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

MEMORANDUM

DATE : November 15, 2000
TO : HS
Through: Sadye E. Dunn, Secretary
FROM : Martha Kosh
SUBJECT: Child-Resistant Packaging for Certain Over-The-Counter Drug Products; Notice of Proposed Rulemaking; 65 Fed. Reg 52678, August 30, 2000

ATTACHED ARE COMMENTS ON THE CP 01-1

<u>COMMENT</u>	<u>DATE</u>	<u>SIGNED BY</u>	<u>AFFILIATION</u>
CP 01-1	9/19/00	Students	Florida International University 6520 SW 44 Street Miami, FL 33155
CP 01-2	10/13/00	John Coster Ph.D, R.Ph. Vice President Federal and State Programs	National Association of Chain Drug Stores 413 North Lee Street P.O. Box 1417-D49 Alexandria, VA 22313
CP 01-3	11/10/00	Eve Bachrach Senior Vice President, General Counsel & Secretary & William W. Bradley Vice President - Technical Affairs	Consumer Healthcare Products Association 1150 Connecticut Ave., NW Washington, DC 20036
CP 01-4	11/13/00	Peter Mayberry Exec. Director	Healthcare Compliance Packaging Council 7799 Leesburg Pike Suite 900N Falls Church, VA 22043

Child-Resistant Packaging for Certain Over-The-Counter Drug
Products; Notice of Proposed Rulemaking; 65 Fed. Reg 52678,
August 30, 2000

CP 01-5	11/5/00	John Armitstead	University of Kentucky
		Director of	Hospital
		Pharmacy Services	Chandler Medical Center
		Clinical Assoc.	800 rose St, Rm C114C
		Professor	Lexington, KY 40536

*cleared
OTC
drug
CPO1-7*

September 19, 2000
OFFICE OF THE SECRETARY
Consumer Product Safety Commission
Washington, D.C. 20207

Re: **16 CFR Part 1700**
Child-Resistant Packaging for Certain Over-The-Counter Drug Products

To Whom It May Concern:

FDA has the responsibility for assuring the safety and efficacy of all regulated marketed medical products including drugs (OTC and monitor drugs), biologics, medical and radiation-emitting devices, and special nutritional products (e.g., medical foods, dietary supplements and infant formulas). Health professionals who monitor for and report serious adverse events and product problems to FDA either or via the manufacturer are integral to this process. Over the counter (OTC) drugs play and increasingly vital role in America's health care system. Today, six out of every ten medications bought by consumers are OTC drugs.

We agree with most of the statements of the proposed rule in reference to child-resistant packaging for certain over the counter drug products, especially those which contain active ingredients (**pseudoephine HCL, pseudoephine sulfate, phinylpropanolamine HCL, Clemastine fumarate**). Overdoses of these ingredients may cause excitation and sometimes might lead hazardous in children. However, we believe that these products should also be available for disabled adults and elderly, who may have difficulties opening the child resistant packages due to arthritis or other sickness.

General Approach:

Over-the-Counter (OTC) drug products are those drugs that are available to consumers without a prescription. There are more than 80 classes (therapeutic categories) of OTC drugs, ranging from acne drug products to weight control drug products. As with prescription drugs, Center for Drug Evaluation and Research (CDER) oversees OTC drugs to ensure that they are properly labeled and that their benefits outweigh their risk. The Primary concern with this rule is that most of the OTC drugs that have been already approved by the FDA do not have child-resistant packaging. Putting children at risk for overdose and toxicity (active ingredients).

Additional Uses, Forms, and Combinations of OTC-Switched Drug Products:

The FDA can approve a new dosage form of a previously approved OTC switched drug product. The proposed rule would require that the new use or new dose be sold in CR Packaging even if the new use or dose was not approved when the drug was only available by prescription. We feel that if the prescription has been already granted by the FDA to an OTC status, then any changes in dosage of that containing some or all of the

active ingredients should have CR Packaging requirement. However, this is proposed only for oral formulation of the drug, and we think this should be enforced for all type of formulation containing the active ingredients mentioned before.

On the other hand, in some cases, after a prescription drug product is approved for OTC sale by the FDA, other forms, dosages, or combinations containing some or all of the active ingredients in that drug product would also be approve for OTC sale. However, we do not agree with this statement because the having the ingredients of the drugs altered it could be more hazardous to children's consumption.

Change in Dosage Between Prescription an OTC Drugs:

This proposal would require CR Packaging for any OTC oral product containing an active ingredient that was available by prescription even if the OTC dosage is lower than the prescription strength. This is consistent with the approach of the CPSC's oral prescription drug product CR packaging regulations, which applies to all dosages approved by the FDA for prescription sale. This recognizes the reality that absent CR Packaging, the dose potentially available to a child is the entire package contains. Regarding the above mentioned, we agree that the prescription drug should be CR Packaging when they are switched to OTC, even if the dosage is lower.

Exemptions:

The only exemption that could be considered under this proposed rule is that the manufactures should provide the Commission with enough documentation to suggest that the drug product would not cost serious injury our illness; ~~or that~~ the drug product is not technically possible to develop and produced CR Packaging for the drug product.

Findings

1. Hazard to children:

We feel that the main issue to consider is whether a drug product switches to OTC status at lower dosage is still hazard to young children. Unfortunately, the vast majority of drugs currently approved by the U.S. Food and Drug Administration (FDA) for adults have not been approved for children. The most common statement in the labeling is "Safety and effectiveness in children have not been establish".

U.S. Consumer Product Safety Commission (CPSC) announced that the lives of over 700 children have been saved since child-resistant packaging for aspirin and oral prescription medicines was required in the early 1970's. But, this story has not eliminated the poisoning problem in America. Each year, approximately 50 children under age 5 die, and more than a million consumers call poison control centers about child poisonings, from medicines or household chemicals.

The American Association of Poison Control Centers has played a very important role saving this people. They save lives and health care costs because every dollar spent on a poison control center saves about \$7 in medical expenses.

So, we are concluded that before issuing a rule requiring children resistant packaging, the Commission must find the degree or nature of the hazard to children in the OTC-switched drug products.

2. Technical Feasibility, Practicability, and Appropriateness:

Three factors must be considered on the design of the new packaging. These are feasibility, practicability, and appropriateness. All of these factors are very much linked to the cost of the new packaging and new label of the OTC products. CR must be studied carefully to cover all standard regulations already established by the Commission.

3. Other Considerations:

Other factor that we feel must be considered is the optional packaging for orderly and disabled. This package will give the household the responsibility to decide whether to buy a CR medicine or regular packaging medicine depends on their needs.

Overall, we agree with almost everything mentioned in the proposed rule but we are very concerned with the fact that disabled and elderly are going to have a hard time with the CR Packaging. We would like for this to be addressed as well. Our recommendations are that all OTC drugs need to be available in CR Packaging as well as regular packaging.

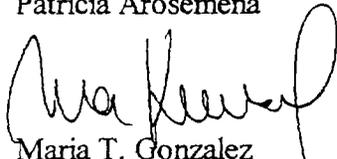
We appreciate the opportunity to provide you with a piece of our minds and hope that our petition is taken into consideration.

Sincerely,

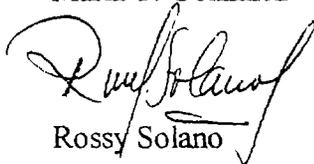
Florida International University Students:



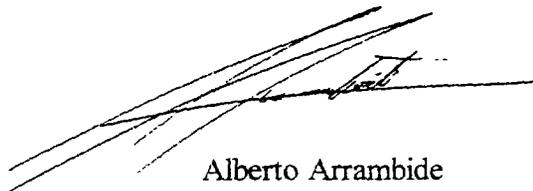
Patricia Arosemena



Maria T. Gonzalez



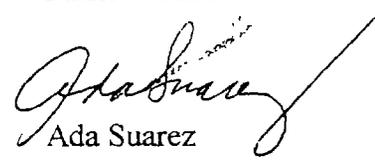
Rossy Solano



Alberto Arrambide



Patricia Lama



Ada Suarez

NACDS

National Association of Chain Drug Stores

L. Fuller
President & CEO

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Comment

November 13, 2000

Office of the Secretary
Consumer Products Safety Commission
Washington, D.C. 20207

Dear Madame Secretary:

The National Association of Chain Drug Stores (NACDS) supports the use of child-resistant containers on over-the-counter products that are potentially dangerous to children. Almost all OTC products already are packaged in these containers. We support the CPSC's initiative to convert products with previously prescription-only ingredients to packaging that contains such enclosures.

