U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

MINUTES OF COMMISSION MEETING
September 28,1994
4330 East West Highway
Bethesda, Maryland

The September 28, 1994, meeting of the U.S. Consumer Product Safety Commission was convened at 10:00 a.m. in open session by Chairman Ann Brown. Commissioner Mary Sheila Gall and Commissioner Jacqueline Jones-Smith were present.

Agenda Matter: Lidocaine and Dibucaine

The Commission considered whether the Commission should issue a child-resistant packaging requirement under the Poison Prevention Packaging Act for the topical anesthetics lidocaine and dibucaine. The Commission was briefed by the staff at the Commission meeting of September 21, 1994, on issues raised in this rulemaking proceeding. (Ref. staff briefing package dated August 3, 1994, and supplemental material dated September 9, 1994.) By memorandum dated September 27, 1994, the Commission received from the Office of the General Counsel a revised draft Federal Register notice that would issue the child-resistant packaging requirements for these products. The revised draft notice and the introductory discussion by staff at today's meeting noted the receipt of additional injury data relating to lidocaine and dibucaine.

Following questions and discussion by the Commissioners, the Commission voted unanimously (3-0) on motion of Chairman Brown to issue a final regulation under the Poison Prevention Packaging Act requiring special packaging for all products containing more than .5 mg of dibucaine in a single package.

Commissioner Gall moved that the Commission issue a final regulation under the Poison Prevention Packaging Act requiring special packaging for products containing therapeutic amounts of lidocaine, with the exception of those in cream, ointment or gel form packaged in tubes of one-half ounce or less. This motion failed by a vote of 1-2, with Commissioner Gall voting in favor and Chairman Brown and Commissioner Jones-Smith voting in opposition.

The Commission then voted, 2-1, on motion of Chairman Brown to issue a final regulation under the Poison Prevention Packaging Act requiring special packaging for all products containing more than 5 mg of lidocaine in a single package. Chairman Brown and Commissioner Jones-Smith voted to approve; Commissioner Gall voted in dissent.

The Commission then approved by unanimous vote (3-0) the following three-part motion offered by Chairman Brown: (1) that the regulation on lidocaine and dibucaine not be considered a final regulation until publication in the Federal Register; (2) that the final regulation be published in the Federal Register on April 8, 1995, or as soon thereafter as practicable; and (3) that the Commission approve the Federal Register notice transmitted to the Commission by memorandum dated September 27, 1994, without change.

Chairman Brown, Commissioner Jones-Smith, and Commissioner Gall filed separate statements concerning the lidocaine/dibucaine matter, copies of which are attached.

There being no further business on the agenda, Chairman Brown adjourned the meeting.

For the Commission:

Sadye E. Dunn

Sadye E. Dunn
Secretary

Attachments

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

The Chairman

Statement of Chairman Ann Brown
Child-Resistant Packaging for Lidocaine and Dibucaine
September 28, 1994

In August 1992, the Commission proposed under the Poison Prevention Packaging Act to require that products containing more than 5.0 milligrams of lidocaine or more than 0.5 milligrams of dibucaine in a single package be packaged in special (child-resistant) packaging. These substances provide an anesthetic effect when applied to the skin or mucous membranes. The Commission proposed these requirements because it preliminarily determined that child-resistant packaging was required to protect children under five years of age from serious personal injury and serious illness resulting from ingesting such substances. What we are talking about is protecting children, our most vulnerable of populations, from totally unnecessary death from poisoning. I have voted today to issue a final rule covering all of the products that were the subject of the proposed rule.

To issue a final rule requiring special packaging for a substance, the Commission must find (1) that special packaging is required to protect children from serious personal injury or illness resulting from handling, using, or ingesting the substance, and (2) that special packaging is technically feasible, practicable, and appropriate for the substance.

Significant numbers of children under five years of age have ingested products containing lidocaine and dibucaine. Although most of the exposures did not result in harm to the victims, the amounts of lidocaine and dibucaine available to the children during these encounters were potentially lethal. The potential lethal effects of the drugs are well documented. Since 1979, there have been nine reported deaths caused by products containing lidocaine and, since 1951, seven deaths from products containing dibucaine. Moreover, the number of ingestions in comparison with the relatively small number of products containing these substances sold each year makes the case for special packaging more compelling.

The ingestions and deaths involve products packaged in both bottles and tubes, demonstrating graphically that curious young children do not distinguish between package types or product formulations when potentially toxic episodes occur. Accordingly, I am satisfied that the risk of injury to children from products containing more than 5.0 milligrams of lidocaine or more than 0.5 milligrams of dibucaine is severe enough to require that these products be packaged in child-resistant packaging.

I am also satisfied that special packaging for products containing lidocaine and dibucaine is technically feasible, practicable and appropriate. Technology exists to produce child-resistant packaging for the products that are the subject of this rule, that those packages are susceptible to techniques of mass production, and that complying packaging would not be detrimental to the integrity of the substance and would not interfere with its storage or use.

