Evaluation of Unit Dose Packaging Dispensed to Outpatients for Child Resistant Features

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The North Carolina Board of Pharmacy (NCBOP) frequently receives queries from pharmacists on whether the unit dose packaging that is dispensed to outpatients is considered "child resistant". Based upon the need to provide information to pharmacists on the child resistant nature of unit dose packaging dispensed to outpatients, the NCBOP requested the assistance of Campbell University School of Pharmacy, Department of Clinical Research (CU) to evaluate the matter.

Child resistant standards are based upon the requirements of the Poison Prevention Packaging Act (PPPA) of 1970. The PPPA requires special packaging of hazardous household substances to protect children from serious personal injury or serious illness from handling, using or ingesting the substances. Drug products containing controlled substances, most human oral prescription drug products (including oral investigational drugs used in outpatient trials) and OTC drug preparations containing aspirin, acetaminophen, diphenhydramine, liquid methyl salicylate, ibuprofen, loperamide, lidocaine, dibucaine, naproxen, iron or ketoprofen, require special packaging (16 CFR § 1700.14).

According to the PPPA, pharmacists must dispense all prescription medicine in a child resistant package unless the patient specifically requests non-child resistant packaging. The U.S. Consumer Product Safety Commission (CPSC) has established a testing protocol to determine whether the packaging meets these child resistant standards16 CFR 1700.20. In the case of unit dose packaging, currently, the same standards apply as for bottle packaging. In summary, the child resistant test protocol states that a package passes if at least 85% of the kids were unable to get it open within the first five minutes, or at least 80% were unable to get it open after the demonstration/use of teeth instruction. The definition of a package failing takes into account a child not gaining access to a number of units which may produce serious personal injury or illness, or more than 8 individual units, whichever is lower. The number of units which a child can gain access to is referred to as the "F value" or failure level. The F level will vary according to the toxicity of the substance. The most toxic substances the packaging required must meet an F=1 level. Therefore, unit dose packaging which meets an F=1 level will be suitable to meet the child resistant packaging requirements for any medicine that the pharmacist dispenses. Packaging designated child resistant must be the primary package. Using child resistant packages as the secondary package would not comply with the PPPA.

Unit packaging has been classified four standard types. An ASTM classification (see www.cpsc.gov/businfo/pppaguid/astmindex.html) does not denote that a package is child resistant, but is an organizational classification scheme. The four unit packaging types are Type IV Non-reclosable packaging (flexible (strip/pouch), 2) Type VIII Non-reclosable packaging – semi rigid (blister), 3) Type XI Reclosable packaging- flexible and 4) Type XIII Reclosable packaging- semi rigid (blister). Of the above types of packaging, the manufacturers have indicated the packaging below is considered child

resistant. As recommended by the CPSC, the pharmacist should contact the manufacturer directly to determine the F level of the packaging listed in Table 1.

Table 1 (modified from www.cpsc.gov/businfo/pppaguid/astmindex.html)

Type	Manufacturer	Packaging
IV C- Nonreclosable packaging flexible strip/pouch	PacTech	Child Resistant Unit Dose Pouch
VIII- Non-Reclosable Packaging - Semi-Rigid (Blister)	Colbert Packaging	PharmaDial
	Keystone Folding Box Company	Key-Pak F1
VIII I-Internal Tear (Hidden) Notch	Cardinal Health	EZ Tear
VIIIJ- Remove a Portion (Tab) and Push Out	Howell Packaging	Howell CRIII
	Mead Westvaco HealthCare Packaging	PerfPak
VIIIM- Bend, Peel Back, Push Out	Intini Marketing, Inc	Bend and Peel Blister Pak
XIA Squeeze Two Specific Points Simultaneously, Lift Zipper Tab And Pull To Open	PacTech, LLC	CRREO Zipper Pouch
XIII- Reclosable Packaging - Semi-Rigid (Blister XIIIA Press Hold, Pull Out (Parts Remain Together), Push Out	Mead Westvaco Healthcare Packaging	DosePak
	Mead Westvaco Healthcare Packaging	ShellPak
XIIIB Pull Trigger, Lift Flap, Push Out	Mead Westvaco Healthcare Packaging	SurePak, FullFormat SurePak
XIIID Unit Dose Blisters In Case, Slide Blisters To Align With Holes In Bottom Of Case, Push Out, Blisters Then Non-Align	Cardinal Health	SlidePack
XIIIE Press Then Flex And Lift To Open	Rondo AG	TopPak
XIIIF Push In, Squeeze and Hold, Hold and Pull	StoraEnso Packaging Boards	PharmaPak SHR

In order to evaluate whether North Carolina pharmacies are currently dispensing medicines in unit dose packaging and whether the packaging meets child resistant requirements, CU attempted to contact the 523 hospital and nursing home pharmacies in the NCBOP database. Of those who were contacted, 51 agreed to participate in the survey and send back sample packaging. Of the 51, only 9 returned a response and 4 returned packaging. An attempt was made to contact the pharmacies who did not respond or return packaging; however on follow up contact, the overwhelming response was that the pharmacy did not dispense unit dose packaging to outpatients or if they did, it was only if the patient provided a waiver that a non child resistant package was requested. Of the 4 packages obtained from pharmacies, there were none that met child resistant features (i.e., the packaging was simple blister packs or zippered lock bags).

In order to fulfill the requirements of dispensing medicines in packaging that meet maximum child resistant requirements, pharmacists may utilize packaging meeting an F=1 level. Of note, zippered lock bags are not child resistant. To be child resistant, the reclosable bag must contain a child resistant feature and pass the child tests. Further, to be child resistant blister packaging requires at least one child resistant feature and pass testing. For repackaging single doses, the packaging example described in Table 1 for XIA may be suitable. However, before using any packaging described as child resistant, pharmacists should confirm with the manufacturer whether the child testing has been passed.

In summary, pharmacists may dispense medication as unit dose without a child resistant feature if the patient requests such packaging (usually obtained by written waiver). The CPSC has published a guide for health care professionals that details specifics about these responsibilities (please refer to website-www.cpsc.gov/cpscpub/pubs/384.pdf).