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PP 03-1

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

OFFICE OF THE GENERAL COUNSEL

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May 27, 2003

Mr. Peter G. Mayberry
Executive Director
Healthcare Compliance Packaging Council
252 N. Washington Street
Falls Church, Virginia 22046

Dear Mr. Mayberry:

The requests in your letter to the Secretary of March 17, 2003 and the supplemental information provided in your letter to me of May 5, 2003 have been reviewed to determine whether the requests and supporting information meet Commission requirements for docketing as petitions for rulemaking. 16 CFR part 1051. The requests are as follows:

- The definition of test failure for unit dose packaging [at 16 CFR 1700.20(a)(2)(ii)] should be an objective standard, *i.e.*, "any child who opens or gains access to more than 8 individual units during the full 10 minutes of testing."

- Allow type testing for unit dose packaging under the [CPSC child resistance testing] protocol.

Your first request has been docketed by the Office of the General Counsel as petition for rulemaking number PP 03-1 under the Poison Prevention Packaging Act (PPPA). Accordingly, the Commission will proceed to address it in accordance with the CPSC regulations, copy enclosed, governing consideration of petitions for rulemaking. 16 CFR part 1051.

Your second request has not been docketed as a petition for rulemaking because the current CPSC regulations implementing the PPPA do not restrict a company from relying on child-resistance test data generated by the package manufacturer or from testing of similar packaging for a different substance. For this reason, your second request and the information

provided in support of it do not set forth facts that establish a claim, as required by 16 CFR 1051.5(a)(4), that an amendment to the rule in question is necessary.

If you desire to make another submission to the CPSC requesting action on your second request, please address the issue raised in this letter. Any such subsequent submission will be considered accordingly under the PPPA and the Commission's rules for docketing of petitions for rulemaking.

Sincerely,

Stephen Lemberg

Enclosure

16 CFR
Commercial Practices
CHAPTER II
CONSUMER PRODUCT SAFETY COMMISSION

SUBCHAPTER A – GENERAL

PART 1051 – PROCEDURE FOR PETITIONING FOR RULEMAKING

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Authority: 5 U.S.C. 553(e), 5 U.S.C. 555(e).

Source: 48 FR 57123, Dec. 28, 1983, unless otherwise noted.

[TOP]

§1051.1 Scope.

(a) This part establishes procedures for the submission and disposition of petitions for the issuance, amendment or revocation of rules under the Consumer Product Safety Act (CPSA) (15 U.S.C. 2051 *et seq.*) or other statutes administered by the Consumer Product Safety Commission.

(b) Persons filing petitions for rulemaking shall follow as closely as possible the requirements and are encouraged to follow as closely as possible the recommendations for filing petitions under §1051.5.

(c) Petitions regarding products regulated under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261 *et seq.*) are governed by existing Commission procedures at 16 CFR 1500.82. Petitions regarding the exemption of products regulated under the Poison Prevention Packaging Act of 1970 (PPPA) (15 U.S.C. 1471 *et seq.*) are governed by existing Commission procedures at 16 CFR part 1702. In addition, however, persons filing such petitions shall follow the requirements and are encouraged to follow the recommendations for filing petitions as set forth in §1051.5.

[48 FR 57123, Dec. 28, 1983 as amended at 64 FR 48704, Sept. 8, 1999]

[TOP]

§1051.2 General.

(a) Any person may file with the Commission a petition requesting the Commission to begin a proceeding to issue, amend or revoke a regulation under any of the statutes it administers.

(b) A petition which addresses a risk of injury associated with a product which could be eliminated or reduced to a sufficient extent by action taken under the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970, or the Flammable Fabrics Act may be considered by the Commission under those Acts. However, if the Commission finds by rule, in accordance with section 30 (d) of the CPSA, as amended by Public Law 94-284, that it is in the public interest to regulate such risk of injury under the CPSA, it may do so. Upon determination by the Office of the General Counsel that a petition should be considered under one of these acts rather than the CPSA, the Office of the Secretary shall docket and process the petition under the appropriate act and inform the petitioner of this determination. Such docketing, however, shall not preclude the Commission from proceeding to regulate the product under the CPSA after making the necessary findings.

[TOP]

§1051.3 Place of filing.

A petition should be mailed to: Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207. Persons wishing to file a petition in person may do so in the Office of the Secretary, at 4330 East West Highway, Bethesda, Maryland.

[48 FR 57123, Dec. 28, 1983, as amended at 62 FR 46667, Sept. 4, 1997]

[TOP]

§1051.4 Time of filing.