NACDS membership consists of more than 160 chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 94,000 pharmacists. The chain community pharmacy industry is comprised of more than 19,300 traditional chain drug stores, 7,800 supermarket pharmacies and 5,300 mass merchant pharmacies. The NACDS membership base operates over 32,000 retail community pharmacies with annual sales totaling over \$160 billion including prescription drugs, over-the-counter (OTC) medications.

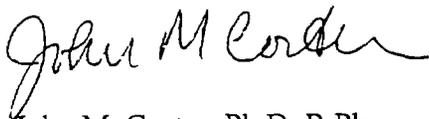
Chain operated community retail pharmacies fill over 60 percent of the approximate 3 billion prescriptions dispensed annually in the United States. The vast majority of OTC products are purchased at chain community pharmacies, and so the impact of agency action on this issue is critically important to our industry and the consumers that we serve. Our organization offers the following comments towards effective implementation of this worthwhile public safety initiative.

- CPSC should advise all manufacturers and sellers with at least ~~18~~ months advanced notice of the effective date of these packaging changes.
- These precautionary measures should be implemented for newly manufactured packages only. Retailers and manufacturers should be allowed to sell and/or distribute their existing stock before selling and/or distributing the newly packaged product.

- A comprehensive list of all affected products and ingredients should be drafted by CPSC and made available to all sellers of these products well in advance of the effective date. This will allow sellers to modify the ordering of non-CR products and to effectively sell through the existing product in anticipation of the newly-packaged products, thus minimizing sales of products with non CR packaging.

We appreciate the opportunity to comment on this proposal. Please direct any questions or comments to me at 703-549-3001 X 126. Thank you.

Sincerely,



John M. Coster, Ph.D, R.Ph.
Vice President, Federal and State Programs



CP01-3
OTC
DWG

Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

By Facsimile

November 10, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207

Re: Child-Resistant Packaging for Certain
Over-The-Counter Drug Products;
Notice of Proposed Rulemaking;
65 *Fed. Reg.* 52678 (August 30, 2000).

Dear Madame Secretary:

In the *Federal Register* of August 30, 2000, 65 *Fed. Reg.* 52678, the Consumer Product Safety Commission (CPSC) proposed to require that child-resistant (CR) packaging requirements applicable to any oral prescription drug product continue to apply when that drug product or any other drug product containing an active ingredient of that product is granted over-the-counter (OTC) status by the Food and Drug Administration (FDA). In the same notice, the Commission proposed to revoke the current prohibition on granting a petition for an exemption from a CR packaging requirement prior to FDA approval of the drug product in question.

These comments are being submitted on behalf of the Consumer Healthcare Products Association (CHPA), the 119-year-old national trade association representing manufacturers and distributors of nonprescription or over-the-counter (OTC) drug products and dietary supplements. CHPA members account for 90% of the volume of OTC drug products sold at retail in the United States.

At the public hearing at which the Commission voted to proceed with the rulemaking, Commissioner Mary Sheila Gall questioned the proposed rule's shift of responsibility from CPSC to industry for determining the need (or lack thereof) for CR packaging of a product, and thus, whether a blanket requirement for CR packaging for all oral products switched by FDA to OTC status is appropriate. It is also not clear that the proposed rule would make as efficient use of CPSC resources as intended.

In the preamble to the proposed rule, for example, CPSC staff concluded that several former prescription drug products already switched to OTC status do not warrant CR packaging. 65 *Fed. Reg.* 52680. If the proposed rule had already been in place, the Commission presumably would have had to consider a number of exemption petitions for those switch products. This suggests that the proposed blanket CR rule may not be as efficient a method of preserving CPSC resources as wished-for, such that CPSC should

consider whether it may be just as efficient to continue its current practice of considering the need for CR packaging on a case-by-case basis.

Unit dose packaging

Because so many OTC drug products, especially those switched from prescription status, are packaged in unit-dose containers such as blister packs, it is particularly important for the CPSC to have a workable rule for determining what constitutes a "test failure" for these packages. The current regulation, 16 CFR § 1700.20(a)(2)(ii), specifies that access to more than eight units is considered a failure in all cases, even if the number of units that may cause serious illness or injury is considerably higher. Particularly if the CPSC is going to require special packaging for all switched drugs, without an individualized toxicity determination, the Commission should revise the rule to remove the flat upper limit (such that the limit is based in all cases on the number of units that may cause serious illness or injury to a 25-pound child) or at least to substantially increase that limit. It is also our understanding that companies make a self-determination of the number of units that can cause serious injury for purposes of the unit-dose test failure rule, which data is submitted to CPSC under the rule. CPSC confirmation of this should be provided.

Exemption Petitions

If the CPSC were to adopt the proposal to require CRP for future OTC switch products, then CHPA would support revocation of the current prohibition on granting a petition for an exemption from a CR packaging requirement prior to FDA approval of the switch product in question. CHPA appreciates the Commission's recognition of the industry's legitimate need for adequate lead time to plan for the packaging of a switch product, before FDA grants OTC status to the product.

However, expedited exemption petitions present at least two practical problems. First, because the timing of CPSC and FDA responses cannot be predicted, even if a company simultaneously files a CPSC exemption petition and a new drug application (NDA) to switch a drug, the company may still not have sufficient time to plan for the packaging and launch of the product once FDA approves the switch.

As a practical matter, the company must plan for the packaging of its OTC far in advance of even the earliest expected CPSC response to an exemption petition. Many time-intensive elements enter into the packaging development process. The switch NDA submitted to FDA ordinarily will include stability data on the proposed packaging to be used for commercial distribution. Thus, the packaging configurations must be identified and tested well before the NDA is filed. Accordingly, the Commission should make clear that it would entertain exemption petitions in this context very early in the process. To allow a meaningful opportunity to gain CPSC approval of an exemption petition for non-special packaging, the Commission would need to accept these petitions two years or more before the NDA is expected to be filed, and to act on them promptly after submission.

That approach would present a second practical difficulty, however. Filing the CPSC exemption petition in advance of the NDA would publicly signal the company's business plans prematurely. From the standpoint of a company that legitimately wishes to maintain the confidentiality of its pending business plans, this would not be an optimum approach, unless a confidential exemption procedure could be devised--and confidentiality may not be possible because exemptions are currently adopted through notice and comment rulemaking. These issues should be carefully examined before CPSC abandons its case-by-case consideration of CR packaging.

Thank you for your consideration of our views.

Sincerely,



Eve E. Bachrach
Senior Vice President, General Counsel
and Secretary



William W. Bradley
Vice President - Technical Affairs

cc. Dr. Suzanne Barone

WB/EEB

ORC *CP01-4*



November 13, 2000

Ms Sadye E. Dunn
 Office of the Secretary
 U.S. Consumer Product Safety Commission
 4330 East West Highway, Room 502
 Bethesda, Maryland 20814

RE: HCPC Opposition to "Child-Resistant Packaging for Certain Over-the-Counter Drug Products." (65 FR 169, pp 52678-52684)

Dear Ms. Dunn:

I am writing on behalf of the Healthcare Compliance Packaging Council (HCPC) in opposition to the Notice of Proposed Rulemaking (NPRM) published by CPSC in the August 30, 2000 edition of the *Federal Register* regarding a proposed automatic requirement that would mandate the use of child-resistant (CR) packaging for future drug products approved for over-the-counter (OTC) sale by the U.S. Food and Drug Administration if the OTC product contains an active ingredient that was previously available only in prescription drugs.

