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Patient Safety Implications on Implementation of the Current FDA-Mandated Medication Guide Program

Supported by:

The American Pharmacists Association (APhA)
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The National Association of Chain Drug Stores (NACDS)
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All prescription medications have benefits and risks, but the risk of taking some medications are potentially greater than others for some patients. For the medications that have a “risk profile” that is greater than average, in some cases, the FDA has required the dispensing of an FDA-approved “Medication Guide.” In theory, these consumer-oriented written Medication Guides are supposed to help inform patients about specific adverse events that may occur from taking these medications. After reading a Medication Guide, patients should be able to better determine whether to take the medication or how to identify potentially serious adverse effects.

With each prescription for a medication with an FDA-approved Medication Guide, pharmacists should provide a copy of the Medication Guide. While pharmacists continue to be eager to provide patients with information on their medications, the implementation of the current FDA-mandated program has made it more difficult for community retail pharmacies to provide Medication Guide information to consumers efficiently. In addition, many patients that receive Medication Guides may not find the information useful given the risk-focused nature of the communication, as well as the quantity of other written information that pharmacies are also voluntarily providing to their patients with their prescriptions.

The purpose of this paper is to provide policymakers with an overview of the current status of the Medication Guide program and offer suggestions on how the communication of risk information to patients can be done more efficiently and effectively.

Background of Medication Guides

On December 1, 1998, the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) issued a final rule that placed a new requirement on manufacturers of prescription medications for which the FDA determined posed potential “serious and significant concern.” Manufacturers of these medications were required to develop a consumer-oriented FDA-approved written medication information sheet, called a Medication Guide, or more commonly known as a “MedGuide.”¹ Medication Guides are patient handouts currently dispensed by pharmacists that are intended to provide patients with specific information on a medication. Most Medication Guides focus solely on providing patients with information on specific risks with that medication, but some also contain information on proper use, storage, dosing, etc.

The final rule establishing Medication Guides in 1998 supplies the criteria for approval of Medication Guides. According to regulation, the FDA may require distribution of Medication Guides for selected prescription drugs that pose a “serious and significant public health concern.”² Also, stated within the regulation, the FDA will require Medication Guides if the agency determines that one or more of the following circumstances exist:

¹ Federal Register: Prescription Drug Product Labeling; Medication Guide Requirements; Final Rule. December 1, 1998 (Volume 63, Number 230.

² *Id* at pg 66379

- Patient labeling could help prevent serious adverse effects;
- The drug product has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product;
- The drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness.³

Content, Format, and Distribution Requirements

The FDA final rule states that Medication Guides may be required for a “small number of products,” and “the FDA anticipates that an average, no more than 5 to 10 products per year would require such information.”⁴ In addition to meeting the above criteria for approval of a Medication Guide, they are also subject to strict content and format restrictions, including minimum letter height, legibility, and presentation considerations.

When a Medication Guide is approved for a specific medication, this Medication Guide is required to be distributed to patients by a pharmacy each time this medication is dispensed. In other words, Medication Guides must be dispensed with new and refilled prescriptions.

Manufacturers of medications with FDA-approved Medication Guides are responsible for providing Medication Guides to pharmacies for dispensing to patients. FDA regulation states that manufacturers shall provide “Medication Guides in sufficient numbers, or the means to produce Medication Guides in sufficient numbers, to permit the authorized dispenser to provide a Medication Guide to each patient who receives a prescription for the drug product.”⁵

Patients Receive Other Written Information from Pharmacies in Addition to Medication Guides

In addition to Medication Guides, pharmacists provide other written information and offer oral consultation. The Consumer Medicine Information (CMI) provided by the pharmacy is usually one to two pages in length and provides patients with a summary of their medication. CMI most commonly contains information on the following topics: use of the medication, dosing, adverse effects, warnings, drug interactions, storage. Pharmacies receive this information from content vendors (i.e. First DataBank, Wolters-Kluwer Health).

