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BRIEFING PACKAGE

CHILDREN'S SLEEPWEAR FLAMMABILITY STANDARDS

Analysis of Public Comments on Proposed Revocation of September 1996 and Subsequent Amendments

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TABLE OF CONTENTS

PAGE

Executive Summary.....6

Briefing Memorandum.....8

I. INTRODUCTION.....8

II. BACKGROUND.....9
A. Original Children's Sleepwear Standards.....9
B. History/Rationale for the 1996 Amendments.....10

III. INFORMATION UPDATE.....11
A. Government Accounting Office reports.....11
B. Current Death and Injury Data..... 12
C. Other Countries' Experience--Regulations/Deaths & Injuries.....14
D. Safety Related Technical Information.....15
E. Information & Education Campaign.....15

IV. ANALYSIS OF PUBLIC COMMENTS.....16

A. Summary of Comments.....16

B. General.....16
Scope of the standards and exemptions
Perceived economic motive behind amended sleepwear standards
Legality of the amendments

C. Children's Sleepwear Marketing Issues.....18
Availability of tight-fitting sleepwear and similar garments used as sleepwear
Affect of cotton sleepwear sales on FR (polyester) sales
Garment returns from retail sales
Costs of revocation

D. Death/Injury Data Involving Children's Sleepwear.....20
Trend in clothing-related burn fatalities
Are infants wearing sizes 0-9 months immobile?
Relationship of mobility to the risk of burn injury for infants
Validity of CPSC data indicating a low, stable frequency of sleepwear-related thermal burn injuries
Exemptions are likely to increase frequency of severe burn injuries
Effect of the 1996 amendments to the Standards

E. Safety-Related Technical Information.....25
Fires addressed by the Standards

Importance of fit
Fire safety
Protection
Snug-fitting, a safe or unproven alternative?
Upsizing practices

F. Information & Education Campaign.....30

G. Garment Design and Production Issues.....30
Expansion of tight-fitting dimensions
Sewing tolerances

H. Compliance Issues.....32

V. LABELING OF TIGHT-FITTING SLEEPWEAR.....32
A. Earlier Commission Consideration of Labeling.....32
B. Concerns with Current Voluntary Labeling.....32
C. Improved Labeling for Tight-fitting Sleepwear.....33

VI. CONCLUSIONS.....34

VII. OPTIONS.....36
A. Revoke Amendments
B. Issue Further Amendments (labeling)
C. Retain Current Regulations
D. Correct Reference Errors in 16 CFR 1615

VIII. RECOMMENDATION.....37

TABS

TAB A *Federal Register* notice, "16 CFR Parts 1615 and 1616, Proposed Revocation of Amendments: Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X; Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14," published by the Consumer Product Safety Commission; January 19, 1999 (64 FR 2867).....39

TAB B United States General Accounting Office Report to Congressional Committees and the Consumer Product Safety Commission, "Injury Data Insufficient to Assess the Effect of the Changes to the Children's Sleepwear Safety Standard," GAO/HEHS-99-64, April 1999.....41

TAB C Memorandum from Martha A. Kosh, OS, to Sadye E. Dunn, Secretary, OS, "Sleepwear Revocation," list of comments on CF99-1, March 17, 1999.....57

Memorandum from Martha A. Kosh, OS, to Sadye E. Dunn, Secretary, OS, "Sleepwear Revocation," list of additional comments on CF99-1, March 29, 1999.....70

U.S. Consumer Product Safety Commission Public Hearing on Proposed Revocation of Amendments to Children's Sleepwear Standards, agenda with presenters, April 22, 1999.....72

TAB D Memorandum from Marilyn Borsari, Office of Compliance, to Margaret L. Neily, Project Manager, "Enforcement History of Children's Sleepwear Standards", May 12, 1999.....73

TAB E Memorandum from Terrance R. Karels, EC, to Margaret L. Neily, Project Manager, "Children's Sleepwear--Issues Related to Proposed Revocation", May 27,1999.....82

Memorandum from Terrance R.Karels, EC, to Margaret L. Neily, Project Manager, "Children's Sleepwear Revocation Project", May 27, 1999.....84

TAB F Memorandum from C. Craig Morris, EHHA, to Margaret L. Neily, ESME, "Sleepwear-Related Thermal Burns in Children under 15 Years Old", June 1, 1999, and attached report, June 1999.....88

Memorandum from C. Craig Morris, EHHA, to Margaret L. Neily, ESME, "Response to Public Comments Related to the Children's Sleepwear Flammability Requirements for Sizes 0 to 9 Months", May 28, 1999.....98

TAB G Memorandum from Carolyn Meiers, Engineering Psychologist, to Margaret Neily, Project Manager, "Labeling of Tight-Fitting Sleepwear", May 27,1999.....102

Memorandum from Carolyn Meiers, Engineering Psychologist, to Margaret Neily, Project Manager, "Human Factors Issues in Sleepwear", May 27,1999.....107

TAB H Memorandum from Linda Fansler, Division of Engineering, to Margaret L. Neily, Project Manager, "Review of Foreign Flammability Standards for Children's Sleepwear", May 25, 1999.....112

Log of telephone call, Linda Fansler, LSE, with Ms. Christine Simpson, Health Canada, Product Safety Bureau, March 31, 1999.....119

Memorandum from Linda Fansler, Division of Engineering, to Margaret L. Neily, Project Manager, "Response to Comments Received as a Result of Publishing the Children's Sleepwear Revocation Proposal, and the Public Hearing on the Proposed Revocation", May 28, 1999.....120

TAB I Memorandum from Margaret L. Neily, Project Manager, to File, "Analysis of Public comments on Proposed Revocation of the 1996 and Subsequent Amendments to the Children's Sleepwear Flammability Standards", May 27, 1999.....132

TAB J RESERVED:
Federal Register documents to be forwarded separately.

Draft *Federal Register* notice, "Consumer Product Safety Commission, 16 CFR Parts 1615 and 1616, Final Rule; Standard for the Flammability of Children's Sleepwear: Sizes 0 through 6X; Standard for the Flammability of Children's Sleepwear: Sizes 7 through 14; Withdrawal of Proposed Revocation of Amendments"

Draft *Federal Register* notice, "Consumer Product Safety Commission, 16 CFR Parts 1615 and 1616, Final Rule; Standard for the Flammability of Children's Sleepwear: Sizes 0 through 6X; Standard for the Flammability of Children's Sleepwear: Sizes 7 through 14", (labeling and hang tags)

Draft *Federal Register* notice, "Consumer Product Safety Commission, 16 CFR Part 1615, Standard for the Flammability of Children's Sleepwear: Sizes 0 through 6X; Correction"

TAB K **RESTRICTED** discussion of GAO evaluation of the Information & Education Campaign.....138

EXECUTIVE SUMMARY

In September 1996 the Commission amended the Flammability Standards for Children's Sleepwear to exempt infant garments sized 9 months and under and tight-fitting garments in larger sizes. The staff reviewed the many design and production problems with these garments reported by the industry following the amendments. On May 21, 1998, the Commission proposed for public comment several technical amendments clarifying the garment measurement points for "tight-fitting garments." With these clarifications in the standards, comfortable, practical tight-fitting garments could be produced. These clarifying amendments became effective February 18, 1999.

Legislation providing the Commission's appropriations for fiscal year 1999 required the Commission to propose revoking the amendments. Based on reviews conducted by the GAO and other available information, the Commission is required to issue a final rule by July 1, 1999. The final rule must (1) revoke, (2) maintain, or (3) modify the 1996 and other later amendments of the sleepwear standards.

The staff has reviewed thermal burn death and injury data involving children's clothing (especially sleepwear), the GAO reports on burn data and the information and education campaign, updated marketing information, and the written and oral comments provided by the public during this proceeding and concludes the following:

1. The risk of burn injury or death from all clothing, including sleepwear, remains low. Continued monitoring of death/injury data over the last 20 years indicates that there is no change since the exempt infant size and tight-fitting sleepwear (and similar garments exempted under the Stay of Enforcement) have been available in significant quantities. There continues to be no evidence that exempted garments and their similar predecessors have caused an increase in children's thermal burn injuries or deaths.

2. Assertions that flame resistant garments provide protection beyond a short exposure to a small open flame are not justified. The intent of the sleepwear standards is to address the unreasonable risk of injury or death from continued burning of sleepwear ignited by a small ignition source such as a match or lighter flame, not larger sources such as house or bedding fires. The heat released and temperatures produced in the larger fire scenarios easily exceed the conditions produced by small open flame sources. The staff cannot conclude based on available data that there are substantial benefits associated with the sleepwear standards beyond those represented by the test method in the standards.

3. **The current voluntary information and education campaign has proved to be inadequate and confusing to consumers.** As a result of an incomplete information and education campaign, mingling of various sleepwear garments in store displays, and inconsistent labeling, consumers are understandably confused. Consequently, the staff recommends mandatory labeling be required for tight-fitting sleepwear. Standardized informative hang tags and permanent labels identifying sleepwear that must be worn snug-fitting for safety are expected to address many of the criticisms expressed by the public commenters. Consumers should be better able to use this information to make informed choices in purchasing and safely using the various sleepwear alternatives.

4. **Reference corrections need to be made in 16 CFR 1615 (the 0-6X standard).** There are several errors in paragraph references in Rules and Regulations sections because of the 1996 amendment adding the infant size exemption to 0-6X standard. These are minor, but should be corrected with a separate, short FR notice.

The staff recommends that the proposed revocation notice be withdrawn and that references in the 0 to 6X standard that were affected by the 1996 amendments be corrected. The staff also recommends that both sleepwear standards be further amended to require labeling of tight-fitting garments with standardized informative hang tags and permanent identifying labels to assure that consumers are informed that the risk of fire injury is related to garment fit and so they can correctly identify garments that must be worn snug-fitting for safety.

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: JUN 3 1999

TO : The Commission
Sadye E. Dunn, Secretary

Through: Jeffrey S. Bromme, General Counsel
Pamela Gilbert, Executive Director

FROM : Ronald L. Medford, Assistant Executive Director
Office of Hazard Identification and Reduction
Margaret L. Neily, Project Manager, ESME
504-0508 Ext. 1293

SUBJECT: Children's Sleepwear Flammability Standards--Analysis of Public Comments on the Proposed Revocation of the September 1996 and Subsequent Amendments

I. INTRODUCTION

Public Law 105-276, the FY 1999 appropriations bill for the Commission, required the Commission to propose, for public comment, revoking the 1996 amendments to the sleepwear flammability standards. This proposal was published in the *Federal Register* on January 19, 1999. **(Tab A)** The U.S. General Accounting Office (GAO) was also required to review burn incident data from the ignition of children's sleepwear from small open-flame ignition sources from July 1, 1997, through January 1, 1999. **(Tab B)** The review was submitted to Congress and the Commission on April 1, 1999. In addition to receiving written public comments, the Commission held an oral hearing on April 22, 1999 to receive additional comments on the proposal. **(TAB C)** Congress also directed the GAO to evaluate the consumer information and education campaign developed by the industry and the Commission staff to determine whether it effectively maximized children's safety. Based on the GAO findings and other available information, the Commission is required to issue a final rule by July 1, 1999. The final rule must (1) revoke, (2) maintain, or (3) modify the 1996 and other later amendments of the sleepwear standards.

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This briefing package provides a review of issues considered by the Commission in adopting the 1996 and subsequent amendments, updated information relevant to these issues, findings of the GAO review of burn incident data, and the staff analysis and response to public comments on the proposed revocation. The package includes draft FR notices that withdraw the proposed revocation, propose labeling of tight-fitting sleepwear, and correct reference errors in 16 CFR 1615 caused by the addition of the infant size exemption.

II. BACKGROUND

A. Original Children's Sleepwear Standards

To develop the original children's sleepwear standards, the Department of Commerce/National Bureau of Standards evaluated clothing fire incidents in the Flammable Fabrics Accident Case and Testing System (FFACTS). This was a non-statistical collection of cases similar to CPSC in-depth investigations. Children in the age range from 0 to 12 years showed a disproportionate involvement in clothing fires compared to their proportion of the U.S. population. Matches and cigarette lighters were the most common ignition sources observed in children's clothing burn cases investigated at that time. Traditional nightgowns, pajamas, and robes were the garments most frequently involved in children's clothing fires.