The CR packaging requirement for "OTC-switched" products would be automatic in the sense that, after implementation, CPSC would not have to make a determination — as required under the Poison Prevention Packaging Act of 1970 (PPPA) — that the hazard presented by any future OTC-switched product is such that "...special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting [the substance]." Moreover, as the NPRM indicates, adoption of this proposed rule would be a significant change from CPSC's long-standing policy whereby the Agency has reviewed each OTC-switched product and has made CR-packaging determinations, as needed, on a case-by-case basis. Indeed, since 1976 the NPRM specifically notes that there have been 22 oral drug

15 USC 1472 (a)(1)

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U.S. Consumer Product Safety Commission
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products approved for OTC sale by FDA that contain active ingredients which had previously been available by prescription only and, of these, CPSC has required CR packaging for only six.²

The HCPC opposes this proposed rule on a number of grounds, a primary one being that the proposal could actually reduce consumer safety by perpetuating and exacerbating an inequitable regulation that exists under the test protocol used to define "child-resistant" packaging in the United States.¹ This is due to a specific provision, 16 CFR 1700.20 (a)(2)(ii), contained within the regulation that holds unit dose packaging to a different performance standard with regard to "Test Failures" than that which applies to other CR packaging options and, therefore, discourages use of unit dose formats as manufacturers' original packaging. This inequity would continue, and likely expand, under the OTC-switched proposal even though CPSC's own statistics demonstrate that unit dose packaging is safer than alternative packaging options.

Summary of HCPC Concerns

The HCPC contends that CPSC has specific responsibilities under the PPPA, and that the proposed regulation unjustifiably shifts these responsibilities from the Commission to industry groups. The HCPC further contends that the proposed regulation oversteps CPSC's legal authority under the PPPA by regulating all OTC-switched drugs as a "substance" when, in fact, the proposed rule would apply to a broad range of drug products (many of which may present no risk of serious personal injury or illness to small children whatsoever). The HCPC also takes issue with the notion that those impacted by the proposed requirements will be able to escape regulation through the exemption process outlined under 16 CFR 1702. The HCPC is further concerned by the fact that CPSC already has a process in place to ensure that the goals spelled out in the preamble to the proposed regulation are met, yet has failed to provide a meaningful justification for altering these procedures.

Also of particular concern to the HCPC is the fact that the test protocol for defining CR packaging as outlined under 16 CFR 1700.20 contains a meaningless and arbitrary provision — 16 CFR 1700.20 (a)(2)(ii) — that applies a different standard to unit dose packaging as opposed to other formats, and serves as a disincentive to greater use of these formats as manufacturers' original packaging. We contend, therefore, that the current proposal would exacerbate the inequitable impact of the already unfair CR packaging regulation on the unit dose packaging industry, and that CPSC must make specific improvements to 16 CFR 1700.20 before implementing any regulation that would automatically require the use of CR packaging for OTC-switched drugs.

²65 FR 169, page 52679

¹16 CFR 1700.20

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Furthermore, the HCPC points to CPSC-generated data and other sources which indicate that unit dose packaging formats offer superior protection against accidental ingestion of drug products (both Rx and OTC) by small children. Since unit dose packaging is inherently safer than other packaging alternatives, the proposal — if implemented without first addressing the arbitrary and inequitable provision found under 16 CFR 1700.20 (a)(2)(ii) -- could have the effect of reducing consumer safety by perpetuating the disincentives which, according to members of the pharmaceutical manufacturing industry, have precluded greater use of these formats as manufacturers' original packaging.

These disincentives result from the fact that, under current regulations, manufacturers who elect to use unit dose formats must add fortifications to their packaging in order to pass the children's portion of the protocol simply because of the number of units in the package. These fortifications may be completely unnecessary to protect small children, yet often make unit dose formats unpopular with older persons because they are more difficult to open and cannot be readily compromised in ways that other packaging options can (e.g., voluntarily leaving the cap off of a CR closure, or leaving the cap loose). Moreover, manufacturers who elect to use unit dose formats for any package that contains more than eight dosage units are automatically required to use packaging that conforms to 16 CFR 1700.20, even if ingestion of the entire contents of the package would not be expected to cause serious personal injury or illness to a small child. In addition, to assure compliance with this requirement, manufacturers are generally compelled to submit their packages to expensive, time consuming, and sometimes unnecessary protocol testing.

Based on CPSC data, in fact, the HCPC contends that an alternative means of defining "child resistant" packaging for drug products as it applies to unit dose formats is warranted. Such an alternative could be implemented under existing PPPA authority, and would have the added benefit of significantly reducing the need to use small children in protocol testing. We urge the Commission, therefore, to study such an alternative prior to adopting the proposed rule.

While the HCPC is considering the possibility of filing a separate petition with the Commission on this last issue, we raise it here in hopes of ensuring that CPSC action will be taken as quickly as possible in an effort to protect small children from accidental ingestion of drug products *and* the risk of injury due to participation in protocol testing.

Each of these concerns will be spelled out, in somewhat reverse order, within the following comments.

Basis for HCPC Comments

The Healthcare Compliance Packaging Council was formed in 1990 as a not-for-profit trade association to promote the many benefits of unit dose blister and strip packaging. HCPC member companies include manufacturers of pharmaceutical films, foils, and paperboard used in

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the production of unit dose formats, as well as manufacturers of machinery used to produce this type of packaging, and contract packaging companies that provide unit dose packaging services to pharmaceutical manufacturers and others. Unit dose blister and strip formats are widely used to package prescription and OTC drugs in the United States, and the HCPC is the recognized voice of the unit dose packaging industry.

The HCPC strongly supports the need to protect small children from accidental ingestion of prescription and OTC drugs, and has been an active participant of both the ASTM D1031 committee on Child Resistant Packaging and the Poison Prevention Week Council almost since our inception. The HCPC has also organized an annual National Symposium on Patient Compliance since 1991, and has regularly used these conferences to detail various aspects of CPSC's implementation of the PPPA to representatives of the pharmaceutical manufacturing and packaging industries. In addition, the HCPC has worked extensively with members of CPSC's Directorate for Health Sciences on numerous issues associated with child-resistant packaging for more than ten years, and was also recruited by the U.S. Food and Drug Administration to provide information on unit dose packaging when FDA was considering its requirement that these formats be used to package any substance that contains 30 mg. or more of iron.⁴

Unit Dose Packaging is Inherently Safer than Other Packaging Alternatives

The HCPC contends that unit dose blister and strip packaging provides numerous safety benefits which make these formats superior to other packaging options (especially cap-and-vial closure systems), and strongly believes that CPSC should do whatever is allowed under the PPPA to encourage — not mandate, or "prescribe" — greater use of unit dose formats. At the very least, we believe that CPSC should remove the disincentives to greater use of unit dose formats as original packaging by pharmaceutical manufacturers which currently exist under 16 CFR 1700.20.

Unit dose formats are safer than other pharmaceutical packages because, by their very nature, unit dose blister and strip packages separate each dosage unit into its own cavity. This impedes access by small children, and requires that each dosage unit be removed from the package one at a time. Even without fortifications needed to pass 16 CFR 1700.20, therefore, these formats slow children down, and allow more time for adult intervention or for children to lose interest. This is a critical, inherent, difference between unit dose formats and cap-and-vial closures in that closures allow a child to gain instant access to the entire contents of the package if its CR mechanism can be defeated or has been compromised.

Moreover, unit dose blister and strip formats are non-reclosable and, therefore, their CR features do not rely on proper use by adults to ensure child resistance every time package

⁴21 CFR 111.50

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contents are accessed. Simply stated, unlike unit dose formats, the CR features of a closure system only exist if adults properly re-secure the safety cap after every use (something which is impossible to account for under 16 CFR 1700.20).

