American Society of Health-System Pharmacists
Comments at FDA's Public Meeting on the Current Status of Prescription Drug Information for Consumers

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The American Society of Health-System Pharmacists (ASHP) appreciates the opportunity to provide comments at this public meeting.

ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care, and other components of health care systems. ASHP has a long history of medication-error prevention efforts, and we believe that the mission of pharmacists is to help people make the best use of medicines. Assisting pharmacists in fulfilling this mission is ASHP's primary objective. Components of the Society's efforts in assisting pharmacists in this regard include position and guidance documents for best practices such as those on pharmacist-conducted patient education and counseling (which were first published in 1975), extensive publishing activities with a strong focus on professional and patient drug information, and educational programs. ASHP has long held that private-sector publishers, including professional associations, must play an important role in the creation and dissemination of useful medication information.

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Private-sector Steps to Improve the Usefulness of Written Information Provided to Patients

For almost 30 years, ASHP has been a strong advocate of the role of pharmacists in providing useful written and oral counseling to patients about their medications. In addition, ASHP has a 25-year history of publishing medication information intended for educating patients about their drug therapy. With release in 1978 of the first edition of the "Medication Teaching Manual: A Guide for Patient Counseling," ASHP became one of the first private-sector organizations to publish medication monographs intended for educating patients. This Manual was developed by an advisory committee that ASHP formed cooperatively with the American Hospital Association (AHA) and the US Department of Health, Education, and Welfare's (now DHHS) Bureau of Health Education.

As a well-respected publisher of evidence-based drug information, ASHP has applied this expertise in publishing high-quality drug information for patients. ASHP is a past recipient of an award of excellence for consumer education materials from the FDA and the National Coalition for Consumer Education (NCCE) and was one of the first private-sector publishers to address the guidelines of DHHS' 1996 Action Plan for criteria, goals, layout, and language on useful prescription medication information in its patient resources.

ASHP's efforts over the years have extended to patient-education programs conducted by health-care professionals in a variety of settings and directly to consumers through resources like ASHP's award-winning safemedication.com website and the National Library of Medicine's MedlinePlus website, which both include patient medication information developed by ASHP.

ASHP's quick response to the Action Plan resulted in a major revision and reformatting in 1997–1998 of its Medication Teaching Manual and associated electronic resources (e.g., MedTeach software, MedMaster database, safemedication.com website) to improve their usefulness. ASHP has continued to enhance its patient information database, two examples of which included a major black-box warning initiative employing a prominent boxed format as described in the 1996 Action Plan and the inclusion of the national toll-free hotline number in the overdose section that connects consumers to poison treatment and prevention experts 24-hours daily, 7 days a week.

Other enhancements to ASHP's patient drug information database included a major restructuring of its data format into XML (eXtensible Markup Language) to optimize data development, revision, extraction, maintenance, formatting, and intelligent electronic interchange and considerable investment in software tools to manage its drug information resources. XML structuring also allows ASHP to deliver its patient drug information database to vendors and customers with style-sheets that produce leaflets in a format that adheres to the guidelines included in the 1996 Action Plan.

Therefore, ASHP believes that it has a long and consistent record of devoting considerable effort and resources in improving the development, maintenance, and dissemination of useful, high-quality patient drug information, a record that has been recognized by both the federal government and others. Through it efforts with other stakeholders, including the FDA,

ASHP also has been actively engaged in steps aimed at further improving the usefulness of patient drug information, including participation in NCPIE's Criteria Committee.

What Barriers Exist for the Private-sector

Prior to FDA's Drug Safety and Risk Management Advisory Committee in July 2002, ASHP viewed the 1996 Action Plan as providing useful guidelines for meeting the goal of improving the quality and availability of "useful" consumer medication information. ASHP applied the document in its original stated intent of providing direction to developers of written patient drug information while not being overly proscriptive. Useful information was to be sufficiently comprehensive and communicated such that consumers could make informed decisions about optimizing their therapy while avoiding harm. The guidelines for both content and format addressed the essential elements and characteristics of useful information and the preferred methods of presentation with the expectation that they would be further refined with experience.

