American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

August 29, 2003

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

RE: Docket No. 03N-0168

Dear Sir/Madam:

Thank you for the opportunity to comment on the current status of useful written prescription drug information for consumers. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The quality of written information distributed to consumers is of obvious interest to the Association and our members. Pharmacists are committed to improving patient health through the appropriate use of both prescription and over-the-counter medications. To ensure the safe and effective use of medications, pharmacists help patients manage their medications with patient education activities including providing written information and oral consultation. Written consumer medication information (CMI) is one method pharmacists use to provide their patients with information on the proper use of their medications, possible side effects, adverse reactions, and general information.

In recognition of the importance of CMI as an adjunct to oral counseling, APhA participated in the 1996 Steering Committee that developed the Action Plan for the Provision of Useful Prescription Medicine Information. The Action Plan's goal was to improve the quality and availability of useful information that is provided to consumers.[1] The Action Plan and the included "Keystone" criteria were successful in serving as a step towards improving the appropriate use of medications. The private sector and the pharmacy profession have made great improvements in providing patients with better information about their drug therapy, including written CMI, since the development of the Action Plan. Less than 25% of patients received written patient information other than the prescription label and associated stickers in

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[1] Action Plan for the Provision of Useful Prescription Medicine Information. December 1996: pg. 5.

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1992. By 1995 that number had increased to more than 55%. The most impressive increase was announced by the Food and Drug Administration (FDA) in June 2002 when the Agency released the results of its study that found that almost 90% of patients now receive CMI.[2] It is clear that pharmacy has taken the charge of distributing CMI very seriously and has achieved a significant increase in the distribution of CMI since Public Law 104-180 was passed in 1996.

APhA and the pharmacy community, however, recognize the need for improvement in the quality of CMI distributed. The results of the 2002 study found that the quality of information distributed varied and did not meet the criteria evaluating "usefulness" a majority of the time. In an effort to facilitate the improvement of CMI, APhA joined the National Council on Patient Information and Education (NCPIE)-coordinated CMI Initiative. APhA strongly believes that the CMI initiative, which involves representatives from all areas of the private sector, will serve as the appropriate catalyst to further advance private sector efforts to improve the quality of CMI in order to meet the 2006 goals.

APhA offers the following comments on questions posed by the FDA in the June 5, 2003 *Federal Register* Notice.

What steps is the private sector taking to improve the usefulness of the written information patients receive with prescription drugs and to meet the Year 2006 goals?
At the conclusion of the July 17, 2002 FDA Drug Safety and Risk Management Advisory Committee meeting on CMI, one of the Advisory Committee's suggested actions was that another group of stakeholders be convened. Shortly after the Advisory Committee meeting, the private sector took the initiative and followed the Advisory Committee's recommendation – convening a working group of stakeholders to address the need to improve the quality of CMI. As noted above, this working group – the CMI Initiative coordinated by NCPIE – is a broad-based working group of pharmacists and other health care professional organizations, the pharmaceutical industry, drug information database vendors, and consumer groups.

The work of the CMI Initiative builds upon ongoing CMI activities. The charge of the CMI Initiative is to develop and implement a detailed program to bring CMI into compliance with the Action Plan and the Keystone criteria. As described at the July 31, 2003 FDA Public Meeting on the Current Status of Useful Written Prescription Drug Information, the CMI Initiative is working toward this goal by collaborating directly with drug information database vendors (the entities responsible for the development of the CMI pharmacists distribute) to identify sources of information to use as content for CMI, what drug information must be included in CMI, and how best to present that information. We are also working to educate database vendors, purchasing managers at pharmacies, pharmacists and other health care professionals on the Keystone criteria and the importance of fully implementing the criteria by 2006. Members of the CMI Initiative are committing significant resources to this endeavor and we are confident that it will be successful in advancing private sector efforts to improve CMI.

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[2] Food and Drug Administration Talk Paper. "Success of Private Sector Patient Information with Prescription Medicines Assessed." June 18,2002.

What barriers exist for the private sector to meet the Year 2006 goal, and what plans exist to overcome these barriers?
Crucial to the private sector's success is the identification and resolution of barriers that hamper efforts to widely disseminate quality CMI. Even with the best of intentions and follow-through by stakeholders, the reality of today's healthcare marketplace creates many impediments to progress on this agenda. APhA is pleased that rather than declaring private sector efforts as "failed" because areas of concern remain, the FDA is interested in examining why the private sector's efforts have not yet obtained the desired level of success in all areas.