For purposes of computing time periods under this part, a petition shall be considered filed when time-date stamped by the Office of the Secretary. A document is time-date stamped when it is received in the Office of the Secretary.

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§1051.5 Requirements and recommendations for petitions.

(a) *Requirements.* To be considered a petition under this part, any request to issue, amend or revoke a rule shall meet the requirements of this paragraph (a). A petition shall:

(1) Be written in the English language;

(2) Contain the name and address of the petitioner;

(3) Indicate the product (or products) regulated under the Consumer Product Safety Act or other statute the Commission administers for which a rule is sought or for which there is an existing rule sought to be modified or revoked. (If the petition regards a procedural or other rule not involving a specific product, the type of rule involved must be indicated.)

(4) Set forth facts which establish the claim that the issuance, amendment, or revocation of the rule is necessary (for example, such facts may include personal experience; medical, engineering or injury data; or a research study); and

(5) Contain an explicit request to initiate Commission rulemaking and set forth a brief description of the substance of the proposed rule or amendment or revocation thereof which it is claimed should be issued by the Commission. (A general request for regulatory action which does not reasonably specify the type of action requested shall not be sufficient for purposes of this subsection.)

(b) *Recommendations.* The Commission encourages the submission of as much information as possible related to the petition. Thus, to assist the Commission in its evaluation of a petition, to the extent the information is known and available to the petitioner, the petitioner is encouraged to supply the following information or any other information relating to the petition. The petition will be considered by the Commission even if the petitioner is unable to supply the information recommended in this paragraph (b). However, as applicable, and to the extent possible, the petitioner is encouraged to:

(1) Describe the specific risk(s) of injury to which the petition is addressed, including the degree (severity) and the nature of the risk(s) of injury associated with the product and possible reasons for the existence of the risk of injury (for example, product defect, poor design, faulty workmanship, or intentional or unintentional misuse);

(2) State why a consumer product safety standard would not be feasible if the petition requests the issuance of a rule declaring the product to be a banned hazardous product; and

(3) Supply or reference any known documentation, engineering studies, technical studies, reports of injuries, medical findings, legal analyses, economic analyses and environmental impact analyses relating to the petition.

(c) *Procedural recommendations.* The following are procedural recommendations to help the Commission in its consideration of petitions. The Commission requests, but does not require, that a petition filed under this part:

(1) Be typewritten,

(2) Include the word "petition" in a heading preceding the text,

(3) Specify what section of the statute administered by the Commission authorizes the requested rulemaking,

(4) Include the telephone number of the petitioner, and

(5) Be accompanied by at least five (5) copies of the petition.

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§1051.6 Documents not considered petitions.

(a) A document filed with the Commission which addresses a topic or involves a product outside the jurisdiction of the Commission will not be considered to be a petition. After consultation with the Office of the General Counsel, the Office of the Secretary, if appropriate, will forward to the appropriate agency documents which address products or topics within the jurisdiction of other agencies. The Office of the Secretary shall notify the sender of the document that it has been forwarded to the appropriate agency.

(b) Any other documents filed with the Office of the Secretary that are determined by the Office of the General Counsel not to be petitions shall be evaluated for possible staff action. The Office of the General Counsel shall notify the writer of the manner in which the Commission staff is treating the document. If the writer has indicated an intention to petition the Commission, the Office of the General Counsel shall inform the writer of the procedure to be followed for petitioning.

[TOP]

§1051.7 Statement in support of or in opposition to petitions; Duty of petitioners to remain apprised of developments regarding petitions.

(a) Any person may file a statement with the Office of the Secretary in support of or in opposition to a petition prior to Commission action on the petition. Persons submitting statements in opposition to a petition are encouraged to provide copies of such statements to the petitioner.

(b) It is the duty of the petitioner, or any person submitting a statement in support of or in opposition to a petition, to keep himself or herself apprised of developments regarding the petition. Information regarding the status of petitions is available from the Office of the Secretary of the Commission.

(c) The Office of the Secretary shall send to the petitioner a copy of the staff briefing package on his or her petition at the same time the package is transmitted to the Commissioners for decision.

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§1051.8 Public hearings on petitions.

(a) The Commission may hold a public hearing or may conduct such investigation or proceeding, including a public meeting, as it deems appropriate to determine whether a petition should be granted.

(b) If the Commission decides that a public hearing on a petition, or any portion thereof, would contribute to its determination of whether to grant or deny the petition, it shall publish in the FEDERAL REGISTER a notice of a hearing on the petition and invite interested persons to submit their views through an oral or written presentation or both. The hearings shall be informal, nonadversary, legislative-type proceedings in accordance with 16 CFR part 1052.

