Advisory Opinion #282

6(b) CLEARED:
✓ No Mfrs Identified
Excepted
Mfrs Notified
Comments Processed

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

OFFICE OF THE GENERAL COUNSEL

November 17, 1981

Michael Weinberger, Esq.
Queller, Fisher, Block &
Wisotsky
110 Wall Street
New York, N.Y. 10005

Dear Mr. Weinberger:

This is in response to your letter of November 5, 1981, in which you asked whether the Consumer Product Safety Commission (CPSC) has the authority to assess civil penalties for the violation of regulations issued under the Poison Prevention Packaging Act (PPPA). In particular, you are interested in whether the CPSC can assess a civil penalty in the situation where a pharmacist dispenses a prescription drug in a closure that does not meet the requirements for special packaging contained in the PPPA.

Section 20(a) of the Consumer Product Safety Act, (CPSA), 15 U.S.C. § 2058(a), authorizes the Commission to assess civil penalties for violations of section 19 of the CPSA, 15 U.S.C. § 2069, the prohibited act section. The CPSA, however, applies only to consumer products as that term is defined in section 3(a)(1) of the CPSA, as amended, 15 U.S.C. § 2052(a)(1). Section 3 excludes from the Commission's jurisdiction,

* * *

> (H) drugs . . . (as such [term] [is] defined in [section] 201(g) . . . of the Federal Food, Drug, and Cosmetic Act), . . .

* * *

Accordingly, the Commission would have no authority under section 20 of the CPSA to assess a civil penalty against a pharmacist for dispensing a drug in a non-child resistant closure.

QUELLER, FISHER, BLOCK & WISOTSKY
110 WALL STREET
NEW YORK, N.Y. 10005

BERTRAM D. FISHER, P.C.*
FRED QUELLER, P.C.**
MARTIN BLOCK
CARL WISOTSKY

MARK R. BOWER
MICHAEL WEINBERGER
SAMUEL J. MATTHEWS

COUNSEL
SEYMOUR L. COLIN

* ALSO ADMITTED TO D. C. BAR
** ALSO ADMITTED TO FLA. BAR

TELEPHONE
(212) 422-3600

CABLE
QUELFISH, NEW YORK

Nov. 5, 1981

Mr. Stephen Lemberg c/o
General Counsel's Office
Consumer Product Safety Commission
1111 18th Street N.W.
Washington, D.C. 20207
Room 500

Dear Mr. Lemberg:

I would appreciate it very much if I could receive an Advisory Opinion (or some similar document or letter) indicating if the CPSC opines that it has authority to issue civil fines or penalties for violations of regulations promulgated pursuant to the Poison Prevention Packaging Act.

I am involved in a civil lawsuit concerning the death of a two year old child due to the issu ance of non-child proof packaging by a pharmacy. The drug was Lomotil. I am in need of the requested information as soon as possible.

Thanking you in advance for your anticipated cooperation, I remain, yours truly,

Michael Weinberger

MW:tg
cc: Alan Schoen

For your information, drugs subject to a "special packaging" requirement under the PPPA that are not in compliance with an applicable regulation are considered "misbranded" under the Federal Food, Drug and Cosmetic Act. However, this Act does not provide for the imposition of civil fines for dispensing of misbranded drugs.

In a telephone conversation on November 12, 1981, with Alan H. Schoem, Assistant General Counsel, you also asked whether section 23(a) of the CPSA, 15 U.S.C. § 2072(a), applies to rules issued under the PPPA. Section 23(a) allows any person injured due to a knowing (including willful) violation of a consumer product safety rule (defined at 15 U.S.C. §2052(a)(2)), or any other rule or order issued by the Commission, to sue any person, who knowingly (including willfully) violated any such rule, in an appropriate United States district court. In our view, this provision applies to rules issued under the PPPA.

Please note that these are the views of the Office of the General Counsel and are not necessarily those of the Commission. I hope this information has been helpful. Please contact me if you have any further questions regarding this issue.

Sincerely,

Margaret A. Freeston
Acting General Counsel