The preamble to the 1971 "Standard for the Flammability of Children's Sleepwear" for sizes 0 - 6x stated the intent of the regulation was "to provide a high and effective level of protection to children approximately 5 years of age and younger against unreasonable risk of death or injury suffered as a result of ignition and continued burning of sleepwear garments, as defined in the standard..." Both the 0-6X and the later standard for size 7-14 garments accomplish this by limiting the char length of specimens subjected to 3-second impingement of a moderate sized (1 1/2 inch) flame. Fabrics must self-extinguish when the flame is removed. The test method and, therefore, the standards did not address garment performance in conflagrations (house or other large fires) or when contaminated with flammable liquids (flammable liquids interfere with the performance of the fabrics).[1]

[1] Superscripts refer to the list of references at the end of this paper.

B. History/Rationale for the 1996 Amendments

In November 1991 the Commission staff initiated a project to reexamine the scope of the sleepwear standards. The staff expressed concerns about the safety implications of marketing changes for sleepwear and enforcement difficulties. Compliance experience and economic data indicated that non-sleepwear garments (especially long underwear) were being used as sleepwear, reflecting a consumer preference for cotton garments. The staff believed that, without reducing safety, specific exemptions from the standards could respond to marketing practices responding to consumer demands for cotton, and reduce market confusion and compliance and enforcement problems.[2]

The staff considered other alternatives for providing protection from burn injury similar to that provided by flame resistant sleepwear. After a detailed evaluation of fire incident data, sleepwear flammability regulations of other countries, technical literature regarding the safety aspects of garment fit, economic and marketing information, the Commission issued amendments to the Children's Sleepwear Standards in 1996. These amendments exempted garments sized 9 months and under and tight-fitting garments for the larger sizes.

Infant exemption: The staff originally recommended an exemption for garments sized for infants 6 months and under because children of that age are immobile and could not expose themselves to ignition sources as could older children. Infants were not involved in the types of incidents that the standards were intended to address (garment ignition from a small open flame). **(TAB G)**

The Commission ultimately voted to extend the exemption to sleepwear garments sized for infants 9 months and under. Industry representatives reported that infant sizing is not true to age. As a common rule, according to the retail industry, parents buy infants' sleepwear at double the age (i.e., for 6 month old infants, purchasing the 12 month size).[3] Most likely, then, an infant six months or younger would be wearing garments sized 9 months and under.[4] These children are typically immobile.

Also, the industry practice is to segment garment sizes by 3/6/9 months (newborn/infant) and 12/18/24 months (toddler). Because an artificial break in these size ranges would cause problems for retailers, industry representatives recommended applying an exemption to the 9 month and under range of newborn/infant sizes.[3] **(TAB G)**

Tight-fitting exemption: The exemption for tight-fitting garments was supported by the technical literature and the

positive experiences of other countries, especially Canada, that had incorporated the concept of close fit in their children's sleepwear regulations. Further, no cases involving these types of garments had been identified through death/injury data sources available to the Commission.

Proposed labeling of exempted garments: In October 1995 the Commission proposed mandatory informative labeling of tight-fitting garments, but did not include such provisions in the 1996 amendments. Rather, the Commission favored a voluntary consumer information and education program, including labeling clearly visible at the point-of-purchase, to educate consumers about tight-fitting sleepwear.

After the exemptions became final with the 1996 amendments, the staff reviewed many design and production problems (with tight-fitting garments) reported by the industry. On May 21, 1998, the Commission proposed for public comment several technical amendments clarifying the garment measurement points for tight-fitting garments. With these slight changes in the standards, comfortable, practical tight-fitting garments could be produced. These clarifying amendments became effective February 18, 1999. The Commission's policy statements were also revised to allow sleepwear meeting the definition of tight-fitting to be sold with complying (flame resistant) sleepwear.

A number of organizations continued to be concerned that these amendments were not in the best interest of children and that the safety of the original flame resistant requirements would be lost. Congress passed Public Law 105-276, the FY 1999 appropriations bill for the Commission, and in that law required the Commission to propose, for public comment, revoking the 1996 amendments to the sleepwear flammability standards. The law also required the GAO studies described below.

III. INFORMATION UPDATE

A. General Accounting Office reports

Congress directed the GAO to review children's burn incident data (the ignition of children's sleepwear from small open flame sources) for the 18-month period of July 1997 through January 1999 and compare this data to child burn incident data from the prior four years. This report, "Injury Data Insufficient to Assess the Effect of the Changes to the Children's Sleepwear Safety Standard," is attached at **TAB B**. GAO notes that the Commission's NEISS (a national sample of hospital emergency rooms) reports few sleepwear-related injuries annually, only thirteen cases total from 1990-98. GAO stated "Consequently, although the overall risk of injury appears to be small, these

data cannot produce precise national estimates, making it difficult or impossible to observe trends in the number of injuries over time." GAO identified other crucial but unobtainable information that would be needed to determine the effect of the sleepwear amendments on the risk of injury to children. These included consideration of multiple contributing factors from the incidents themselves and information on consumer use of various types of garments (such as tight-fitting cotton versus flame-resistant polyester). Further, GAO reports, this information was not collected before the standard amendments to allow comparison with current experience.

The Commission responded that sleepwear burn incidents have remained small from 1990 through 1995 and since 1996 when the sleepwear amendments were published. In fact, the risk of burn injury from any type of sleepwear is extremely low; and, therefore, specifically quantifying that risk with exposure data is not necessary. The GAO assessment showed that available data do not support the conclusion that the 1996 sleepwear amendments have increased burn injuries to children. **(TAB B)**

A draft of the second GAO report requested by Congress, an evaluation of the information and education campaign for tight-fitting sleepwear, was received. It is discussed in the **RESTRICTED TAB K.** When the final report is received, it will be forwarded to the Commission as a supplement to this briefing package.

B. Current data (deaths/injuries)

In addition to considering the GAO report, the Commission staff again reviewed incident data involving thermal burn fatalities and injuries to children under 15 years old from clothing fires. The purpose of this review was to determine whether or not garments exempted from the sleepwear standards or those allowed under the Stay of Enforcement have begun to appear in these cases. Several data sources are available to the Commission, each offering different perspectives on children's clothing burn incidents. National Center for Health Statistics (NCHS) data provide counts of thermal burn fatalities for clothing; NEISS provides estimates of thermal burn injuries for sleepwear and other clothing types; but only CPSC in-depth investigations provide specific identification of the garments actually involved and details of the incident scenarios. Relevant statistics from each of these sources are summarized here.

The clothing-related thermal burn fatality data from the NCHS have often been incorrectly characterized as sleepwear fatalities by commenters and the media. *Clothing-related* (not just sleepwear) thermal burn fatalities in the U.S. declined

sharply for all age groups during the 1970's. Among children under 15 years old, there were 60 deaths in 1970, 15 in 1975, 7 in 1980, 6 or fewer each year from 1981 to 1992, and either 2 or 3 each year from 1993 through 1996. NCHS data do not allow examination of trends in sleepwear fatalities since sleepwear is not coded separately from clothing in the NCHS data.

Estimated U.S. hospital emergency room-treated thermal burn injuries involving *sleepwear and other clothing* among children under 15 years old remained low and showed no statistically reliable annual trends from 1990 to 1998. Based on these data, one can be highly confident that, over the nine-year interval, the annual average number of sleepwear-related burn cases was 90 ± 59. The source of these data is the CPSC's National Electronic Injury Surveillance System.

The staff reviewed CPSC in-depth investigations of reported clothing-related thermal burn incidents from 1993 through early 1999. These included 21 cases recently reported to the Commission by Shriners Burn hospitals. None of the cases investigated involved scenarios or garments addressed by the standard, including garments previously subject to the Stay of Enforcement (sleepwear sold as long underwear) or exempted from the flame resistant requirements of the standard (tight-fitting sleepwear or sleepwear sized 9 months and under).* **(TABS F and I)**

The most recent tabulation of garments involved in the in-depth investigations is presented in the GAO report on children's burn injuries. Many types of garments used for sleeping are involved in these cases with t-shirts the most prevalent. **(TAB B)** Because the Commission's in-depth investigations are not a representative sample of cases, they do not necessarily reflect the real distribution of garment types involved in these incidents. They do, however, provide valuable details on the incident scenario.

*Three cases were identified by the staff as possibly within the scope and intent of the children's sleepwear standard. A closer review showed that all three of these cases involved infant daywear or plain white long underwear clearly not subject to the standard or stay of enforcement and/or involved house fire or bedding fire scenarios.

C. Other countries' experience--regulations/deaths & injuries

As reported in earlier briefing packages, five countries, including the United States, have adopted regulations governing the flammability of children's sleepwear. These countries, Australia, Canada, New Zealand and the United Kingdom, like the United States, have all incorporated fabric flammability (measured by different test methods) and garment design (defined by garment style and/or dimensions) into their standards. The following is a brief description of the current regulations.

The United Kingdom's sleepwear regulation provides flammability test requirements for nightdresses, dressing gowns and other similar "looser-fitting" sleepwear garments for children over 3 months and under 13 years of age. Other sleepwear garments and all garments for infants (under 3 months) only require labels showing whether they meet the flammability requirements.

The 1990 New Zealand regulations cover nightwear for children 6 months to 14 years of age. The Australian standard covers sleepwear size 0 to 14. The two regulations are similar. Both use fabric flammability tests in combination with garment design and style to categorize garments by their perceived fire hazard. New Zealand sets garment design restrictions while Australia limits some garment dimensions (garment length and width of hemline, sleeves and pants) for nightwear not made with "low fire danger" fabric. Garments are labeled for fire hazard category or fabric type. Australia allows the sale of garments not meeting flammability/style requirements; New Zealand does not. Australia is currently expanding coverage of their flammability standard to some children's daywear garments that are commonly worn both day and night.

The Canadian and United States regulations include similar flammability test methods requiring garments from size 0 to 14x and 14, respectively, to be flame resistant. Sleepwear for infants weighing up to 7 kg (approximately age 6 months, according to enforcement guidelines) in Canada and sleepwear sized 9 months and under in the U.S. are exempt from the flammability requirements. The exempt U.S. tight-fitting sleepwear in larger sizes must meet more restrictive garment dimensions than Canada's exempted polo pajamas. In 1998 Canada updated its flammability requirement guidelines to clarify sizing and design restrictions for exempted garments, including polo pajamas.

The staff contacted Health Canada for an update of their experience involving deaths/injuries with children's sleepwear. Health Canada's representative stated that there have not been any deaths since 1987 and injuries are down. **(TAB H)**

Garment dimensions allowed by these other countries are all larger than those specified by CPSC for the tight-fitting exemption. A drawing of the garment dimensions specified by these various regulations, compared to the exempt tight-fitting sleepwear, is shown in **TAB I.**

D. Safety related technical information

The staff has reviewed the technical literature and contacted industry representatives to determine whether any additional research and/or testing has been conducted relevant to the ignition or burning characteristics of tight-fitting garments. No new information was found, and none was reported by commenters in this proceeding. **(TAB H)**

E. Information & Education Campaign

Some members of the manufacturing and retail industry continue their voluntary labeling of tight-fitting garments, posting of in-store signs, and employee training.[5] At the April 22 hearing, American Apparel Manufacturers Association (AAMA) representatives described a point of sale campaign conducted by manufacturers and retailers in cooperation with CPSC. According to AAMA, the campaign uses distinctive artwork for hang tags and other signage identifying garments as sleepwear. The hang tags identify garments as snug-fitting or flame resistant and include a simple explanation of the need for the sleepwear standard: "Fabric and fit are important safety considerations for children's sleepwear. Sleepwear should be flame resistant or snug-fitting to meet U.S. Consumer Product Safety Commission sleepwear requirements." Other campaign elements include brochures posted by cash registers and on the AAMA web site, signs and display toppers identifying sleepwear garments, segregation of sleepwear from other garments in stores and catalogues, and information and training materials distributed to sales associates and telephone operators to help customers. AAMA also issued press releases and conducted media interviews.

Last year the Commission issued press and video news releases warning about the use of loose-fitting garments, especially T-shirts, for sleepwear. The VNR described the safer alternatives available under the existing sleepwear regulations--flame resistant and snug-fitting sleepwear--and the hang tags that identified them in retail stores.

Many comments received by the Commission, however, were highly critical of the implementation, extent, and effectiveness of the information and education program based on observations from retail store surveys and interviews with shoppers and store sales personnel. The issues of adequacy and effectiveness of

this voluntary program are discussed in the analysis of comments and discussion sections below. **RESTRICTED TAB K** contains a discussion of the draft GAO report evaluating the information and education campaign.

