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ADVISORY OPINION

FEB 28 1975

6(b) CLEARED: 3/15/84

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Comments Processed

Carl Roberts, Esq.
Associate General Counsel
American Pharmaceutical Association
2215 Constitution Avenue, N.W.
Washington, D.C. 20037

Dear Mr. Roberts:

This is in response to your letter of December 16, 1974, requesting advisory opinions relating to the special packaging of prescription drugs subject to the Poison Prevention Packaging Act of 1970 (PPPA).

Your first question is whether the Act prohibits pharmacists from dispensing prescription drugs subject to a special packaging standard in noncomplying packaging based on either an order of a prescriber or a request by the purchaser that all of that purchaser's prescription drugs be packaged in noncomplying packaging. This practice is referred to in your letter as a "blanket direction" or "blanket request."

Section 4(b) of the PPPA permits pharmacists, pursuant to an order of a licensed medical practitioner, to dispense a drug subject to a special packaging standard in noncomplying packaging "only when directed in such order or when requested by the purchaser." (emphasis added). With respect to practitioners' orders, our interpretation of the above-quoted language is that the direction for the use of noncomplying packaging can only be validly applied to the drug or drugs actually being dispensed pursuant to that order. Thus, a drug dispensed to the same purchaser pursuant to a different order of the same or other prescriber must be dispensed in special packaging unless such other order directs that that drug be placed in noncomplying packaging, or unless the purchaser requests noncomplying packaging. Regarding requests from the purchaser, however, we believe that the statutory language is not so limiting and that a valid request from a purchaser that all of his or her prescriptions be filled in noncomplying packaging would be sufficient to satisfy the requirements of section 4(b).

As a matter of policy, however, we believe that the practice of obtaining blanket orders and requests for noncomplying packaging should not be encouraged because of congressional intent for noncomplying packaging to be the exception rather than the rule and because changing circumstances in the household of the purchaser may present young children with the opportunity to gain access to prescription drugs. As stated in the House Report on its version of the Poison Prevention Packaging Bill, "The Committee expects that pharmacists, as professionals, will demonstrate the operation of special packaging and will take pains to encourage its use by those who should use it." H.R. Rep. No. 845, 91st Cong., 2d Sess., 11(1970).

Your second question is whether the PPPA prohibits pharmacists from voluntarily advising either a prescriber or patient as to the availability of noncomplying packaging and the fact that a prescriber may direct its use or that a patient may obtain such noncomplying packaging merely be requesting it.

It is our opinion that neither the order of a prescriber nor the request of a purchaser for noncomplying packaging would be rendered invalid by the fact that the pharmacist informed either the prescriber or the purchaser of his or her right to order or request noncomplying packaging instead of special packaging. Whether any particular order or request is valid, however, depends on whether the pharmacist is offering a real choice so that such order or request is knowing and voluntary.

While the views expressed in this letter are based upon the most current interpretation of the law by this office, they could subsequently be changed or superseded by the Commission. Please do not hesitate to contact me if you have further questions regarding these matters.

Sincerely,

Original signed
Michael A. Brown

Michael A. Brown
General Counsel

DSLemberg:mli:3/24/75

bc:Commissioners
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Bob Poth BBS

AMERICAN PHARMACEUTICAL ASSOCIATION
The National Professional Society of Pharmacists

December 16, 1974

Michael A. Brown, Esquire
General Counsel
Consumer Product Safety Commission
Washington, D.C. 20207

Attn: Stephen Lemberg, Esquire

Dear Mr. Brown:

The American Pharmaceutical Association is the national professional society of pharmacists. Its approximate 52,000 members include pharmacists practicing in community pharmacies and hospitals, pharmacists serving as health care administrators, pharmacy educators, pharmaceutical scientists, and pharmacy students.

Implementation of special packaging requirements for prescription-legend drugs under the Poison Prevention Packaging Act of 1970 have raised certain legal issues with regard to which APhA wishes to request advisory opinions from the Commission.

Section 4(b) of the Act provides, with regard to prescription-legend drugs, that the pharmacist may dispense such drugs in standard packaging only under two conditions:

1. if directed by the prescriber
2. if a request for standard packaging is made by the patient

The specific legal issue with regard to which an advisory opinion is requested is as follows: Does the Poison Prevention Packaging Act of 1970 prohibit a prescriber from directing that all prescriptions for a particular patient be dispensed in standard packaging or prohibit a patient from requesting that all of his or her prescriptions be dispensed in standard packaging?

From the pharmacist's standpoint, the question is whether the Act prohibits the dispensing of all prescriptions for a particular

patient in standard packaging on the basis of a so-called "blanket direction" or "blanket request" which would be valid until revoked by the prescriber or patient.

It has been the position of this Association that the Act does not prohibit such directions or requests and that the Act does not require that a 4(b) direction or request must be made on a prescription by prescription basis. To hold otherwise would place an unwarranted emphasis on the accidents of a prescriber's or patient's memory rather than intent. Thus, although the prescriber or patient had expressed a direction or desire for standard packaging, the pharmacist's right to use such packaging would turn rather on whether the prescriber or patient remembered in each instance with regard to a particular prescription to "renew" the direction or request.

The Commission's views in the form of an advisory opinion on the above-stated legal issue will be greatly appreciated.

Sincerely,

Carl Roberts

Carl Roberts
Associate General Counsel

CR:mjw