As defined in the Action Plan, the consumer medication information is intended to be a summary that does not include all actions, precautions, adverse reactions, side effects, or interactions but that is flexible in addressing what is considered applicable and relevant to the consumer. Even inclusion of all black box warning information is not required by the Action Plan, but rather it is open to interpretation as to addressing that which is considered "relevant to the consumer." Likewise, the Action Plan includes flexibility regarding which precautions to include, stating not that all precautions should be addressed but instead that precautionary

"statements are encouraged in serious situations." These are the guidelines ASHP applied in its development of useful consumer medication information. Although ASHP still considers the guidelines embodied in the Action Plan as useful in providing direction to developers of patient information, the latitude applied by Dr. Svarstad's study in interpreting the Action Plan and in applying a more stringent interpretation to their assessment of "usefulness" has challenged the original intended flexibility of the guidelines in the Plan.

ASHP did not agree with the interpretation of Dr. Svarstad's December 21, 2001 final report to FDA on written prescription information as an indictment on the usefulness of this information when it made comments to the Agency in July 2002 and does not agree with that interpretation today. Instead, ASHP believes that this study should be viewed principally as a further refinement of the definition of "useful" rather than as an indictment of the current voluntary efforts and that it should be a stimulus for further refinement of the Action Plan itself, involving the combined efforts of all stakeholders, including publishers, consumers, researchers, FDA, and others. In fact, the Action Plan states that as it is implemented it is expected that additional information will be gained regarding what constitutes "useful," and that any associated guidelines should be subject to periodic review, evaluation, and refinement. That is precisely why various stakeholders have been actively engaged with FDA in addressing the "usefulness" issue over the past year.

Careful inspection of the criteria used in the in the December 2001 report indicates that "usefulness" was defined in many cases by criteria that were not specifically required or enumerated in the 1996 Action Plan. Examination of the criteria included in the 1996 Action

Plan versus the subcriteria applied in this report reveals that only about two-thirds to three-fourths of the subcriteria were explicitly required by the Action Plan, with the remainder being optional, open to interpretation, or having no apparent direct tie to the Action Plan criteria or to the FDA-approved professional labeling for the studied drugs.

Therefore, if patient drug information is to be held accountable to criteria that are more stringent than those embodied in the Action Plan, then a broad-based consensus development process and wide dissemination of the drug-specific criteria must be in place before the usefulness of selected patient drug information can be fairly evaluated.

FDA's Role

ASHP strongly believes that the proper course for the FDA is to continue to defer regulatory action for now, while pharmacists, pharmacy facilities, and private-sector medication information publishers and providers maintain their commitment to improve the usefulness of information that is provided to 95% of patients by 2006. As part of ASHP's commitment to the mission of pharmacists for helping patients make the best use of their medications, the Society will continue to follow the findings of, and make recommendations to, FDA and other groups as well as make appropriate enhancements to its patient medication information aimed at improving usefulness. In addition, ASHP will continue to assist the FDA in further implementing the recommendations of the 1996 Action Plan, both as a professional pharmacy association and publisher, and in serving in any formal advisory capacity that the Agency pursues in this regard. To this end, ASHP continues to interact with FDA staff on this issue and has joined other

stakeholders through the efforts of NCPIE to work cooperatively in helping the Agency achieve the 2006 goals.

One thing to not lose sight of is the fact that FDA-approved patient labeling for nitroglycerin fared poorly in Dr. Svarstad's December 2001 report. In fact, one disturbing finding in the report was the absence of information on the contraindicated use of sildenafil (Viagra) with nitroglycerin. Fully 5 years after approval of Viagra and the FDA-approved contraindication on concomitant use with nitrates such as nitroglycerin, the Agency has not required manufacturers of nitrates to incorporate this important information in their labeling. Not only is this contraindication missing from much of the patient information provided by manufacturers, but FDA has been remiss in requiring manufacturers of nitrates to include this critical information in their professional labeling despite posting on the MedWatch website a Dear Doctor letter reinforcing the importance of this contraindication. In fact, of the currently (as of 7/28/2003) available professional labeling for 10 nitroglycerin products reviewed, only 2 included the contraindication while 5 included no mention of sildenafil and the remainder included a warning rather than the stronger contraindication. This is just one compelling example of why the voluntary efforts of the private sector publishers are important in ensuring the dissemination of "useful" patient drug information.

ASHP reiterates its 2002 recommendation that FDA continue to solicit advice in the form of an advisory panel of experts and public- and private-sector stakeholders regarding further refinement of the definition of "usefulness" and the associated specific criteria that will be used in evaluating adherence to this definition. Mechanisms should be developed for ensuring that