IV. ANALYSIS OF PUBLIC COMMENTS

A. Summary of comments

The Commission solicited public comments concerning the proposed revocation of the 1996 amendments through the January 19, 1999, *Federal Register* notice and in a public hearing held on April 22, 1999. The written comments were often form letters supporting one position or the other. While a number of commenters provided information supporting their opinions, other comments were often based upon inaccurate information about the hazard addressed by the standards, inaccurate or incomplete death and injury data, and a lack of understanding of the garments actually exempted by the 1996 amendments. The comments are discussed by significant issues throughout this briefing paper and in the tabs of the package.

There were over 3,400 responses to the *Federal Register* notice. A list of these commenters, including consumers, burn victims, medical professionals, fire safety organizations, federal and state government officials, manufacturers and retailers, cotton industry representatives, and farmers, is attached. There were also twenty-one speakers who gave testimony at the oral public hearing. **(TAB C)**

B. General comments

Scope of the Standards and Exemptions

Comment:
Some comments evidenced the belief that the exemption eliminated all clothing flammability requirements for children's sleepwear.

Others affirmed that the amendments did not affect loose pajamas, nightgowns, and robes, which are the kind of sleepwear involved in burn injuries and fatalities. Those items still must meet the requirements of the Children's Sleepwear Flammability Standards and be fire resistant.

Response:
The Commission exempted infant sleepwear and only one limited style of sleepwear (defined as tight-fitting) in larger sizes. Other sleepwear garments like nightgowns, robes, and looser fitting pajamas remain subject to the requirements for

flame resistance. Exempted children's sleepwear (including infant sizes 0 to 9 months and tight-fitting sleepwear in larger sizes) must still meet the less stringent general clothing textile flammability requirements of 16 CFR 1610.

Comment:

A number of commenters believed that the Commission issued the 1996 amendments with the expectation that consumers would switch to tight-fitting sleepwear from loose-fitting T-shirts.

Response:

The 1996 amendments were intended to provide consumers who prefer natural fibers (cotton) with a safer alternative to the loose fitting, non-complying garments used frequently as sleepwear, such as long underwear. While the staff did not necessarily expect consumers using T-shirts to switch to the tight-fitting garments, they did anticipate that any such substitutions by consumers could reduce the number and severity of burn injuries should they occur.[3]

Perceived economic motive behind amended sleepwear standards

Comment:

Some commenters perceived an economic motive, including influence by the cotton industry, behind the exemptions provided in the amended sleepwear standards.

Response:

The Commission staff's recommendation to change the standards was not based on pressure from any outside interests. Rather, this recommendation was based on two issues: (1) safety and (2) enforcement.

The staff studied this issue for several years, relying on laboratory and other analytical data, including injury and death data, to arrive at its conclusions and recommendations. Based on this work, the staff concluded that "tight-fitting" cotton garments would not pose a hazard to children because: (1) they fit closer to the body, thus trapping less air for combustion; and (2) there would be a reduced possibility for contact with an ignition source.

The staff also believed that this exemption (by defining these sleepwear garments with measurements) eased enforcement by minimizing the artificial distinction between sleepwear, underwear, and playwear. The staff believed that the tight-fitting cotton sleepwear would offer a safer alternative to consumers who want cotton garments for their children.

Legality of the Amendments

Comment:
Two commenters asserted that the amendments were issued without the proper findings of unreasonable risk required by the Flammable Fabrics Act. One commenter stated that CPSC never showed that the net effect of the amended standards on all affected children would be beneficial.

Response:
The restricted OGC memorandum responds to these commenters' position.

C. Children's Sleepwear Marketing Issues

Availability of Tight-fitting Sleepwear and Similar Garments Used as Sleepwear

Comment:
Several commenters thought that tight-fitting garments have only been available since the exemption became effective in January 1997, and, therefore, it would be difficult to determine their safety.

Response:
Non-flame resistant garments of this style (skin tight or nearly skin tight) have been used as sleepwear with increasing frequency for at least 20 years. One of the earliest indications that non-flame resistant garments were being sold and/or used as sleepwear was the 1979 petition from Bates Nitewear requesting mandatory negative labeling on thermal underwear. During the 1980's the Compliance staff saw an increase in the number of 100 percent cotton garments labeled as "long underwear" or "playwear" that appeared to be sleepwear. These garments did not comply with the standards, but were widely used as sleepwear. **(TAB D)**

Industry sources estimated that, prior to the staff's work on the amendments, the share of total sleepwear purchases accounted for by complying cotton garments was about 1-2%. The 1993 Stay of Enforcement continued until June 9, 1998, allowing the sale of skin-tight or nearly skin-tight non-flame resistant garments marketed as underwear. **(TAB E)**

Trade sources postulated that any increase in purchases of cotton sleepwear over the period of 1992 through 1996 were purchases of garments under the Stay of Enforcement (underwear used for sleepwear). Beyond that and through June 1998, consumer purchases were a combination of flame resistant and the new tight-fitting garments. According to National Purchase Diary data, cotton sleepwear (the consumer's intended use) purchases

have increased from 9.7% to 27.5% of the total sleepwear purchases from 1992 to 1998. **(Tab E)**

Effect of cotton sleepwear sales on FR (polyester) sales

Comment:
One commenter stated that with the emergence of cotton garments, flame resistant children's sleepwear would be forced out of the market. Manufacturers would find that they could not sell flame resistant sleepwear.

The American Apparel Manufacturers Association stated in their written comments that "polyester garments still dominate the market for children's sleepwear. Sales of synthetic pajamas are very strong and are expected to remain so for the foreseeable future."

Response:
Information from the National Purchase Diary shows that purchases of children's sleepwear are increasing. While the proportion of cotton sleepwear purchases is growing, the market for other sleepwear (flame resistant) has steadily increased in volume from 106.6 million in 1992 to 112.5 million garments in 1998. Flame resistant polyester garments reportedly represented over 70% of the total children's sleepwear purchases in 1998. **(TAB E)**

Garment Returns from Retail Sales

Comment:
One commenter, a major retailer of children's clothing, noted that it has experienced returns of tight fitting sleepwear at about 8% of sales, which it describes as high.

Response:
The staff expected some consumer returns of tight-fitting sleepwear during the transition period following the exemption of these garments. Manufacturers contacted by the staff late in 1998 indicated returns ranging from "negligible" to 5%, considered high. The retailer in the current comment noted that consumers were not seeking refunds, but rather were exchanging the garments. Except for some marginal costs associated with the transaction costs of the exchange, retailers are not likely to bear a significant cost burden associated with returns. With the clarification of measurements, availability of stretchable fabrics, manufacturer adjustments to new design and production demands, increasing consumer familiarity with the fit of this style of garment, the staff expects returns/exchanges to decrease. **(TAB E)**

Costs of Revocation

Comment:

Commenters noted that manufacturers and others have borne significant costs in order to produce and market tight-fitting sleepwear garments under the exemption. A trade group noted that firms changed their business practices as a result of the amendments, but they did not quantify the associated costs. A retail chain reported that revocation would cost that firm approximately $7 million.

Response:

The staff agrees that there would be some costs to manufacturers and others associated with revocation; these costs could be reduced if the effective date of the revocation were sufficient to allow manufacturers to sell off inventories of finished goods and use up supplies of any materials purchased specifically for use in production of tight-fitting cotton sleepwear. **(TAB E)**

C. Death/Injury Data Involving Children's Sleepwear

Trend in clothing-related burn fatalities

Comment:

Some commenters asserted that enactment of the sleepwear standard in 1972 reduced the number of annual sleepwear-related burn deaths from 60 to 4. Others have expressed this in reverse: there would be ten times as many deaths without the sleepwear standard.

Response:

These conclusions are incorrect because those statistics, which come from the National Center for Health Statistics (NCHS), refer to all clothing-related burn deaths. The NCHS mortality file does not distinguish sleepwear-related burn cases from other clothing-related burn cases. There is no data system in place which specifically monitors all sleepwear-related burn fatalities in the U.S. Finally, it is important to note that prior to the issuance of the Children's Sleepwear Flammability Standards in the 1970's, there were no national estimates for sleepwear-related burn injuries or deaths. The CPSC is the only entity that makes such national estimates, and CPSC was not established until 1973. Therefore, it is not possible to formally evaluate the effectiveness of the original Children's Sleepwear Flammability Standard in terms of deaths and injuries. **(TAB F)**

Are Infants Wearing Sizes 0-9 Months Immobile?

Comment:

Many commenters rejected the contention that infants wearing sizes 0-9 months are immobile. "These children may not be able to walk; however, they certainly can crawl or roll, which may put them in a situation where they may be exposed to open flame."

An industry commenter stated at the April 22 hearing that infant sizing is not true to age (it is not standardized by regulation). An infant who is 6 months of age wears a 12 month size, and an infant who is 5 months of age probably wears a 9 month size. That means that infants wearing 9 month size garments are not mobile.

Response:

In the 1994 briefing package on the proposed exemptions, CPSC staff reported from the literature that infants' first ambulatory motions usually consist of crawling-type movements, which begin around 7 to 8 months of age. Industry representatives had previously reported, as above, that infant sizing is not true to age[3] and garments of the same size, imported and domestic, vary in dimensions. Most likely, an infant 6 months or younger would be wearing garments sized 9 months and under.[4] These children are typically immobile. **(TAB G)**

Relationship of Mobility to the Risk of Burn Injury for Infants

Comments:

Many commenters rejected the claim that the risk of burn injury to infants is minimal because of their immobility. Commenters note that infants are less able to remove themselves from a potentially dangerous situation. Ignition sources also come to them. Many commenters stated that the relative immobility of infants puts them at greater risk, not less, of being severely burned in an otherwise minor conflagration.

Response:

CPSC files document several incidents in which a fire started by another child or source approached and ignited the clothing of a pre-ambulatory infant who thereby sustained severe burns from burning clothing. However, analyses of over 150 potentially survivable fire and thermal burn cases involving infants 0-9 months old from January 1990 to May 1999 in CPSC files revealed insufficient information about the type of clothing involved in these cases to conclude that there is an increased risk of sleepwear-related burn injury for pre-ambulatory infants. **(TAB F)**

Validity of CPSC data indicating a low, stable frequency of sleepwear-related thermal burn injuries

Comment:

Many commenters questioned the validity of CPSC data indicating a low, stable frequency of sleepwear-related thermal burn injuries. They asserted that "problems in the reporting of burn injuries" are partly the reason some "argue that there has been no increase in the number of burn injuries and deaths since the standard changed." The General Accounting Office (GAO) report asserted that CPSC's sleepwear burn data were both too sparse to provide reliable national estimates and subject to coding biases possibly leading to underestimation of sleepwear-related burns.

Response:

There is no reason to believe that the number of burn injuries in the U.S. is underestimated by CPSC's National Electronic Injury Surveillance System. The NEISS sample of 101 hospitals, 2.2% of the universe of 5,387 U.S. emergency-room hospitals, includes 4 or 4% of the 119 hospitals that are self-identified burn treatment centers. Further, although severely burned children may sometimes be admitted directly to burn treatment facilities, most severely burned victims are most likely taken to the nearest hospital emergency room for stabilization and then transferred to burn treatment facilities. NEISS does provide a powerful case-finding tool with 101 hospitals searching for sleepwear burns. Each case is carefully reviewed and any serious burn cases are quickly identified and investigated. A change in *frequency* of sleepwear-related pediatric burn injuries would be readily detected, while a change in *severity* would be more difficult because of the few sleepwear-related burn cases reported in NEISS. **(TAB F)**

In response to the GAO review, CPSC staff asserted that CPSC's National Electronic Injury Surveillance System (NEISS) would be sensitive to an increase in the incidence of clothing-related thermal burn injuries yet none has occurred.

Size 0-9 months exemption is likely to increase frequency of severe burn injuries

Comment:

Several commenters (physicians) gave accounts of cases where they believe flame-resistant sleepwear could or did, in their opinion, reduce the severity of the injuries sustained by infants and other children in fires. In some of these cases, children had burns on the exposed portions of their bodies while those areas covered by the flame retarded clothing were not injured. The severity of cases like these could be positively affected by a return to flame resistant sleepwear for infants.

Response:

The typical scenarios involving infants are bedding or larger room/house fires. The children's sleepwear standards were not intended to address the risk of death and injury from exposure to a whole house or bedding fire. The test method in the Standards defines the unreasonable risk from ignition and continued burning of sleepwear in terms of a three second exposure to a moderate sized flame and a requirement that the fabric self-extinguish. The ignition source in the fire scenarios mentioned by commenters is larger and more intense and sustained well beyond three seconds. Standard test methods exist that use larger, appropriate ignition sources to reproduce fire scenarios involving sheets of burning newspaper, small trash can fires, and burning rooms. The heat released and temperatures produced in the larger fire scenarios easily exceed the conditions produced by the small open flame sources.

