ISSN 1041-9489

SAFETY BRIEF

May, 2003 Volume 23, No. 3

Triodyne Inc.
Consulting Engineers & Scientists – Safety Philosophy & Technology
666 Dundee Road, Suite 103, Northbrook, IL 60062-2732
(847) 677-4730 FAX: (847) 647-2047
e-mail: infoserv@triodyne.com *www.triodyne.com*

Child Resistant Packaging-Regulations and Effectiveness, 1980-2002

By Cheryl A. Pattin, Ph.D., P.E.*

Figure 1 - Child Resistant Container

ABSTRACT

The Poison Prevention Packaging Act (PPPA) is a federally preemptive piece of legislation covering an ever expanding group of substances. The test methods used to establish compliance with the PPPA do not address the range of substances covered (e.g. liquids); the changing patterns of use of household substances such as increased use of liquid medications for children; or repeated access to and multiple reclosures of containers common in the home situation. To examine the effectiveness of the PPPA in addressing actual poisonings in children under 5, national databases from 1980 through March of 2002 were examined. The average age of children treated in hospitals was under 2, and fatalities due to *Assisted access* and *Transfer of contents* incidents were reported in children averaging under one year of age. These age ranges are below those of children used in child resistant packaging testing (3.5 to 4.25 years). More importantly, the average body weights -- directly related to the susceptibility to poisoning injury -- of children seen in hospitals is below the toxicity threshold set in the PPPA standard which is based on a 25 pound child. Training for children, the elderly, and parents would help increase awareness of *Transfer of contents* and *Assisted access* poisonings, which are disproportionately represented in fatal poisoning incidents of young children.

INTRODUCTION

Poisoning from household substances has been and continues to be a hazard to children under 5 years of age. In an effort to address this problem, the Poison Prevention Packaging Act (PPPA) of 1970 [1] was enacted as of December 30, 1970. The PPPA was enacted under the authority of 15 U.S.C. Chapter 39A, 1471-76. This act specified the formulation of a technical advisory committee and set forth a statement of federal preemption to be associated with the standards developed. Upon advice from the advisory committee and others, a federal regulation, 16 CFR, part 1700 [2], was developed. This federal regulation specified the substances covered by the PPPA (1700.14) and the testing method for evaluation of child resistant packaging (CRP) (1700.20). Figure 1 shows a child resistant container with a push-and-turn closure.

* Senior Mechanical and Biomechanical Engineer, Triodyne Inc., Niles, IL.

1. FEDERAL PREEMPTION (EXCLUSIVE SCOPE)

Even before substances to be regulated had been specified, this act had exclusive powers in the arenas in which it was applicable, as stated in 15 U.S.C. 1476:

"1476. Federal preemption.

Whenever a standard established by the Secretary under this Act applicable to a household substance is in effect, no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the standard established under section 1472 of this title (and any exemption therefrom and requirement related thereto) of this Act. (Pub. L. 91-601, 18, Dec. 30, 1970, 84 Stat. 1673.)"

2. SUBSTANCES COVERED (EXPANDING SCOPE)

Since the inception of the PPPA, the list of substances covered by the PPPA has grown to 31. Table I is a summary of the substances covered by the PPPA, and the year in which the CFR section was modified to include that substance, if known. Those substances added before 1973, when records began to be kept, are listed as <1973.

3. TESTING PROCEDURE

Poison prevention packaging standards are specified in 16 CFR 1700.15. Part (a) of this section discusses household substances in general, which include liquids, as shown in Table I. It states that CRP must continue to meet the effectiveness specifications, but no additional requirements for access from closed containers or containers containing varying substances are established.

*(b) **Effectiveness specifications.** Special packaging, tested by the method described in §1700.20, shall meet the following specifications:*

(1) Child-resistant effectiveness of not less than 85 percent without a demonstration and not less than 80 percent after a demonstration of the proper means of opening such special packaging. In the case of unit packaging, child-resistant effectiveness of not less than 80 percent.

(2) Adult-use effectiveness of not less than 90 percent.