Indeed, when it comes to protecting small children from the accidental ingestion of drug products, the superiority of unit dose blister and strip packaging was noted by the Food and Drug Administration in its mandate under 21 CFR 111.50 that these formats be used to package any substance that contains 30 mg. or more of iron. In the preamble to that FDA rulemaking, the Agency specifically notes that:

...unit-dose packaging, *even conventional unit-dose packaging*, limits pediatric access to multiple dosage units of product. Moreover, the effectiveness of unit-dose packaging to limit pediatric access to product is not dependent on proper reclosure of the packaging. In contrast, the effectiveness of closure type packaging to limit pediatric access is dependent on proper reclosure of the container. If the closure is compromised (i.e., opened, improperly reclosed, or damaged), all the contents of the package are readily available for ingestion. FDA's concern is limiting the possibility that the product will be injurious to health. Unit-dose packaging, *even conventional unit-dose packaging*, will help to accomplish this end by limiting the amount of iron that a child can consume in a short period of time.⁵ (Emphasis added)

FDA's reasoning on this issue is validated by poisoning data that has been compiled by CPSC. Prior to drafting these comments, the HCPC filed a Freedom of Information Act request for any CPSC data regarding accidental poisonings of children six years old and younger that involved drug products since 1983. In response, on October 18, 2000, the HCPC received: 1) 22,664 reports from CPSC's National Electronic Injury Surveillance System (NEISS); 2) a summary of 365 death certificates compiled by CPSC; 3) 2,042 incident reports from CPSC's National Injury Information Clearinghouse; and 4) 1,140 summaries of CPSC accident investigations. While the HCPC has admittedly had only a limited time to review these data, we note that they clearly indicate the safety advantages of unit dose packaging in protecting small children from accidental ingestion of Rx and OTC drug products.

In HCPC's review of these data, for instance, we note that:

- Of the 2,042 incident reports compiled by CPSC, the accompanying narratives specifically identify the type of packaging involved in 1,752 incidents (85.6 percent of all incidents).⁶

⁵62 Federal Register 10, p. 2228 (January 15, 1997)

⁶Complete summary is included as Attachment Number I

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- Child-resistant closures were specified as being involved in 747 of these 1,752 incidents (42.6 percent of all incidents where specific packaging was identified).
- Of these 747 incidents, there were 333 reports of a child being able to access the contents of a "closed" CR closure (nearly half of all instances where CR closures were identified); 142 incidents where the child was able to gain access to the contents of a CR closure because the cap was either left loose or had been damaged (less than 20 percent of those cases where a CR closure was identified); and 98 incidents where the child was able to gain access to the contents of a CR closure because the package was left open (13 percent of those incidents involving a CR closure).
- Packaging identified as "blister," "bubble," or "calendar packs," on the other hand, was involved in only 37 incidents (*a mere 2.1 percent of total incidents where the packaging was identified*) and, of these 37 occurrences, "child-resistant" blisters were cited in only 8 instances (*less than 0.5 percent of all incidents where packaging was identified*).
- Packages identified as "samples" were involved in 33 of these incidents (1.9 percent of the total) and, of these 33, there were 11 that were identified as physician samples (0.6 percent of the total). It is unclear from the narratives, however, whether these sample packages were unit dose formats, closures, or some other format.

Similarly, in its review of the 1,140 CPSC accident investigations involving children six years old and younger who ingested drug products (Rx and OTC) since 1983, the HCPC counts 537 instances where packaging is specifically identified.⁷ Of these incidents, the HCPC notes that:

- Closures were cited in 493 of the 537 investigations that specifically identified packaging (*nearly 92 percent of all such identifications*); and "child-resistant" closures were specifically cited in 343 of these incidents (63.9 percent of all incidents, nearly two thirds, where the investigations specifically identified the packaging involved).
- *In more than half of the investigations that identified packaging involved in an accidental poisoning (53.8 percent), children were able to defeat a CR closure that was functioning properly (289 incidents).* Children gained access to CR closures on which the top had been left loose in 30 incidents (5.6 percent of total,

⁷Complete summary is included as Attachment II

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and about nine percent of the incidents where CR closures were specified); and to CR closures where the packaging was left open in 12 incidents (2.2 percent of the total, and less than four percent of those incidents that involved CR closures). There were also 12 incidents where children gained access to a CR closure that, reportedly, had been damaged.

- There are 92 additional investigations where closures are cited, but the respondent either did not know if the closure had a CR cap or the narrative does not specifically state that a CR closure was involved. Of these 92 investigations, 16 of the closures had reportedly been left open when the incident occurred, and five had been improperly re-secured (i.e. left loose) prior to the incident.
- *Child-resistant blister packages, on the other hand, were cited in just two of the CPSC investigations conducted over more than 17 years.*⁸ Moreover, in one of these cases (900302HEP903) the edges of the blister had been "roughened" due to extended storage in a purse and, therefore, the package was more easily opened. In addition, the emergency room physician in this specific incident was not convinced that the drug product had actually been ingested.
- Of the 16 other accident reports which described blister packaging, four of the products involved were oral contraceptives, and two were physician samples — products that do not require CR formats.

In terms of outcomes, the CPSC accident investigations also point to the superiority of blister packaging over closures. CPSC investigations, for instance, show that closures of all types have been involved in 47 deaths and 109 hospitalizations since 1983. CPSC accident investigations further reveal that 28 of these deaths and 65 of these hospitalizations involved "child-resistant" closures and, even worse, *cases where children were able to defeat properly-functioning CR closures resulted in 22 deaths and 47 hospitalizations.* This can be directly contrasted with the 18 reported cases over more than 17 years where blister packaging was cited in the CPSC investigations — *none of which resulted in death*, and only two of which resulted in hospitalization.

In reviewing these CPSC data, one might conclude that fewer blister formats are involved in accidental poisonings because fewer products are packaged in those formats. While this may be the case of prescription drug products, it is certainly not the case for OTC drug products.

Indeed, unit dose blister and strip packaging is estimated to be used in approximately 20 percent of the prescription drug market in the U.S., and these formats are widely used for

*Attachment III

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packaging OTC drugs in the United States. Yet in at least 150 of the 537 accidental poisonings investigated by CPSC — and three of the fatalities — the product involved was a solid oral dosage form OTC drug product and, therefore, would most likely have been available to the consumer in a unit dose format.

Moreover, the death certificates provided by CPSC show a dramatic reduction in fatalities of small children due to accidental ingestion of iron beginning in 1997 once FDA required, among other things, that unit dose formats be used as manufacturers' original packaging for any substance that contains 30 mg. or more of iron per dosage unit, while those involving aspirin and acetaminophen (where unit dose packaging is not specifically required) have remained somewhat stable.⁹

With aspirin and aspirin substitutes — products which are available in both unit dose and closure formats — CPSC's accident investigations include 82 incidents where children ingested products packaged in a closure format, yet only one which involved a blister. Similarly, CPSC accident investigations record 68 incidents where small children were treated in emergency rooms, and in some cases hospitalized, due to ingestion of vitamins that were packaged in closures. These same data, however, reveal only one case involving vitamins that were in a unit dose format.

Simply stated, the disproportionate share of poisonings involving closure formats recorded by CPSC from 1983–October 3, 2000 is far greater than the difference in numbers of closures over unit dose formats in the market, especially when it comes to OTC drug products.

