Public Workshop: Ensuring Access to Effective Patient Medication
Information
Engelberg Center for Health Care Reform at Brookings

Thomas R. Bizzaro, R.Ph.
Vice President, Health Policy and Industry Relations
First DataBank
October 12, 2010

I would like to thank you for the opportunity to participate in this workshop. First DataBank has approximately 30 years experience in providing patient medication information (PMI) to consumers. It is our desire to support efforts to continually improve the PMI made available to the consumer. I have no doubt that each of us has as the ultimate goal, an improvement in the quality of care for the patient and to help achieve the best possible outcome. We want to provide to the patient the most accurate, timely information possible. This information must be easy to understand and should take advantage of multiple delivery mechanisms. There are a number of issues that must be considered and dealt with if we are to be successful.

Information must be provided in a timely manner. Drug information changes rapidly and often. It is imperative that any pertinent new information about a drug that may affect the welfare of the patient be incorporated into PMI as soon as possible. The timely distribution of this updated information is just as important as making the appropriate changes to the PMI. When considering the distribution network, we must examine the transfer of information each step of the way, from the author to the end user. We must assure that at no point on that path will a delay occur that could have been avoided.

The level at which information is attached to the drug can affect the efficiency with which the information can be authored, updated, and distributed. Attaching information at the packaged drug level, the NDC level, for a pharmaceutical entity would be burdensome. Using multiple authors for a single entity would be problematic. The PMI for any individual entity should be maintained at the least specific level possible. In most cases, this could be done at a level that takes into account the pharmaceutical entity and dosage form. This would provide a consistent message to any consumer taking that drug regardless of the manufacturer or whether it is a single-source or multiple-source product. Having multiple authors craft language for a single entity will undoubtedly provide an inconsistent message to the patient. This points to a need for a single author for PMI with a common repository of information that is readily available for distribution by various mechanisms. I believe that a public-private solution can achieve the desired results.

The current method of distribution by companies like First DataBank allows the information to be gathered and presented by the healthcare provider within the workflow, whether the PMI is provided at the pharmacy, by a physician, or by a nurse doing a hospital discharge. The opportunities for additional methods of distribution are only limited by the number of methods that are available for the distribution of electronic data. Currently, state and federal requirements

for the distribution of PMI do not take advantage of the current technology. Why can't we have consumers request that PMI be made available to them from a website, on their cell phone, e-mail account, or in a video that also provides interpretation of the information using sign language as well as demonstrating the use of a delivery device?

As a young pharmacist, I had a patient who was getting no relief from her rescue inhaler. I asked her to show me how she used the inhaler. She shook the inhaler, took a deep breath, exhaled, and then placed the inhaler beside her mouth and delivered the dose into the air. A nurse had demonstrated the inhaler to her in that manner. After I told this patient that the inhaler had to go into her mouth to deliver the dose it was, of course, much more effective. This is an extreme example, but it illustrates the difficulty in providing appropriate PMI.

Currently, the information contained in PMI is so burdened by concerns over avoiding liability that the most pertinent and beneficial information may be buried within the document. We must ensure that the document provides patients with information that helps them understand the benefits of the therapy and why it is important for them to adhere to the drug regimen. Providing information that provides only risk related information does not encourage compliance.

We must also provide information on the accepted off-label uses for the drug. Information on those acceptable uses must be included and should not be ignored simply because they are not included in the package labeling.

The thought that we could have multiple authors for PMI without approval of the content by the FDA or an oversight body is disturbing. To think that issues with a PMI document would have to be addressed by one of hundreds of authors or that PMI for the same drug could have conflicting data will not be acceptable. I would again suggest that some type of public-private entity could provide the solution. In some cases, we have dozens of manufacturers/distributors of a single pharmaceutical entity. To think that each of those entities could author, update, and distribute the appropriate information in a consistent manner is impractical at the least and impossible at the worst.

The information provided should adhere to a set of well thought out standards for the format and content as well as for the delivery of the materials. I have 20 years experience in retail pharmacy, and in my current role, I have heard many, many arguments about how long the current patient education monographs are. The monographs should only be as long as necessary to provide information that is of benefit to the patient. If they are too long, they will not be read; if they are two short, they may not contain all information needed. To set an arbitrary length for the document seems inappropriate. Providing the most important information at the beginning of a document or video seems to be only common sense. Let's do that and whatever else is proven to show that the consumer will use and understand the content of the PMI. We must make sure that PMI is designed to provide the maximum benefit to the patient and this will require testing the value derived from the PMI by the patient.

Thomas R. Bizzaro, R.Ph.
Vice President, Health Policy and Industry Relations
First DataBank
October 12, 2010

Finally, if the information is of great value and well-written and distributed in a timely manner, but not understood by the patient, it has the same value as the drug being prescribed and never dispensed or taken.

Thank you again for the opportunity to participate in this forum, and I look forward to additional discussion.