According to goals established in Public Law 104-180 by Congress in 1995, 95% of consumers receiving new prescriptions should be provided with useful written information on their medications. Since then, the agency has seen progress in meeting these goals and the retail pharmacy supply chain continues to work closely with the FDA and other stakeholders to improve the usefulness of written medication information.⁶

³ *Id* at pg 66379

⁴ *Id* at pg 66379

⁵ *Id* at pg 66381

⁶ Svarstad, Bonnie L, et al. Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001. Accessible at <http://www.fda.gov/cder/reports/prescriptionInfo/default.htm#C.%20RESULTS>.

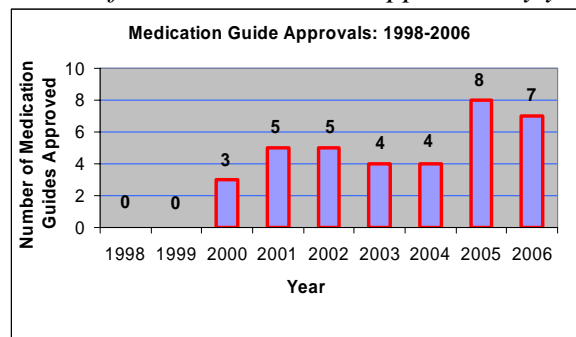
While CMI is distributed to patients with every prescription, patients may also receive additional written information in the form of a Patient Package Insert (PPI). These documents, provided by pharmaceutical manufacturers, vary in length and format and are not available for all products. Patient Package Inserts and Medication Guides are both written by manufacturers and approved by the FDA.

In addition to the documents described above, the FDA began producing its own version of consumer information called, “Patient Information Sheets” (PIS) in 2005. Ranging in length from one to three pages, PIS are written by FDA and are posted on the FDA web site. The agency encourages healthcare providers to download PIS and provide them to patients at the point of prescribing or when a medication is dispensed.

Medication Guides in Today’s Community Pharmacies

Since the late 1990’s, the FDA has gradually approved Medication Guides for individual medications, developing a list of over 20 Medication Guides by 2004. Starting in 2005, however, the FDA has begun approving Medication Guides for entire classes of medications. Thus far, the antidepressant and Non-Steroidal Anti-inflammatory Drug (NSAID) classes have had a Medication Guide approved and it is very likely that the Attention-Deficit/Hyperactivity Disorder (ADHD) stimulant medication class is soon to follow.

Number of Medication Guide Approvals by year⁷

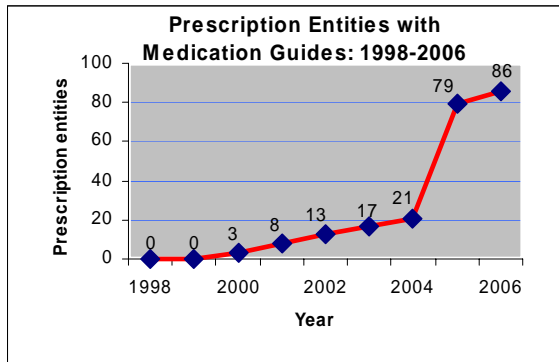


As of April 2006, 36 Medication Guides have been approved by the FDA (visit www.fda.gov/cder/Offices/ODS/medication_guides.htm to see a list provided by the FDA). Taking into account classes of medications, these 36 Medication Guides apply to over 80 prescription entities translating into over 1400 individually manufactured prescription products with different National Drug Code (NDC) numbers.⁸ Also, these 36 Medication Guides vary in length, from two to 15 pages.

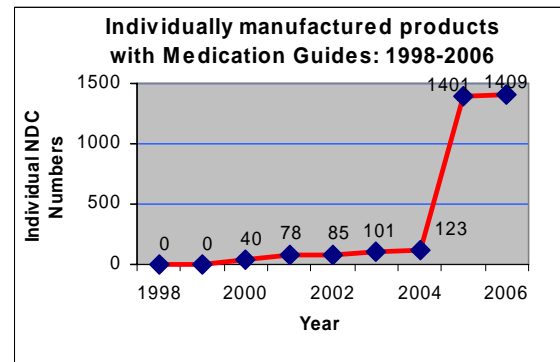
⁷ FDA MedWatch. The FDA Medication Safety and Adverse Event Reporting Program. Accessed 4/21/06. Available at <http://www.fda.gov/medwatch/safety.htm>.