One major barrier that has affected the success of private-sector voluntary CMI is the fact that many stakeholders are not familiar with the Keystone criteria. In an effort to overcome this barrier, the private sector is widely distributing information on Public Law 104-180 and the Keystone criteria. As part of this effort, APhA is expanding pharmacist and student pharmacist education on the topic through Association publications and electronic communications, and is exploring the possibility of CMI-related educational programming. These efforts are being echoed by other members of the CMI Initiative – all of whom are reaching out to their respective audiences to raise awareness of the Keystone criteria.

Another potential barrier is related to the technology infrastructure currently in place in pharmacies. CMI is usually generated by the pharmacy's computer system. Any change to the length, content, or format of written CMI will likely require a change in the pharmacy's computer system and/or hardware such as printers. Such changes may affect the pharmacy's infrastructure and normal operating processes. For example, many pharmacies currently operate a system that only supports CMI of a one-page length. And for the small – and decreasing number – of pharmacies without a computer system, the problem is even more fundamental. To overcome this barrier, representatives from pharmacy and the data vendors must work together to ensure that Keystone compliant CMI can be supported by systems currently in pharmacies.

Another difficulty in the private sector's efforts to reach the 2006 goal is a lack of clear understanding of what exactly "reaching the goal" means. While Public Law 104-180 states that useful written CMI must be provided for 95% of all new prescriptions by 2006, it is not clear how the FDA will measure the private sector's success. What dispensing sites will be included in the 2006 study? Will success mean that 95% of new prescriptions at community pharmacies are accompanied by CMI? Or will success mean that 95% of new prescriptions at all dispensing sites – community, mail service, managed care, internet, and outpatient hospital pharmacies, long-term care facilities, physician offices, and others – are accompanied by written CMI? APhA recommends that the study be expanded to include all settings that provide medication. Limiting the study to community pharmacies creates the impression that this sector of the health care community is solely responsible for ensuring the provision of useful information to patients – which is clearly not the case.

It is also unclear as to when CMI will be judged to have met the "usefulness" criteria. When CMI is evaluated against the Keystone criteria what rating will indicate a "passing grade"? For example, must CMI be rated a four or five on a five-point scale (such as the scale utilized in the FDA sponsored University of Wisconsin-Madison study in 2001) to be considered useful? Without a clear idea of the assessment to be conducted – a clear understanding of what success will look like in 2006 – success will be impossible.

While not a barrier to the private sector meeting the 2006 goal for distribution of useful information, it is appropriate to note that getting written information actually used by consumers is the biggest challenge. Even though the law is focused on having CMI distributed to consumers, the efforts of the private sector to widely distribute CMI will be ineffective if consumers do not read the CMI, comprehend it, and start a dialogue with their pharmacist and other health care providers. Messages from the FDA, private stakeholders, and others should reinforce the need for communication between the patient, the pharmacist, and the physician or other prescriber.

What should the role of the FDA be in assuring full implementation of the Action Plan to meet the Year 2006 goal?
The private sector CMI Initiative is a major, long-term project – working with stakeholders to ensure that the quality of CMI is improved prior to the next FDA assessment. While this effort was initiated by the private sector, FDA's participation in the process is crucial. As discussed earlier, the private sector needs information and interaction with the Agency if our efforts are to succeed. The FDA must inform the private sector how the 2006 assessment will be conducted – what dispensing sites will be surveyed and what measures will equate success in meeting the "usefulness" goal. One mechanism for providing this information could be a FDA-issued guidance document. The document should provide the private sector with a clearer understanding of the Agency's general expectations for quality CMI. The guidance could also clarify important issues, such as clarifying that off-label use of a medication can be included.

The FDA can also assist the private sector in our efforts by providing feedback on CMI Initiative activities, helping us understand if we are moving in the right direction, helping us motivate others in the private sector to take action, and adding credibility to our message that the private sector must improve CMI before the 2006 deadline or face the consequences. We see the Agency's role in this process as that of a partner with the private sector – working together to assure that the 2006 goals are met. APhA and other members of the CMI Initiative appreciate the Agency's participation in our meetings to date and look forward to a continuing relationship as we work together on this issue.

