



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Comments of

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on

Consumer Medication Information

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Mr. Chairman and Members of this Committee, my name is John Coster, Ph.D., Vice President of Federal and State Programs for the National Association of Chain Drug Stores (NACDS). I am a pharmacist by training. On behalf of NACDS and our 200 member companies, we appreciate this opportunity to appear before you today to discuss how we can improve the effectiveness and quality of consumer information about prescription drugs. Our members operate approximately 33,000 community retail pharmacies, including traditional chain pharmacies, food pharmacy combinations, and mass merchandise pharmacies. We provide approximately 70 percent of all outpatient retail prescriptions. I served as a member of the original committee established to develop the private-sector action plan required under Public Law 104-108.

In particular, we want to provide our perspectives on the current status of the quality and quantity of written information that pharmacies provide to consumers with their prescriptions. This written information has been referred to by many names, but for the purpose of this presentation, I would like to refer to them as voluntary medication guides. This is to distinguish them from the mandatory medication guides that are required by the FDA for certain drug products that have been identified to have serious and significant side effects. FDA finalized a rule relating to mandatory medication guides in 1998.

Let me start by saying that we are strongly committed to working with the FDA, consumers, and our member pharmacies to continue to make strides in improving the quality of written prescription information received by consumers. We believe that the private sector action plan developed in 1997 – also known as the Keystone plan – is working, given the finding that 89 percent of consumers are receiving some form of written information with their prescriptions. As the FDA's own data indicates, the percent of consumers receiving information from pharmacies increased over the last 10 years from 32 percent to the current level of 89 percent.

We are equally concerned, however, by the University of Wisconsin study found that only 50 percent of written information provided met the "quality" goals as outlined in the Keystone action plan. Like the FDA, we want to know why there are such disparities between the quantity being provided and the quality of the information. We want to know where the process might be breaking down.

While I may not have all the answers for you today, I can tell you that our members are responding to consumers' and governments' call to provide quality written information to patients.

The provision of written information by pharmacies to consumers about their prescriptions really began as a "value-added" service. After the passage of the drug use review provisions of OBRA 90, and with almost every state requiring that pharmacists offer to counsel patients about their prescriptions, pharmacies attempted to find a way to reinforce the counseling patients receive about their medications. In essence, these written information leaflets act as "leave behinds" for patients to help reinforce the oral counseling they receive from their physician and pharmacist.

Consumers are more educated than ever about their health care and are hungry for information. However, it is often difficult for patients to remember important facts about their medication that were conveyed verbally by their health care professional. These leaflets act as handy references for patients. These information sheets, however, cannot and should not be viewed as a substitute for the professional advice and counseling of health professionals, and we believe that patients should always call their health professional first if they have any questions or are experiencing adverse reactions to medications.

Let me describe to you our understanding of how the information process flows from the producer of the information to the patient. Retail pharmacies do not produce this written prescription information on their own. They purchase – or more accurately license – the information from major database companies that produce the information. Due to recent consolidation in the database company marketplace, there are currently only a few producers of this information currently in the marketplace. We understand that First Databank and Medispan provide written prescription information to the majority of the retail pharmacy marketplace. Other providers of written and electronic prescription information include Gold Standard, Micromedex, USP, and Facts and Comparisons. These companies provide their products and services to various marketplaces.

While the database companies can talk in greater detail about how they produce the written information, our understanding is that they rely on the FDA-approved labeling as well as the peer-reviewed literature to develop this information. Sometimes, pharmacists will note that information in the written product is incorrect or needs to be updated, and will contact the database company to bring this issue to their attention.

Pharmacies then obtain this information from the database companies either directly, or through the software vendor that runs their pharmacy prescription processing system. Let me explain briefly the role of the software vendor. Every retail pharmacy in the United States has a software system that maintains pharmacy records, processes prescriptions and produces labels, checks for adverse drug reactions, and interacts with a "switch" that allows for the online adjudication of prescription claims. These systems have greatly enhanced the efficiency of the prescription delivery process and have helped to improve the quality of care by providing real-time information to the pharmacist about other drugs that the patient may be taking.

The software vendor incorporates the written drug information into that particular pharmacy's software system. We understand that there are some 75 plus pharmacy software database vendors, such as TechRx, QST, PDX, and others. Some of these may be very small operators that only serve a small number of pharmacies. Pharmacies, however, do not necessarily know whether the information that the software vendor provided meets the Keystone standards. Some of these software programs are more modern than others. In some cases, the information may have to be updated to fit within the processing or printing capabilities of the software system or the pharmacy's labeling and billing system.

Some large chain pharmacies do not utilize software vendors. They develop and operate their own software systems, and directly license the written information from the database companies. Several of these large pharmacy operators have told us that they make no changes to the information that they receive from the database companies. In fact, I understand that as part of the new and renewal license agreement, at least two of the major providers are requiring that no changes be made to the information that they provide to pharmacies, unless they indemnify the database company.