Table I - Substances covered by the PPPA

Year	Number	Substance requiring special packaging
<1973	1	Aspirin (Except: effervescent, unflavored)
<1973	2	Furniture polish
<1973	3	Methyl salicylate
<1973	4	Controlled drugs
<1973	5	Sodium and/or potassium hydroxide
<1973	6	Turpentine
<1973	7	Kindling and or illuminating preparations
<1973	8	Methyl alcohol (methanol)
<1973	9	Sulfuric acid
<1973	10	Prescription drugs (long list of exceptions)
1973	11	Ethylene glycol
1973	12	Iron-containing drugs
1973	13	Dietary supplements containing iron
1973	14	[Reserved]
1973	15	Solvents for paint or other similar surface-coating material
1973	16	Acetaminophen (except: effervescent, unflavored)
1973	17	Diphenhydramine
1973	18	Glue Removers containing acetonitrile
1973	19	Permanent wave neutralizers containing sodium bromate or potassium bromate
1973	20	Ibuprofen
1973	21	Loperamide
1973	22	Mouthwash
1973	23	Lidocaine
1973	24	Dibucaine
1973	25	Naproxen
1973	26	Ketoprofen
1973	27	Fluoride
1973	28	Minoxidil
1973	29	Methacrylic acid
1973	30	Over-the-Counter Drug Products
1973	31	Hazardous substances containing low-viscosity hydrocarbons
1973	32	Drugs and cosmetics containing low-viscosity hydrocarbons

The time interval specified is 5 minutes, so the required effectiveness of the CRP is as follows:

Child CRP opening

85% effectiveness (up to 15% of children* can open without training) given 5 minutes.

80% effectiveness (up to 20% of children* can open with training) given an additional 5 minutes.

* 50 to 200 children aged 42 to 51 months (3.5 to 4.25 yrs) old

Adult CRP closure/resecuring

90% effectiveness (up to 10% of adults** cannot open and resecure within 6 minutes)

** Originally, the test panel was 100 adults, aged 18 to 45: an additional group of 100 seniors, aged 50 to 70, was added as of 1996.

The PPPA, as written, allows 20% of children tested to open child-resistant packaging within 10 minutes. This poorly understood aspect of the PPPA can lead to a false sense of security. Parents may feel that children will be unable to open a child-resistant package and thus leave them unattended for a period of time. Further, 10% of adults may be unable to open and reclose the package properly. This difficulty may provide an unintended incentive to transfer contents from CRP to non-CRP which is easier to open.

Section 1700.15 (a) states that the packaging must continue to meet the above effectiveness standards "when in actual contact with the substance contained therein," but this requirement "may be satisfied by appropriate scientific evaluation" of the chemical and physical properties of the substance. Continued effectiveness for the "number of openings and closings customary for its size and contents" may be shown by "appropriate technical evaluation" such as fatigue and wear testing. However, child and adult testing is performed on packages after at most a few openings and reclosures and which "may be empty or they may contain product" (16 CFR 1700.20).

The PPPA does not contain standards limiting access to various substances, including liquids, from *closed* CRP, nor does it address re-closure difficulties which might be encountered upon repeated use. Although the PPPA requires special packaging for a growing number of widely varying substances, the test protocol focuses on container integrity, not on access to substances contained within those containers. 16 CFR 1700.20 states that a "test failure shall be any child who opens the special packaging or gains access to its contents," but the testing procedure is performed on containers which "may or may not contain product." Thus, the procedure as stated does not include tests of "access to contents" of the enclosed substance.

The effectiveness of actual closures involved in poisoning incidents is lower than that required by the CRP standard quoted above. The Centers for Disease Control (CDC) reports on a 1987 study of closures retrieved following poisoning incidents in their Morbidity and Mortality Weekly Report (MMWR)[3]. This study investigated "the circumstances surrounding oral prescription drug ingestions by children under 5 years of age and of the efficacy of the closures used on the containers involved." The Consumer Product Safety Commission (CPSC) contacted selected individuals who had reported childhood poisoning incidents during 1986 and requested that the containers involved be sent to the CPSC for further testing. In response to the CPSC's request, 306 child-resistant containers were received for testing. "Tests proved that 200 (65%) of the 306 child-resistant containers received were ineffective."

