

NACDS

National Association of Chain Drug Stores

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April 28, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Status of Useful Written Prescription Drug Information for Patients; Docket No. 00N-0352, 65 Fed. Reg. 7022 (February 11, 2000)

To Whom it May Concern:

The National Association of Chain Drug Stores (NACDS) is pleased to submit comments to the FDA on the methodology that it will use to assess the quantity and quality of written information being provided to consumers with their prescription medications.

NACDS membership consists of more than 145 retail chain community pharmacy companies operating over 31,000 community pharmacies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 94,000 pharmacists. The chain community pharmacy industry is comprised of more than 19,000 traditional chain drug stores, 7,000 supermarket pharmacies and 5,000 mass merchant pharmacies. Chain operated community retail pharmacies fill over 60 percent of 3 billion prescriptions dispensed annually in the United States.

The 31,000 community pharmacies represented by NACDS are the most significant source of written information provided to consumers with their prescriptions. NACDS members support the provision of useful, comprehensive written information to consumers with their prescription medications. Chain community pharmacies voluntarily started to provide this written information to consumers over 20 years ago. This information helps reinforce - but cannot and should not supplant - information that consumers receive from their physician and pharmacist about taking prescription medications appropriately.

NACDS supported the provision in P.L.104-180 that established a private-sector process (hereinafter known as the "Keystone Process") to increase the quality and quantity of written information provided to consumers about their prescriptions. This provision in Federal law prohibited the FDA from implementing a Proposed Regulation (60 FR 44182, August 24, 1995, hereinafter referred to as the "Proposed Regulation") that would have developed prescriptive standards for the distribution of written information by pharmacies.

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We opposed, and continue to oppose, the Proposed Regulation and support the “private-sector” approach because the private sector has made, and continues to make, significant strides in providing this information without Federal regulation. We do not believe that FDA has the authority to regulate this voluntarily provided written prescription information, given that the professional practice of pharmacy is regulated by the states.

We also supported the Keystone Process because of our concern with the “one size fits all,” government -prescribed approach to providing written consumer prescription information that was advocated in the Proposed Regulation. However, we do not support, nor do we believe that it is in the best interest of the consumer, to limit the flexibility of health professionals to customize information based upon a consumer’s specific circumstances.

With that said, we have serious concerns that the agency is engaging in an incremental approach to achieving the prescriptive goals in the original Proposed Regulation that the law sought specifically to prohibit. For example, NACDS strongly believes, based on legislative history, that the FDA was not permitted by law to implement any part of the original Proposed Regulation. However, in 1999, using another interpretation of legislative history, it finalized a part of the original Proposed Regulation relating to standards for written prescription information provided to consumers for prescription medications with “serious and significant side effects.”

The agency has now issued an interim report that assesses the usefulness of written information being voluntarily provided by pharmacies, and is seeking comments on the methodology used to conduct this assessment. The agency will use these comments to finalize its assessment process to determine whether the initial goal of P.L. 104-180 is being met; that is, 75 percent of consumers should be receiving useful written information with new prescriptions by 2001. If this goal is not met, the Secretary may implement the FDA’s Proposed Regulation.

We believe, based on the initial assessment document, and the additional issues for which the agency is seeking comments through this notice, that the agency is attempting to create prescriptive standards for written information through this “private sector” process. We believe that this is contrary to the goals of the private sector process, and, more importantly, the intent of Congress. Nonetheless, we offer the following comments on the assessment process that has been undertaken to date:

Minimum Threshold for Useful Written Prescription Information: The initial assessment document may, in fact, represent a well-constructed “checklist” to determine whether prescribed elements of information are actually contained in written information provided with new prescriptions. Unfortunately, however, we do not believe that the original “usefulness” elements identified by the Keystone Process were ever tested with consumer groups to determine whether these are, in fact, the information that consumers want and need. Therefore, before any final assessment is undertaken, the actual “usefulness” of the “usefulness” elements should be validated by another independent, consumer-based process. “Useful” is a subjective criterion. What is useful to one consumer may be of little use to another.

NACDS believes that for information to be useful to the consumer it has to be read, it has to be understood and it has to be acted upon. We do not believe that long or otherwise lengthy documents are particularly useful to consumers. They will likely go unread, defeating the purpose for which the information is distributed. Health professionals must have the discretion to not include information that is irrelevant to the patient, or information that might create concerns for the patient and result in their not being compliant with their medications.

Moreover, we also believe that the appropriate balance of information must be included in the written information. That is, both the advantages and risks of taking prescription medications must be appropriately indicated for the consumer. However, caution must be taken not to create false concerns about prescription medications by over emphasizing warnings, or listing every warning, caution or risk that might be associated with a particular medication.

The information should be written in a manner that encourages the consumer to take the medication as prescribed by the physician. It must also, however, provide them with sufficient information to recognize when they might need to contact a health professional, such as a physician or a pharmacist, with a concern about their medication.

