

National Community Pharmacists Association
B. Douglas Hoey, R.Ph., M.B.A.
June 28, 2000
11:25 a.m. (presentation)

JUN 28 2000

Good morning. My name is Douglas Hoey, I'm a pharmacist on the staff of the National Community Pharmacists Association. On behalf of NCPA, we would like to thank the FDA for allowing us to comment on this issue that is so important to patient safety.

NCPA represents the 25,000 independent community pharmacies in the United States and the 60,000 community pharmacists who practice at these pharmacies.

The FDA posed several questions for feedback in the April 27 Federal Register announcing this hearing. My comments today will address three of the areas mentioned—public safety, NCPA's suggestion for a solution, and who should initiate switching product from Rx to OTC status. NCPA will also file more written comments and supporting documents prior to the August 25 deadline.

All of us have patient safety as our highest priority. Patient medication safety is perhaps more complex then ever before because there are more medications—both prescription and OTC--available to consumers then ever before.

At the same time, patients have access to more information and are more interested in being involved with healthcare decisions affecting them and their family then ever before.

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Although the FDA's recent regulation providing easier to read labeling will help patients better understand the actions and side effects of medications they are taking, in the pharmacy, I still see a considerable amount of confusion that sometimes exists when it comes to patients taking OTC medications.

Illiteracy and difficulty reading English contributes to the confusion. According to information from the National Institute for Literacy, nearly one-third of Americans do not have a sufficient foundation of basic reading skills.

This lack of universal understanding about medications becomes even more important as the FDA begins to consider medications used for chronic conditions for which patients often have no immediate symptoms.

For example, the class of drugs featured in yesterday's USA Today story and on the evening news last night interact with drugs from at least 15 categories of medications—including some OTC vitamins and OTC products.

I mention those news stories only to raise the awareness that the potential for drug or food interactions. These potential interactions make it imperative that ready and accessible expert healthcare advice be

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available to patients to provide information about their medicine and help them to make a rational selection.

How can FDA be assured of consumer understanding?

Consumers need both oral and written information to ensure understanding about the medication they wish to take. Pharmacists are an excellent source of this information. According to a 1999 FDA survey, already 87% of patients are receiving written information about their medications from pharmacists.

With the explosion of Direct to Consumer advertising it seems more appropriate than ever that access to a medicine expert, the pharmacist, could provide more safe and effective care.

Additionally, Pharmacists were voted the most trusted professional in the United States in Gallup poll surveys for 11 straight years and are the most accessible health care professional.

Pharmacists have a minimum of 6 years of education. If a patient comes to the pharmacy where they also pick up their prescription medicine, the pharmacist has the advantage of having the patient profile readily available. This knowledge and information allows the pharmacist to assist the patient in making a rational selection for their

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condition. It helps to eliminate the risk of duplicate therapies or therapies that conflict with a regimen the patient is already taking.

NCPA supports a transitional category of prescription drugs. This method seems to offer the best of all worlds by providing a bridge between the prescription and OTC categories. Prescription drugs in a transitional category provides the FDA with the ability to assess the use and safety of the drug in an environment similar to OTC status but one that would provide the safety elements of the patient conferring with a licensed healthcare professional.

The transitional category we are suggesting would be for an interim period of say, 3 to 4 years during which time the public health experience with the drug as an OTC candidate could be evaluated. This extra time allows the Agency the flexibility to assess the drug and allow it to go OTC, or, if safety concerns warrant, return the drug to Rx status as it did with Metaproterenol in 1983.

To add to the FDA's collection of data, perhaps a reporting mechanism, specific to the transitional category, might be initiated.

Approaches similar to the transitional category have already been successfully implemented in other countries. Many countries in Europe have employed a third category of medications for years. At a symposium on Capitol Hill in 1991, a panel of pharmacy leaders from

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Australia, Canada, Great Britain, and the Netherlands described how a transitional category of drugs has worked in their countries.

Robert Davies, the Executive Director of the Pharmacy Guild of Australia said:

"We believe our system of graduated drug control provides the greatest flexibility in balancing the conflicting interests of protecting public health and providing drugs at a reasonable level of convenience."

Furthermore, an additional category of drugs has been in place in U.S. pharmacies for decades. The Controlled Substance Act allows for a fifth schedule of controlled drugs or C-5 category. Drugs like Robitussin AC, Donnagel PG, and terpin hydrate with codeine, are sold only under a pharmacist's supervision or by prescription.

The advantages of the this transitional category of prescription to OTC could be:

- 1) Drugs that might be abused could be identified and controlled.
- 2) Reduced medication errors, duplicate therapies, inappropriate therapies
- 3) Enhanced compliance—particularly for medications taken for chronic conditions
- 4) To allow the FDA the ability to further evaluate patient safety and provide flexibility in recalling the drug

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Who should initiate product category switches?

Regarding who should initiate product switches, we would make the following observations: There should be a formal mechanism where representatives from the manufacturer, health care professionals, FDA, and consumers can review prescription products on an ongoing basis to determine their potential for OTC status.

If the OTC Advisory Committee has the proper composition, structure, and authority to do this, they may be an appropriate group to perform this function. If it is not the appropriate group, then another committee could be formed that could be a link between public and private interests.

Again, NCPA appreciates the opportunity to discuss the importance of patient access and patient safety as these potent medications are contemplated to be considered for OTC status. We hope the FDA will strongly consider this concept of a transitional category to act as a safety link between prescription and OTC status. Thank you.

National Community Pharmacists Association (formerly NARD)

- Represent 25,000 independent community pharmacists
- Represent the 60,000 community pharmacists employed at these sites

Focus of Presentation

- Public Safety
- Solution
- Initiating product switches

Written comments will be sent to FDA prior to the August 25, 2000 deadline.

Illiteracy

- 33% of U.S. population literacy challenged
- Approximately 44 million adults score at a level 1 illiteracy level (can read a little but not well enough to read a food label)*
- 45-50 million adults score at a level 2 ("lack foundation of basic reading skills")*

*National Institute for Literacy

How can FDA be assured of consumer understanding?

- Pharmacists are the most accessible health care professional
- 87% of patients receive information from their pharmacy
- Most trusted professional 11 consecutive years

Assisting the patient in making a rational selection

- Pharmacist has a minimum of 6 years training in Rx and OTC medications
- Access to patient profile

Experiences in other countries

- Australia
- Canada
- Great Britain
- Netherlands

"We believe our system of graduated drug control provides the greatest flexibility in balancing conflicting interests of protecting public health and providing drugs at a reasonable level of confidence."

—Robert Davies, Executive Director of the Pharmacy Guild of Australia

Advantages of a Transitional Category

- Drugs of abuse could be identified prior to unsupervised distribution
- Medication errors, duplicative and inappropriate therapy would be reduced
- Enhanced compliance—particularly for medications used for chronic conditions
- Public health experience with the drug as an OTC candidate could be evaluated during this interim

Who should initiate product switches?

- Proactive review of prescription products by panel of experts representing consumers, manufacturers, and healthcare professions
- Would act as a link between private and public sectors