Because of their melting and ignition temperatures and the high temperatures and sustained fire growth that occurs in these larger fire scenarios, and the many other factors affecting the outcome of an incident, flame resistant sleepwear garments cannot be counted on to provide enough protection to prevent life-threatening burn injury from occurring. A more detailed discussion of these factors is given below in the section on Fires Addressed by the Standards. **(TAB H)**

Comment:

Burn centers, burn victims, and others shared information on various burn injury cases stating that the exemptions should be revoked to prevent an increase in burn injuries.

Response:

The CPSC staff investigated all cases possible within the time constraints of this proceeding. Cases involving thermal burns from children's clothing were referred to the staff by four Shriners burn hospitals. One hundred thirty-four cases were referred to the Commission; most of these involved garments or fire scenarios not addressed by the sleepwear standard. Thirty cases meeting certain criteria relevant to this proceeding were requested for investigation; and, with permission from the hospitals and victims' families, 21 cases were assigned, expedited, and completed for the staff analysis. The CPSC in-depth investigations revealed that none of these cases involved garments exempted from the standard by the 1996 amendments or garments previously subject to the Stay of Enforcement. **(TABS F and I)**

Several commenters were burn victims or parents of burn victims. Two of the garments involved in these incidents were nightgowns. These garments must still be flame resistant under the 1996 amendments. The other case involved an infant wearing a

cotton sleeper injured in a bedding fire, a scenario not addressed by the standard.

One commenter was a burn victim whose only injury was singed hair when his "tight-fitting" (by his description) thermal underwear ignited from a stove burner. This case and another previously mentioned in Tab C of the January 1999 briefing package (tight-fitting T-shirt) are examples of how the fit of a garment can minimize injury severity when exposed to a small ignition source. **(TAB I)**

Effect of the 1996 Amendments to the Standards

Comment:
The National Fire Protection Association (CF99-1-104) commented that "the absence of data on actual injuries involving garments intended to protect children through a tight fit...is disingenuous in that it asks for proof of failure of a program not yet implemented."

The GAO report, "Injury Data Insufficient to Assess the Effect of the Changes to the Children's Sleepwear Safety Standard" **(TAB B)** suggests that CPSC's burn injury data are somehow incomplete. The report asserts that the number of burn injuries associated with children's sleepwear is unknown and that, even with reliable burn data, exposure data would be necessary to assess the relative safety of various types of sleepwear.

Response:
CPSC's burn injury data are comprehensive and reliable. The NEISS sample of 101 hospitals, 2.2% of the universe of 5,387 U.S. emergency-room hospitals, includes 4 or 4% of the 119 hospitals that are self-identified burn treatment centers. Further, although severely burned children may sometimes be admitted directly to burn treatment facilities, most severely burned victims are most likely taken to the nearest hospital emergency room for stabilization and then transferred to burn treatment facilities. NEISS provides a powerful case-finding tool with 101 hospitals searching for sleepwear burns. Each case is carefully reviewed and any serious burn cases are quickly identified and investigated. **(TAB F)**

NEISS burn injury data demonstrate that children's clothing burn injuries have not increased since the amendment of the standards. Indeed, there has been no increase for 20 years in spite of the steadily increasing use of 100% cotton tight-fitting sleepwear with the 1997 amendments and similar garments sold under the Stay of Enforcement from 1993-1998. In fact, CPSC knows of no burn incidents involving the types of children's sleepwear that the amendments affected. Because there are few

incidents, if there were to be an increase in the incidents, this fact would show up quickly in CPSC data. **(TAB B)** As noted earlier in this paper, cotton sleepwear purchases (consumer's intended use) have been steadily increasing since 1992 from 9.7% to 27.5% of total sleepwear sales.

Where there are few incidents and it is known that many consumers are exposed to the product, exposure data do not provide useful information. In such a scenario it already is known that the risk rate is extraordinarily low. The precise measurement of that low risk--which could be done with exposure data--would provide the Commission with information of academic interest only. In this case, CPSC knows that there are very few burn incidents involving sleepwear. CPSC also knows that millions of children wear various types of sleepwear. The risk of burn injury in <u>any</u> type of sleepwear is extremely low, and specifically quantifying that risk with exposure data is unnecessary. **(TAB B)**

D. Safety-Related Technical Information

Fires Addressed by the Standards

Comment:

A number of commenters expressed concerns that the exemptions would eliminate protection of children from a variety of fire scenarios, including house fires and bedding/mattress fires. Others claimed that injuries would be less severe in these cases had victims been wearing flame resistant sleepwear.

Other commenters responded by saying that while these cases are tragic and still occur, the standard (flame resistance) does not protect against injuries from house fires or the rare infant crib/bedding fires.

Response:

The children's sleepwear standards were never intended to address the risk of death and injury from exposure to a whole house or bedding fire. The intent of the sleepwear standards is to eliminate the risk of serious personal injury or death from fire as a result of contact between the sleepwear garment and a small ignition source such as a match or lighter flame. The test method reproduces this fire scenario with a three second exposure to a moderate sized flame; and the standard requires the fabric to self-extinguish.

Scenarios involving a whole house or bedding fire are quite different from a fire science perspective. The garment is not the first item ignited, therefore, the ignition source in these fire scenarios is larger and more intense and sustained well beyond three seconds. Standard test methods exist that use

larger, appropriate ignition sources to reproduce fire scenarios involving sheets of burning newspaper, small trash can fires, and burning rooms. The heat released and temperatures produced in the larger fire scenarios easily exceed the conditions produced by the small open flame sources.

Even flame resistant polyester cannot be expected to provide reliable protection from serious burn injury in these larger fires. Polyester fibers generally begin to melt between 480 and 570°F. These temperatures alone are enough to burn human skin. Polyester generally ignites and burns at temperatures exceeding 840 and 1290°F respectively. Cotton, while it does not melt, typically ignites and burns at temperatures in the range of 490 to 1560°F. Human burns occur when the skin temperature exceeds approximately 110°F which may explain how a child can, under particular circumstances, be burned on exposed skin and "protected" in areas covered by sleepwear or other garments, flame resistant or not.

Many characteristics of fabric structure and finishing influence fabric performance in fire tests, including the 3 second test of the sleepwear standards. Because of the melting and ignition temperatures of the fabrics and the high temperatures and sustained fire growth that occurs in these larger fire scenarios, and the many other factors affecting the outcome of an incident, flame resistant sleepwear garments cannot be counted on to provide enough protection to prevent life-threatening burn injury from occurring. **(TAB H)**

Comment:

One commenter stated that the tight-fitting sleepwear concept was developed and rigidly examined by CPSC for safety in all foreseeable fire scenarios.

Response:

CPSC staff reviewed available literature discussing the concept of tight-fitting and fire safety. However, even with the amendment in place, it is still the intent of the children's sleepwear standards to protect children from suffering serious thermal burn injuries due to clothing ignition from a small flame ignition source, not to safeguard them in all foreseeable fire scenarios. **(TAB H)**

Importance of fit

Comment:

A number of commenters expressed concerns that the combination of non-flame resistant material and loose fit are dangerous.

Others argued that tight fit is a reasonable choice with reduced likelihood of ignition. Although he opposed the tight-fitting exemption, one commenter gave a personal example of tight-fitting thermal underwear that only singed his hair when accidently ignited.

Response:

Garment fit, along with fiber content can influence a garment's flammability. Children's sleepwear made from cotton fabric needs to fit close to the body, to provide an acceptable level of risk. There is a great deal of information in the literature discussing the concept of tighter fitting garments being less hazardous than loose fitting garments. The ease of ignition increases when the wearer's clothing stands away from the body and the excess fabric functions as a connector to the ignition source. Without a tight fit, if ignition occurs, the oxygen under the garment and the absence of a heat sink (the body) increase the opportunity for sustained burning.

Research reported earlier by the staff[5] indicates that reasonably safe sleepwear garments can be made from cotton fabrics that do not meet the flammability requirements of the children's sleepwear standards, i.e. they do not self-extinguish. Other countries have adopted the concept of close fit in their regulations for children's sleepwear as well, but with less restrictive dimensional requirements. Comfortable, practical, tight-fitting sleepwear garments can and are being produced that are acceptable to consumers in the United States. **(TAB H)**

Fire Safety

Comment:

One commenter was convinced that non-flame resistant cotton sleepwear is dangerous when a local fire department demonstrated the burning behavior of two sleepwear garments (burned on hangers), one flame resistant and the other untreated cotton.

Response:

It is not surprising that the commenter observed that the cotton sleepwear "flamed up and burned very quickly". Light weight, cellulosic fabrics usually ignite readily when in contact with an ignition source, burn steadily, and are often difficult to extinguish. Flame resistant fabrics made from thermoplastic fibers are not as easily ignited and have a tendency to shrink away from the heat source. These fabrics self-extinguish when the flame source is removed.

The fire department demonstration did not take into account garment fit and the presence of a heat sink, major factors influencing a garment's flammability. The garments were burned

on hangers, and as stated above, a tight fit reduces the possibility of ignition occurring. If ignition of tight-fitting clothing occurs, flame spread is slower and less intense, allowing the wearer to take action sooner. Because tight-fitting clothing is less likely to support flame propagation, it is often easier to extinguish the flames. **(TAB H)**

Comment:

Commenters presented differing views concerning the relative protection offered by cotton and flame resistant garments in house and bedding fires. Medical professionals noted cases where exposed portions of a child's body were burned but portions covered by flame resistant garments were not. The National Cotton Council stated that cotton sleepwear may be slightly more protective than flame resistant garments in a crib or house fire.

Response:

The fire scenarios described above are not addressed by the children's sleepwear standards that define the protection provided in terms of self extinguishment after a 3 second exposure to a small gas burner flame. A number of variables contribute to the outcome of burn injury such as the circumstances surrounding the incident, the victim's reaction/activity, the fabric characteristics (weight, weave, finishes/treatments applied, fiber content, dyes, etc.), size of the flame and the garment location contacted by the flame, flame propagation, rate of heat transfer, presence of undergarments, etc. Much of this data cannot be obtained through investigations. The staff cannot conclude based on available data that there are substantial benefits associated with the sleepwear standards beyond those represented by the test method. (For additional discussion, refer to the earlier response on "Fires Addressed by the Standards".) **(TAB H)**

Tight-fitting, a Safe or Unproven Alternative?

Comment:

Many commenters view tight-fitting untreated cotton products as a safe, reasonable alternative based upon technical research and the lack of incidents involving these garments.

Other commenters are not convinced and consider the safety of these garments unproven. They say there is no evidence showing that tight-fitting garments will deliver safety comparable to the requirements of the original sleepwear requirements. They say there is no evidence that the safety benefits of tight-fitting garments outweigh the dangers associated with more flammable materials.

Response: Burn injuries can be reduced by requiring that sleepwear be tight-fitting when using non-flame resistant fabrics such as cotton. Commission staff has reviewed data which indicated that close fitting garments can be less hazardous even when made from a potentially flammable fabric. Studies have been conducted to examine the thermal injury data from clothing burns and the burning behavior of garments and fabrics in the laboratory. This same research also shows that the degree of fit is very important. For this reason, the amendments clearly define tight-fitting. Tight-fitting children's sleepwear must meet the definition of tight-fitting (dimensional restrictions designed to ensure contact with the body at key points) to comply with the amendments. **(TAB H)**

Upsizing Practices

Comment:

Commenters noted that parents may "upsize," that is, buy sleepwear in sizes larger than their children's current size, because they will get longer wear from the garments. In store interviews, customers indicated that if they were to purchase tight-fitting sleepwear, they would buy a larger size. Others added concerns that handing down clothes to younger children and second hand sales will interfere with parents using the correct garment size. These commenters are skeptical that the tight-fitting concept can be maintained in practice.

Response:

No information was provided by the commenters about what parents are actually doing, in terms of sizing, when they purchase the tight-fitting sleepwear. The staff contacted manufacturers and retailers for this perspective. A representative of a sleepwear retailer, based on discussions with parents during garment fittings, believes that parents would probably purchase only one size larger, otherwise the garment would be too large overall (e.g. the sleeves and legs would be too long). A manufacturer/retailer of successful tight-fitting sleepwear, does not believe their customers are upsizing.