4. EFFECT IS DEBATED

Many studies have shown a reduction in mortality among children below 5 years old associated with accidental ingestion of oral medication, including studies conducted by Rodgers, Clarke, and Walton at the CPSC [4-7]. However, these declining mortality figures occur within the context of greater awareness of child poisoning risks : "Long-term safety trends likely played a particularly important role in the declining mortality rate [7]." In an analysis controlling for increased safety awareness and examining a variety of substances, Viscusi contends that the claimed benefits of CRP are not significant and that there is a false dependency or "lulling effect" whereby "consumers ... are lulled into a less-safety-conscious mode of behavior by the existence of safety caps [8]."

Attempts to assess the efficacy of CRP are complicated by various factors including:

1) Changing substance use patterns [4]
2) Changing substance coding by federal agencies [7]
3) Lack of study with non-drug substances [7]
4) Lack of regulation governing substance access instead of container integrity during testing.

5. POISONING INCIDENTS 1980 - MARCH 13, 2002

National Electronic Injury Surveillance System (NEISS) and CPSC incident reports were obtained from 1980 through March 13, 2002 [9]. The presence or absence of CRP was noted in most reports. The cases where CRP use was noted involving substance ingestion, as opposed to burns or other consequences, were selected for analysis. The disposition of the poisoning incident was characterized as follows: *treated and released, hospitalization or further treatment required,* or *dead on arrival / died in the emergency department (DOA).* These incidents are taken from representative data collected by NEISS. Each incident reported here corresponds to approximately 50 national incidents, based on estimates provided by the CPSC.

The incidents involving CRP were then further subdivided into six categories (Table II). These categories are not mutually exclusive, but unique situations were noted where they arose, regardless of the nature of the substance involved. These categories were assigned based on verbal accounts and numerical codes provided. For example, if a child gained access to a container and the verbal account indicated that an older child fed some of the contents to a younger child, a category of Assisted access (10) was noted, regardless of the container contents. If liquid CRP content was noted, a category Liquid (5) was assigned. In the absence of verbal comments or relevant data, incidents were assigned to the most general category, Tablets/general medication (7).

Table II - Poisoning categories used in this study

Code	Description
5	Liquid Substance
6	Indications of problems with proper container closure
7	Tablets, general medication (if unspecified)
8	Loose tablets or medication
9	*Transfer of contents:* The contents of CRP were transferred to non-CRP
10	*Assisted access:* An older child gained access to the CRP and gave the contents to the younger victim

The results from 1,422 poisoning incidents involving the use of CRPs obtained from the NEISS and CPSC databases involving children under five were analyzed and placed in one of the above six categories. The results of this analysis are shown in Table III.

Table III allows an examination of trends in the poisoning data from 1980 through March 13, 2002. Areas of discussion will be: Mortality mechanisms (factors associated with DOA incidents); Liquid poisonings; and Age range of victims.

5.1 Mortality Mechanisms:

Assisted access to the contents of CRP and *Transfer of contents* from CRP to non-CRP were significantly ($p < 0.001$) overrepresented in the "DOA" poisoning incidents as compared to "treated and released" incidents. This finding must be interpreted with some caution, as the conditions resulting in DOA incidents are carefully examined, whereas cases involving hospital visits only may not be scrutinized to the same extent. With this caveat, the data show that the average age of the children who died as a result of *Assisted access* was 8 months (maximum 18 months), while that for those dying from *Transfer of contents* was one year (maximum 20 months). The average ages of DOA victims for all other categories (tablets, liquid, poorly secured caps and loose pills) were all over 16 months (maximum 24 months). Specific aspects associated with increased risk for child poisoning fatalities from *Assisted access* and *Transfer of contents* incidents are discussed below.

5.1.1 Assisted access.

The risk of poisoning from medication obtained by an older child is significant to a smaller, younger child. The younger child has a smaller body weight, and thus requires less medicine to sustain a fatal overdose than the older child. The older child who distributes the medication may have little or no understanding of this discrepancy or of dosing. The Victorian Injury Surveillance System in Australia notes "cases where an older child, usually a sibling, located and administered to or shared medication with the younger child - most commonly one year old [10]." A typical U.S. example of this is found in a May 24, 1989 report from the CPSC database: "Baby (10 months old) fed *** syrup by 2 yr. old sister [9]."