⁸ PriceCheck PC®. Accessed 5/3/2006

Prescription Entities with Medication Guides



Individually Manufactured Products with Medication Guides



Manufacturers are Responsible for Providing Medication Guides to Community Pharmacies

In order to comply with their requirement of providing “Medication Guides in sufficient numbers” to pharmacies to be dispensed to patients, pharmaceutical manufacturers have used different methods for distributing Medication Guides, which include:

1. Providing tear-off pads of the Medication Guide, which are shipped directly to pharmacies;
2. Attaching Medication Guides to the prescription product container;
3. Including a Medication Guide within the prescribing information attached to the prescription product container;
4. Providing toll free 800 numbers to allow pharmacies to order hard copy Medication Guides, which are then shipped to the pharmacy.

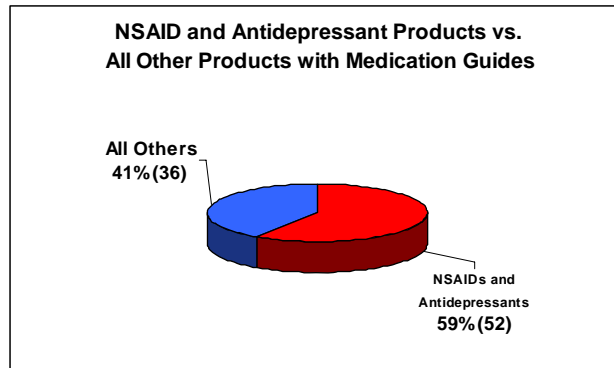
The proposed rule announcing Medication Guides in 1995 makes reference to using “third party information systems” to simplify the process of dispensing patient information leaflets to patients.⁹ Although all pharmacies already rely on content vendors to provide information for Consumer Medicine Information (CMI), this proposed rule was left out of the 1998 ruling because the Medication Guides are considered part of the products’ approved labeling. It is becoming increasingly challenging for pharmacists to obtain Medication Guides through the various methods described above. Allowing pharmacies that have the infrastructure in place to use third party systems would increase pharmacies’ ability to provide Medication Guides to patients.

⁹ 21 CFR Part 201, et al. Prescription Drug Product Labeling; Medication Guide Requirements; Proposed Rule. August 24, 1995.

Antidepressant and NSAID Medication Guide Distribution Programs

The Medication Guides for antidepressant and NSAID classes represent the majority of Medication Guides dispensed in community pharmacies. To facilitate distribution of these guides to community retail pharmacies, brand and generic manufacturers of these medications formed coalitions with the intention of providing pharmacies with a uniform version of Medication Guides which can be dispensed with any medication within that class.

Breakdown of Individually-Manufactured Products with a Medication Guide¹⁰



Status of Antidepressant Medication Guide Program

In March of 2005, all manufacturers of prescription antidepressants formed a coalition to print and distribute hard-copy tear-off pads of Medication Guides which could be dispensed with any antidepressant medication. Each product was not required to have a specific Medication Guide. The retail pharmacy supply chain considers the formation of this coalition as a positive development in terms of enhancing the efficiency of distributing Medication Guides to patients. As a result of this coalition, all community pharmacies were shipped an initial quantity of antidepressant Medication Guides from a fulfillment company (The Hibbert Group) contracted by the manufacturers. Each tear-off pad included an order form to re-order more in the event the initial supply was exhausted.

Community pharmacists had become familiar with this procedure and have been providing antidepressant Medication Guides to their patients for more than one year. However, this coalition dissolved as of January 31, 2006 and ended their contract with the fulfillment company. Since that time, each manufacturer of an antidepressant has decided to comply with their requirement of providing Medication Guides to pharmacies in different ways (examples listed on previous page).

Currently, pharmacies have no standard method for obtaining antidepressant Medication Guides and have had much difficulty attempting to track them down. In many cases, this leads to a pharmacy's inability to provide a Medication Guide to patients. This issue needs to be addressed at the FDA level to assure that pharmacies do not need to obtain different Medication Guides from dozens of manufacturers of the same class of medications.