[TOP]

§1051.9 Factors the Commission considers in granting or denying petitions.

(a) The major factors the Commission considers in deciding whether to grant or deny a petition regarding a product include the following items:

(1) Whether the product involved presents an unreasonable risk of injury.

(2) Whether a rule is reasonably necessary to eliminate or reduce the risk of injury.

(3) Whether failure of the Commission to initiate the rulemaking proceeding requested would unreasonably expose the petitioner or other consumers to the risk of injury which the petitioner alleges is presented by the product.

(4) Whether, in the case of a petition to declare a consumer product a "banned hazardous product" under section 8 of the CPSA, the product is being or will be distributed in commerce and whether a feasible consumer product safety standard would adequately protect the public from the unreasonable risk of injury associated with such product.

(b) In considering these factors, the Commission will treat as an important component of each one the relative priority of the risk of injury associated with the product about which the petition has been filed and the Commission's resources available for rulemaking activities with respect to that risk of injury. The CPSC Policy on Establishing Priorities for Commission Action, 16 CFR 1009.8, sets forth the criteria upon which Commission priorities are based.

[TOP]

§1051.10 Granting petitions.

(a) The Commission shall either grant or deny a petition within a reasonable time after it is filed, taking into account the resources available for processing the petition. The Commission may also grant a petition in part or deny it in part. If the Commission grants a petition, it shall begin proceedings to issue, amend or revoke the rule under the appropriate provisions of the statutes under its administration. Beginning a proceeding means taking the first step in the rulemaking process (issuance of an advance notice of proposed rulemaking or a notice of proposed rulemaking, whichever is applicable).

(b) Granting a petition and beginning a proceeding does not necessarily mean that the Commission will issue, amend or revoke the rule as requested in the petition. The Commission must make a final decision as to the issuance, amendment, or revocation of a rule on the basis of all available relevant information developed in the course of the rulemaking proceeding. Should later information indicate that the action is unwarranted or not necessary, the Commission may terminate the proceeding.

[TOP]

§1051.11 Denial of petitions.

(a) If the Commission denies a petition it shall promptly notify the petitioner in writing of its reasons for such denial as required by the Administrative Procedure Act, 5 U.S.C. 555(e).

(b) If the Commission denies a petition, the petitioner (or another party) can refile the petition if the party can demonstrate that new or changed circumstances or additional information justify reconsideration by the Commission.

(c) A Commission denial of a petition shall not preclude the Commission from continuing to consider matters raised in the petition.

May 5, 2003

VIA FACSIMILE: 301/504-0403

Stephen Lemberg
Assistant General Counsel
Office of the General Counsel
U.S. Consumer Product Safety Commission
Washington, D.C. 20207

Dear Mr. Lemberg:

Thank you for your letter of April 25, 2003 asking for additional information on two issues raised by the Healthcare Compliance Packaging Council's petition of March 17. Specifically, you have asked for clarification on the following points:

1) "...the HCPC requests that the Commission eliminate the first criterion related to the toxicity of the substance to be packaged and allow a unit dose packaging failure to consist solely of a child gaining access to more than eight individual doses. Because such a change seems to decouple the definition of a child resistance test failure from consideration of the toxicity of a particular substance to be packaged it may not be allowable under the PPPA."

   On this point you further note that the HCPC's request for a numerical pass/fail criteria for unit dose formats could be precluded "...because of the apparent requirement of the PPPA that the Commission consider the toxicity of the specific substance at issue in establishing a special packaging requirement."

2) "The current CPSC regulation does not require a company to test, or preclude a company from relying on test data generated by the package manufacturer or from testing of similar packaging. Thus, the second change requested by the HCPC would seem to be unnecessary."

Following are the HCPC's detailed responses to the points raised in your letter of April 25, 2003:

252 N. Washington Street
Falls Church, Virginia 22046
(P) 703/538-4030
(F) 703/538-6305
(E) pgamayberry@aol.com
www.unitdose.org

I. The PPPA, Toxicity, and 16 CFR 1700.20

With regard to toxicity issues, the PPPA requires CPSC to consider toxicity in determining whether a particular substance requires special packaging. But the PPPA does not require the subjective, zero-tolerance standard that 16 CFR 1700.20 applies solely to unit-dose packaging. The PPPA not only permits the action sought in HCPC's petition, but Congress specifically anticipated it. Indeed, Congress directed the Commission to set a standard that would make the packaging "...significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, ***but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.***" (Emphasis added).