Training of siblings and parents regarding this issue might help prevent these poisonings. This could take the form of :

1) Warning children not to "share" medications with other children, especially younger children. These warnings could come from pediatricians, pharmacists, parents and child-focused labeling on the medicine packaging. The subject should be addressed in sibling classes that are common in many hospitals.

2) Warning parents in parental awareness venues, prenatal classes, parenting classes, and child first aid/CPR classes. Parents should also be verbally warned by the pediatrician when prescribing medication and via on-product warnings. Pharmacists should also verbally warn parents when they pick up prescriptions and over-the-counter medications.

Table III - Poisoning incidents involving the use of CRP from January 1980 through March 2002 (percentages in parentheses)

Disposition	Liquid (5)	Seal improperly closed (6)	Tablet / General (7)	Loose medicine (orginally in CRP) (8)	*Transfer of contents* (9)	*Assisted access* (10)	Total
Treated/ Released	306 (26.49%)	155 (13.42%)	531 (45.87%)	143 (12.38%)	8 (0.69%)	12 (1.04%)	1,155
Hospitalized / Further Treatment	84 ** (37.00%)	23 (10.13%)	88 * (38.77%)	25 (11.01%)	2 (0.88%)	5 § (2.20%)	227
DOA	4 * (10.00%)	5 (12.50%)	16 (40.00%)	5 (12.50%)	4 ** (10.00%)	6** (15.00%)	40

Statistical significance of Hospitalization/Further Treatment Required and DOA incidents versus incidents which were Treated and Released
Each of the incidents reported here represents approximately fifty actual cases.

** => $p < 0.001$
* => $p < 0.05$
§ => $0.05 < p < 0.1$
rest not significant, $p > 0.1$

5.1.2 Transfer of contents.

Greater morbidity associated with CRP to non-CRP transfer is due to a combination of the original harmful nature of the medication (as evidenced by the CRP it was originally packaged in) dosed for an adult and its subsequent placement into a container providing easier adult access which is then accessed by a young child. The CPSC has found that "about 20 percent of childhood poisonings occur in grandparents' houses" [11] where strong medications may be found in proximity to younger visiting grandchildren. In their 1987 study of the conditions relating to child poisonings, the CDC states [3] "Grandparents' medications accounted for a substantial number (17%)" of poisonings due to unintentional ingestions of prescription drugs in 1986. Grandparents often transfer potent medications to packages which are not child-resistant. A 2000 memo from the Healthcare Compliance Packaging Council (HCPC) to CPSC refers to "incidents ... where children gained access to drug products that had been transferred from their original packaging into non-CR 'reminder' packages" (Mayberry, 2000 [12]). Figure 2 shows some non-child resistant "reminder" packages.

Increased public awareness of *Transfer of contents* poisoning is needed. Training of elderly patients and parents regarding this issue might help prevent these poisonings. Elderly patients should be warned by the prescribing physician, the pharmacist, and labeling on the medicine packaging to keep medications securely stored when young children come to visit. Parents need to be made aware of the increased risk associated with *transfer of contents* accidents, when their children are visiting elderly relatives. Warnings could be provided in prenatal and other parenting classes and by the children's health care provider. Print and television public service announcements might help as well.

5.2 Liquid Poisonings:

Liquid medications form a growing part of the child medication market [13, 14]. Their use is preferred for young children, who have difficulty swallowing or chewing pills. As can be seen in Table III, poisonings involving liquid medications were significantly more likely to lead to hospitalization than treatment and immediate release. Poisoning incidents involving liquids accessed from CRP