¹⁰ *Id.* Accessed 5/3/2006

Status of NSAID Medication Guide Program

With encouragement by the FDA and the pharmacy community, manufacturers of NSAIDs have formed a coalition similar to that of the antidepressants and have created a uniform version of the NSAID Medication Guide which could be distributed to all patients receiving any NSAID. This coalition has distributed an initial shipment of hard-copy tear-off pads of NSAID Medication Guides to pharmacies in the first week of April, 2006. Similar to the antidepressants, within the tear-off pads of Medication Guides, there is a re-order form to obtain more Medication Guides. This NSAID Medication Guide replenishment program is currently still available for pharmacies.

Concerns with the Current Medication Guide Program: An Overview of Consumer Perceptions

The retail pharmacy supply chain strongly supports providing patients with information about medication risks and appropriate use so patients can better understand their medications. With that said, we have multiple concerns with the current implementation of the Medication Guide program.

The purpose of the Medication Guide program is to “improve public health by providing information necessary for patients to use their medications safely and effectively.”¹¹ However, the current program may be ineffective at accomplishing this goal, and this should be a concern for policymakers, health care providers, and patients.

Because the pharmacy industry has very close interactions with patients on a day-to-day basis, we believe consumers find the Medication Guide program more confusing than it is helpful. The following outlines our collective concerns as they relate to consumer perceptions:

- **Content of Medication Guides and other written medication information can conflict:** Currently patients are receiving medication information from a number of sources, including Consumer Medicine Information (CMI), Medication Guides, Patient Package Inserts (PPIs), and potentially Patient Information Sheets (PIS). In some cases, the content on these documents can conflict. For example, many Medication Guides start off with a section titled, “What is the most important information I should know” about this medication. Specifically, the antidepressant Medication Guide begins with this section which outlines the risk of suicidal thoughts in children and teenagers.¹² Because this Medication Guide is required to be dispensed to all patients of any age receiving any antidepressant, this statement is misleading. A patient may read this first statement and think the rest of the information provided to them is not as important. In our opinion, this could result in patients missing valuable information about their medication.

¹¹ Federal Register: Prescription Drug Product Labeling; Medication Guide Requirements; Final Rule. December 1, 1998 (Volume 63, Number 230).

¹² FDA-approved antidepressant Medication Guide. FDA website. Accessed 4/21/06. Available at <http://www.fda.gov/cder/Offices/ODS/labeling.htm>.

- **Overloading patients with duplicative written medication information:** The retail pharmacy supply chain is very concerned that the Medication Guide program is providing patients with too much duplicative written information about their medications causing many patients to not read any of it. As stated above, Medication Guides vary in length to up to 15 pages. In addition to receiving Medication Guides, patients also receive Consumer Medicine Information (CMI) from the pharmacy with each prescription and in some cases receive a “Patient Package Insert” (PPI) and/or a Patient Information Sheet (PIS).

Both the CMI and the PPI are usually one to two pages in length and provide patients with a summary of drug information. Combined, these three documents could have patients leaving the pharmacy with nearly 20 pages of duplicative reading material about one individual medication; with major portions of the material containing the same or similar information. This duplication and volume makes it extremely difficult for patients to understand their medications.

A recent statistic from Caring Today, a leading caregiver publishing company, indicated that **90 million adults in this country read at an 8th grade level or lower.**¹³ This statistic demonstrates that a significant percentage of the U.S. population has a literacy level that potentially makes any amount of written medication information difficult to understand, let alone 20 pages.

- **Imbalance of risk/benefit information:** Most Medication Guides provide patients with information on a specific risk related to that medication. For example, the antidepressant Medication Guide provides patients with two pages of information solely on the risk of increased suicidal thoughts in children and teenagers.¹⁴ As mentioned above, all patients also receive one to two pages of summarized Consumer Medicine Information (CMI) with their prescriptions, which includes information on a medication’s risks, benefits, appropriate use, and more. Providing patients with an entire two pages of information solely on a specific and rare risk and two more pages to summarize the key information for a medication gives patients an inaccurate balance of risk/benefit information.