The implication that removing the subjective element of the test protocol for unit-dose packaging will somehow reduce the level of consumer safety is contradicted by the evidence – including CPSC's own data – outlined in HCPC's petition. To the contrary, removing the subjective element of the test protocol for unit dose closures will enhance consumer safety by making its more practicable for drug manufacturers to utilize this safer type of CR packaging.

Moreover, while it is clear that the PPPA grants CPSC authority to determine which household substances must be shipped from the manufacturer in special packaging, the Act does not specify that this determination be based on the *amount* of product that a child ingests. On the contrary, the only time the PPPA speaks to the issue of quantity is in Section 1472 (d) when Congress specified that:

> Nothing in this Act shall authorize the Commission to prescribe specific packaging designs, ***product content, package quantity***, or, with the exception of authority granted in section 1473(a)(2) of this title, labeling. (Emphasis added)

Indeed it is counter intuitive – and not in keeping with the legislative intent of the PPPA – to say that a unit dose format is not child resistant if children can gain access to a single unit (should that be the amount an individual manufacturer – not CPSC, not even another manufacturer of a product with the same active ingredient – determines to be capable of causing serious personal injury or serious illness to a small child), but then allow 30, 60, 90, 500, or 1,000 dosage units of the same product to be dispensed into households in a format that allows children instant access to the entire contents of the package should the CR cap not be properly replaced, or replaced at all, each and every time the product is accessed by an adult. It is simply incongruous for CPSC to maintain a subjective and discriminatory zero-tolerance standard for unit dose packaging, while allowing the exact same substances to be packaged in cap-and-vial closures, which CPSC knows through its own data allows children to access much greater quantities of the substances because the cap is often left off, or not properly replaced, by consumers.

Also, as noted in our petition, the provision that we have asked to be altered does not relate to toxicity *per se*. Rather, it places unique requirements on manufacturers who wish to use one type of packaging (unit formats) instead of another. Specifically, as outlined in our petition, we are seeking to change a provision contained under 16 CFR 1700.20 that uniquely requires manufacturers who wish to use unit formats to: 1) determine the number of individual units that "...may produce serious injury or serious illness," then 2) fortify the package to a point where children cannot open or gain access to this amount of product during protocol testing.

This "serious personal injury or serious illness" standard that applies solely to unit dose formats is far more vague, subjective, and stringent than the pass/fail standard which applies to other packaging formats, and ignores CPSC's responsibility under the PPPA to require special packaging *only* for substances which "the degree or nature of the hazard to children...by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness result from handling, using, or ingesting such substance."

HCPC recognizes that the Commission cannot as a practical matter offer definitive guidance regarding the exact number of individual units that could be expected to cause serious personal injury or serious illness to a small child for each Rx, OTC-switched, and OTC drug product required to be shipped in special packaging. Yet, the current test protocol puts the onus on drug manufacturers to do so ***only when they elect to use unit dose formats.*** Because of product liability and other cost concerns, this system has led drug manufacturers to follow the path of least resistance – i.e., opting for less safe cap-and-vial closures.

Absent definitive guidance from CPSC, therefore, the objective pass/fail criteria requested by the HCPC's petition is warranted.

II. The Necessity/Benefits of Type Testing

In your letter of April 25, you questioned the necessity of the HCPC's petition request for type testing. Specifically, you noted that "The current CPSC regulation does not require a company to test, or preclude a company from relying on test data generated by the package manufacturer or from testing of similar packaging."

CPSC regulations do require that certain household substances – including virtually all Rx and OTC-switched drug products, as well as a number of OTC drug products – be packaged in formats that comply with 16 CFR 1700-1750, and the only way for a manufacturer to ensure that their packaging does comply is through protocol testing. This is especially true with unit formats due to the subjective pass/fail criteria contained under 16 CFR 1700.20.

Although CPSC regulations may not *require* protocol testing, CPSC certainly has the legal authority, and the enforcement capabilities, to ensure that non-complying packages are kept off the market.

Similarly, although CPSC regulations do not preclude a company from relying on test data generated by the packaging manufacturer is not reflective of standard industry practice, the practical reality is that the objective standard for cap-and-vial closures has led to a general acceptance of type testing for that type of CR packaging. Conversely, the subjective standard of 16 CFR 1700.20 makes it impractical for manufacturers to utilize type testing for unit-dose packaging.