What other initiatives should FDA consider for providing patients with useful written information about prescription drugs as endorsed by Public Law 104-180? Such initiatives could include the possibility of FDA requiring manufacturers to provide authorized dispensers with the means to distribute useful written information approved by the FDA.
APhA would have significant concerns with any proposal to require the mandatory distribution of FDA-approved CMI. The majority of the content of CMI is currently obtained from manufacturer-provided materials – which are FDA-approved – but few CMI leaflets or brochures have been approved by the FDA. The few exceptions are for products considered to possess a higher risk such as alosetron hydrochloride or isotretinoin which are required to be accompanied by a FDA-approved MedGuide. If the Agency were to require distribution of FDA-approved CMI for all drug products, it would face enormous logistical barriers. For example, it would require an overwhelming number of FDA staff and resources to review and approve CMI leaflets and brochures for the thousands of prescription medications currently on the market. One can only guess on the number of years it would take before the Agency could approve CMI for every drug product. Requiring FDA-approval would also cause significant delays in efforts to update the content of CMI. Currently, drug information database vendors regularly update the content of CMI, with important safety information such as new contraindications and side effects. If FDA-approval was required before updated CMI could be distributed, important

safety information could be withheld from patients for weeks, months, or years at a time. This lag time is obviously problematic.

Requiring FDA-approval of CMI would also take away pharmacists' ability to customize CMI based upon the needs of their patients. Patient information must be tailored to each patient and used to supplement information communicated by the pharmacist and other health care professionals – attempts to completely standardize the content of CMI would reduce pharmacists' ability to provide information specific to the particular drug and the particular patient. For example, CMI approved by the FDA would not include information on off-label uses – information that is significant to a patient who has been prescribed the medication for an indication not currently approved by the Agency. Consider a patient with polycystic ovarian disease who is prescribed metformin hydrochloride to induce ovulation. With FDA-approved CMI, the patient would not receive information about this unapproved indication of the drug, but information on the FDA-approved indication – the management of Type 2 diabetes – which would be of little use to the patient. This is in direct conflict with the Public Law's goal of arming patients with important information about their medications.

FDA-approval of the content and design of CMI will not guarantee the quality of CMI. A voluntary system that takes full advantage of technology and pharmacists' knowledge of their patients can create a better educational experience for consumers. For example, a female patient who is prescribed an antibiotic – and also takes oral contraceptives – will have a greater need for information regarding the antibiotic's ability to reduce the effectiveness of her birth control method, than an elderly man prescribed the same antibiotic. The customized information may stimulate questions to health care providers and lead to improved care. Requiring FDA-approval of CMI would eliminate pharmacists' ability to take into account their patients' unique situations.

When FDA-approved information is mandated for products that pose serious and significant public health concerns, the use of unit-of-use packaging is essential to addressing the logistical challenges of distributing this written information. Unit-of-use packaging resolves many of the logistical problems currently associated with distributing written patient information. Patient information could be attached to or included on the unit-of-use packaging when it arrives at the pharmacy for later distribution to the patient, helping ensure the delivery of written CMI to patients with their medication and it would eliminate the need for pharmacists to print and manually distribute CMI.

In conclusion, the Agency is taking the right approach to improving the quality of written consumer medication information. The private sector is committed to working together to identify methods to improve the usefulness of CMI for the consumer. The CMI Initiative coordinated by NCPIE has reenergized private sector efforts to meet the 2006 goals. There is much work to be done and several barriers that will have to be overcome, but we are confident that the private sector – working as a partner with the FDA – can meet the goals set forth in Public Law 104-180. Therefore, APhA would strongly oppose any efforts to halt private sector efforts and require the Agency to regulate the content, design, distribution, and form of CMI. While supporters of FDA-approved CMI may view that option as the obvious course of action, the logistical complications, the resulting lag times in distribution of important safety information, and the restriction against patient-specific information, make it the option of last resort. APhA appreciates the Agency's recognition that the pharmacy community has

made significant progress since Public-Law 104-180 was implemented, and is pleased to have the opportunity to advance our efforts further.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan C. Winckler, Vice President, Policy & Communications and Staff Counsel, at 202-429-7533 or SWinckler@APhAnet.org, or Susan K. Bishop, Senior Manager, Regulatory Affairs & Political Action, at 202-429-7538 or SBishop@APhAnet.org with any questions.

Sincerely,

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