Many of the commenters in this proceeding erroneously assume that the unavailability, for immediate delivery, of child-resistant closures that fit existing product containers requires inaction on the part of the Commission. Accordingly, many firms appear to have made little, if any, effort in the two years since the proposed rule was published to determine what package designs could be adapted to lidocaine and dibucaine-containing products. In response to this pattern of conduct, I would only note that the PPPA contemplates that packages change to protect young children. This change can be reasonably effected for lidocaine and dibucaine products within the time frame established in the final rule.

STATEMENT OF COMMISSIONER JACQUELINE JONES-SMITH ON A PROPOSAL TO ISSUE CHILD-RESISTANT PACKAGING REQUIREMENTS FOR LIDOCAINE AND DIBUCAINE UNDER THE PROVISIONS OF THE POISON PREVENTION PACKAGING ACT

September 28, 1994

Today, I voted in support of the staff's recommendation to issue a child-resistant packaging requirement for the topical anesthetics lidocaine and dibucaine. Such special packaging is required under the provisions of the Poison Prevention Packaging Act (PPPA) upon a determination that child resistant packaging is needed to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting a substance, and that the special packaging is technically feasible, practicable, and appropriate for such substance.

While the two substances under consideration differ somewhat in their intended use, as well as their composition, packaging and marketing -- and while I have reviewed them independently based on their individual characteristics -- in the interest of brevity my legal analysis discusses these two products in tandem.

Incident data available to the Commission provides sufficient evidence to conclude that these products are sufficiently toxic and sufficiently accessible to young children so as to pose a risk of serious illness and death. Indeed there have been ten reported deaths attributed to the ingestion of these products.

Thus, the critical issue before the Commission has been whether special packaging is technically feasible, practicable, and appropriate for these substances. Again, I have concluded that the evidence available to the Commission is sufficient to support these requisite legal findings.

It should be noted that the issue of technical feasibility did pose, initially, several challenging dilemmas. As staff concedes, there is not currently on the market child resistant packaging that would suit the requirements of these packages. They are generally marketed as ointments in small metal tubes ranging in size from one half to two ounces. This posed a need for alternative packaging. Based upon the evidence at my disposal, I am confident that the technology exists to produce appropriate child-resistant packaging.

There remains, however, the question of timing. Given the fact that individual product manufacturers, as well as packagers, may need a reasonable amount of time to research and develop suitable packaging, today's vote instructed the staff to delay publication of the notice of final rulemaking until April 8, 1995 -- with an effective date beginning one year after publication.

This delay will not only provide industry with ample opportunity to produce packaging in compliance with this regulation; but, also, will provide the Commission sufficient time to publish its PPPA protocol revisions -- designed to make child resistant packaging "older adult friendly". This is important because it would obviate the inconvenience and financial burden of requiring manufacturers to change their packaging again subsequent to the publication of these expected modifications.

STATEMENT OF COMMISSIONER MARY SHEILA GALL ON REQUIRING SPECIAL PACKAGING FOR PRODUCTS CONTAINING LIDOCAINE AND DIBUCAINE

SEPTEMBER 28, 1994

Today's decision by the Commission to promulgate a final rule under the Poison Prevention Packaging Act (PPPA) requiring child-resistant packaging for products containing dibucaine and lidocaine may have the effect of offering children enhanced protection from the dangers associated with exposure to these products. While I voted to support requiring special packaging for products containing dibucaine, I could not accept the majority's view concerning the 1/2 ounce size tube packages containing lidocaine.

There is no question that forms of both dibucaine and lidocaine can be toxic. In the case of products containing dibucaine, I am persuaded that the mandated packaging is required to protect children from the serious injuries and illnesses contemplated by the statute. However, I reject the staff's position that the technical feasibility element of the statutory findings can be met by the theoretical possibility that such packaging might be able to be produced. Nonetheless, after numerous meetings with Commission staff, I am satisfied that the technology exists to produce complying packaging, and that this action is supportable.

Concerning lidocaine, it has still not been demonstrated that over-the-counter (OTC) 1/2 ounce tubes of cream, ointment and gel formulations containing this substance must be in child resistant packaging in order to protect children from serious personal injury or serious illness as is required by the PPPA. The theoretical dangers posed by these items is not an adequate basis upon which to regulate.

Some may claim that the Commission cannot wait for injuries and deaths to occur in order to act. However, in this case, there has not been a single incident of serious personal injury or illness attributable to OTC lidocaine products in tubes. In light of data presented by the staff only this morning concerning increased ingestion, it is apparent that the extant danger fails to rise to a level which allows for government intervention.

Unfortunately, as often happens when common sense is not a part of the government's regulatory equation, overly burdensome intervention takes place. Here, a majority of the Commission has ordered that OTC lidocaine products in the 1/2 ounce size tube be sold exclusively in CR packaging. Since it is generally agreed that it will be impossible to develop complying packaging in this size, the practical consequence is that the government has restricted consumer choice without affording additional protection for children as the PPPA contemplates.

It is my hope that in future Commission actions will have more clearly delineated factual and legal underpinnings.