This point was well articulated during a roundtable discussion published in the June 2001 edition of *Pharmaceutical & Medical Packaging News*[1] in which a panel of packaging professionals was asked whether they would rely on protocol test data from a vendor who had developed a unit-dose package format, put it through the CPSC protocol, and offered it for sale to drug manufacturers as being compliant with 16 CFR 1700-1750. In response to this scenario, the following answers were given:

> John Bitner (Manager of Packaging Design and Development, Pharmacia): "Vendor testing doesn't do us much good. We still have to test our packages. When a vendor comes to us with a child-resistant package that's passed with a given tablet, test protocol, and regimen, we still have to test it."
>
> Arthur Jaeger (Director of Packaging Development, Merck & Company, Inc.): "Supplier test results provide very useful information whenever we are developing new packages. However, the ultimate responsibility for ensuring package performance in the marketplace rests with the manufacturer."
>
> Bruce Cohen (Director, Packaging Technology, GlaxoSmithKline): "In some cases, we have found that even when using the same bottle with different closure suppliers and the same liners, we get different results [from those provided by the vendor]."

Clearly, these industry professionals would not allow their products to be released into the market without conducting a protocol test first, no matter what is actually required under current CPSC regulations. What the HCPC is asking for, therefore, is some means of ensuring that packaging which has successfully passed protocol not have to be re-tested. Perhaps this does not need a formal alteration of existing regulations. It may, in fact, be achieved through: 1) a policy statement from the Commission; 2) publication of a list of acceptable formats by the Commission; and/or 3) indication from the Commission that enforcement discretion will be exercised if packaging is used that has successfully passed CPSC's protocol.

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[1] Copy attached

Please also note that the primary purpose of the HCPC's petition request for type testing is to minimize the number of small children who are subjected to protocol testing annually. To the HCPC, this goal alone makes our request necessary – especially considering that thousands of children are subjected to protocol testing each year, often to evaluate packages with CR features that have been on the market for decades.

It is my hope that this is a thorough and adequate response to the issues you raised in your letter. Please feel free to contact me should you have any questions or need additional information.

Thank you.

Sincerely,

Peter G. Mayberry
Executive Director

Enclosure

How important is child-resistant packaging to you when you select packaging materials?

Cohen: Certainly for solid-dose formulations, child-resistant packaging is part of the decision. It really depends upon the toxicity level of the product and how the package is going to be presented to the marketplace. If the product is going to be a unit of dispense, then we have to take into consideration everything that's required for child resistance for that particular drug. If it has optional pack or line extensions that make it a pharmacy dispensing pack, then child resistance falls away at that point.

Is child-resistant packaging an issue that first comes up in clinical trials?

Cohen: When we get into the end of Phase II and the beginning of Phase III clinicals, we want to narrow down the packs that marketing has in mind for the product. We try to use the final marketed pack for Phase III, if it's a package that we can get at that point. If not, child-resistant packaging probably wouldn't show up until the launch.

Bitner: We try to get materials into ICH stability testing that we perceive will be useful for child-resistant packaging, even though we have additional development time beyond ICH.

Vega Feliciano: One of the things we consider is cost. We need to be very aware of cost in the over-the-counter (OTC) market because our margins are smaller.

Mayberry: When a product goes from prescription to OTC status, it doesn't necessarily have to be packaged in a child-resistant format. CPSC evaluates each of those drugs case by case. But last year CPSC proposed a rule that would automatically require a child-resistant format for what it refers to as OTC-switched drugs. It accepted public comment on that proposal through November, and now it's deciding what to do based on those comments.

Did anyone here file any comments with the CPSC?

Mayberry: HCPC and the Consumer Healthcare Products Association both did. There were two other comments as well—one from a group of students in Florida and another comment from a private citizen.

Does anyone else here have any reaction to that CPSC proposal?

Cohen: The proposal would put more pressure on both the manufacturers of the components as well as the manufacturers of the drug to reduce costs as products move to OTC status.

special

"What we are trying to accomplish with the child-resistant package is to make it as intuitive as possible. And it's hard to make a blister intuitive at a high toxicity level."

John Bitner
manager of package design and development, Pharmacia (Skokie, IL)

Would it delay OTC product launches?

Jaeger: If products will be packaged in bottles, the proposal is probably not a big deal. However, if you start going into flexibles, you've got other issues: what the toxicity levels are, what the opening features look like, which patients will use the package, and how difficult will the package be to open.

What packages are best at meeting child-resistance requirements?

