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American Society of Health-System Pharmacists
Food and Drug Administration
Public Hearing April 27, 2007
Electronic Distribution of Prescribing Information for Prescription Drug Products

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Good afternoon. My name is Douglas Scheckelhoff and I am the Director of the Section of Pharmacy Practice Managers at the American Society of Health-System Pharmacists (ASHP). ASHP is a professional association with over 30,000 members and represents pharmacists who practice in hospitals and organized health systems, including ambulatory care clinics, home care, and long-term-care. We appreciate the opportunity to present the views of ASHP on the concept of electronic distribution of FDA-approved prescribing information.

Pharmacists routinely provide patient-specific drug information and accurate comprehensive information about drugs to prescribers, other health professionals, and to patients. Pharmacists also rely on available drug information to verify compounding, preparation, or dilution procedures of various dosage forms as appropriate. Clearly, pharmacists need to have up-to-date, accurate information available to them. ASHP practice guidelines support the notion that up-to-date drug information should be available. In fact, most state laws require that pharmacies have up-to-date drug information references as a condition of licensure. It is safe to assume that all licensed pharmacies, be they in hospitals or the community setting, have drug information books or electronic sources available to them in addition to what is distributed in the package insert.

While the Society supports electronic distribution and access of prescribing information, we also believe that paper package inserts (PI) should remain available (but distributed upon request) for all drugs in cases where access to the Internet is not available.

There are certain situations, though, for which paper leaflet PIs should always be distributed. First, paper leaflet PIs should continue to be available for drugs that have been on the market for less than two years. The paper PIs are important to these products because prescribing and other information may not yet be available in routine drug information sources or yet be well known to pharmacists. The second situation where paper leaflet PIs should continue to be available is for those drugs with higher risk, such as anticoagulants, antineoplastics, opiates, and medications with black box warnings. The third situation where paper leaflet PIs should be maintained are for injectable drugs or vaccines or any that require special compounding, preparation, dilution or reconstitution. Paper leaflet PIs should also refer the reader to the appropriate Web site for the latest information.

ASHP firmly believes that electronic distribution and access of the prescribing information would improve public health by expanding access to such information. Electronic information cannot be thrown away, can be accessed via the Internet at any time and from many locations, and if updated on a regular basis, is more timely and accurate than traditional paper sources.

Furthermore, research has shown that a large number of prescribing errors are attributable to prescribers' lack of knowledge about a drug. Prescribers with access to electronic prescription information would potentially have current drug information more readily available and accessible, which might lead to fewer prescribing errors. Prescribing habits would be improved, contributing to the overall improvement of public health.

Regarding the logistics of accomplishing electronic distribution of prescribing information, a Web-based source of information would provide a high-level of confidence in the timeliness of prescribing information. FDA should provide a list of all approved medications on its Web site, and maintain a database of all the prescribing information. The PI information should be available in a sufficiently low-grade electronic format so that technologically advanced, high-powered computers are not required for access. Paper leaflets and/or CD-ROMs should also be made available, free of charge, to those who request this information from the manufacturer.

The technology and infrastructure is currently available to accomplish electronic distribution and access, since the Internet is available to many providers. However, FDA should examine the issue of Internet availability, especially in settings such as small community pharmacies, community health centers, and critical access hospitals, which might have unique barriers to accessing the Internet. For those who have limited or no Internet capability, prescription information should be made available, at no cost to the requestor, via email, telephone, CD-ROM, and/or paper formats. Physicians' clinics should have ready access to a pharmacist during the clinic's hours of operation.

Should the decision be made to move to electronic distribution of information, parallel processes should be maintained until the new system is adopted and established. An educational campaign regarding electronic distribution and access of prescription information would ensure that there is an awareness of how to access electronic prescribing information. An easily accessed portal to the prescription information via the Internet would ensure continued use of the new system.

The FDA must also consider the level of back up systems needed to ensure that PI information can be accessed in cases where the Internet is not available, including emergency situations, such as power outages.

Electronic access to prescribing information would increase access to the information and potentially reduce inefficiencies in the current system. Special consideration needs to be given to those drugs that are new, high risk, or have special preparation requirements.

Thank you for the opportunity to present these comments.