

Docket No. 03N-0168

CMI Education Committee

Presented on behalf of the

National Council on Patient Information and Education (NCPIE)

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FDA Public Meeting

Good afternoon. I am Susan C. Winckler, a pharmacist and attorney with the American Pharmacists Association where I serve as Vice President for Policy & Communications and Staff Counsel. Today I'm speaking on behalf of the Consumer Medicine Information (CMI) Education Committee convened by the National Council on Patient Information and Education (NCPIE). APhA is a founding and current board member of NCPIE. My comments reflect the consensus of NCPIE organizations that have participated on this committee; however, they do not necessarily reflect the individual views of all members of the broader NCPIE coalition.

In order for the private sector to successfully meet the Year 2006 CMI targets for distribution and usefulness, a comprehensive educational outreach plan is essential. The mission of our committee is to develop, and support implementation of, such a plan. We see our role as: (1) developing messages and programs that continue to raise awareness of the Keystone criteria and motivate various audiences to achieve the Year 2006 goals; and (2) building and nurturing clear lines of communication among parties responsible for fully incorporating the Keystone criteria (*Action Plan for the Provision of Useful Prescription Medicine Information*, Dec. 1996).

Major topics for our educational outreach will include:

1. Publicizing the criteria to appropriate audiences;
2. The significance of implementing the criteria;
3. How the private sector must adapt to meet the 2006 targets.

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Target audiences include, but are not limited to: data vendors, system integrators, purchasing managers at chain and independent pharmacies; pharmacists and other health care professionals, pharmaceutical manufacturers; and the public. We are developing an action plan targeting each specific audience.

Outreach to these audiences will be phased in gradually. Each organization in the NCPIE CMI Initiative will be responsible for implementing outreach campaigns to their own constituencies.

Early phases of our campaign will target CMI (drug information) vendors, system integrators, and CMI purchasing managers at pharmacies. Subsequent phases will target health care professionals and possibly pharmaceutical manufacturers. Finally, we plan to launch a national consumer education campaign touting the benefits of “useful” CMI. Making written information useful is one challenge; encouraging consumers to actually use it is another.

For nearly two decades, each October, NCPIE has sponsored the national health observance, “Talk About Prescriptions” Month. NCPIE, the American Pharmacists Association, and other coalition members support this effort. The CMI Initiative will be fully integrated into this national health observance.

Further, educational sessions on CMI will be featured prominently at NCPIE’s national conferences on medicine information and education. The next meeting will occur Dec. 8-9, 2003 in Washington, DC and in 2005. Historically, FDA officials (including the Commissioner) have keynoted NCPIE conferences. This year, we are planning several sessions chaired by those who have worked closely on our CMI Initiative. Also, we expect that CMI stakeholders will develop CMI educational programs for their respective members or customers. Such programs will generate additional opportunities for FDA to speak out on the CMI Initiative.

Throughout the implementation period of our CMI Initiative and into 2006, constant and efficient communication among stakeholders will be essential. To address this, NCPIE and CMI

partners will develop a CMI website. Initially, it will facilitate communication among internal stakeholders; eventually, it would be modified to serve patients and consumers as well.

One example of stakeholder-specific communication vehicles is the National Association of Chain Drug Stores' proposed CMI Assessment Guide. This would help NACDS members assess if their current CMI leaflets meet criteria for usefulness. With input from the Criteria Committee, we will be able to provide NACDS members with specific benchmarks that will permit necessary adaptations. As a precursor, in April 2003, NACDS distributed a two-page "assessment tool" that listed all the Keystone criteria for written information.

Another example of CMI work already undertaken is a NCPIE-produced generic article about the CMI issue. Written in June 2003, this article will be reproduced in various internal publications of NCPIE members. For example, the American Pharmacists Association's news periodical *Pharmacy Today* will soon feature a CMI article that builds on the NCPIE information. It will also be adapted for state newsletters of the National Association of Boards of Pharmacy. NCPIE is planning a series of CMI updates that CMI Initiative members can customize and use in their own newsletters (print and electronic).

In addition, CMI outreach is planned for many stakeholder educational conferences. For example, at next month's NACDS "Pharmacy & Technology Conference," and at the American Society for Automation in Pharmacy's annual meeting in September, members of the CMI Initiative will speak. NCPIE is confirmed to present on CMI at the ASAP meeting.

These are a few examples of our Education Committee's efforts. As we build upon these preliminary opportunities, we envision developing a media plan to inform, motivate, and reinforce behaviors that are necessary to meet the Year 2006 CMI goals.

Thank you for the opportunity to present the NCPIE CMI Education Committee's plans. I, or a member of NCPIE's staff, would be pleased to answer any questions.

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