With regard to the CPSC's accident investigations, the HCPC also finds it noteworthy that large quantities of drug products can be ingested when small children are able to gain access to CR closures. As shown in Table I, CPSC narratives include more than 40 incidents where children ingested large numbers of solid oral dosage units accessed from CR closures, while the maximum number of units accessed from CR unit dose formats was two:

⁹Complete summary is included as Attachment Number IV

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Table J: Summary of CPSC Accident Investigations, Quantities of Dosage Units Accessed from CR Closures and Unit Dose Formats by Children 6 Years Old and Younger (1983-10/3/00)

<u>Number of Solid Oral Dosage Units</u> <u>Ingested: CR Closures</u>	<u>Number of Incidents</u>
--	----------------------------

10-15	6
16-20	5
21-25	3
26-30	6
31-35	1
36-40	3
41-50	11
51-60	1
61-75	<u>5</u>

Total: 41

<u>Number Solid Oral Dosage Units</u> <u>Ingested: CR Unit Dose Packaging</u>	<u>CPSC Investigation #</u>
--	-----------------------------

1	900302HEP9003
2	900306HEP9004

CPSC accident investigations also point to two other advantages that unit dose formats have over closures: 1) unit dose formats used as manufacturers' original packaging can be designed to enhance compliance with pharmaceutical regimens (packaging used for oral contraceptives being an example) and, therefore, do not have to be transferred to non-CR containers by patients who need help managing their medications; and 2) should a child gain access to drug product, unit dose formats typically provide a more exact indication of how many dosage units were consumed — information that can mean the difference between life and death when medical treatment is required.

Pill counts tend to be more precise with unit dose formats because it is generally possible to simply count the number of compromised cavities. With closure systems, on the other hand, consumers usually only have a vague idea, at best, of how many dosage units had been removed from the package before a small child gained access to the package. This can be demonstrated by the fact that, in 12 of the 18 CPSC accident investigation narratives where unit dose formats were involved, there is an exact count — or reasonable approximation — of the number of units

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consumed, and there are only three incidents where the number of solid oral dosage units is listed as "unknown" (this could be due to a failure by the respondent to remember, or by the investigator to inquire, or for some other reason). The remaining three narratives that specifically refer to unit dose packages make no mention of the number of solid oral dosage units involved. With closures, on the other hand, there are scores of CPSC accident investigations where the quantity ingested is listed as "unknown."

As for enhanced compliance, CPSC accident investigation narratives include eight separate incidents (resulting in six hospitalizations) where children gained access to drug products that had been transferred from their original packaging into non-CR "reminder" packages.¹⁰

Lastly, the HCPC notes that hospital medication errors were listed as the cause of death in two of the death certificates provided by CPSC.¹¹ Hospital medication errors are a grave national problem that has received considerable attention in the recent past and, to the HCPC's knowledge, every organization that has studied the issue and made recommendations on how the problem should be best addressed has recommended use of unit dose packaging.

In its 1999 report *To Err is Human: Building a Safer Health System*,¹² for instance, the Institute of Medicine specifically recommends that pharmacists ~~repackage~~ bulk drug products into unit dose formats prior to patient distribution.¹³ Similarly, the National Patient Safety Partnership (a coalition that includes representatives from the American Hospital Association, the American Medical Association, the Joint Commission on Accreditation of Healthcare Organizations, the Association of American Medical Colleges, and the U.S. Department of

¹⁰ Attachment V

¹¹ Attachment IV

¹² National Academy Press, 1999

¹³ "If medications are not packaged in single doses by the manufacturer, they should be prepared in unit doses by the central pharmacy. Unit dosing...reduces handling as well as the chance of calculation and mixing errors....Unit dosing was a major systems change that significantly reduced dosing errors when it was introduced nearly 20 years ago. Unit dosing has been recommended by the American Society of Health-System Pharmacists, JCAHO, NPSF, and the MHA." *To Err is Human. Building a Safer Health System*, *ibid.*, pp 166-167.

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Veterans Affairs) has specifically recommended that unit dose formats be used for distribution of drug products in both in-patient and out-patient settings.¹⁴

While the HCPC realizes that CPSC has no specific jurisdiction over pharmaceutical distribution practices, we underline the fact that a number of the most distinguished healthcare organizations in the United States have recommended greater use of unit dose formats, and suggest that this is yet another reason for CPSC to encourage greater use of these formats as manufacturers' original packaging.

Unit Dose Packaging and the CR Protocol

Despite the many safety advantages offered by unit dose packaging, however, these formats are not widely used in the United States as manufacturers' original packaging for prescription drug products, and not as widely used as they *should be* for OTC drug products. A primary obstacle to greater use of unit dose packaging which has repeatedly been cited to HCPC members by pharmaceutical manufacturers is that CR blister and strip packages are unpopular with older persons because they are extremely difficult to open, and their CR features cannot be readily compromised as they can be with other formats (e.g. leaving the CR cap off of the vial, or loosely replacing the cap on the vial).

The HCPC contends that unit dose formats are made especially more difficult for older persons to open due to fortifications required to pass the children's portion of 16 CFR 1700.20 and, if the need for such fortifications were reduced, use of unit dose packaging would increase and accidental child poisonings, in turn, would decrease.

CPSC itself has recognized that CR packaging, including CR unit dose formats, can be difficult for older persons to open and, therefore, altered 16 CFR 1700.20 in 1995 to require that persons aged 50-70 be included in the adult portion of protocol testing. CPSC based this change on the belief that a large number of accidental poisonings were due to children gaining access to drug products because older persons had either left CR caps off of their prescription vials, transferred medications from CR to non-CR formats, or placed the CR caps on the vials loosely after use. The HCPC worked with CPSC throughout the development of these protocol changes, and notes that the Commission intended these changes to result in packaging that "...is easier for adults to use properly while still maintaining its child resistance."¹⁵

¹⁴"Use unit dose drug distribution systems for inpatient care; also use such systems for outpatient care where appropriate." NPSF Press Release, May 12, 1999.

¹⁵"Poison Prevention Packaging: A Text for Pharmacists and Physicians," CPSC Publication 384 (Revised 1999)

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While it may still be too early to tell if the protocol changes which were adopted in 1995 (and fully implemented by 1998), will eventually achieve their intended goal, the HCPC's review of CPSC accident investigations indicates that CR closures were not left loose or open, and that product had not been transferred, in the large majority of incidents where small children were able to access drug products.

We also note that virtually all of the packaging designs that were capable of passing 16 CFR 1700.20 prior to the protocol changes were also capable of passing the protocol after those changes.

Moreover, in the HCPC's review of NEISS data compiled by CPSC from 1983-1999, we count a definite *increase* between 1995 and 1999 in the number of incidents where children age six and younger were treated in emergency rooms at NEISS reporting hospitals due to poisonings that involved either: 1) "tablets or capsules;" 2) "drugs or medications not specified;" and 3) "aspirin or aspirin compounds." While the HCPC realizes that these data do not specify whether CR packaging was involved in these incidents, we contend that the information in Table II indicates that, to date, the protocol changes put in place by CPSC in 1995 have not had a meaningful impact on child safety.

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Table II: Compilation of NEISS Data Regarding Poisonings of Children Six Years Old and Younger and Drug Products Classified as "Tablets or Capsules;" "Drugs or Medications Not Specified;" and "Aspirin or Aspirin Compounds" (1995-1999)

<u>Year</u>	<u>Combined Number of Incidents</u>
1995	479
1996	468
1997	692
1998	714
1999	805

NEISS Data Regarding Poisonings of Children Six Years Old and Younger involving "Aspirin or Aspirin Compounds" (1995-1999)*

<u>Year</u>	<u>Combined Number of Incidents</u>
1995	34
1996	25
1997	39
1998	41
1999	47

*These data are broken out because — while an increase in the number of pharmaceutical drugs approved *may* account for the increase in NEISS reports over this period — to the HCPC's knowledge, there has been no significant increase in the number of aspirin or aspirin compounds made available over the past five years.

Based on these data, the HCPC contends that changes to 16 CFR 1700.20 which are much broader than those put in place by CPSC in 1995 are warranted.