Further emphasizing this point, the Medication Guide for the Non-Steroidal Anti-inflammatory Drugs (NSAIDs) includes the following statement about aspirin, “*Aspirin is an NSAID medicine but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.*”¹⁵ Although these risks can occur, aspirin has been proven to significantly reduce morbidity and mortality associated with cardiovascular-related events. These well documented benefits are not mentioned in the NSAID Medication Guide.

¹³ Research on file. Caring Today. www.caringtoday.com.

¹⁴ FDA-approved Antidepressant Medication Guide. Accessible at www.fda.gov.

¹⁵ NSAID Medication Guide. Accessible at www.fda.gov.

As a result of this imbalance of information, patients may be more likely to be overly concerned about their medication after reading the Medication Guide and may decide to discontinue taking it without consulting with their physician. The lack of adherence to chronic prescription medications has been well documented in the U.S. and we believe that providing patients with too much information on medication risks may further contribute to adherence problems.

- **Providing Medication Guides with each new and refill prescription can overload patients with repetitive information:** The proposed regulation for Medication Guides from 1995 (21 CFR Part 201, et al.) stated that Medication Guides be provided to patients receiving all new prescriptions and that they are made available to patients upon request for refill prescriptions.¹⁶ However, the final ruling in 1998 stated that Medication Guides must be dispensed with every new and refill prescription for a drug product.¹⁷ Because of the concerns of overloading patients with information on a specific medication, providing Medication Guides to patients only with new prescriptions more appropriately allows patients the opportunity to assess the “serious and significant concern” with their medication at the point of therapy initiation.

Patients receive new prescriptions for chronic medications once a year at the very least. Because Medication Guides rarely change, we believe patients are unnecessarily provided with repetitive written information on a Medication Guide throughout the year.

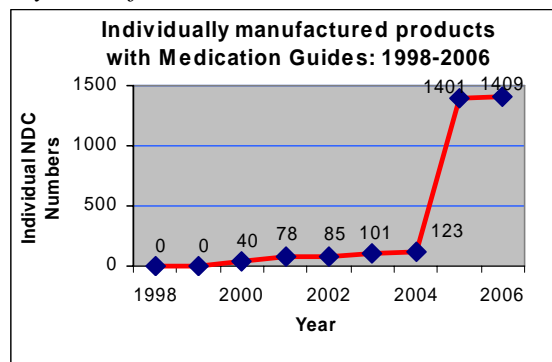
- **No evidence exists that demonstrates Medication Guides enhance a patient’s understanding of medication risks:** The retail pharmacy supply chain is unaware of any research which demonstrates that Medication Guides improve the public’s awareness of medication risks. Nor are we aware of evidence that demonstrates that significant risks have been avoided, that adherence rates have been affected, or that health outcomes have been improved as a result of patients receiving Medication Guides. With the potential overload of written information that Medication Guides create, we question whether patients better understand their medications as a result of receiving a Medication Guide and believe research is imperative to evaluate their utility.
- **The number of Medication Guides is growing rapidly:** With the addition of antidepressant and NSAID classes of medications to the list of Medication Guides, the number of individually-manufactured products that require FDA-approved Medication Guides has increased significantly over the past year.¹⁸

¹⁶ 21 CFR Part 201, et al. Prescription Drug Product Labeling; Medication Guide Requirements; Proposed Rule. August 24, 1995.

¹⁷ Federal Register: Prescription Drug Product Labeling; Medication Guide Requirements; Final Rule. December 1, 1998 (Volume 63, Number 230).

¹⁸ PriceCheck PC®. Accessed 5/3/2006

Individually Manufactured Products with Medication Guides



This growth of the program does not coincide with the FDA anticipation that “an average, no more than 5 to 10 products per year would require such information.”¹⁹ Therefore, we are concerned that the FDA is expanding the Medication Guide program and approving Medication Guides outside of the scope of the final regulation. The Medication Guide regulation should not become a back door way to require that all medications have FDA-approved Medication Guides.