Bitner: It depends upon the toxicity of the product, the market we're aiming for, and the regimen of the medication. If you're looking at a regimen of three tablets a day, for instance, for a chronic condition, then it's going to be very difficult to get that product into a blister. It would be much better off in a bottle.

Mayberry: There's a quirk in the regulation regarding toxicity and blisters. Under the protocol, if you're using a bottle, it's a failure if the child gets the top off, regardless of the quantity. There could be 100 tablets in the bottle. When you use unit-dose packaging, such as a blister, there is an eight-pill standard, so if during the test children open or gain access to eight tablets in the blister or to an amount that would cause serious illness or serious injury, then that's considered a failure. But CPSC doesn't define what the serious illness or serious injury is, so it's up to the manufacturers to determine the toxicity level. Such a consideration needs to be made for blisters but not for bottles.

Vega Feliciano: I don't think that it's a matter of liking one better than the other, it's a matter of what is best for your product. Some products are more suitable for blisters; some products are more suitable for bottles. There are even some products that will require a pouch because of some specific characteristic.

Jaeger: Most market research shows that, given the choice, a lot of patients seem to prefer bottles—not because they're better or worse, but because they understand them. They've seen push-and-turn caps for so long that they can use them without thinking. However, the bottle is not always appropriate.

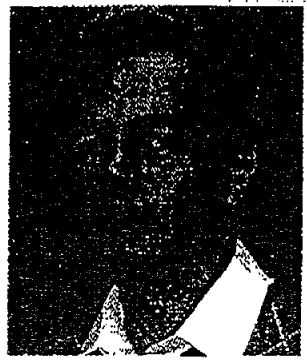
Lang: It also depends upon what market you're trying to get into, like OTC decongestants. Everything on the shelf is in blisters.

Bitner: What we're trying to accomplish with the child-resistant package is to make it as intuitive as possible. And it's hard to make a blister intuitive at a high toxicity level. When a failure means that children can access just one tablet, a blister becomes a very difficult package to present, especially to arthritis patients or the elderly.

Cohen: On occasion we've sized the blister with the toxicity level in mind to include as few tablets as possible but still meet patient requirements. For instance, we have one product that has three tablets in a blister pack and that is the sale item. That particular regimen of three might serve a patient for a day and a half or two days, depending on their needs. But because of the toxicity levels, if a child were to get into all three, it wouldn't be harmed.

Jaeger: The access level permitted for an individual product being packaged makes a big difference. If a product has a high allowable access level, you've got a lot more options. You can go with something that's child resistant but not nearly as unfriendly to a lot of patients, especially elderly patients.

Cohen: There's a popular pack out on the market for an antibiotic that marketing wants us to use. But that particular product's toxicity level is nowhere near what's presented in the package, so therefore the package is not child resistant. It's a nice blister pack, and everybody talks about it, but we can't necessarily put every product in it because of the higher toxicity levels.



"Let's be more aggressive about teaching people how to properly use a child-resistant package. We need to teach the consumer that no package is 100% safe."

Rafael Vega Feliciano
senior package engineer, Wyeth-Ayerst Pharmaceuticals, packaging services group (Philadelphia)

"When comparing blisters to bottles, it is evident that children access more units when circumventing a child-resistant closure on a bottle."

Peter Mayberry
executive director, Healthcare Compliance Packaging Council (Falls Church, VA)

Mayberry: In the United Kingdom, there's effort to establish a child-resistant packaging standard for nonreclosable packaging. The draft standard was similar to the U.S. standard, and they got more than 300 complaint letters. An overwhelming majority of the complaints focused on the issue of determining toxicity. Based on that, the United Kingdom is leaning more toward a numerical amount rather than an amount determined by toxicity testing.

Cohen: But what if five is your toxicity limit? Then manufacturers are not going to use a blister with a count of eight unless they're looking for trouble.

Mayberry: There are products that are highly toxic, so you need to put them in a count of one, two, or three pills. Then there are others where a package of 30 is not likely going to cause a problem. But the vast majority is in a gray area.

Cohen: At some point, we need to have some standard test, like an ASTM method. We could put blisters through it to ensure that they meet a minimum requirement and are therefore deemed child resistant, rather than spend all the time and effort that all of us do in looking at a group of children who varies by location and ability. If you go to one test lab, test your pack, and get a failure, and then you go to a second test lab, test the same pack, and get a pass, where does that lead you? To a third test somewhere else to try to get another pass. What makes one better than the other? They're very subjective. We need some type of reproducible, mechanical, electronic, standard test.