Indeed, the HCPC notes that considerations are currently underway within the European Union to develop a CR standard for non-reclosable packaging, and that one option being explored by the CEN Working Group responsible for developing this standard is to rely on mechanical testing instead of using small children to test packages. The HCPC applauds this effort because, among other things, it recognizes the differences between reclosable and non-reclosable packages as well as the differences between drug products and other hazardous substances, and that unit dose packaging can be made from barrier materials with any degree of

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rigidity (from very easy to very difficult to open). In the United States, however, a "one-size-fits-all" approach has been adopted under 16 CFR 1700.20 which, with a few differences in protocol test instructions, applies a similar standard to products that have widely varying degrees of toxicity (i.e., pesticides, fuels, solvents, chemicals, etc.).

The HCPC is also monitoring these EU efforts because we are troubled by the fact that small children are involved in U.S. protocol testing. While we understand (but do not readily agree with) the logic of subjecting small children to these tests for packaging used to store household substances that are especially toxic; the HCPC believes that unit dose formats used for many prescription and OTC products could be based solely on the thickness of pharmaceutical films and/or foils as gauged by mechanical testing -- and still meet Congressional intent under the PPPA.

In short, with regard to unit dose formats for all but the most toxic drug products, we agree with those CEN Working Group members who argue that children are unnecessarily placed at risk by participating in protocol testing and, instead, support the development of mechanical measurements which — in the case of unit dose formats intended for use with many drug products — could eliminate this risk.

One way that CPSC could encourage greater use of unit ~~dose as~~ manufacturers' original packaging in the United States, therefore, would be to explore ways in which the U.S. can work more cooperatively with CEN in an effort to develop a CR standard for non-reclosable packaging that would more universally apply to unit dose formats. To date, it is the HCPC's understanding that CPSC participation in the CEN process has centered on encouraging the EU to simply adopt 16 CFR 1700.20, and we urge the Agency to rethink this approach. After all, FDA acknowledges that unit dose formats are inherently safer than closures, even without fortifications, and there is ample evidence included in CPSC's own data to support this finding.

There is also a specific provision within 16 CFR 1700.20 that applies a different performance standard to unit dose formats than that which applies to other packages and, as such, can serve as a disincentive to greater use of unit dose formats as original packaging by drug manufacturers. This provision is found under 16 CFR 1700.20 (a)(2)(ii), and states that:

In the case of unit packaging...a test failure shall be any child who *opens or gains access* to the number of individual units which constitute the amount that may produce *serious personal injury or serious illness*, or a child who opens or gains access to more than *8 individual units*, whichever number is lower, during the full 10 minutes of testing. The number of units that a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part. The determination of the amount of a substance that may produce serious personal injury or serious illness shall be based on a 25-pound (11.4 kg) child. Manufacturers or packagers

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intending to use unit packaging are requested to submit such toxicological data to the Commission's Office of Compliance. (Emphasis added)

The HCPC has repeatedly requested that CPSC staff either provide a reasonable justification for the "8 individual units" provision, or strike the provision from 16 CFR 1700.20. Similarly, we have repeatedly requested that CPSC staff provide a more substantive definition for "opens or gains access" and "serious personal injury or serious illness" as these terms apply to unit dose packaging. To date, CPSC staff has not honored these requests either.

With regard to the "8 individual units" section of this provision, the HCPC contends that this is an arbitrary and meaningless designation that results in unnecessary requirements that fortifications be added to many unit dose formats, and also automatically necessitates expensive, time consuming protocol testing for any unit dose format that contains more than eight units. To date, however, CPSC staff have offered no reasonable justification for requiring that a unit dose format must be capable of passing the CR test protocol simply because it contains more than eight individual units. Indeed, CPSC accident investigations show that there are numerous incidents in which children have ingested ten or more tablets of OTC drug product that they were able to remove from CR closure packaging, yet required no medical treatment beyond "observation."

Clearly there are drug products which would cause serious injury to a small child if even a single dosage unit were ingested and, for those products, packaging which offers maximum protection is certainly warranted. But the HCPC does not understand why a unit dose package must be capable of passing the children's portion of 16 CFR 1700.20 simply because it contains more than eight units of any non-exempt drug product.

Similarly, the HCPC contends that it is CPSC's responsibility under the PPPA to provide a clear, substantive definition of "serious personal injury or serious illness."

In numerous public meetings and pharmaceutical packaging industry gatherings, CPSC staff have stated that drug manufacturers "know" the amount of product that will cause serious personal injury or illness to a small child and, therefore, a more solid regulatory definition is not needed (i.e., CPSC relies on manufacturers to determine for themselves what dosage level constitutes a "hazard" to small children). The appropriateness of this approach as a means of protecting small children is questionable because it results in subjective determinations which can vary from manufacturer to manufacturer and product to product. This approach also ignores CPSC's responsibility under 15 USC 1472 (a)(1) to make a specific determination that CR packaging is required *only* in those instances where "the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance..."

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The PPPA, in other words, clearly requires CPSC to determine if CR packaging is needed to protect children from serious injury or illness, yet the Commission — through its lack of a substantive definition of “serious personal injury or serious illness” — has admittedly left it to manufacturers and packagers to make such determinations for themselves.

As for the lack of a robust definition of “opens or gains access to,” the HCPC notes that this is another case where, when unit dose formats are involved, CPSC leaves it to manufacturers to make their own, separate determinations as to the actual meaning of the requirement. This is due to the fact that individual cavities can be punctured or slightly torn during the children’s portion of the protocol test, yet the product remains inside the cavity and often intact. In such cases, it is left to the manufacturer’s discretion to determine whether this should be considered a “failure.” These determinations also tend to vary from manufacturer to manufacturer and product to product.

CPSC’s OTC-Switched Proposal

With regard to the proposed rule that CPSC published in the August 30 *Federal Register*, therefore, the HCPC contends that improvements to 16 CFR 1700.20 would be needed before the test protocol is automatically required for any future OTC-switched product. Even then, the HCPC is unconvinced that CPSC has offered a compelling justification for its proposal.

Indeed, included in the NPRM is a detailed description of CPSC procedures that have been used since the late 1970s to determine when CR packaging is needed, under PPPA authority, for OTC-switched products. In this section of the NPRM, CPSC specifically states that “For the past several years [CPSC] staff has focused on potential toxicity of active ingredients contained in drug products that are going to be switched instead of waiting for poisonings to occur after a product is released and marketed for OTC sale.”¹⁶ To the HCPC this seems like a reasonable means of executing CPSC authority and responsibility under the PPPA because it focuses on the “potential toxicity” of individual active ingredients on a case-by-case basis, and mandates CR packaging *only* in those instances where the substance, due to its packaging, poses a hazard of serious personal injury or serious illness to small children.

Moreover, the HCPC fails to see a justification within the NPRM for altering this “proactive” approach. According to the NPRM, the proposed change would: 1) “provide children with the same protection when a drug product is more widely available as an OTC preparation that they had when it was available only by prescription;” and 2) “eliminate the possibility of a drug product being available in non-CR packaging for an extended period of time before the CR packaging requirement is reimposed by Commission rulemaking.” Considering that CPSC staff have already “... made the evaluation of potential switched drug products the first

¹⁶65 FR 169, page 52680

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priority," and are "[attending] FDA advisory panel meetings when possible, to better understand any issues about a potential switch and the likelihood of approval of OTC status," it appears to the HCPC that the Commission has gone to great lengths to ensure that PPPA requirements are applied, when warranted, to OTC-switched drugs; and that reasonable steps are being taken to ensure that products which may eventually be subject to CR packaging requirements are not available for an extended period of time in a non-CR format.

Short of a reduction in outlays of CPSC staff resources, therefore, the HCPC fails to understand exactly what would be gained by the proposal.

While conservation of CPSC resources may be seen by some as a benefit in itself, the HCPC reiterates our belief that the Commission has specific responsibilities under the PPPA and — if additional resources are needed to meet those responsibilities — we respectfully suggest that those resources be sought through the annual appropriations process. Moreover, considering the amount of work involved in responding to an exemption petition filed under 16 CFR 1702, CPSC resources may be strained more than they currently are if the proposed rule is implemented, and even a small number of manufacturers and/or packagers of drug products avail themselves to the petition process.

