

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



**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 a sample of hospital emergency

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

²Sleepwear 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.

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.³ 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

³In practice, CPSC rarely uses its regulatory power to order a recall; instead, the agency usually works cooperatively with manufacturers to carry out recalls.

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 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.

⁴CPSC 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.

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

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-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.⁶ 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.

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

⁶This 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).

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, sweatshirts, 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

⁷Neither 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 9.

⁸Thirty-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.

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 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

⁹In 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 CPSC'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, 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.

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 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.

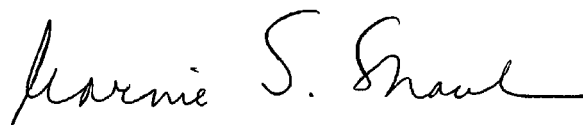
CPSC's response also stated that the agency's staff do not rely solely on injury data for its continued support of the amendments but consider other information such as laboratory and analytical evidence. We agree that it is important to consider these other types of information in

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.



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The Honorable James T. Walsh, Chairman
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The Honorable Ann Brown, Chairman
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The Honorable Mary Sheila Gall, Commissioner
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The Honorable Thomas Moore, Commissioner
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Comments From the Consumer Product Safety Commission



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March 8, 1999

Ms. Carlotta C. Joyner
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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.

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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

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.

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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.

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