- **Patients can be provided with risk information quicker via Consumer Medicine Information (CMI):** The database companies that provide the Consumer Medicine Information (CMI) to pharmacies already include the new and emerging risk information that would be the subject of a Medication Guide. These companies can update the CMI and release this important risk information more rapidly than pharmaceutical manufacturers because they do not have to navigate the FDA approval process to which Medication Guides are subject.
- **Non-standardized method for distributing Medication Guides may create an inability for pharmacies to dispense them to patients:** While pharmacies continue to make efforts to dispense Medication Guides to patients when applicable, the current processes used by individual manufacturers to provide Medication Guides to pharmacies are causing significant challenges. This is especially a problem for the “classes” of drugs for which FDA is requiring Medication Guides, such as the antidepressants and NSAIDs. As stated above, manufacturers are using different methods for distributing Medication Guides to pharmacies. Because of the lack of standardization across the industry and the fact that manufacturers are not actively communicating their individual processes, in many cases, pharmacies are not able to obtain and dispense Medication Guides to their patients.

¹⁹ Federal Register: Prescription Drug Product Labeling; Medication Guide Requirements; Final Rule. December 1, 1998 (Volume 63, Number 230. Pg 66379.

- **Patients may not receive Medication Guides because the FDA has not enforced the requirement for manufacturers to provide Medication Guides to pharmacies:** With the lack of standardization across all manufacturers, the retail pharmacy supply chain is concerned that some manufacturers are not complying with their requirement of providing “Medication Guides in sufficient numbers, or the means to produce Medication Guides in sufficient numbers” to pharmacies.²⁰ For example, manufacturers of antidepressants had originally produced and distributed hard-copy tear-off pads of Medication Guides. However, since January 2006, this distribution program is no longer available and we believe some manufacturers have yet to develop another method for providing Medication Guides. In addition, some manufacturers are including one Medication Guide within each bottle. Commonly, a pharmacy must split this bottle up into smaller quantities for distribution to multiple patients. Thus, pharmacies are left with insufficient quantities of Medication Guides.

Also, the agency has made little effort to have Medication Guides provided to pharmacies electronically. We understand the FDA has recently announced that pharmaceutical manufacturers will soon be required to provide the “highlights” section of the Prescribing Information (PI) to physicians in electronic formats. However, no similar requirement exists for Medication Guides.²¹ Providing electronic Medication Guides to pharmacies and their database partners will decrease the time between pharmacists learning of new Medication Guides and patients receiving them.

- **Resources shifted from manufacturers to community pharmacies:** With an increasing number of products now with FDA-approved Medication Guides and with manufacturers all complying in various ways, community pharmacies are finding it increasingly burdensome to continue to provide Medication Guides to their patients. In many cases, pharmacies have not been provided with Medication Guides from manufacturers and are left with no option but to print a copy off the FDA website in order to provide them to their patients. Although the FDA has clearly placed the burden of providing Medication Guides on manufacturers, community pharmacies have found themselves saddled with a significant portion of the administrative and cost burdens in order to continue to provide patients with this medication information. As Medication Guides become more and more difficult to obtain, community pharmacies’ costs and resources for printing, toner, paper, etc. continue to escalate. Although pharmacies are devoted to providing Medication Guides to patients in any fashion possible, we are concerned the community pharmacy industry is shouldering a manufacturer burden.

²⁰ Id at pg 66381.

²¹ Guidance for Industry: Using Electronic Means to Distribute Certain Product Information, Food and Drug Administration, May 4, 2006.

Retail Pharmacy Supply Chain's Recommendations to Enhance Efficiency and Patient Safety Aspects of Medication Guides

The retail pharmacy supply chain is committed to providing patients with written information which helps enhance patients' understanding of medications and helps them use their medications safely and appropriately. While we understand the purpose of the Medication Guide program established by the FDA, the program in its current format is falling short of its goals, potentially compromising patient safety. Because of the concerns addressed above, we make the following recommendations to policy makers regarding the program:

- **Assess the length and content of Medication Guides:** To reduce the overloading of medication information provided to patients, we encourage the evaluation of the appropriate quantity of medication information patients should receive. In addition, we urge the FDA to assess whether Medication Guide content and Consumer Medicine Information (CMI) already provided by pharmacies should be incorporated into one document to eliminate redundancy resulting in easier understanding by the patient. Many CMI documents already include the information that is included in the Medication Guide.

