives on March 1, 1974, one private citizen supported the Commission's proposal to withdraw the ban, and another suggested that all aerosol

sprays be banned. No new data was submitted and the ban was lifted on March 1, 1974.

The Commission did not issue a press release or otherwise publicly announce the ban's withdrawal on March 1, 1974. Commission representatives told us a press announcement was not necessary on March 1 because the Commission had issued a press release and published the Federal Register notice after the January 18, 1974, decision. Although the Commission made no announcement, the news services carried stories early in March reporting the ban's withdrawal. The Commission's General Counsel sent identical letters to 3M and Borden on March 4, 1974, informing them that the ban had been withdrawn.

After banning the spray adhesives in August 1973, the Commission received numerous telephone calls and letters inquiring about the ban. The Commission maintained a log of these inquiries and, after the ban was lifted, wrote these parties explaining its reasons for withdrawing the ban. Enclosed with the letter was either a copy of the January 25, 1974, press release or the January 28, 1974, Federal Register notice. Commission representatives said approximately 460 letters were mailed during late March and early April 1974.

CONCLUSIONS

The Commission's actions in banning the aerosol spray adhesives were directed at protecting consumers from potentially hazardous products and were within the legal provisions of applicable laws. Although the Commission gave the two manufacturers an opportunity to refute its reasons for banning the products before the ban was effective, provisions for advance notice and public hearings were not applicable because the adhesives were banned as an imminent hazard under the FHS Act. In view of the FHS Act's definition of an imminent hazard and the potential seriousness of Dr. Seely's preliminary research findings, we are not questioning the Commission's decision to ban the adhesives. The Commission responded in a manner it believed most appropriate to inform the public of what it considered to be a hazardous product.

However, the basis for the Commission's decision could have been strengthened and the controversy surrounding its public announcements minimized if the Commission had

--coordinated its evaluation of the preliminary research with OMD and other medical specialists before imposing the ban and

--relied less on undocumented verbal evidence and more on documented evaluations in reviewing the preliminary findings and conclusions.

If the Commission had documented its review of Dr. Seely's research and coordinated its evaluation with OMD and other medical specialists, the decision and the press announcements could have indicated the limited evidence available and placed the decision in its proper perspective.

The Commission has no policy, regulations, or procedures for reviewing possible imminently hazardous products and documenting the basis for its decisions. In view of the scope of the Commission's authority, such policy, regulations, and procedures should be established.

RECOMMENDATION

We recommend that the Commission establish a policy, regulations, and procedures to evaluate potential imminent hazards and document the basis for its decisions on the results of such evaluations. Such policy, regulations, and procedures should require that hazard evaluations be coordinated with appropriate specialists and interested parties.

PRINCIPAL OFFICIALS OF THE CONSUMER PRODUCT SAFETY COMMISSION RESPONSIBLE FOR ADMINISTERING ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
COMMISSIONERS:		
Richard O. Simpson, Chairman	May 1973	Present
Barbara H. Franklin	May 1973	Present
Lawrence M. Kushner	May 1973	Present
Constance B. Newman	May 1973	Present
R. David Pittle (note a)	Oct. 1973	Present
EXECUTIVE DIRECTOR:		
Stanley R. Parent	Jan. 1975	Present
Frederick E. Barrett (note b)	May 1974	Jan. 1975
Albert S. Dimcoff (acting)	Apr. 1974	May 1974
Frederick E. Barrett (note b)	Dec. 1973	Apr. 1974
John W. Locke (acting)	May 1973	Nov. 1973

a/ The Commission functioned with four Commissioners until Commissioner Pittle's appointment on October 10, 1973.

b/ Mr. Barrett was a consultant, functioning as the Commission's Executive Director.