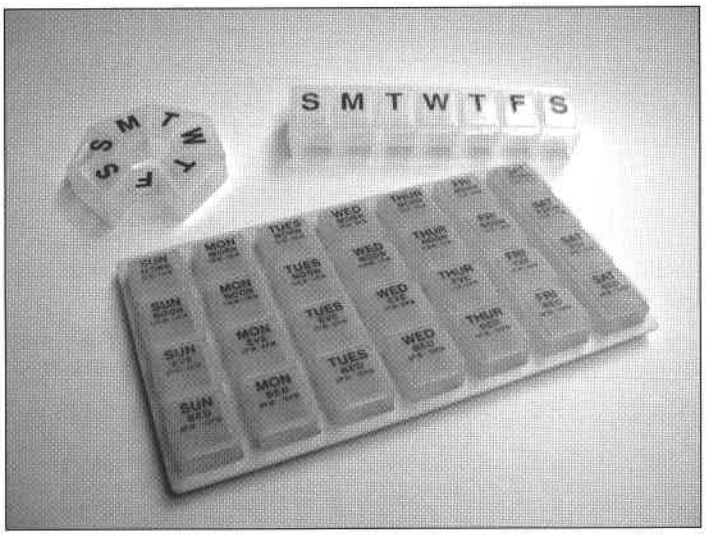

Figure 2 - Non-Child Resistant "Reminder" Packages

are also on the increase. Table IV shows incidences over 5-year intervals since 1980 of treated and released poisonings involving CRP with liquid contents. Note that this is a conservative count, since incidents involving incorrectly or loosely sealed CRP were categorized separately in Table III under "Seal improperly closed." Liquid incidents (5) involve access to the liquid contents of a CRP where sealing problems were not noted.

5.2.1 Increased use of liquid medications.

Table IV shows a dramatic increase in the percentage of liquid medication poisonings relative to the total cases treated and released over the last 7 years. This may well be due to the increased use of liquid oral medications for children. These newer liquid medications are often flavored, making them attractive to children even when they are no longer sick.

5.2.2 Test protocol independent of contents.

The test protocols established in the PPPA do not explicitly address limitations on access to liquid contents from closed containers as the containers tested "may not contain product" as discussed above. The 2000 memo from the HCPC cited

Table IV - Incidents involving a liquid substance contained in CRP

Years	Total Treated and Released	Liquid Posionings (5) treated and released	Percentage
1980-1984	55	7	12.7%
1985-1989	76	17	22.4%
1990-1994	426	60	14.1%
1995-1999	325	122	37.5%
2000-2001	294	100	34.0%

Each of the incidents reported here represents approximately fifty actual cases.

above states "in the United States ... 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.) [12]." It may be further noted that physical properties, such as viscosity, or resistance to fluid flow, vary widely over the substances controlled under the PPPA.

5.2.3 Effectiveness of closed CRPs with liquid contents.

As shown in Table III, 394 poisoning incidents have resulted from access to liquid enclosed in CRP. Many such poisonings involving a liquid substance occur without opening the CRP. The incident reports obtained refer to CRP as child-resistant containers (CRCs). 161 out of the 306 (or 53%) poisoning cases involving a liquid in which the victim was treated and released involved cases where "CRC was closed" is noted in the incident comments. 66 out of the 84 (or 79%) liquid poisoning cases in which hospitalization or further treatment was required involved cases in which the "CRC was closed." Here is a typical report entry: "a boy, age 3, ingested some liquid antihistamine from a child-resistant container that was closed." It is likely that at least some of the 53% of the liquid CRP-involved cases which were treated and released, and 74% requiring further treatment involved access from closed CRP which remained closed.

5.2.4 Effectiveness of CRPs with repeated access.

Poisoning incidents involving liquids may be related to degrading performance of the closure on the CRP. A 1987 report from the CDC based on 1986 data cites failures of CRP enclosing liquid medications [3]. The CPSC contacted selected individuals who had reported childhood poisoning incidents during 1986 and requested that the containers involved be sent to the CPSC for further testing. In response to the CPSC's request, 306 child-resistant containers were received for testing. Of these, "two hundred and twenty-nine containers used for liquid medications had continuous-thread closures. Sixty-nine percent of these were ineffective; 87% of these failures were associated with a buildup of liquid residue on the threads." The CRP testing protocol should examine container integrity under continuous use, especially of containers enclosing liquid substances.

5.2.5 Existing protocol governing access to liquid contents.

The PPPA does not address access to liquid contents of child resistant containers. The testing protocol for containers intended to enclose liquid product should be modified by including a liquid such as water or corn syrup and allowing the children on the test panel to attempt to gain access. Although the PPPA does not address such active attempts to access liquid contents, there is a Canadian regulation governing access to liquid contents of CRP. Canadian regulation H-3 - SOR/2001-269 specifies methods for testing child resistant containers for leaks [15]:

"2. Except in the case of a single-use container,

(a) open the test sample;

(b) remove any seal that is present under the closure in accordance with the manufacturer's instructions or, if no instructions are provided, puncture the seal; and

(c) reclose the sample as tightly as possible without stripping the threads of the closure."