We also encourage the FDA to further evaluate the content of Medication Guides so that they provide patients with the type of information they want and understand. A recent consumer petition indicated patients' goals for Direct-to-Consumer (DTC) advertisements on medications were "simpler, clearer messages that communicate both the risks and benefits of prescription medicines, more informed doctor/patient dialogue, and improved patient compliance."²² It follows that patients may have similar requests for Medication Guides and we encourage the FDA to closely evaluate the content of Medication Guides so that these goals are met.

- **Evaluate the usefulness and effectiveness of the Medication Guide program:** Because the FDA is designed to make evidence-based decisions, we encourage the FDA to evaluate the usefulness and effectiveness of Medication Guides by researching patients' views of the program. The FDA should use these data to make appropriate changes to the Medication Guide program which will help patients gain a better understanding about the risks and benefits of their medications. In a 2002 presentation entitled, *Communicating Risks and Benefits Through Labeling and Leaflets*, FDA's Karen Lechter, Division of Surveillance, Research, and Communication Support Office of Drug Safety, addressed the need for research on Medication Guides.²³ Areas for research on Medication Guides called for by FDA in Dr. Lechter's presentation are:

²² Coalition for Healthcare Communication. Citizen Petition Requesting Promulgation of an Amended Regulation for Prescription Drug Advertising to Establish Separate Criteria for Practitioner-Directed and Consumer-Directed Advertising and to Establish a Standing Advisory Committee on Health Care Communications. 3/31/06. Accessible at www.cohealthcom.org.

²³ Lechter, Karen. Division of Surveillance, Research, and Communication Support Office of Drug Safety. FDA Presentation: *Communicating Risks and Benefits Through Labeling and Leaflets*. Available at: <http://www.fda.gov/cder/present/DIA62002/risks/sld001.htm>

- Are patients receiving Medication Guides? If not, why not?
- Do patients read Medication Guides? If not, why not?
- Do patients understand the information, especially low literate patients? If not, how can the information be improved?
- Will patients heed the information? If not, why not?
- Do Medication Guides reduce risks and increase benefits of drugs? If so, which combination works best, and why?
- How can risks be conveyed without discouraging patients from using a drug that has a favorable benefit vs. risk profile for them?

The retail pharmacy supply chain strongly encourages the FDA to follow the recommendations outlined by Dr. Lechter in 2002.

- **Allow for more efficient methods of Medication Guide distribution:** Although paper distribution is currently the most commonly used method for distributing Medication Guides to pharmacies, this method is significantly outdated and inconsistent with the move toward more electronic communication of health-related information. Many pharmacies have the capability to print a copy of the Medication guide using their computer system. While this method provides short term solutions, we request the FDA waive certain formatting requirements which Medication Guides are subject to (excluding font size and white space). If the FDA were flexible on these requirements, some pharmacies would be able to integrate the printing of Medication Guides into their current systems. To prevent the shifting of significant resources from manufacturers to pharmacies, manufacturers should be responsible for providing financial support to pharmacies which are able to print the Medication Guides with their computer systems. This will result in the most efficient distribution of Medication Guides.

Many pharmacies also currently collect e-mail information from patients. Pharmacies should be able to e-mail the Medication Guide to the patient rather than having to distribute it by paper. This is consistent with a recent FDA policy decision to require manufacturers to provide information about approved uses of their drugs and serious side effects to physicians' computers and hand-held devices.

In the preamble to the final regulation, the agency assumes that "manufacturers will work with information system vendors to incorporate Medication Guides into existing pharmacy software systems."²⁴ Because pharmacies use information system vendors to obtain the content for Consumer Medicine Information (CMI), we encourage the FDA to ensure that manufacturers are working toward this goal so that pharmacies that have the capabilities are provided with the option to print Medication Guides electronically. In addition, manufacturers must still make hard copy Medication Guides available to requesting pharmacies.

²⁴ Federal Register: Prescription Drug Product Labeling; Medication Guide Requirements; Final Rule. December 1, 1998 (Volume 63, Number 230. Pg 66390.