Mayberry: John and I are both on the ASTM subcommittee D10.31 regarding child-resistant packaging, and just earlier this month at a meeting in Phoenix, it was apparent that ASTM doesn't want to look at specific aspects of the child-resistant packaging testing protocol because ASTM members doubt that CPSC will change it.

Bitner: We've got a protocol that's worked for 30 years. We've cut the number of pharmaceutical-related deaths dramatically to one to two per year.

Mayberry: Yes, but there are data that show there are still thousands of poisonings every year supposedly involving child-resistant closures for bottles or vials. There have been more than 5 million calls to poison prevention centers over the past 17 years involving children 6 years old and younger who ingested prescription or OTC drugs, as documented by the American Association of Poison Control Centers.

Bitner: Those calls may be more prevalent because of education. Patients know that some of these medications can be poisonous and they know who to call now. There are also more poison prevention centers in the country.

Mayberry: We asked CPSC for all its data from 1983 through October of 2000 regarding accidental exposures to prescription drugs or OTC drug products by children 6 years old or younger. What we got back were reams of data. There were hundreds of instances where children were sent to the hospital because they supposedly got these products out of child-resistant bottles, and there were 365 deaths over that period of time. Yet, there were 33 documented cases involving blisters in which children accessed drugs, and of those there were only two—two in 17 years—where child-resistant blisters were involved.

Bitner: Or documented to be involved.

Mayberry: But when comparing blisters to bottles, it is evident that children access more units when circumventing a child-resistant closure. There were 11 instances where children gained access to between 41 and 50 tabs. There are 5 instances where children gained access to between 61 and 75 tabs.

Jaeger: Today there are more once-a-day products with higher concentrations and higher potencies. So there are a lot of products where accessing just one or two tablets may be a problem.

How do you feel about child-resistant blisters currently on the market?

Cohen: It depends upon your toxicity level and what your marketing folks want. We use peel-and-push blisters for most of our child-resistant blister packages. We've had to put some of our blisters into a chipboard card in order to increase the complexity and reduce the number of child openings.

Bitner: Most are extremely difficult for a senior or a debilitated patient to operate. But if you make them too easy, children are just going to rip them apart, easily accessing the medication.

Jaeger: There aren't all that many different types of child-resistant packaging materials to choose from. I'm not talking about suppliers. If it's a blister material, one side needs to be backed with polyester. If it's a pouch, you need

an adequate thickness of polyester on the outside, and the rest depends on die-cutting configuration, graphics, and opening instructions.

Bitner: You bring up a good point regarding the number of vendors. There aren't that many vendors out there with the capability, the intelligence, the resources, the mentality, and the interest to develop programs for us.

Mayberry: Some vendors have gone to the trouble of designing a more intuitive package and putting it through the child-resistant testing protocol themselves to ensure that it'll pass the protocol. They then make it available for licensing, and then no one picks it up. Fortunately, there is one intuitive package that requires cognitive ability over physical strength that has passed the protocol and won HCPC's Compliance Package of the Year Award for 2000.

"We need a standard test, like an ASTM method, that we could put blisters through to ensure that they meet a minimum requirement and can be deemed child resistant."

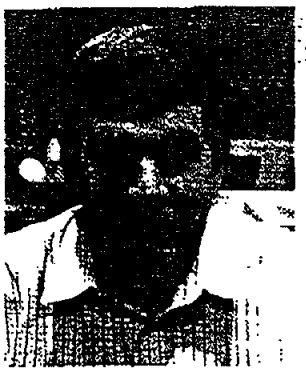
D. Bruce Cohen
director, packaging technology, GlaxoSmithKline (Research Triangle Park)

Bitner: Vendor testing doesn't do us much good. We still have to test our packages. When a vendor comes to us with a child-resistant package that's passed with a given tablet, test protocol, and regimen, we still have to test it.

Jaeger: Supplier test results provide very useful information whenever we are developing new packages. However, the ultimate responsibility for ensuring package performance in the marketplace rests with the manufacturer.

Cohen: In some cases, we have found that even when using the same bottle with different closure suppliers and the same liner, we get different results.

Bitner: As end-users, we know what



"Protocol testing certainly meets the regulation, but it does not always give you all the information you need to ensure your package will be well received in the marketplace."

Arthur Jaeger
director of packaging development, Mead Company, Inc. (West Point, PA)

we want to accomplish, but the vendor still has the greatest converting technology and the understanding of how those materials react, as well as firsthand knowledge of new developments.

Do you need more vendor support?

