U.S. Consumer Product Safety Commission
LOG OF MEETING

SUBJECT: Healthcare Compliance Packaging Council

DATE OF MEETING: November 18, 2002

LOG ENTRY SOURCE: OEX

DATE OF LOG ENTRY: 12/27/02

LOCATION: Room 410 CPSC Headquarters

CPSC ATTENDEE(S): see attached list

NON-CPSC ATTENDEE(S): see attached list

SUMMARY OF MEETING: see attached outline

CPSA 6 (b)(1) Cleared 1-458 3

___No Mfrs/PrvtLblrs or Products Identified

___Excepted by_____

___Firms Notified, Comments Processed.

11/18/02

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Presentation to the U.S. CPSC

Prepared by:
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Healthcare Compliance Packaging Council
November 18, 2002

Introductions

- Members of HCPC Board of Directors
- Peter Mayberry

Rx Drug Distribution: US v. EU, Asia, Latin America, Mexico

- U.S.
  - Pharma manufacturer ships drug in bulk bottle w/ CR cap.
  - Pharmacy personnel transfer drugs from bulk to cap-and-bottle closure (provided by pharmacy) when prescription is presented.
  - Cap can be either CR or non-CR depending on consumer preference.
- Other Countries
  - Manufacturer ships drug in unit dose format.
  - Manufacturers' original packaging (OP) is dispensed to consumer when prescription is presented.

Disadvantages of U.S. System

- Pharmacy Repackaging = mistakes
- Pharmacy Repackaging compromises product integrity & efficacy
  - Environmental exposure inevitable
  - Stabilities are out the window
- Pharmacy Repackaging facilitates diversion/theft (U.S. DEA)
- Pharmacy Repackaging prevents use of bar codes of information (NDC, lot, expiration date) on each dosage unit

Disadvantages of U.S. System

- Pharmacy repackaging allows instant access to the entire contents of the closure system if the CR cap is not properly replaced every time the package is used – assuming there was a CR cap in the first place.
  - 47 fatalities of children less than 6 years old who defeated cap-and-vial closures (1983-2002, CPSC).
  - 22 of these fatalities involved "CR" closures
  - Dozens of incidents where children ingested large amounts of drug from defeated cap-and-vial closures
    - Five incidents where children ingested 61-75 dosage units

Consumer Advantages of Unit Dose

- Each dosage unit is protected from the time it is manufactured until the time it is ingested.
- Each dosage unit can be accounted for from the time it is manufactured until the time it is ingested.
- Reduces handling of Rx products by pharmacy personnel.
- Can be designed to deter theft, tampering, diversion and counterfeiting.

Consumer Advantages of Unit Dose

- Inherently more child-resistant than cap-and-vial closures.
  - FDA Iron regulations
    - "…unit-dose packaging, ***even conventional unit-dose packaging***, limits pediatric access to product and is not dependent on proper reclosure of the container."
    - "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 accomplish this goal by limiting the amount of iron that a child can consume in a short period of time."
      - *Federal Register*, January 15, 1997, pp. 2227-2231, emphasis added
  - Provides emergency responders more accurate idea of how many dose units have been ingested
  - 0 fatalities discerned from CPSC data

Support for Original Packaging in the United States

- **Department of Veterans' Affairs**
- **U.S. Centers for Disease Control**
- **U.S. Pharmacopeial Convention (USP)**
- **Institutes of Medicine**
  - "If medications are not packaged in single doses by the manufacturer, they should be prepared in unit doses by the central pharmacy" (*To Err is Human: Building a Safer Health System*, 1999, p. 166)
- **National Patient Safety Partnership**
  - Best Practice: "Use of unit dose drug distribution systems for inpatient care; also use such systems for outpatient care, where appropriate"
  - NPSC Members: U.S. Department of Veterans' Affairs, the American Hospital Association, the American Medical Association, the American Nurses Association, the Association of American Medical Colleges, and the Joint Commission on Accreditation of Healthcare Organizations
- **American Society of Health-System Pharmacists**

Why so little Unit Dose in the US?

- Good question.
  - CPSC protocol plays a role
    - Subjective pass/fail criteria for unit dose v. objective pass/fail criteria for bottles.
    - Protocol can be used to facilitate bulk distribution which is cheaper/easier for pharma manufacturers.
    - Protocol allows consumers to disarm CR or simply refuse CR.
      - Many consumers do not like, want, or feel they need CR packaging.
      - Congress recognizes this in the PPPA.

Poison Prevention Packaging Act of 1970 (PPPA)

- Enacted: 1970
- CR protocol established by FDA: 1973
  - Few unit dose packages on the market
  - No representation by unit dose industry in FDA decision making process
  - FDA personnel say that protocol provisions developed at the time were based on "arbitrary decisions"

PPPA/CR Protocol

- Subjective criteria – 16 CFR 1700.20 (a)(2)(ii):

- 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. (Emphasis added)

PPPA

- Prohibits CPSC from mandating use of one type of packaging over another.
- But
- Grants CPSC authority to alter protocol as the Commission sees fit.
  - 1995 "adult friendly" alterations

Recommendations

- CPSC should alter protocol to remove subjective pass/fail criteria for unit dose formats.
- Or
- CPSC should allow unit dose that allows consumers to defeat CR features at will.
  - Congressional intent