- **Eliminate the need to provide Medication Guides with refill prescriptions:** We support an update to FDA regulation which will eliminate the need to dispense Medication Guides with refill prescriptions. This will help reduce the quantity of redundant medication information patients receive, while preserving the opportunity to make informed decisions on taking their medication based on the content provided to them in the Medication Guide at the point of therapy initiation or prescription renewal. In the event a Medication Guide is updated or revised, patients would receive a new copy of the Medication Guide with their next new prescription.
- **Assess the most appropriate and effective point of delivery for Medication Guides:** While community pharmacies may seem like a logical location for patients to obtain Medication Guides, the dissemination of Medication Guide information should be the responsibility of all health care providers involved with the prescribing and dispensing of medications. Community pharmacists continue to be a primary source used by patients for medication information and we believe they are an appropriate location for the dissemination of written information, including Medication Guides. However, we encourage the FDA to explore whether other locations are also appropriate. For example, patients receive written prescriptions at their physician’s office. If the Medication Guide was provided at the point of prescribing, patients can assess the medication risks and make a decision with their physician to start that therapy or switch to an alternative regimen. Because medications with Medication Guides pose a “serious and significant concern,” we believe patients should have the opportunity to evaluate this concern before leaving the physician’s office.
- **Allow pharmacists to withhold Medication Guides:** Under the FDA rule, a prescriber of a drug product with a Medication Guide can direct that the Medication Guide be withheld from the patient. Pharmacists can assess whether Medication Guides can cause confusion among patients. Therefore, we request the FDA to explicitly authorize pharmacists to use their judgment for withholding a Medication Guide.
- **Evaluate methods used by FDA to approve Medication Guides:** The Government Accountability Office (GAO) report on Drug Safety released this April indicates that the FDA “lacks clear and effective processes for making decisions about post-market safety issues.”²⁵ Because many Medication Guides, especially those for entire drug classes, have been approved as the result of post-market safety issues, we support an evaluation of the FDA’s decision-making process for establishing Medication Guides.
- **Establish standards for Medication Guide distribution and dispensing:** In order to continue to provide patients with Medication Guides, a standard procedure for distribution to pharmacies should be followed by all manufacturers. Because pharmacies continue to struggle to obtain Medication Guides for antidepressant medications, we encourage the FDA to enforce standards which require all manufacturers of a certain drug class to follow similar distribution procedures.

²⁵ GAO-06-402. Government Accountability Office Report to Congressional Requesters on Drug Safety. Improvement Needed in FDA’s Postmarket Decision-making and Oversight Process. March 2006.

The variety of methods currently used by manufacturers is causing confusion in pharmacies and they often result in a pharmacies' inability to provide Medication Guides. A more consistent method will result in more efficient receipt of Medication Guides by patients.

We appreciate your consideration of this position paper. With the patients' best interest in mind, the retail pharmacy supply chain, represented by APhA, First DataBank, FMI, HDMA, NACDS, NCPA, and Wolters-Kluwer Health would be more than willing to work with the FDA, pharmaceutical manufacturers and others to enhance the Medication Guide program.

The following groups indicate they support the position outlined above*:

- The American Pharmacists Association (APhA) consists of more than 57,000 individual members, including practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession.
- First DataBank and Wolters-Kluwer Health are leading providers of electronic drug information to the healthcare industry.
- The Food Marketing Institute (FMI) conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world.
- For more than 125 years, the Healthcare Distribution Management Association (HDMA) has worked with its members to secure a safe, efficient and reliable healthcare distribution system that is able to provide life-saving health products and services.
- The National Association of Chain Drug Stores (NACDS) represents the nation's leading retail chain pharmacies, consisting of more than 35,000 community pharmacies, which employ over 120,000 pharmacists.
- The National Community Pharmacists Association (NCPA) represents the pharmacist owners, managers, and employees of nearly 25,000 independent community pharmacies across the United States.

* Senior staff from the National Council on Patient Information and Education (NCPIE) provided input into the final version of this paper. NCPIE remains a leading organization in helping enhance the written information received by patients. NCPIE is a coalition of over 100 diverse organizations whose mission is to stimulate and improve communication of information on appropriate medicine use to consumers and healthcare professionals.