During the development of the technical amendments in 1997, the staff observed that garments using *fabrics with adequate stretch* provided children with ample room for movement and comfort while maintaining the tight fit required by the exemption. The staff also observed children wearing garments one size larger than their age-appropriate size. The differences in garment dimensions between sizes are small. The larger garments still conformed closely to the contours of the children's bodies, touching them at many points thereby reducing the likelihood of ignition. While it is not possible to quantify a difference in protection, upsizing is undesirable.

Informational labeling is important for tight-fitting children's sleepwear to help consumers distinguish between flame resistant and non-flame resistant (tight-fitting) garments. Consumers need to be informed that certain sleepwear is no longer flame resistant and that proper fit is necessary for safety. **(TAB G)**

E. Information & Education Campaign

Comment: Many commenters criticized the voluntary information and education program as inadequate and confusing in the market place. Several commenters surveyed retail stores and reported on the mixing of garment types, inconspicuity and inconsistency of label messages, and absence of information for the consumer.

Response:

Many of these criticisms appear valid. Commenters reported that the current labeling on the hang-tags is not distinctive or conspicuous but is inter-mixed with promotional and brand literature. The hang tags are not consistent and wording on permanently-affixed labels is indistinguishable from size and washing instructions. Some commented that Spanish-speaking consumers would not be able to understand the labeling. Examples of labels currently available on tight-fitting sleepwear are shown in **TAB I.**

The enforcement policy statements were amended earlier this year to allow sleepwear meeting the definition of tight-fitting to be sold with complying (flame resistant) sleepwear. The mingling of these garments reportedly caused greater confusion because consumers cannot clearly distinguish between the two types of garments.

The staff will recommend labeling to address many of these concerns. **(TAB G)**

F. Garment Design and Production issues

Expansion of tight-fitting dimensions

Comment:

Several commenters recommended increasing slightly the dimensions, especially the upper arm, that define a tight-fitting garment exempt from children's sleepwear flammability standards. They argued that this may make the garments more attractive to parents currently avoiding tight-fitting sleepwear without compromising the garment's safety. A slightly larger garment is far safer than an oversized T-shirt.

Response:

Commission staff carefully considered the option to allow a less than tight fit for exempted children's sleepwear during the rulemaking process in amending the sleepwear standards. The reduced probability of ignition of tight-fitting clothing is related to three factors: the limited supply of oxygen from underneath the garment, the role that the body plays as a heat sink, and reduced likelihood of contacting the flame source. However, while a tighter fitting garment can reduce the possibility of the garment coming in contact with a source of ignition, a review of the literature did not reveal a specific safe level or range of fit. Commission staff concluded that for tight-fitting garments to be exempt from the children's sleepwear standards, the garment should touch the body at all critical locations. To do this, children's sleepwear garments must be equal to or less than the body dimension at these locations. Comfortable, tight-fitting sleepwear garments are currently being manufactured and successfully marketed without making additional dimensional adjustments that might diminish safety. **(TAB H)**

Sewing tolerances

Comment:

An industry commenter again requested that the standard be amended to allow specific tolerances to accommodate mass-production variances and sewing errors. Such tolerances, a long-recognized practice in the apparel industry, would provide sleepwear makers and retailers with a workable margin of error.

Response:

The Commission staff recognizes that tolerances are normally used in the production of all garments and allow for permissible variations to the pattern specifications that can occur during cutting or sewing of the garment. However the addition of a production tolerance which would increase the garment dimensions from those specified in the amended children's sleepwear standards, would result in a less than tight-fitting sleepwear garment. The importance of a tight fit has been stated earlier.

The garment dimensions specified in the standards are maximum dimensions for the seven body locations indicated. Manufacturers are allowed to sell tight-fitting sleepwear garments as long as the garment dimensions for a specific size are not exceeded. Knit fabrics are available with a sufficient degree of stretch that even if the manufacturer undercuts the fabric somewhat, the garment would still fit the intended size child.

Sleepwear garments manufactured to the dimensions specified in the sleepwear standards are currently being sold to consumers. Manufacturers are able to produce acceptable sleepwear garments through the selective use of specific knit fabrics that allow for

the necessary stretching and recovery and result in a garment that hugs the body. Through careful planning before and during the manufacturing process they build in acceptable tolerances to the pattern so that the finished garment after assembly will meet the required specifications. **(TAB H)**

G. Compliance issues

Comment:

One commenter questioned the Commission's efforts to enforce the amended standards that exempt tight-fitting sleepwear garments.

Response:

Earlier this year, the Commission staff initiated a program for CPSC investigators to inspect retail stores throughout the United States to determine whether sleepwear marketed and promoted as being tight-fitting meets the measurements required for an exemption. This program is ongoing, and the staff is conducting full investigations of firms found to be selling or manufacturing violative merchandise. The staff also learns of potential violations from firm inspections, incident investigations, and trade complaints. **(TAB D)**

V. LABELING OF TIGHT-FITTING SLEEPWEAR

A. Earlier Commission consideration of labeling

In 1995 the Commission proposed mandatory labeling for exempt tight-fitting garments. The staff was concerned that labels might be ignored, but believed that consumers should have information about these garments at the point-of-purchase. When the Commission issued the final exemptions, it did not require mandatory labeling. The Commission believed that an effective information and education campaign could educate consumers about tight-fitting sleepwear. An information label clearly visible at point-of-purchase would help consumers with their purchasing decisions. Following the Commission decision to issue the final rule, the current voluntary information and education campaign evolved. Developed cooperatively between the Commission staff and the AAMA, the campaign was ultimately implemented voluntarily by members of the industry.

B. Concerns with current voluntary labeling

Commenters, at the April 1999 hearing to discuss the proposed revocation of the 1996 amendments, were critical of current industry instructional and educational labeling efforts to inform consumers about tight-fitting sleepwear. Major problems identified by the commenters were: hang-tags that make it

difficult to distinguish between flame-resistant and tight-fitting sleepwear; hang-tags written only in the English language; absence of any type of sleepwear labeling regarding flammability; informational hang tags that are obscured by price tags and brand advertising tags; identical looking hang-tags that convey different information; and hang tags that are extremely confusing. One commenter stated that "without mandatory labeling, parents won't know what they are buying or how much their child's safety depends on the tight fit."

The staff did not anticipate the level of consumer confusion that has apparently been created in the retail environment with the marketing of the new tight-fitting sleepwear. As a result of an incomplete information and education campaign, mingling of various sleepwear garments in store displays, and inconsistent labeling, consumers are understandably confused.

Because "tight-fitting" is a new, unfamiliar concept in sleepwear sizing and fit, consumers must be educated about this change. Current voluntary labeling that identifies tight-fitting garments and informs consumers about the importance of fit is inconsistent, and often garments have no safety related labeling. The text, format, and size of the labels vary. Because of these variations, consumers do not have an easily recognizable means of identifying sleepwear garments that should be worn tight-fitting. Consumers may mistake some of these labels as promotional literature and fail to read important safety precautions.

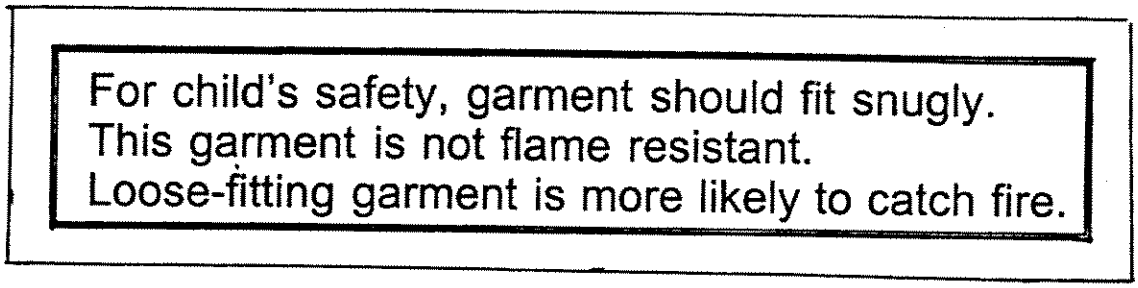
C. Improved labeling for tight-fitting sleepwear

Because of the many problems identified with current labels, the staff recommends mandatory labeling to assure that consumers are presented with vital information necessary to make informed choices in sleepwear. Mandatory labeling would require that information be presented in a consistent and attention-getting style. All tight-fitting sleepwear would be required to have uniform labeling that would distinguish it from flame-resistant sleepwear. As consumers become familiar with the labeling, it should help make informed selection of sleepwear easier and quicker. The term "snug-fitting" rather than "tight-fitting" is used on the labels and brochures of the voluntary information and education campaign. The staff continues to use "snug-fitting" in the recommended labels to help consumers better understand and accept the fit necessary for these garments made of stretchy fabrics.

Two types of labeling for tight-fitting sleepwear are recommended--hang tags and permanently affixed labeling. Hang tags would inform consumers at the point-of-purchase about the tight-fitting requirements. The permanent labeling would distinguish, over the long term, tight-fitting sleepwear from

other types of sleepwear and reinforce the information presented on the hang tag.

The hang tag should be 1 1/2 in. x 6 1/4 in. with the boxed, black text (Arial 18pt) on a yellow background:



Where garments are sold in packages, the package should be prominently, conspicuously, and legibly labeled with a smaller version of this hang tag message.

The permanent label should read "Wear Snug-fitting, Not Flame Resistant", Arial 11pt, boxed and located on the front of the garment size label, readily visible near the center back of the garment.

The explicit language of the labels will help consumers pay attention to and understand the safety information. These labels will provide safety information that is consistent for all non-flame resistant sleepwear and that can be readily distinguished from promotional and other types of information displayed on the garment or packaging. The staff considered practical cost implications of labeling and attempted to avoid unnecessary restrictions of common industry labeling practices and packaging. See **TAB G** for details of the labeling provisions.

The staff recommends a 12 month effective date for new labeling requirements. The period of time from which orders are taken, goods produced, and shipped for sale is about nine months and can be longer for imported goods. An effective date of 12 months would be least disruptive and would provide for an orderly transition for manufacturers to adapt existing labels and hang tags to those recommended here. **(TAB E)**

VI. CONCLUSIONS

The staff has reviewed thermal burn death and injury data involving children's clothing (especially sleepwear), the GAO reports on burn data and the information and education campaign, updated marketing information, and the written and oral comments provided by the public during this proceeding and concludes the following:

1. The risk of burn injury or death from all clothing, including sleepwear, remains low.

Continued monitoring of death/injury data over the last 20 years indicates that there is still no change since the exempt infant size and tight-fitting sleepwear (and similar garments exempted under the Stay of Enforcement) have been available in significant quantities. Deaths and injuries are still low for all children's clothing, including sleepwear. Recent investigations of cases, including those from burn centers, identified no cases involving exempt garments ignited by small open flame ignition sources.

Sales of cotton sleepwear have risen to 27.5% of total sleepwear sales; sales of flame-resistant (mostly polyester) sleepwear have also increased. Even if parents are buying tight-fitting garments in a larger size, as a number of commenters believe and one retailer has observed, there are no known incidents involving these garments.

There continues to be no evidence that exempted garments and their similar predecessors have caused an increase in children's thermal burn injuries or deaths. Finally, since there were no national estimates for sleepwear-related burn injuries or deaths before the standards were issued in the 1970's, it is not possible to formally evaluate the effectiveness of the standards in terms of deaths and injuries as some commenters have suggested.

2. Assertions that flame resistant garments provide protection beyond a short exposure to a small open flame are not justified.

Commenters claimed that flame resistant garments could protect (or reduce the severity of injuries) to children from a variety of fire scenarios, including house fires and bedding/mattress fires. The available incident data and the fire science do not support this contention.

The intent of the sleepwear standards is to address the unreasonable risk of injury or death from fire as a result of contact between the sleepwear garment and a small ignition source such as a match or lighter flame. The test method in the standards reproduces this fire scenario with a three second exposure to a moderate sized flame; and the standard requires the fabric to self-extinguish. The children's sleepwear standards were not intended to address the risk of death and injury from exposure to a whole house or bedding fire. The ignition source in these fire scenarios is larger and more intense and sustained well beyond three seconds. The heat released and temperatures produced in the larger fire scenarios easily exceed the conditions produced by small open flame sources.

Because of the melting and ignition temperatures of the fabrics and the high temperatures and sustained fire growth that occur in these larger fire scenarios, and the many other factors affecting the outcome of an incident, flame resistant sleepwear garments cannot be counted on to provide enough protection to prevent life-threatening burn injury from occurring.