The container is then positioned "in an inverted position at a 45° angle below the horizontal" over a clean piece of blotting paper for one hour. After one hour, the tester shall "examine the paper for evidence that any of the contents have leaked from the sample."

This regulation could be a starting point for the development of a U.S. testing protocol, but the amended regulation would also need to address active attempts to gain access to liquid contents (such as sucking on the mouth of the CRP) from the children test panel and container performance after multiple openings and reclosures (see 5.2.4).

5.2.6 Suggested CRP testing protocol modifications.

The testing procedure to determine the child-resistance of a container should include liquid contents. The liquid contents used for testing could be water or a more viscous fluid, such as syrup. A viscous fluid could be used to duplicate the problem of residue buildup as seen in retrieved container studies. Such a modification to the CRP testing protocol would be appropriate given the increased use of liquid medications for children and the corresponding increase in poisoning incidents related to children's liquid medication use. The continued effectiveness of CRP during repeated access to liquid contents, such as seen in the home situation, might also be tested, given the study of retrieved containers [3].

5.3 Age range of victims and substance ingestion threshold

5.3.1 Ages of poisoning victims.

Children involved in actual poisoning incidents are younger than those used to establish child-resistant capability. Table V presents data on the average age of the poisoning victims studied here. Children used to test CRP opening capability are 3.5 years (42 months) to 4.25 years (51 months) old. The average age of children involved in poisoning incidents of all varieties — treated and released, hospitalized, and DOA — was less than two years old, well below the 42 month lower limit of the children used in the test protocol. Children who are victims of fatal incidents involving *Transfer of contents* and *Assisted access* are younger still, averaging under a year old. The two-stage 10-minute test protocol is undoubtedly more feasible for older children, but older children may not be as motivated by the curiosity or oral fixation characteristic of children under 3 years old [10].

Table V - Average and 5th percentile weights of children in the United States (Snyder, 1975)

Age Range	N	Average weight (pounds)	Average weight (kg)	5% weight (pounds)	5% weight (kg)
0 - 3 months	127	10.4	4.7	6.8	3.1
4 - 6 months	84	15.4	7.0	11.9	5.4
7 - 9 months	49	18.3	8.3	14.3	6.5
10 - 12 months	41	20.3	9.2	16.5	7.5
Average age of fatalities from assisted access and transferred contents below this level					
13 - 18 months (1 - 1.5 years)	47	22.5	10.2	18.1	8.2
19 - 24 months (1.5 - 2 years)	51	26.0	11.8	22.3	10.1
Average age of CRP-involved cases in current study below this level					
25 - 30 months (2 - 2.5 years)	54	28.5	12.9	23.5	10.7
31 - 36 months (2.5 - 3 years)	60	29.8	13.5	24.3	11.0
37 - 42 months (3 - 3.5 years)	157	32.9	14.9	27.1	12.3
CRP testing protocol uses children from 42 to 51 months of age (3.5 - 4.25 years old)					
43 - 48 months (3.5 - 4 years)	163	34.4	15.6	27.8	12.6
49 - 54 months (4 - 4.5 years)	203	37.0	16.8	30.6	13.9

Weights below the 25 pound (11.4 kg) limit are shaded

5.3.2 Weight of poisoning victims.

Younger children also weigh less and the weight of the poisoning victim has a profound effect on the severity of injury suffered [16]. The poisoning toxicity threshold that should be used is below that specified in the act. 16 CFR 1700.20 states, "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." Table V shows average (50th percentile) and 5th percentile weights of combined male and female children up to the age of 4.5 years (Snyder, 1975). Weights below the 25 pounds specified in the act are shown in gray. The N column indicates the number of children weighed for each age range.

5.3.3 Suggested CRP testing protocol modifications.

The 25 pound guideline for assessing toxicity is obviously too high for the young children treated in hospitals due to poisoning incidents. It is, however, applicable to the older children used in the CRP test protocol. The toxicity limit stated in 16 CFR 1700.20 should be revised to reflect this disparity.