To this point, however, we also take issue with CPSC's ~~supposition~~ that the exemption process outlined under 16 CFR 1702 offers a reasonable means for manufacturers or packagers of OTC-switched drugs to escape mandatory CR requirements if their products "do not pose a risk of serious injury or illness to small children."¹⁷ In the first place, the exemption procedures spelled out under 16 CFR 1702 present a formidable, expensive, and time-consuming challenge which manufacturers and/or packagers would have to undertake in an effort to prove to CPSC's satisfaction that their products should be granted an exemption — all with no guarantee of eventual success, and only after a tremendous expenditure of CPSC resources.

But even more importantly, the PPPA clearly places the responsibility on CPSC to require "special" packaging *only* in those cases where it is needed to protect small children from the hazard of serious injury or illness. The legal responsibility, therefore, clearly rests with the Commission to make these specific determinations — not on manufacturers and/or packagers to try to prove to the Commission's satisfaction that their products *do not* pose such a hazard.

Lastly, the HCPC is unaware of any such exemption that has been granted by CPSC since at least 1990.

The HCPC also questions whether it is appropriate for CPSC, under PPPA authority, to categorize *all* future OTC-switched drugs as a "class" of products that, unless specifically

¹⁷65 FR 169, p. 52681

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exempted, must be packaged in a CR format. To this point, the HCPC notes that the PPPA explicitly states that the Commission must make a determination that a household *substance* not class or category of products — presents a hazard to small children due to its packaging and, therefore, must be in a CR format.

Opposition to prescription drugs being classified as a "substance" was, in fact, raised with FDA during the Agency's implementation of the PPPA in 1973 and, in addressing the issue, FDA stated that:

A pharmacist, several manufacturers, and a manufacturers association opposed [the] comprehensive approach taken in the proposal. They stated that promulgating standards only for those products actually found to be toxic would be preferable. As stated in the proposal's preamble, the comprehensive approach was adopted following considerable consultation with members of the pharmaceutical community and with the concurrence of the Technical Advisory Committee. In the interest of consumer protection...[FDA reaffirms] that the nature of the hazard to children posed by orally administered prescription drugs for humans, by reason of their availability and packaging, is such that special packaging is necessary to protect children from serious personal injury or serious illness resulting from handling, using or ingesting such substances.¹⁸

The HCPC notes that this determination was made nearly thirty years ago, that it has never faced a legal challenge, and that it was reached through a process which involved industry representatives and the FDA's Technical Advisory Committee (which no longer exists). FDA's determination was also made without the benefit of data which exist today. Data which clearly show that packages which are capable of passing 16 CFR 1700.20, especially closure formats, are somewhat limited in protecting small children from serious personal injury or illness.

One source of such data, in fact, are the annual reports published by the American Association of Poison Control Centers. Included in each of these reports is a table (22B) which lists the "Demographic Profile of Exposure Cases by Generic Category of Substances and Products: Pharmaceuticals." These annual tables report the number of "exposures" to pharmaceutical products that occur each year based on calls to Poison Control Centers throughout the country, and break out the number that involve children under six years of age. The HCPC has compiled the results of these AAPCC annual reports in Table III below and we point out that, according to the AAPCC, there were *more than 4.7 million such exposures between 1984 and 1999* — this despite the fact that PPPA requirements were in place for the overwhelmingly vast majority of drug products listed in the AAPCC's annual tables.

¹⁸38 FR 72, 4/16/73, pp. 9432-33

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Table III: "Demographic Profile of Exposure Cases by Generic Category of Substances and Products: Pharmaceuticals," AAPCC Annual Reports, Table 22B, 1984-1999

<u>Year</u>	<u>Number of Exposures Children <6</u>
1999	480,824
1998	477,452
1997	504,725
1996	470,024
1995	445,674
1994	423,806
1993	415,303
1992	449,866
1991	453,461
1990	425,146
1989	34,147
1988	30,326
1987	26,651
1986	28,581
1985	26,167
1984	21,118
Total:	4,713,271

While the HCPC is aware of the limitations of the AAPCC data,¹⁹ and the fact that child-resistant packaging is not *child-proof*, we have to wonder in light of the large number of ingestions that have been reported by AAPCC over the past 16 years — whether the categorical approach that was adopted by FDA nearly three decades ago in an effort to protect small children from exposure to pharmaceutical products can still be justified today.

¹⁹Among other things, these data: 1) do not indicate if the drug products were packaged in CR formats; 2) provide outcomes data; or 3) describe the type of packaging involved (closure, unit dose, sample, etc.). In addition, AAPCC data presented in Table 22B include a small number of exposures that involved illegal street drugs, and the accuracy of these data is dependent on the number of Centers that report on a year-to-year basis (hence the dramatic increase in exposures recorded between 1989 and 1990).

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Conclusions

The HCPC believes that packaging is extremely important in protecting small children from accidental ingestion of drug products (Rx and OTC) in that packaging can serve as the last line of defense in preventing such ingestions. We also agree with CPSC that there are specific cases which can be cited whereby CR packaging has saved young lives. It is our strong belief, however, that available data point to the need to make significant improvements to 16 CFR 1700.20 -- at least as the test protocol applies to unit dose packaging -- and that these changes must be made before CPSC automatically applies PPPA requirements to OTC-switched drugs in the future.

To that end, we specifically support CPSC study of an alternative to 16 CFR 1700.20, based on mechanical testing, for unit dose formats intended to be used as manufacturers' original packaging for all but the most toxic drug products.

Such an alternative, we contend, would significantly reduce the need to use small children in protocol testing, and would also: 1) encourage use of unit dose formats as original packaging by drug manufacturers in the United States; 2) decrease the risk to small children of ingesting drug products as well as the severity of adverse outcomes that result from such ingestions; 3) reduce the number of Rx drug products that are being transferred into compliance-prompting formats that offer no child resistance whatsoever; and 4) help ensure that older persons can use unit dose formats properly.

At the very least, we urge CPSC to remove the disincentives to greater use of unit dose packaging as manufacturers' original packaging formats in the United States that exist under 16 CFR 1700.20 as currently implemented.

Until these changes to 16 CFR 1700.20 have been made, and until CPSC offers a more compelling justification for altering its current policies regarding OTC-switched drug products, the HCPC will continue to oppose the NPRM that was published by CPSC in the August 30, 2000 edition of the *Federal Register*.

On behalf of the Healthcare Compliance Packaging Council, I thank you for the opportunity to submit these comments. Please feel free to contact me should you have any questions or need additional information.

Peter G. Mayberry



Executive Director

Attachment Number 1

CPSC National Injury Information Clearinghouse Narratives Drug Poisonings: Age Six and Under (1983-10/03/00)

Total Number of poisonings reported: 2,042
 Narratives which specifically define packaging involved: 1,752 (85.6% of total)

Packaging Involved in Incidents	Total	% of Defined Pkgs
1. CR Container (type not specified):	255	14.6
2. Specified as CR Closures (total):	747	42.6
— CR packages described as "closed" when accessed by children:	333	19.0
— CR packages described as "loose" when accessed by children:	142	8.1
— CR packages described as "open" when accessed by children:	98	5.6
3. Specified as Blisters or "Calendar" Packs	37	2.1
— CR blister/calendar:	8	0.5
4. Non CR Packaging (type not specified):	207	11.8
— Non CR Requested by patient	17	0.97
5. Transferred from Original Packaging (OP) to Some Other Format:	96	5.5
6. Total Incidents Where Product Was Described as "Loose" from OP at time of incident:	377	21.5
— Not in container (no reason cited):	212	12.1
— Spilled:	63	3.6
— Intentionally Removed from OP by adult (CR/Non-CR unspecified)	49	2.8
— Removed from CR container by adult:	30	1.7
— Laid out by adult for later ingestion:	23	1.3
7. Total incidents where products were described as being a "sample" but specific packaging type is not defined:	33	1.9
— Packages described as physician samples:	11	0.6
Total:	1,752	100%