We have done our own unscientific survey of the information that is currently being distributed by about 8 chain pharmacies. It appears that all these information leaflets come from First Data Bank. The information presentation appears pretty consistent, with some variability in the type face and the size of the printing font. We understand that there is variability in terms of how often the written information is updated in the pharmacy systems as well. For those that obtain the information directly from the database company, the information might be updated more frequently. In other cases, it may be updated quarterly. Whether the frequency of updates had an impact on the quality of the information that was collected for the survey remains unclear. It is also unclear whether it is even necessary to update the information quarterly, especially for drugs that have been on the market for a long time.

Many of our members are probably unaware of the Keystone criteria for written information, and do not perform their own assessment of the information they receive based on these criteria. I think they trust that the information is factually correct and provides the information necessary to patients to take their medications correctly. Thus, for many large and small pharmacies, they are relying on the information given to them either directly by the database companies or through their software vendors.

We believe that any information that is presented to patients must not only be useful, but also must compel patients to actually read the information. Written information that is two or even three pages long may not be read by patients because of its length. Clearly, this is not a desired outcome. We understand that more than 80 percent of the information produced is already greater than two pages in length, with the average length being one and a half pages. We are therefore concerned about any additional mandates that would require more information due to patient readability, as well as concerns cost increases that would accompany such mandates.

Information that is too short, or not specific enough to a particular drug will also not be useful. For example, information that simply states "report any side effects to your doctor" clearly does not help patients understand what side effects to look for while taking their medication. Thus, we believe that a balance is needed between too much information and not enough.

There are also logistical issues for pharmacies who provide this information. Most pharmacy systems in chains use the same printer to produce both written prescription information as well as all other written materials needed to fill the prescription. These other written materials include the actual prescription label, the patient's receipt, auxiliary labels, and third party log stickers. Clearly, the prescription filling process is slowed when two or three additional pages of written information are printed off, potentially creating delays for patients to obtain their prescription.

Up until April 2000, First Data Bank was producing both a short and long form of their written prescription information. After that time, although discontinued, some pharmacies continued to use the short form because it remained in their prescription processing system. We are not sure which pharmacies were still doing this, but if these forms were collected as part of the 2001 survey, then it would partially explain why the quality results might fall short. We also understand that mergers and acquisitions in the database marketplace in 2000 may have created some issues relating to updating written information, which also might have affected the quality of the information that was collected in 2001 for this survey.

Action Plan

Now that we all have a somewhat better understanding of the process, how do we move forward from here? The following suggestions provide a reasonable action plan for moving forward to improve the quality of written information currently being provided to consumers, as well as move forward in meeting the 2006 goal of 95 percent of new prescriptions receiving quality written information.

Assure Database Companies are Producing Keystone Compliant Information: Without stating the obvious, the database companies that produce information should be providing Keystone compliant information to their customers. Given the few suppliers of this information, it would not appear to be that difficult to work with these companies to assure that the information being produced is Keystone compliant.

Work with Software Vendors and Database Companies to Assure that “Quality” Materials are Being Produced: It is clear that many pharmacies don't know whether the information that they are distributing is Keystone compliant. Most just rely on their pharmacy software vendor or the database company itself to provide information that meets the “useful” criteria. We believe that the information that is being supplied by these vendors should comply with Keystone standards. The question is, how can pharmacies know that the information is compliant? FDA may want to consider convening a workshop for these companies to educate them about the Keystone criteria, and the need to provide information that complies with these criteria. FDA should consider working with the ASAP to reach out to the suppliers of written prescription information.

Continue to Educate Pharmacies about Importance of Providing MedGuide Compliant Information: NACDS has consistently reminded our members about the importance of distributing Keystone-compliant materials, and of not significantly editing the materials. We have to continue to communicate this message, but we also must be sure that our smaller members – those that have under 50 stores – are only using written materials that are Keystone compliant.

Continue to Allow for Health Professional Discretion and Flexibility: NACDS supports continued action by the private sector to improve the quality of written information. We would oppose any attempts to develop any more prescriptive or government-required standards for written patient information. In the end, health professionals have to retain discretion for how and what they communicate to patients. Moreover, every patient is different, and health professionals who know their patients will be best able to determine which form and scope of communications will best encourage them to use their medications appropriately.

Include Other Outpatient Dispensing Sites in the Survey. The University of Wisconsin survey only examined independent and chain community pharmacies. While these two entities clearly distribute the majority of the outpatient prescriptions, there are other entities that provide outpatient prescriptions as well, including hospital pharmacies, clinics, and Federal health care facilities. These entities should be included in future surveys.

Assess the Term "Useful": As the Committee already knows, "useful" is a subjective term. What is useful to you may not be useful to me. Clearly, there needs to be some minimum standard for "quality, useful" information. To my knowledge, the Keystone criteria that are the basis for the assessment of "usefulness" have never been tested or validated. We would urge that this validation process be done so that we have a better sense of whether the nature and scope of information outlined by the Keystone group is, in fact, what is most useful to patients.

Members of the Committee, we very much appreciate the opportunity to present these comments to you here today. We look forward to working with you, the FDA, our partners in health care delivery, and consumers to assure that quality, useful information is distributed about prescriptions. I would be happy to answer any questions that you may have. Thank you.