The staff cannot conclude based on available data that there are substantial benefits associated with the sleepwear standards beyond those represented by the test method.

3. The current voluntary information and education campaign has proved to be inadequate and confusing to consumers.

Consumer information provided by voluntary labeling and in-store signage is judged by many to be inadequate. The staff did not anticipate the level of consumer confusion that has apparently been created in the retail environment with the marketing of the new tight-fitting sleepwear. As a result of an incomplete information and education campaign, mingling of various sleepwear garments in store displays, and inconsistent labeling, consumers are understandably confused.

Consequently, the staff recommends mandatory labeling be required for tight-fitting sleepwear. Standardized informative hang tags and permanent labels identifying sleepwear that must be worn snug-fitting for safety are expected to address many of the criticisms expressed by the public commenters. Consumers should be better able to use this information to make informed choices in purchasing and safely using the various sleepwear alternatives.

4. Reference corrections need to be made in 16 CFR 1615 (the 0-6X standard).

There are several errors in paragraph references in Rules and Regulations sections because of the 1996 amendment adding the infant size exemption to 0-6X standard. These are minor, but should be corrected with a separate, short FR notice.

VII. OPTIONS

A. Revoke amendments exempting infant sleepwear size 9 months and under and tight-fitting sleepwear in larger sizes

B. Issue further amendments (labeling for tight-fitting sleepwear)

C. Retain current regulations (1996 amendments and subsequent amendments)

D. Correct reference errors in 16 CFR 1615 (the 0-6X standard)

VIII. RECOMMENDATION

The staff recommends that the proposed revocation notice be withdrawn, that references in the 0 to 6X standard that were affected by the 1996 amendments be corrected, and that the sleepwear standards be further amended to require labeling of tight-fitting garments in order to assure that consumers are informed that the risk of fire injury is related to garment fit and so they can correctly identify garments that must be worn snug-fitting for safety.

Draft *Federal Register* notices are attached at **TAB J** for each of the recommended actions. The revocation withdrawal and corrections of 16 CFR 1615 would both be effective immediately upon publication. Taking into account industry production cycles, the staff recommends a 12 month effective date for new labeling requirements. **(TAB E)**

References

1. Original Children's Sleepwear Standards--FR Vol. 36, No. 146, July 29, 1971, Notices (final rule).

2. CPSC Briefing Package: Sleepwear Evaluation Project, Terrance R. Karels, Project Manager, November 3, 1992.

3. CPSC Briefing Package Children's Sleepwear Project, Terrance R. Karels, Project Manager, October 11, 1995.

4. "Statement of Commissioner Thomas Hill Moore on the Children's Sleepwear Flammability Standard", April 30, 1996.

5. CPSC Briefing Package: Children's Sleepwear Project, TAB E, July 19, 1994.

Tab A

(Lat. 42°52' 51" N., long. 85°31' 22" W)

Spectrum Medical Center/Downtown Campus, MI Point in Space Coordinates (Lat. 42°57' 09" N., long. 85°39' 48" W)

That airspace extending upward from 700 feet above the surface within a 7.0-mile radius of Kent County International Airport, and within a 6.0-mile radius of the Point in Space serving Spectrum Medical Center/ Downtown Campus, excluding that airspace within the Sparta, MI, Class E airspace area.

* * * * *

Issued in Des Plaines, Illinois on December 31, 1998.

Michelle M. Behm,

Acting Manager, Air Traffic Division.

[FR Doc. 99-1101 Filed 1-15-99; 8:45 am]

BILLING CODE 4910-13-M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1615 and 1616

Proposed Revocation of Amendments; Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X; Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed Revocation of Amendments.

SUMMARY: As directed by the fiscal year 1999 appropriations legislation for the Departments of Veterans Affairs and Housing and Urban Development, and several independent agencies, including the Consumer Product Safety Commission, the Commission proposes to revoke certain amendments to the standards for the flammability of children's sleepwear, sizes 0 through 6X and sizes 7 through 14.

DATES: Written comments concerning this proposed revocation are due not later than March 22, 1999.

ADDRESSES: Comments should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207; telephone: (301) 504-0800 or delivered to the Office of the Secretary, Room 501, 4330 East-West Highway, Bethesda, Maryland 20814. Comments should be submitted in five copies and captioned "Sleepwear Revocation." Comments may also be filed by telefacsimile to (301) 504-0127 or by e-mail to cpsc-os@cpsc.gov.

FOR FURTHER INFORMATION CONTACT: Margaret L. Neily, Project Manager, Directorate for Engineering Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504-0508, extension 1293.

SUPPLEMENTARY INFORMATION:

A. Background

The Consumer Product Safety Commission enforces two flammability standards for children's sleepwear. The flammability standard for children's sleepwear in sizes 0 through 6X is codified at 16 CFR Part 1615. The flammability standard for children's sleepwear in sizes 7 through 14 is codified at 16 CFR Part 1616.

On September 9, 1996, the Commission issued a final rule amending the flammability standards for children's sleepwear to exclude from the definition of "children's sleepwear," codified at 16 CFR 1615.1(a) and 1616.2(a), (1) garments sized for infants nine months of age or younger and (2) tight-fitting garments for children older than nine months. 61 FR 47634. In addition, on January 12, 1999, the Commission voted to issue technical changes to the September 9, 1996 amendments. At the same time, the Commission amended the policy statements at 16 CFR 1615.64(d) and 1616.65(d) so that infant garments and tight-fitting garments can be marketed and promoted with other sleepwear.

B. Legislation

The bill providing fiscal year 1999 appropriations for the Commission and other agencies was enacted on October 21, 1998. Public Law 105-276. Section 429 of that law requires the Commission to propose, for comment, to revoke the 1996 amendments to the sleepwear standards, along with any subsequent amendments, not later than 90 days after October 21, 1998. The law also requires the General Accounting Office ("GAO") to review burn incident data from the ignition of children's sleepwear from small open-flame sources for the period July 1, 1997 through January 1, 1999. The review must be completed by April 1, 1999 and be submitted to the Congress and the Commission.

Based on the GAO findings and other available information, the Commission is required to issue a final rule by July 1, 1999. The final rule must (1) revoke, (2) maintain, or (3) modify the 1996 and other later amendments of the flammability standards for children's sleepwear. The rulemaking conducted with respect to this matter is not subject to (1) the Consumer Product Safety Act, 15 U.S.C. 2051 *et seq.*, (2) the Flammable Fabrics Act, 15 U.S.C. 1191 *et seq.*, (3) the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, (4) the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*, (5) the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104-121, or (6) any other statute or Executive order.

Based on the foregoing, the Commission proposes to revoke the September 9, 1996 amendments, and subsequent amendments, including the technical amendments and the amendment to the policy statements. The following amendments would reinstate the substance of flammability standards for children's sleepwear as they existed before the 1996 and later amendments.

List of Subjects in 16 CFR Parts 1615 and 1616

Clothing, Consumer protection, Flammable materials, Infants and children, Labeling, Records, Sleepwear, Textiles, Warranties.

Conclusion

Pursuant to Public Law 105-276, the Commission proposes to amend 16 CFR parts 1615 and 1616 as follows:

PART 1615—STANDARD FOR THE FLAMMABILITY OF CHILDREN'S SLEEPWEAR: SIZES 0 THROUGH 6X

1. The authority citation for part 1615 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569-70; 15 U.S.C. 1193.

2. Paragraph 1615.1 is amended by removing paragraph (c).

3. Paragraphs 1615.1(d) through (n) are redesignated paragraphs 1615.1(c) through (m), respectively.

4. Section 1615.1 is amended by removing paragraph (o) and revising paragraph (a), to read as follows:

§ 1615.1 Definitions.

* * * * *

(a) Children's Sleepwear means any product of wearing apparel up to and including size 6X, such as nightgowns, pajamas, or similar or related items, such as robes, intended to be worn primarily for sleeping or activities related to sleeping. Diapers and underwear are excluded from this definition.

* * * * *

5. Section 1615.64 is amended by revising paragraph (d) introductory text to read as follows:

§ 1615.64 Policy to clarify scope of the standard.

* * * * *

(d) Retailers, distributors, and wholesalers, as well as manufacturers, importers, and other persons (such as converters) introducing a fabric or garment into commerce which does not meet the requirements of the

flammability standards for children's sleepwear, have an obligation not to promote or sell such fabric or garment for use as an item of children's sleepwear. Also, retailers, distributors, and wholesalers are advised not to advertise, promote, or sell as an item of children's sleepwear any item which a manufacturer, importer, or other person (such as a converter) introducing the item into commerce has indicated by label, invoice, or otherwise, does not meet the requirements of the children's sleepwear flammability standards and is not intended or suitable for use as sleepwear. Additionally, retailers are advised:

* * * * *

PART 1616—STANDARD FOR THE FLAMMABILITY OF CHILDREN'S SLEEPWEAR: SIZES 7 THROUGH 14

1. The authority for part 1616 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–570; 15 U.S.C. 1193.

2. Section 1616.2 is amended by removing paragraph (m) and revising paragraph (a) to read as follows:

§ 1616.2 Definitions.

* * * * *

(a) Children's sleepwear means any product of wearing apparel size 7 through 14, such as nightgowns, pajamas, or similar or related items, such as robes, intended to be worn primarily for sleeping or activities related to sleeping. Underwear and diapers are excluded from this definition.

* * * * *

3. Section 1616.65 is amended by revising paragraph (d) introductory text to read as follows:

§ 1616.65 Policy scope of the standard.

* * * * *

(d) Retailers, distributors, and wholesalers, as well as manufacturers, importers, and other persons (such as converters) introducing a fabric or garment into commerce which does not meet the requirements of the flammability standards for children's sleepwear, have an obligation not to promote or sell such fabric or garment for use as an item of children's sleepwear. Also, retailers, distributors, and wholesalers are advised not to advertise, promote, or sell as an item of children's sleepwear any item which a manufacturer, importer, or other person (such as a converter) introducing the item into commerce has indicated by label, invoice, or, otherwise, does not meet the requirements of the children's sleepwear flammability standards and is not intended or suitable for use as sleepwear. Additionally, retailers are advised:

* * * * *

Dated: January 13, 1999.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 99–1140 Filed 1–15–99; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 1 Through 124

[USCG–1999–4975]

Regulatory Flexibility Act Section 610 Review

AGENCY: Coast Guard, DOT.

ACTION: Notice of regulatory review; request for comments.

SUMMARY: The Coast Guard requests comments on the economic impact of our regulation on small entities. As required by the Regulatory Flexibility Act and as published in the Department of Transportation's (DOT) Semi-Annual Regulatory Agenda, we are analyzing our first group of regulations during fiscal year 1999 to identify rules which may have a significant economic impact on a substantial number of small entities. At the end of this year of analysis, we will publish a list of those regulations that may have a significant economic impact on a substantial number of small entities and seek public comment on how we can reduce the burden on small entities.

DATES: Comments must reach the Docket Management Facility on or before April 19, 1999.

ADDRESSES: You may mail comments to the Docket Management Facility, (USCG–1999–4975), U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington DC 20590–0001, or deliver them to room PL–401, located on the Plaza Level of the Nassif Building at the same address between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

The Docket Management Facility maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at room PL–401, located on the Plaza Level of the Nassif Building at the same address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also access this docket at the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: For questions on this document, contact Ms. Christena Green, Office of Regulations and Administrative Law (G–LRA), U.S. Coast Guard Headquarters, Room 3406, telephone 202–267–0133. For questions or viewing or submitting material to the docket, contact Dorothy Walker, Chief, Dockets, Department of Transportation, telephone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages you to participate in our review of regulations by submitting written data, views, or arguments. If you submit comments, you should include your name and address, identify this notice (USCG–1999–4975) and the specific rule to which your comments apply, and give the reason for each comment. Please submit all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing to the DOT Docket Management Facility at the address under **ADDRESSES.** If you want acknowledgment of receipt of your comments, you should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period.

Although the Coast Guard has not scheduled a public meeting concerning this request for comments, you may request a public meeting by submitting a request to the address under **ADDRESSES.** The request should include the reasons why a meeting would be beneficial. If we determine that a public meeting should be held, we will hold the meeting at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

In 1980, Congress passed the Regulatory Flexibility Act (RFA), Public Law 96–354, requiring periodic review of those regulations that have a significant economic impact on a substantial number of small entities. The Department of Transportation (DOT) published its Semiannual Regulatory Agenda on November 9, 1998, listing in Appendix D (63 FR 62857) those regulations each modal agency will review under Section 610 of the RFA during the next 12 months to see if the agency can minimize their burden on small entities.