Attachment Number II

CPSC National Injury Clearinghouse Accident Investigation Narratives Drug Poisonings: Ages Six and Under (1983-10/03/00)

Total number of poisonings investigated: 1,140
 Narratives which specifically define packaging involved: 537 (47.1% of total)

Packaging Involved In Incidents:

	Total	% of Defined Pkgs
1. Closures (Total):	493	91.8
Outcomes: 47 deaths, 109 hospitalizations, 354 ER		
Closures, CR Specified:	343	63.9
Outcomes: 28 deaths, 65 hospitalizations, 259 ER		
— CR Closures functioning properly when accessed by children:	289	53.8
Outcomes: 22 deaths, 47 hospitalizations, 220 ER		
— CR Closures described as "loose" when accessed by children:	30	5.6
Outcomes: 1 death, 7 hospitalizations, 22 ER		
— CR Closures described as "open" when accessed by children:	12	2.2
Outcomes: 3 deaths, 9 ER		
— CR Closures described as "damaged" when accessed by children:	12	2.2
Outcomes: 2 deaths, 2 hospitalizations, 8 ER		
Closures, CR Unknown or Unspecified:	92	17.1
Outcomes: 9 deaths, 32 hospitalizations, 55 ER		
— Closure, CR unknown or unspecified	71	13.2
Outcomes: 7 deaths, 22 hospitalizations, 42 ER		
— Closure, CR unspecified, described as "open" when accessed:	16	3.0
Outcomes: 1 death, 6 hospitalizations, 9 ER		
— Closure, CR unspecified, described as "loose" when accessed:	5	0.9
Outcomes: 1 death, 4 ER		
Closures, Specified Non-CR:	62	11.6
Outcomes: 10 deaths, 12 hospitalizations, 40 ER		
2. Transferred from Original Packaging to Some Other Format:	26	4.8
Outcomes: 3 deaths, 1 hospitalization		
3. Blister Packaging:	18	3.4
Outcomes: 2 unknown, 2 hospitalizations, 14 ER		
— CR specified	2	0.4
— Oral Contraceptives	4	0.7
— Physician sample package	2	0.4

Attachment III

CPSC Accident Investigation Narratives Involving CR Blister Packaging Accessed by Children Ages Six and Under: 1983-10/03/00

1. Investigation Number: 900302HEP9003

Date: 3/1/90

Disposition: Treated and Released

Narrative:

The 16 month old victim showed no symptoms after it was thought that he ingested 1 tablet of Zantac which was in a blister packet CRC in the purse on a bedroom floor. The packet was in the purse for a long time the edges could have been roughened allowing them to be easily opened. The victim was taken to the hospital where he was observed and released. *The doctor was not sure if he had ingested any Zantac.* (Emphasis added)

2 Investigation Number: 900306HEP9004

Date: 3/2/90

Disposition: Treated and Released

Narrative:

The 3 year old male victim *showed no symptoms* after ingesting two tablets of children's aspirin substitute. When his 6 year old sister climbed onto the clothes hamper in the bathroom and then onto the sink to open the medicine cabinet and get the medicine and give to the victim. The two tablets were in a sample blister CRC. Mother was unsure who opened the packet and how they opened it. The victim was taken to the hospital, treated and released. (Emphasis added)

Attachment Y

CPSC Accident Investigation Narratives Involving Medications Transferred from Original Packaging to Compliance-Prompting
Formats: 1983-10/03/00

- 1 Investigation Number: 970523HEP9001
Date: 04/27/97
Disposition: Treated and Released
Narrative: The 2-year-old female victim suffered a possible poisoning. She was found by her mother holding a *plastic weekly reminder* pill holder containing vitamins and medicine that had been left out after use. The child had opened the container and was pointing at the pills. Poison control was called, and she was rushed to the hospital where her stomach was flushed. She was then released after spending most of the night at the hospital. (Emphasis added)
- 2 Investigation Number: 970911HEP9002
Date: 08/10/97
Disposition: Hospitalized
Narrative: A 2-year-old female victim ingested pills that were stored in her brother's *weekly pill holder*. The pill holders were tightly closed, but are not child proof. She was immediately taken to the emergency room and was admitted. (Emphasis added)
- 3 Investigation Number: 970911HEP9004
Date: 08/24/97
Disposition: Hospitalized
Narrative: A 2-year-old male victim ingested one pill that was stored in his grandfather's *weekly pill holder*. The pill holder was tightly closed, but was not childproof. After calling poison control, the victim's mother took him to the emergency room. The victim was admitted and spent one night in the hospital. (Emphasis added)
- 4 Investigation Number: 971029HEP9002
Date: 10/22/97
Disposition: Hospitalized
Narrative: The 2-year-old male victim suffered a possible poisoning after he may have ingested prescription pills. The pills were stored in a closed plastic *weekly pill holder*. The child was taken to the emergency room and admitted for observation. (Emphasis added)

Attachment Y

5. Investigation Number: 980330HEPP9005

Date: 03/16/98

Disposition: Hospitalized

Narrative: A 3-year-old male was treated for ingestion [of a] generic form of diabetes. The victim found the pills in a *weekly pill holder*, that is not child resistant. The container was closed and in his grandmother's suitcase. The victim was taken to the hospital and admitted. He had his stomach pumped and was observed over night before he was released. (Emphasis added)

6. Investigation Number: 980430HEPP9014

Date: 04/16/98

Disposition: Treated and Released

Narrative:

A 20-month-old male victim was visiting his grandmother's house when he apparently ingested a sleeping pill. He climbed onto a chair and then onto a freezer chest where the victim's grandmother had a plastic, *seven compartment, pill box* that was easy to open. When the victim's mother found the victim, he was making noises like he was choking and she found the open pill box next to him. She quickly rinsed his mouth and then gave him a glass of milk. The victim's mother called 911 and an ambulance was transported to the hospital where he was observed for a few hours and then released. (Emphasis added)

7. Investigation Number: 990419HEPP9029

Date: 03/12/99

Disposition: Hospitalized

Narrative:

The 3-year-old male victim was injured at his grandmother's house. The victim got into his grandmother's purse and opened her *weekly pill holder* ingesting 2 or 3 pills. The victim was taken by ambulance to the hospital where he was admitted and treated for poisoning. The victim was released from the hospital three days later. (Emphasis added)

8. Investigation Number: 000505HEPP9020

Date: 04/17/00

Disposition: Hospitalized

Narrative:

The victim is an 18-month-old female who was injured at home when she ingested her mother's prescription medication that was stored in a *7-day pill holder*. The victim was taken to the hospital, treated for poisoning and held overnight for observation. She was released the following day. (Emphasis added)



FAX COVER SHEET

To: Office of the Secretary

Company: U.S. Consumer Product Safety Commission

Fax #: 301/504-0127

Phone #: 301/504-0800

Number of Pages Including Cover Sheet: 28

From: Peter G. Mayberry, Executive Director

Date: November 13, 2000

Re: HCPC Comments

Message: Attached please find a copy of comments from the Healthcare Compliance Packaging Council in response to CPSC's Notice of Proposed Rule Making on "OTC-Switched" drugs that appeared in 8/30/00 edition of the *Federal Register*. We are also sending a confirmation copy via U.S. mail. Please feel free to call should you have any questions or need additional information. Thank you.

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www.untdose.org

OTC
comment
CP01-5

Todd A. Armitstead
Armitstead, Todd A.

From: John A. Armitstead
Sent: Thursday, August 31, 2000 2:07 PM
To: cpsc-os@cpsc.gov
Subject: CPSC - 16 CFR Part 1700 - Support

I agree with the stance documented in the CPSC notice relative to the proposed new rule on child-resistant packaging. These packaging requirements are needed by consumers to protect children. I am in support of the CPSC on this issue and urge submission and acceptance of these regulations.

John A. Armitstead, MS, RPh, FASHP

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