



July 21, 2005

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

Re: Docket 2005D-0169

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Food and Drug Administration (FDA) on the May 26, 2005 draft guidance titled "Useful Written Consumer Medication Information (CMI)." CMI is written information about prescription drugs developed by organizations or individuals other than a drug's manufacturer that is intended for distribution to consumers at the time of drug dispensing.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's 4,800 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

The FDA established a goal that by 2000, at least 75 percent of people receiving new prescriptions would receive useful written patient information about the prescribed medication, and that by 2006, the percentage would increase to 95 percent. The results of the 2001 study to assess the usefulness of written prescription drug information indicated that, on average 89 percent of patients received some form of written medication information. However, the expert panel indicated that the average "usefulness" of the information was only about 50 percent.

The Academy commends the FDA for providing additional guidance to assist individuals and organizations in developing useful CMI. The additional guidance should prove valuable in increasing the percentage of written patient information classified as "useful" in future studies.

AMCP does have concerns about five specific recommendations offered in the guidance. Each of these concerns is described below:

1. In lines 243 – 246, the FDA recommends that the CMI "state the risks to the patient of developing tolerance to or physical or psychological dependence on the drug if this information is included in the PI [package insert]. In the case of these medicines, provide an explanation of tolerance, dependence, or addiction, and list the physical and psychological signs of addiction and withdrawal." The concepts of tolerance, dependence and addiction and the difference between each

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are challenging concepts to explain. A broad term such as “habit-forming” may be used to address dependence or addiction; however, it does not adequately address the differences. An explanation of tolerance, dependence or addiction and the additional signs of each is more information than CMI publishers can address in a patient-friendly document. Therefore, the Academy recommends that the FDA only require that the CMI state the risk of tolerance to or physical or psychological dependence on the drug.

2. In lines 274 – 282, the FDA recommends that the CMI address patient activities and behaviors that patients should avoid. Some examples are clear, such as smoking tobacco, drinking alcohol, being exposed to sun, or driving or operating heavy machinery. The guidance recommends that CMI also include statements specifying that certain behaviors be avoided if a statement in the FDA-approved professional labeling or package insert (PI) implies that such behavior be avoided. The guidance lists the example that “if the PI states that the medication has been shown to result in photosensitivity, then advise patients to avoid sun exposure. If the PI states that the product can cause drowsiness, then advise patients to avoid driving or operating heavy machinery until patients know how they will react to the medication.” This FDA recommendation would require publishers of CMI data to take responsibility for patient recommendations that the FDA has not required the product manufacturer to communicate in the PI. In some situations it may require the publisher to make an inference as to the degree of the implication. Therefore, the Academy recommends that the FDA not require that CMI include such information if the information is not required to be included in the product PI.
3. In lines 284 – 287, the FDA recommends that the CMI address any risks to the mother and the fetus or the infant from use of the drug during pregnancy, labor or breast-feeding. The FDA also recommends that for all drugs with unknown risks, CMI should include a statement such as, “Talk to your doctor if you are pregnant or breast-feeding. It is not known if the medicine will affect your baby.” Although the second sentence is factually true about practically all medications, it does not provide any additional or useful information to the patient. The Academy recommends that the first sentence alone sufficiently directs the patient on what actions should be taken.

In addition, the sentence, “Talk to your doctor ...” does not include pharmacists, the recognized experts on medication information. The Academy recommends that the patient’s pharmacist, should be added to the first sentence so it would read, “Talk to your doctor *or pharmacist*”

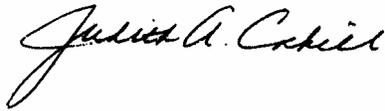
4. In lines 289 – 292, the FDA recommends that the CMI list specific risks to identifiable patient populations, such as children, elderly patients, people with compromised immune systems, or people with impaired kidney or liver functioning, if such information is in the PI. The FDA also recommends that the CMI publisher provide enough detailed information for the consumer to understand the significance of the hazard described. For many of the risks, especially impaired kidney or liver functioning, the “significance for the hazard described” will vary with the degree of impairment. The CMI publisher could not appropriately provide information on the significance without knowing the creatinine clearance rate for kidney function or the results of liver function tests. Therefore, the Academy agrees that the FDA

should recommend that the CMI list specific risks and include wording indicating that there may be significant harm; however, the FDA should not require that the CMI provide detailed information quantifying the significance of the hazard.

5. In lines 320 – 327, the FDA recommends that the CMI include a statement encouraging discussion with a health care professional about the prescription medicine. The Academy supports this recommendation. However, the example used by the FDA, “If you would like more information, talk with your doctor,” excludes the patient’s pharmacist, the recognized expert on medication information. In addition, many times the prescriber is not a doctor, but may be a physician’s assistant or nurse practitioner. Therefore, the Academy recommends that the statement read: “If you would like more information, talk with *the person who wrote your prescription or your pharmacist.*”

AMCP appreciates the opportunity to comment on this extremely important issue. If you have any questions, please contact me at (703) 683-8416 or at jcahill@amcp.org.

Sincerely,

A handwritten signature in cursive script that reads "Judith A. Cahill". The signature is written in black ink and is positioned below the word "Sincerely,".

Judith A. Cahill, CEBS
Executive Director