Appendix D also contains DOT's 10-year review plan for all of its existing

Tab B

United States General Accounting Office

GAO

Report to Congressional Committees and the Consumer Product Safety Commission

April 1999

CONSUMER PRODUCT SAFETY COMMISSION

Injury Data Insufficient to Assess the Effect of the Changes to the Children's Sleepwear Safety Standard

41

Printed copies of this document will be available shortly

GAO/HEHS-99-64

GAO

United States
General Accounting Office
Washington, D.C. 20548

Health, Education, and
Human Services Division

B-281912

April 1, 1999

To Congressional Committees and
the Consumer Product Safety Commission

In the late 1960s and early 1970s, reports of children being severely burned when their nightgowns or pajamas caught fire caused concern over the safety of children's sleepwear. As a result, in 1972 the federal government implemented a safety standard that required children's sleepwear to be flame-resistant.[1] In 1996, the Consumer Product Safety Commission (CPSC) amended this standard to exempt "snug-fitting" sleepwear and sleepwear for children 9 months old or younger.[2] Although some industry and consumer advocates applauded this decision, others (including some fire prevention groups) expressed concern that the 1996 changes could lead to an increase in the number of children injured. The fiscal year 1999 Appropriations Act covering CPSC and its accompanying conference report directed us to review the data available on burn injuries to children and to discuss the implications of these data for the effect of the recent amendments to the sleepwear standard. Specifically, this report addresses the following questions: (1) how many burn injuries involving children's sleepwear occurred annually before and after the amendments? and (2) what conclusions, if any, can be drawn from these data about the effect of the changes to the sleepwear standard on the risk of injury?

To do our work, we obtained and analyzed data on burn injuries to children involving clothing in general and children's sleepwear in particular from CPSC and other sources. We reviewed the regulations related to children's sleepwear and the agency's documentation supporting these regulations. We also interviewed CPSC staff, health and consumer advocates, and industry representatives to obtain information about burn injuries and the sleepwear standard. We did our work between January and March 1999 in accordance with generally accepted government auditing standards.

Results in Brief

The exact number of burn injuries associated with children's sleepwear before and after CPSC amended its standard is uncertain. Although CPSC collects some burn injury data from

[1]Unless otherwise indicated, in this report dates associated with regulations refer to the year a regulation became effective.

[2]Sleepwear is considered snug-fitting under this standard if it follows prescribed measurements and if it touches a child's body at seven crucial points: the chest, waist, seat, thigh, ankle, wrist, and upper arm.

a sample of hospital emergency rooms, few sleepwear-related injuries are reported annually. For example, over the period 1990-98, CPSC's sample of about 100 hospital emergency rooms reported a total of only 13 burn injuries that involved children's sleepwear. This included a maximum of four cases in any one year, and in some years—including 1998—no cases were reported at all. Consequently, although the overall risk of injury appears to be small, these data cannot produce precise national estimates, making it difficult or impossible to observe trends in the number of injuries over time.

Even if more precise data were available, it would not be possible to draw firm conclusions from burn injury data about the effect of the changes to the standard without other equally crucial but unobtainable information. Assessing the effect of the sleepwear standard would be particularly difficult because multiple factors contribute to burn injuries, including the ignition source, the child's behavior, and the fabric and fit of the child's clothing. Furthermore, using injury information to compare the risks associated with different types of sleepwear (such as snug-fitting cotton versus flame-resistant polyester) would also require information on how many consumers actually use each type. Without such data, it would be difficult or impossible to distinguish the type of sleepwear associated with the most injuries from the type of sleepwear most commonly used. However, this information was not gathered for the period before the changes in the standard, and it is not yet available for the period since the final changes to the standard were made. In the absence of these key data, and without baseline data for comparison, it is not possible to determine the effect of the sleepwear amendments on the risk of injury to children.

Background

CPSC was established in 1972 under the Consumer Product Safety Act (P.L. 92-573) to regulate consumer products that pose an unreasonable risk of injury, to assist consumers in using products safely, and to promote research and investigation into product-related deaths, injuries, and illnesses. CPSC has the authority to issue regulations that establish performance or labeling standards for consumer products. In addition, CPSC may order a product recall, in which an item is removed from store shelves and consumers are alerted to return the item for repair, replacement, or refund.[2] Although the agency has broad regulatory powers, much of its efforts are carried out by nonregulatory methods. CPSC often assists in the development or improvement of voluntary safety standards and addresses product hazards by providing safety information to consumers.

With about 15,000 consumer products under its jurisdiction, CPSC has to carefully consider which potential product hazards it will address. The agency has established criteria for setting priorities to keep within its budget ($47 million in fiscal year 1999). These criteria include, among others, the frequency and severity of injuries and deaths, the extent to which a hazard is likely to be reduced through CPSC's action, and whether the hazard affects vulnerable populations, such as children or the elderly. CPSC staff provide information on

[2]In practice, CPSC rarely uses its regulatory power to order a recall; instead, the agency usually works cooperatively with manufacturers to carry out recalls.

these criteria and other factors to the agency's three commissioners, who must approve all regulatory changes by a majority vote.[4]

In response to widespread concern about the number of burn injuries and deaths caused by ignited clothing, the Congress passed the Flammable Fabrics Act in 1953 to legislate a general flammability standard for all clothing. In 1972, before CPSC was established, the Department of Commerce implemented an additional, stricter flammability standard for children's sleepwear.[5] The Department of Commerce's conclusion that a more stringent standard was necessary for children's sleepwear was based on anecdotal reports of approximately 100 incidents, including news coverage of a 4-year-old Minnesota child who suffered third-degree burns when her pajama top caught fire.

The 1972 standard required that fabrics used for children's sleepwear self-extinguish when exposed to a small open flame. The standard did not prescribe specific fabrics or require flame-retardant treatments. However, while some fabrics, mostly polyester, met the requirement without treatment, others, mostly cotton, would do so only if treated with a flame-retardant chemical. In the 1970s, the chemical generally known as tris was widely used to treat sleepwear, until it was classified as a potential carcinogen and all garments treated with it were pulled from the marketplace. In the absence of tris, polyester became widely used to manufacture children's sleepwear since it generally could meet the standard without being treated with a flame-retardant chemical.

In the 1980s, however, many consumers began to express a demand for natural fibers, such as cotton, for children's sleepwear. To meet this demand, retailers began stocking cotton and cotton blend long underwear sets that did not meet CPSC's flammability standard for children's sleepwear, sometimes intermingling them with flame-resistant sleepwear on children's sleepwear racks. CPSC compliance staff, consumer groups, and industry sources agreed that enforcing the standard had become difficult and required a significant amount of agency resources.

As a result, in 1991 CPSC decided to begin work to reexamine the children's sleepwear standard. In 1994, it formally proposed to amend the sleepwear standard to exempt snug-fitting sleepwear for children and all sleepwear for children younger than 6 months old. CPSC relied primarily on laboratory and analytical evidence, rather than injury data, to support its proposal. (Because the prohibition against marketing children's sleepwear made from non-flame-resistant materials had been in effect for 20 years, only very limited data were available on injuries that had occurred under alternatives to the existing sleepwear standard.) CPSC stated that garments are safer if they fit closer to the body because (1) there is less trapped air for combustion, so the sleepwear will burn less intensely and may self-extinguish, and (2) there is a reduced possibility for contacting an ignition source. CPSC also expressed concern that enforcing a ban against marketing long underwear as sleepwear might prompt consumers to substitute loose-fitting cotton and cotton blend garments, such as oversized T-

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[4]CPSC currently has three commissioners, who are responsible for establishing agency policy. One of these commissioners is designated the chairman; the chairman directs the executive and administrative functions of the agency.

[5]The 1972 sleepwear standard covered only sizes 0 to 6X; in 1975, CPSC extended the children's sleepwear standard to sizes 7 through 14.

shirts, which CPSC believed to be more hazardous. Furthermore, CPSC stated that children younger than 6 months old are relatively immobile and therefore unlikely to go near an ignition source. When CPSC announced its proposal to amend the standard, it issued a stay of enforcement that allowed manufacturers and retailers to sell long underwear or snug-fitting sleepwear that were similar to the proposed exemptions.

In April 1996, a majority of the commissioners voted to amend the children's sleepwear standard to exempt snug-fitting sleepwear and all infants' clothing up to size 9 months. The revised standard became effective in January 1997, but CPSC continued to work on technical revisions after that date. While making the final changes to the standard, and to allow manufacturers to adapt their production processes, CPSC continued the stay of enforcement for snug-fitting underwear or sleepwear until June 1998. Snug-fitting sleepwear garments meeting the revised standard were made widely available to consumers during the fall 1998 selling season. The final technical changes to the sleepwear standard were published on January 19, 1999.

Few Data Are Available on Burn Injuries Involving Children's Sleepwear

The number of burn injuries associated with children's sleepwear is uncertain, and few data are available. Some information on sleepwear-related injuries can be obtained from CPSC's National Electronic Injury Surveillance System (NEISS), which gathers data from a statistical sample of 101 hospitals across the United States that have emergency rooms.[4] NEISS has a broad focus and is intended to allow CPSC to collect data on injuries associated with a wide variety of consumer products, rather than being designed to capture information on specific types of injuries such as burns.

Unlike other national data sources, NEISS can distinguish burn injuries associated specifically with sleepwear from burns associated with other clothing. However, very few cases were reported under NEISS's sleepwear code, and the actual number of annual injuries is uncertain. For example, over the period 1990-98, NEISS reported a total of only 13 cases. This included a maximum of four sleepwear cases annually, and in some years, including 1998, no cases were reported at all. Consequently, although the overall risk of injury appears to be small, these data cannot produce precise national estimates, making it difficult or impossible to observe trends in the number of injuries over time. Data from other sources—for example, the National Fire Incident Reporting System (NFIRS), compiled by the U.S. Fire Administration—are even less useful, because these databases were not designed to permit distinctions between sleepwear and other clothing.

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[4]This representative sample includes about 2 percent of the 5,297 hospitals in the United States that have more than six beds and also have 24-hour emergency rooms. Although a few hospitals with burn centers are included in the NEISS sample, NEISS does not focus on burns specifically but is intended to provide a representative sample of hospitals that treat a wide variety of product-related injuries. For more information on NEISS and other data sets CPSC uses, see Consumer Product Safety Commission: Better Data Needed to Help Identify and Analyze Potential Hazards (GAO/HEHS-97-147, Sept. 29, 1997).

In addition, national data on burn injuries must be interpreted cautiously because these data necessarily provide only limited detail about the circumstances surrounding each individual case. Most significantly, none of these sources provides information on whether the clothing or sleepwear involved in the injuries would meet the children's sleepwear standard.[7]

To obtain additional information on the circumstances surrounding burn injuries to children, CPSC conducted further investigations of selected cases. Rather than focus exclusively on reported cases that involved garments designed as sleepwear, CPSC investigated selected cases involving all types of clothing. Although CPSC's safety standard applies only to garments specifically intended for use as sleepwear, such as nightgowns and pajamas, parents and children often use other types of clothing—including T-shirts, sweat shirts, and long underwear—for sleeping. Injuries associated with these garments are generally not reported under NEISS's sleepwear code, even if the garments were used for sleeping. Instead, such cases may be recorded under the more general category of clothing-related burns.

To obtain more detailed data on these injuries, as well as others involving garments designed specifically as sleepwear, CPSC conducted special investigations of selected clothing-related burn injuries that occurred between 1993 and 1998. During each investigation, CPSC staff interviewed family members and asked detailed questions about the incident. For example, CPSC's investigation protocol for these cases calls for staff to ask questions about the time of the accident, the room in which the accident took place, the part of clothing that first caught fire, and the age of the clothing.

Many of the injuries represented in the cases CPSC chose to investigate were severe; for example, one 8-year-old boy suffered third-degree burns and had to be hospitalized for a month at a specialized burn center. In addition, most of these injuries were associated with garments that are beyond the scope of CPSC's sleepwear standard. For example, of the 40 cases CPSC investigated involving garments used for sleeping, 28 (or 70 percent) involved oversize or loose-fitting T-shirts.[8] An additional six cases involved nightgowns or nightshirts. Of the remaining cases, three involved traditional flame-resistant sleepwear, one involved a tight-fitting T-shirt, and two involved cotton pajamas.[9] With so few incidents involving

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[7]Neither NEISS nor NFIRS was intended to account for all sleepwear-related injuries. For example, NEISS includes only injuries treated in hospital emergency rooms—not injuries treated in other settings such as a physician's office, outpatient clinic, or walk-in medical center. Given the acute and severe nature of clothing-related burn injuries, however, NEISS's emergency room data would probably include information on many such injuries. More seriously, as CPSC staff pointed out, data systems such as NFIRS that rely on reports from fire departments would miss burn injuries in which a child or parents were able to put out the flames without assistance from the fire department. Consistent with this hypothesis, of 40 such cases CPSC investigated, the fire department was called in only nine.