Medication non-compliance is already a serious public health and economic problem that will only be exacerbated if consumers receive information that creates unwarranted and unnecessary concerns. Moreover, NACDS puts significant faith in the ability of most consumers to contact their physician or pharmacist if they believe that they are experiencing an adverse reaction from a particular medication.

We also have concerns about using a “weighting” system to determine whether information meets the usefulness criteria. That is, some would contend that “warning” information might have to be more prominent for some drugs, while “storage” or “use” information might have to be more prominent for others. This might require that a different format be developed for each and every drug. It would be virtually impossible to develop a weighting system of this type, given the significant number of prescription drugs on the market.

Moreover, while some prescription medications have more potential for “risk” than others, not every drug has significant risk or warnings. The purpose of this information is not to raise concerns or fears in consumers about prescriptions. The goal is to help them understand how to take their medications appropriately. Creating weights that emphasizes warnings or potential for adverse events can lead to a system where the potential risks of drugs are emphasized over their benefits.

Role of Information Database Companies: It is important to recognize that written prescription information provided by community retail pharmacies is developed by a limited number of data base companies that supply this information to pharmacies.

Therefore, it is incumbent upon the FDA and these database companies to assure that the information contained in the products that they provide to pharmacies is consistent with validated, consumer- tested criteria for “useful” information. These companies should also be responsible for updating this information and sending it to pharmacies on a timely basis.

Pharmacies can only print and provide the content of information that is provided to them by these database companies. NACDS believes that if database companies are unable to provide products that meet validated, consumer-tested “usefulness” criteria, then FDA should suspend its survey until such products are available.

Collection of the Information: We believe that the shoppers’ survey used by the FDA in conjunction with state boards may represent an appropriate approach for the collection of information. We believe, however, that a more geographic representative sample of pharmacies needs to be included, including rural and urban pharmacies.

We also believe that other methods of retail pharmaceutical distribution should be included in the sample. For example, in addition to chain and independent community pharmacies, mail order pharmacies should be included, as well as outpatient hospital pharmacy departments, and HMOs. Each distribution outlet should be included in proportion to the percentage of prescriptions dispensed annually by each of these outlets.

Format of the Information: FDA is seeking comments on whether additional information should be added to the criteria for assessing “usefulness,” and about the type style or font size that should be used for the written information. First, NACDS strongly believes that consumer readability is enhanced if the written information provided is limited to one page. Adding more and more information to the written information, in our opinion, reduces the likelihood that the information will be read.

Second, it must be remembered that any such format or text changes must be considered in the context of the pharmacy-based operational systems that produce this information. The written information provided by pharmacies is produced by very intricate pharmacy software programs. These programs are also used to maintain patient profiles, process and adjudicate prescriptions, bill third parties, and perform drug use review checks, among other functions.

The written information is often printed as part of a complete set of information and documents with a prescription, which includes the prescription label, the receipt, and the written information. Making changes to the format or design of these systems is incredibly expensive and time consuming.

Therefore, we urge that FDA meet with pharmacy chains and pharmacy computer software companies to determine the feasibility and cost of making changes to the current programs. Finally, we oppose a standard format for written prescription information as a criterion for judging "quality." Such a standard would be inconsistent with the goal of the voluntary action plan, which was to avoid a FDA-proposed standardized format for written prescription information provided to consumers.

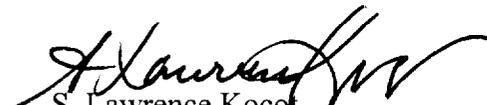
Role of Consumers and Others in Assessing Usefulness: As stated, we believe that it is important to identify consumer-validated elements of useful information before any assessment moves forward. We are concerned that the FDA has taken an "academic" approach to assessing the usefulness of information that is being provided by pharmacies, and was collected for this survey. While the survey used "objective" criteria to make its conclusions, we believe an assessment of the usefulness of written information must also have a "subjective" component. Therefore, we believe that objective criteria should only be used as part of the agency's assessment, and that subjective evaluations should provide the other half of the weight.

That is, consumer evaluation should have a much greater part overall. Written information that is of excessive length or that contains confusing and alarming information, can hardly be considered useful. Consumers should be asked to rate the information for readability, usefulness, comprehension, and other factors consistent with the criteria developed in the statutory language. This is the true test of whether written prescription information is useful to consumers.

Moreover, we believe that the agency should also include representatives of pharmacy organizations and database companies to any assessment group. This will help provide a perspective on the ability of technology to produce this type of information, as well as new and emerging technologies that might help enhance the usefulness of written information provided to consumers.

Please contact John M. Coster, Ph.D., R.Ph., NACDS Vice President, Federal and State Programs (703-549-3001), for additional information about these comments. Thank you.

Sincerely,



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