6. Conclusions:

The PPPA (the Act) should be modified in the following manner:

The Act should address access to liquid contents

- Childhood poisonings due to liquid medications are increasing
- Use of liquid medications is on the rise, especially for young children

The Act should use a lower body weight for the determination of a toxicity threshold

- The toxicity threshold is currently based on a 25 pound level (16 CFR 1700.20)
- Based on the results presented in Table V, a reference weight of 15 pounds would be more appropriate

The Act should address repeated product opening and reclosures

The public should be made aware of limitations allowed by the PPPA:

- 20% of children aged 42 to 51 months old may be able to open a child resistant container after 10 minutes.

- 10% of adults and elderly individuals may be unable to open or properly reclose a child-resistant container.

- Children used in testing of child resistant containers are older than those seen in poisoning incidents.

The public may mistakenly assume that child-resistant containers are "child proof" and exercise less caution in placing the medications out of easy reach of children. Clarification should come from health care providers, pharmacists and through product labeling on children's medication.

The following measures would immediately increase community awareness of two particularly serious types of childhood poisonings.

Assisted Access

- **Children** should be warned not to "share" medications, especially with younger children.

- **Parents** should be warned in parenting classes, by health care providers, and through product labeling on children's medication.

Transfer of Contents

- **Elderly patients** should be warned to keep medications securely stored when young children come to visit.

- **Parents** should be warned of the dangers which may be posed to young children left in the care of those who may transfer their medicines into easier opening bottles, pillboxes, plastic bags, or other containers.

REFERENCES

1. Poison Prevention Packaging Act of 1970. 15 USC sections 1471-1476, 1970.

2. 16 CFR Part 1700.

3. "Epidemiologic Notes and Reports [of] Unintentional Ingestions of Prescription Drugs in Children Under Five Years Old," Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, March 13, 1987 36(9);124-6,131-2

4. Clarke, A. and Walton, W.W., "Effects of Safety Packaging on Aspirin Ingestion by Children," Pediatrics, 1979; 63:5; 687-693.

5. Walton, W. W., "An evaluation of the poison prevention packaging act," Pediatrics. 1982; 69: 363-370.

6. Rodgers, G. B., "The Safety Effects of Child-Resistant Packaging for Oral Prescription Drugs : Two Decades of Experience", JAMA, 1996; 275:1661-1665.

7. Rodgers, G. B., "The Effectiveness of Child-Resistant Packaging for Aspirin", Archive of Pediatrics & Adolescent Medicine, Vol. 156, Sept. 2002.

8. Viscusi, W.K., "The lulling effect: the impact of child-resistant packaging on aspirin and analgesic ingestions", American Economic Review., 1984; 74: 324-327.

9. U.S. Consumer Product Safety Commission, 2002.

10. Routley, V., Ozanne-Smith, J., Ashby, K., "Poisonings in early childhood" Hazard, Edition 27, June 1996 Victorian Injury Surveillance System, Monash University, Accident Research Centre

11. Mayer, C. E., "Child-Resistant Caps to Be Made 'Adult Friendly' Commission Orders Companies to Make Packaging Easier to Open to Encourage Use", Washington Post, June 16, 1995.

12. Mayberry, P.G., "RE: HCPC Opposition to 'Child-Resistant Packaging for Certain Over-the-Counter Drug Products,' (65 FR 169, pp 52678-52684).", Nov. 13, 2000, http://www.unitdose.org/cpsc_comments.htm.

13. "Children's Motrin To Market Expanded OTC Pediatric Ibuprofen Line" http://www.kidsource.com/kidsource/content/news/motrin6_29_96.html

14. "Times&Trends: A Snapshot of Trends Shaping the CPG Industry", http://www.gmabrands.com/publications/gmairi/2002/august/august.pdf, Information Resources, Inc, 2002.

15. "Test Method for Determining whether a Container Leaks", Hazardous Products Act : Consumer Chemicals and Containers Regulations, 2001 SOR/2001-269, Schedule 3, Section 7, effective October 1, 2001.

16. Nordenberg, T. "Pediatric Drug Studies: Protecting Pint-Sized Patients", FDA Consumer Magazine, May-June, 1999.

SAFETY BRIEF

May 2003 – Volume 23, No. 3

Editor: Paula L. Barnett

Illustrated and Produced by

Triodyne Graphic Communications Group