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CONSUMER
SAFETY C

April 9, 1974

cc: Commissioners
Secretary
Executive Director
BCM
OSCA
OFC (to be distributed to Area Directors)
S. Lemberg
GC Files
GC Chron
GC Reading

AIRMAIL
SPECIAL DELIVERY

Franz J. Ingelfinger, M.D.
Editor
The New England Journal of Medicine
10 Shattuck Street
Boston, Massachusetts 02115

Dear Dr. Ingelfinger:

Thank you for your letter of April 3, 1974, in which you enclosed a draft of an editorial to be published in the May 2 issue of the New England Journal of Medicine, and asked for any comments I might have with respect to the draft.

As discussed with your administrative assistant, Mrs. Mary Howe, in a telephone conversation on April 9, household products subject to child resistant packaging standards do not include as broad a category as "cleaners and polishes." Instead, child resistant packaging is required for aspirin, certain furniture polish, methyl salicylate, controlled drugs, sodium and/or potassium hydroxide, turpentine, certain kindling and/or illuminating preparations, methyl alcohol, and sulfuric acid. Standards for ethylene glycol will become effective June 1, 1974, and for oral prescription drugs for human use on April 16, 1974. A copy of the regulations promulgating these standards is enclosed.

Additionally, regarding the issue as to whether the standards for prescription drugs will be applicable to samples of such drugs when they are distributed to physicians, the Commission has not yet formally made its decision. I will, however, be happy to submit your views concerning this issue to the Commissioners.

Please contact me if you have further questions regarding this matter.

Enclosure

Sincerely,

D. Stephen Lemberg
Attorney
Office of the General Counsel

The New England Journal of Medicine

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OFFICIAL PUBLICATION OF THE MASSACHUSETTS MEDICAL SOCIETY

OFFICE OF THE EDITOR

April 3, 1974

Mr. Steven Lemberg
Office of General Counsel
Consumer Product Safety Commission
Washington, D.C. 20207

Dear Mr. Lemberg:

Thank you ever so much for the time you gave me on the phone the other day. The information you provided was invaluable if a bit startling.

I am enclosing a rough draft of an editorial I hope to publish in the New England Journal of Medicine in the issue of May 2. If you detect any errors, or have any other suggestions, I would of course appreciate your telephoning me (please telephone collect) and give me the benefit of your advice. If I am not in the office, please speak to my administrative assistant, Mrs. Mary Howe.

I am of course prepared to write a formal letter to the Consumer Safety Products Commission, if you believe this is indicated. On the other hand, if possible, perhaps you would submit to the Commission this editorial. I believe it expresses my feelings on the matter very definitely.

Things become much more real when they affect one's own family. For years, off and on, the Journal has published some editorials on Poison Prevention Week, but I have never been too seriously concerned. Now all is different.

Thanks again for your help.

Sincerely yours,

Franz J. Ingelfinger, M.D.

FJI:mpp

TOXIC MAIL

Once in a while, in spite of regulations and social sanctions, noxious or offensive material reaches an unsuspecting victim through the mails. There is, moreover, little that can be done to control the hate letter that plagues the prominent, the politician, and even the editor. Granted that such purposeful acts of aggression via the mails are difficult to contain, why should not regulations at least be such as to protect the addressee from harm that may be accidental rather than intentional, but that may be nonetheless lethal!

Recently the mailmain left at the private residence of two hospital-based physicians a nice little package. The couple's 3 year old son found the parcel, opened it, and discovered two 25 ml. bottles containing some pretty orange colored liquid. The contents happened to be [redacted] syrup (bitter) containing chlophedianol hydrochloride and promoted as an anti-tussive. The child, not yet aware of the importance of reading the label (which recommended ½ teaspoon as the single dose for children) unscrewed the ordinary cap and drank an unknown amount. Finding that the material had a pleasant flavor, and not knowing that the Modern Drug Encyclopedia warns "Not recommended for children under 2 years of age",(1) he thereupon fed an unknown amount to his 1½ year old siblings. Fortunately the prompt arrival of the physician-mother, followed by the generous administration of syrup of ipecac to all three youngsters, prevented what might have been another accidental household poisoning.

Protection of physicians' families from a similar sequence of events is urgently ~~in order~~ required. Of various possible measures, a screening of the mail is obviously impractical. And it may be too much to demand that pharmaceutical firms, in distributing their samples, discriminate between doctors' home and office addresses. But doctors are certainly justified in insisting on stringent regulations that will prevent the mailing of any drug samples except in so-called child-resistant containers. Only by imposing such a rule can tragedies be prevented when drug samples are inadvertently mailed to a physician's home rather than his place of work.

The poisoning of children by drugs or household products is widely publicized these days. A certain period of every year is designated with much fanfare as "Poison Prevention Week". Medical journals publish articles on the need for child-resistant containers. (2 In this social climate, it is somehow unbelievable that a pharmaceutical firm would not on its own initative adopt the routine use of child-resistant containers for mailed drug samples. But though unbelievable, happen it did. Thus, in spite of the disadvantages that greater bureaucratic control incurs, government must once again step in to impose safety rules when considerate and spontaneous action might have solved the problem long ago. Indeed, as of April this year, the Consumer Safety Products Commission is charged with implementing a regulation initiated by the FDA to the effect that prescription drugs--with some exceptions--must be dispensed in child protective packaging. Even mailed samples of household products, such as cleaners and

polishers, have to be enclosed in similar containers. Yet, ironically, these regulations that affect such a vast number of items do not as yet apply to mailed drug samples. Doctors, though often identified as providers, should not be excluded from the protection afforded other consumers. Let the Consumer Product Safety Commission act in haste so that physicians' children will no longer be exposed to the delivery of potentially toxic mail.

Franz J. Ingelfinger, M.D.

References

1) Lewis AJ (ed). Modern Drug Encyclopedia. 12th ed. New York, Yorke Medical Group, 1973

2) Scherz RG, Prevention of childhood aspirin poisoning. N. Engl. J. Med. 285:1361-1362, 1971