Bitner: Once we have a concept and engineering designs, we'll do the testing—it's our market, it's our protocol, it's our focus group. But we need more experts to show how to convert materials and how to make our concepts reality.

What are you doing to meet the needs of patients who suffer from conditions that make it difficult to open complex packages?

Bitner: At Pharmacia, we consult a panel of what we call patient partners, who are patients suffering from arthritis. Most are registered with the Arthritis Foundation and doctors, so half a dozen of them can represent hundreds of patients across the country. We run different designs by them and design packages according to their feedback. Before we go to protocol testing, we do some screening and some preliminary tests with 70- to 80-year-old people and patients with arthritis.

Jaeger: More than just CPSC protocol testing is needed. Protocol testing certainly meets the regulation, but it does not always give you the information you need to ensure your package will be well received in the marketplace.

Bitner: If a vendor comes to us and says it passed the CPSC protocol, that's not all that is necessary. We can pass the protocol with any number of different packages. But that doesn't necessarily mean that a patient or consumer is going to use that package in the home.

Lang: You also need to put clear, concise instructions regarding opening features on the package in short bullet points so seniors know how to open it.

Are you leery of using a blister?

Mayberry: Manufacturers don't want to market products that aren't going to be popularly received, and a blister is likely going to be more difficult to open than a bottle, unless tremendous forethought is given to its design.

How do you properly balance child resistance with senior friendliness?

Mayberry: CPSC's response is you need better packages. John mentioned earlier that you can engineer packaging that does not rely on strength as much as on cognitive ability.

Jaeger: I've heard some companies say they've resorted to instructing patients to use scissors to open packages. But you shouldn't need a tool to open the package.

Cohen: We have several packs on the market that require scissors to open, and I have no complaints that I'm aware of, as opposed to the blister packs we have that frustrate seniors.

Mayberry: Are the scissors-only packages pouches?

Cohen: A couple of them are. One pouch features a tear notch that is an open, unsealed circle within the package that you have to fold over.

Bitner: Scissors are brutal to an arthritis patient, and you certainly don't want a hemophiliac patient using scissors. We have a fantastically successful pouch that has wider heat-seal areas with big, fold-over areas where the notch is positioned on the crease so you can't miss it. A target and arrows point the child to an area that is laser scored and cut. Ninety-nine percent of the kids went right for that score and tore the opening feature off in the first five seconds of the test, disarming the package. Trying to do that same thing with a blister is more challenging.

"You need to put clear, concise opening instructions regarding opening features on the package in short bullet points so seniors know how to open it."

Ken Lang
engineering, strategic improvement department, OTC drugs, Bristol Myers Squibb (Mt. Vernon, IN)

Are there any innovations that you think should become standard, like using squeeze-and-turn closures instead of push-and-turn ones?

Bitner: Squeeze-and-turn designs are one of the most discouraging developments in the last 30 years. They are not senior friendly. Arthritis patients have a lot of trouble with that type of motion.

Cohen: We've looked into squeeze-and-turn closures for a number of reasons, including the fact that they eliminate the torque requirements for opening. They also represent a reduction in price, and there are fewer components that will end up in the trash. But as John said, people who have difficulty squeezing because of limitations in their hands or wrists find that they can open the push-and-turn closures with the palm of their hand and the top of a table. There is a new proposed cap with a one-piece, push-and-turn mechanism that may be a better compromise—it requires the same force and the same procedure that most people are used to, but it is a little less strenuous.

Mayberry: For the first five years of HCPC's existence, I never heard about anything novel with blisters—it was all peel-and-push or notch-and-tear. But over the past five years, there has been an attempt to design better blisters both child resistant and senior friendly.

What else could make your job easier?

Bitner: We need a more formal universal program of national education about poisons. Poisonings occur because of ignorance. FDA responded in a surprising and disappointing way to iron tablets, mandating for the first time in history that iron tablets above a certain level have to be in blisters because they're dangerous to children. This was based on a false assumption that blisters are inherently child resistant. If all parties concerned had made it better known that iron can present a poisonous situation, iron wouldn't have been left out for children to get into.

Mayberry: The protocol gives consumers a false sense of security. In the data that we got from CPSC there were seven instances in which children were given drug products in a bottle with a child-resistant closure as a rattle or toy because an adult believed that it was childproof.

Vega Feliciano: CPSC could do a better job educating people on how to use the package and why it's important to put it away even though it's considered child resistant. Let's be aggressive about teaching people to properly use a child-resistant package. We need to teach the consumer that no package is 100% safe. PMP News