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Public Comments of Mukesh Mehta

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Before the

Department of Health and Human Services
Food and Drug Administration

Members of the FDA, I appreciate the opportunity to be here today to discuss this very important topic of providing useful medication information to patients.

Thomson Healthcare is committed to help achieve the goal adopted by Public Law 104-180. As provided in the public law, by 2006 ninety-five percent of individuals receiving new prescriptions will have access to useful written information about their medications.

For 58 years, physicians and other healthcare professionals as well as patients have depended on the authoritative prescribing information found in Thomson Healthcare products and services, including the Physicians' Desk Reference (PDR®). Thomson Healthcare continues this long tradition with the most comprehensive publications, databases, and services for the entire healthcare community.

Today, through products such as the USP DI® Advice for the Patient®, DrugNotes Documents, the CareNotes™ System, and the PDR Family Guide to Prescription Drugs®, Thomson Healthcare is a leading provider of useful prescription medication information written specifically for patients.

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Thomson Healthcare participated in the Keystone Committee's Action Plan for the Provision of Useful Prescription Information and hopes to remain an active contributor to this process.

I would to like to take the opportunity to speak with you today about what Thomson Healthcare views as the three critical issues in ensuring the 2006 goal is met. These issues are:

1. Meeting the criteria for "useful" medication information as defined by the FDA and the Action Plan;
2. Identifying the barriers associated with dissemination of the "useful" medication information; and
3. The FDA's vital role in ensuring the goal is met.

First, Thomson Healthcare currently provides "useful" written medication information as that term has been defined. The FDA's 1995 Prescription Drug Product Labeling Medication Guide Requirements and the Action Plan for the Provision of Useful Prescription Medication Information both established criteria for written patient medication information. The FDA defined "useful" in the 1995 proposed rule as "written in nontechnical language and containing a summary of the most important information about the drug." The FDA has also determined that patient information would be evaluated according to its scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable

language and legibility. The Action Plan includes similar criteria that written prescription medication information must be scientifically accurate, unbiased in content and tone, sufficiently specific and comprehensive, presented in an understandable and legible format that is readily comprehensible to consumers, timely and up-to-date, and useful.

Thomson Healthcare has created and revised its patient education information to specifically meet these criteria. For example, our patient education product, DrugNotes, is written in nontechnical, easy to understand language. Compliance with this internal standard is verified using standard literacy testing tools on each document. The most important information related to adverse effects, contraindications, and warnings are summarized in bullet points. Content undergoes a rigorous, standardized, peer-review process utilizing subject matter experts to ensure scientific accuracy. Documents are created according to a standardized template to provide consistent presentation.

Thomson Healthcare's medication information for patients is unbiased and non-promotional in tone and content. Information is presented in an explanatory fashion and does not promote a specific brand, manufacturer, or distributor.

Further, Thomson Healthcare meets the Action Plan guideline that prescription medication information is sufficiently specific and comprehensive to enable patients to correctly use their medications, receive maximum benefit, and avoid harm. Documents include information on administration, storage, missed doses, contraindications,

warnings, interactions, and adverse effects. Expanded, more comprehensive information on each of these sections is available in USP DI Advice for the Patient. Thomson Healthcare employs full-time patient education experts, and consults with outside experts as needed, to ensure that its medication information for patients meets the defined term of "useful."

Our clinicians and writers use various sources, including approved prescription drug labeling, USP DI® Drug Information for the Health Care Professional, the DrugDex® System, Thomson Healthcare's comprehensive evidence-based drug information database, and the PDR to create useful medication information for patients.

Although useful medication information is available in the private sector from companies like Thomson Healthcare, the second critical issue I am addressing today is the identification of the barriers to meeting the 2006 goal. There are three prominent barriers to ensuring that patients have the needed medication information. They are the difficulties the community faces in dissemination of useful medication information, the need for heightened recognition of the importance of such information, and the costs involved in meeting the 2006 goal.

Ensuring that ninety-five percent of individuals with new prescriptions will receive useful written information is a worthy, but very aggressive goal. Thomson Healthcare believes that to meet this goal, we should consider multiple means of reaching patients. The Internet has become an increasingly accepted method of disseminating information.

However, studies have shown that approximately 37% of households in the United States do not have Internet access (Knowledge Network/Statistical Research (Feb 2002). In addition, the GAO report to the Congressional Committees on Electronic Dissemination of Government Publications recognized that some individuals may have difficulty accessing and using electronic information. These individuals may lack computer skills or are unable to navigate the Web environment. Because of these limitations, additional delivery systems must be available to provide medication information to patients. These additional methods would include books, provided within pharmacies and public libraries, medication information available in physicians' offices, written information attached to prescriptions, and traditional means of disseminating information such as mail or faxing. All will be needed to meet the 2006 goal.

In addition to providing information through multiple delivery systems, healthcare providers interfacing with patients must recognize the importance of patient education materials, as defined in the Action Plan, and the need to provide such information as a routine practice.

Both of these issues point to the largest barrier to reaching the 2006 goal, and that is, who bears the cost of creating and disseminating useful medication information.

No simple solution exists to resolve these issues. Overcoming these barriers will be difficult, and therefore the third issue today is a discussion of the FDA's vital role in ensuring the 2006 goal is met.

While the FDA has provided criteria for useful information and the Keystone Committee has offered further guidance, difficult questions remain unanswered. Foremost, is the issue of off-label uses of drugs and the best means to inform patients about their prescribed drug for an off-label use. FDA guidance in this area may be needed.

The FDA also plays a vital role in raising the healthcare community and the public's awareness of the importance of understanding all aspects of their prescribed medications. The FDA should continue to provide assistance through encouraging research, defining best practices and standards, and supporting the work of thought-leading organizations that will serve to guide the direction of patient education.

Further, the FDA should continue to support initiatives that ensure patients receive the best available medication information. One example is the FDA's work with Pharmaceutical Research Manufacturers of America (PhRMA) and other manufacturers and pharmacy organizations on the Paperless Labeling Initiative. This initiative will ensure that every dispensing site in the United States and its territories will have access to the most current FDA approved prescribing information. The ultimate impact is that patients will benefit by receiving better information from their healthcare providers. This effort will also promote better healthcare and patient safety by reducing medication errors due to the use of outdated prescribing information. Thomson Healthcare has been a thoroughly committed contributor to establishing a nationwide paperless labeling system on behalf PhRMA and rest of the industry.

These difficult issues must be addressed before the 2006 goal can be met. The FDA needs to lead the discussion on these issues, and if resolution is not imminent, set the necessary standards to meet the stated goals. Thomson Healthcare would like to work with the FDA to develop any guidelines that the providers of medication information should follow.

In closing, Thomson Healthcare believes that the private sector, with support and guidance from the FDA, is capable of meeting the challenge of providing useful patient medication information. We remain a committed partner with the FDA in making this goal a reality for all Americans. Thank you.