[8]Thirty-four of these 40 cases were reported to CPSC through NEISS, four cases came to CPSC's attention through newspaper clippings, and the other two were reported directly to CPSC by consumers.

[9]In one of these two cases, CPSC obtained and measured the cotton pajamas involved in the incident and determined that they did not meet the specifications of the new sleepwear standard. In the other case, the pajamas were not available for examination; however, CPSC staff believed, on the basis of information provided by the child's mother, that these pajamas did not comply with the sleepwear standard. The patterns CPSC reported in these investigations are consistent with data from other sources. For example, we reviewed case files from one burn center that was not included in CPCS's NEISS sample. These cases involved 12 injuries to children younger than 15 in 1997 and 1998 that the staff at the burn center identified as involving sleepwear. Many of these children suffered severe and debilitating injuries, including third-degree burns, serious lung injuries, and psychological damage. Although burn center staff did not have information on the fabric content of the children's sleepwear,

garments subject to the standard, these investigations can provide CPSC with only limited ability to assess the relative number of injuries associated with different types of covered sleepwear.

Costly Additional Information Would Be Needed to Draw Firm Conclusions About the Effect of the Changes to the Sleepwear Standard

Without valid and precise information on injuries associated with different types of sleepwear both before and after the amendments, it is not possible to use injury data to draw firm conclusions about the actual effect of the changes to the children's sleepwear standard. Even if these basic data were available, assessing the effect of the sleepwear standard would be particularly difficult because multiple factors contribute to burn injuries, including the ignition source, the child's behavior, and the fabric and fit of the child's clothing. Determining the role of any single factor, including sleepwear type, can be difficult. For example, in one case we reviewed a 6-year-old girl accidentally backed into an open space heater that quickly set the nightgown she was wearing on fire. It is uncertain whether either reducing the flammability of the nightgown or improving the design or performance of the space heater could have prevented her injury.

Moreover, using injury information to compare the risks associated with different types of sleepwear (such as snug-fitting cotton versus flame-resistant polyester) would require information on how many consumers actually use each type. Without such data, it would be difficult if not impossible to distinguish the type of sleepwear associated with the most injuries from the type of sleepwear most commonly used. For example, if one type of sleepwear were associated with twice as many injuries, but four times as many children used it, the risk of injury to each individual child might actually be lower. Garments designed specifically to meet the amendments' criteria for snug-fitting pajamas have been widely available to consumers for only a short time. Consequently, data on consumers' response to the newly available styles are not yet available and may not represent the patterns of use that will prevail in the future. In the absence of these key data, and without baseline data for comparison, it is not possible on the basis of injury data to determine whether one type of sleepwear or clothing is truly more hazardous than another.

Although the precise effect of the changes to the standard remains unknown, if additional data were to become available CPSC could use this information as it studies sleepwear-related injuries and informs consumers about ways to help prevent them. However, obtaining such information would be both difficult and costly. To obtain better data on the number of injuries, CPSC would need to either expand the number of hospitals in the NEISS sample or design and implement another large data collection effort. To obtain data on the number of each different type of sleepwear in use, CPSC would also need to undertake an additional data collection effort, as existing market data are not designed to capture information at this level of detail. Finally, to obtain additional detail on the circumstances surrounding burn injuries, CPSC would have to invest additional resources into conducting

for nine cases they noted the general type of sleepwear. The results from this small group were similar to those CPSC found—six of the nine cases involved loose-fitting nightgowns or shirts.

investigations of selected incidents. In allocating its limited resources, CPSC has to consider its needs for additional data on the many other potential product hazards within its extensive jurisdiction, as well as children's sleepwear issues.

Agency Comments

We provided a draft of this report to CPSC for its review and comment. In its response, the agency stated that CPSC's burn injury data are comprehensive and reliable and demonstrate that children's burn injuries have not increased since the amendments to the sleepwear standard. We disagree. Although few cases are reported and the overall risk appears to be small, CPSC's data can produce only imprecise national estimates, making it difficult to observe trends in the number of injuries over time. CPSC's data include only 13 observations over 9 years—a period that extends from before the changes to the standard and the stay of enforcement were proposed to 2 years after the amendments were enacted. As a result, we are unable to draw firm conclusions about trends in the number of injuries over time. We made several changes to the language of the draft report to clarify the reasons for our conclusions.

CPSC's response also stated that the agency's staff do not rely solely on injury data for its continued support of the amendments but consider other information such as laboratory and analytical evidence. We agree that it is important to consider these other types of information in examining the changes to the standard. However, because our analysis focused only on burn injury data, an evaluation of these other types of information is beyond the scope of this report.

Finally, CPSC commented that because relatively few incidents are reported, exposure data (information about how many consumers actually use each sleepwear type) would not be helpful in assessing the relative safety of various types of sleepwear. Again, we disagree with CPSC's view. Although exposure data might be of limited use in quantifying the risk associated with all sleepwear types as a group, such data would be necessary if injury data were to be used to compare the risks associated with different specific types of sleepwear (such as the snug-fitting cotton allowed under the amended regulations and the flame-resistant fabrics required under the previous standard). Without such data, it would be difficult or impossible to distinguish the type of sleepwear associated with the most injuries from the type of sleepwear most commonly used. For example, of the sleepwear-related burn incidents CPSC investigated, CPSC staff believe that three cases involved traditional flame-resistant sleepwear and no cases involved snug-fitting cotton pajamas. Without the additional context provided by exposure data, this information could be misinterpreted to indicate that snug-fitting cotton pajamas are safer than traditional flame-resistant sleepwear. Although exposure data are useful, we recognize that they can be difficult and costly to collect. As we stated in our report, CPSC has to consider its needs for additional data on many other potential product hazards in allocating its resources.

CPSC also made technical comments about the report that we incorporated as appropriate. CPSC's comments appear in the appendix.

We are sending copies of this report to appropriate congressional committees and we will also make copies available to others upon request. If you or your staff have any questions about this report, please contact Marlene S. Shaul, Associate Director, or Larry Horinko, Assistant Director, at (202) 512-7014. Major contributors to this report include Sarah L. Glavin and Sheila R. Nicholson.

Marnie S. Shaul
Associate Director, Education,
Workforce, and Income Security Issues

William F. Scanlon
Director, Health Financing
and Public Health Issues

List of Addressees

The Honorable Christopher S. Bond, Chairman
The Honorable Barbara A. Mikulski, Ranking Minority Member
Subcommittee on VA, HUD, and Independent Agencies
Committee on Appropriations
United States Senate

The Honorable James T. Walsh, Chairman
The Honorable Alan B. Mollohan, Ranking Minority Member
Subcommittee on VA, HUD, and Independent Agencies
Committee on Appropriations
House of Representatives

The Honorable Ann Brown, Chairman
Consumer Product Safety Commission

The Honorable Mary Sheila Gall, Commissioner
Consumer Product Safety Commission

The Honorable Thomas Moore, Commissioner
Consumer Product Safety Commission

COMMENTS FROM THE CONSUMER PRODUCT SAFETY COMMISSION

Now on page x.

Now on pages x and x.

Now on page x.

Now on page x.

Now on page x.

Now on pages x-x.

APPENDIX

Now on page x.

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U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Pamela Gilbert
Executive Director

U.S. Consumer Product Safety Commission

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March 8, 1999

Ms. Carlotta C. Joyner
Director, Education and Employment Issues
General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Joyner:

This letter presents the comments of the staff of the U.S. Consumer Product Safety Commission ("CPSC") on the draft report of the General Accounting Office ("GAO") entitled "Data Insufficient to Assess Impact of Changes to Children's Sleepwear Standard" ("GAO Report"). GAO reviewed data from CPSC and other sources to see whether the 1996 changes to CPSC's sleepwear flammability standard are causing burn injuries.

The GAO Report suggests that CPSC's burn injury data are somehow incomplete. See GAO Report, p. 3. This is not true. CPSC's burn injury data are comprehensive and reliable. They demonstrate that children's burn injuries have not increased since the amendment of our standard; indeed, there has been no increase for 20 years. We specifically disagree with how GAO discussed two issues: (i) the significance of the low number of sleepwear burn incidents; and (ii) the importance of exposure data in this case.

1. Small Number of Cases

GAO asserts that the number of burn injuries associated with children's sleepwear is unknown. Id. at 2, 7. This erroneous assertion assumes that, because CPSC knows of so few actual burn incidents associated with children's sleepwear, the public cannot rely on its national sleepwear burn injury estimates. Id.[1]

We disagree. CPSC's National Electronic Injury Surveillance System ("NEISS") is a stratified probability sample of 101 hospitals representative of the Nation's hospitals. NEISS

[1] GAO found that CPSC has the only burn injury data in which incidents can be separated by sleepwear and all other clothing types. Id. at 7.

collected 13 pediatric thermal burn cases involving nightwear from 1990-98. Using statistical methods, we have estimated that 872 (se=278) such incidents occurred nationwide over that time. National estimates projected from few incidents are generally associated with larger relative standard errors than if there were many incidents. However, we can be highly confident that the actual number of nightwear-related burn cases over this nine-year interval does not exceed 1,427, and that it could be as low as 317.

CPSC's national burn injury estimates have remained small since the 1996 amendments. In fact, CPSC knows of no burn incidents involving the types of children's sleepwear that the amendments affected. Because there are few incidents, if there were to be an increase in the incidents, this fact would show up quickly in our data.[2] Nevertheless, the staff does not rely on this unchanged injury picture for its continued support of those amendments. Instead, as GAO acknowledges, the CPSC relied on laboratory and analytical evidence for the 1996 amendments, and that evidence has not altered. The full bases for the staff's recommendation and the Commission's decision are set forth in the Briefing Package on Children's Sleepwear Project (Memorandum from T. Karels to the Commission) (Oct. 11, 1995); see also 62 Fed. Reg. 47634 (Sept. 9, 1996).[3]

2. Exposure Data

GAO also asserts that, even with reliable burn data, exposure data would be necessary to assess the relative safety of various types of sleepwear. Id. at 11. Although exposure data is sometimes helpful, here they would not be. Where there are few incidents and it is known that many consumers are exposed to the product, exposure data do not provide useful information. In such a scenario, it already is known that the risk rate is extraordinarily low. The precise measurement of that low risk -- which could be done with exposure data -- would provide the Commission with information of academic interest, but would not affect the regulatory outcome.[4]

In this case, CPSC knows that there are very few burn incidents involving sleepwear. We also know that millions of children wear various types of sleepwear. The risk of burn injury in

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[2] Tight-fitting or nearly tight-fitting cotton garments that are not flame-resistant have been marketed under a stay of enforcement since January 1993. Any increased risk from such clothing would be apparent in CPSC data by this time.

[3] The Commission adopted the 1996 sleepwear amendments with Commissioners Thomas H. Moore and Mary Sheila Gall voting in favor and Chairman Ann Brown opposed.

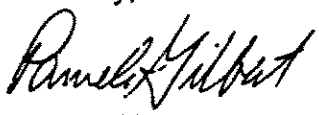
[4] GAO correctly points out that collecting exposure data is extremely expensive and would require specifically-tailored data collection efforts, because available market information often is inadequate to provide detailed information. GAO also properly acknowledges that the Commission has jurisdiction over 15,000 types of consumer products and must prioritize its spending. Id. at 11-12.

any type of sleepwear is extremely low, and specifically quantifying that risk with exposure data is not necessary.[5]

* * *

In conclusion, we strongly disagree with GAO's characterization of the reasons for the low observed burn injuries and with its suggestion that exposure data might possibly shed further light here. However, GAO's investigation has shown that available data do not support the notion that the 1996 sleepwear amendments have caused burn injuries to children.

Sincerely,



Pamela Gilbert

[5] We agree with GAO that even with reliable injury and exposure data, the precise contribution of sleepwear to a burn injury may be difficult to determine without further investigation because of the many factors that affect fire ignition and spread. Id. at 10. This is why CPSC conducts followup investigations on selected incidents, including 126 burn incidents from 1993 through 1998. In those followup investigations, we found no incidents involving a garment that was or would have been affected by the 1996 amendments.