

My name is Nicholas Ratto. I hold a Doctor of Pharmacy degree (Pharm.D.) from the University of California at San Francisco Pharmacy School. I am the Manager of Consumer Drug Information at First DataBank, a private drug information company. Earlier in my career, I practiced in a number of healthcare settings, including acute and ambulatory care. My responsibilities included direct patient care in pharmacist-operated refill/triage, diabetes, and anticoagulation clinics during 11 years in the VA system, as well as direct participation on the medical and infectious disease teams. Consequently, I have personally counseled many hundreds of patients.

The written patient education survey utilized a scoring document which is valid, though we take issue with a few of criterion on each individual drug surveyed. We also suggest that in future surveys, selected authoritative secondary references such as the AHFS Drug Information (published by the American Society of Health-System Pharmacists--ASHP) be utilized in conjunction with the professional labeling. For example, we discovered a labeling reference to "reactions to allergy shots" for atenolol did not have any literature sources backing it up, after conducting a Medline search.

The conclusion is that we (all those involved in written patient education, including FDA/Medguides) have work to do regarding overall quality improvement. First DataBank has developed a clinically well-substantiated, field-tested, thorough Editorial Policy and Procedure for patient education. We are in the process of reviewing the 2000 monographs for full compliance with this Policy, given that the Policy has evolved over time and the volume of monographs is so large.

There are those inside and outside FDA that would tout FDA-approved Medguides as the best solution to this quality issue. However, even Medguides are not fully Action Plan compliant. For example, I performed a cursory review of the Ziagen (abacavir) Medguide, and found that while it contained a considerable amount of useful risk information, it lacked any advice to report any other medications being taken, did not give any advice regarding suspected overdoses, lacked storage information, provided no advice to keep the drug away from children and not share it with others, and only partially met the criteria for missed dose advice.

My point is not to criticize FDA or deflect the discussion away from First DataBank and other providers, but instead to demonstrate that no written document is ideal at this time.

Those that tout FDA-approved Medguides and the routine distribution of the professional FDA-approved labeling to patients are highly skewed toward the risks of drug therapy. Don't misunderstand me, provision of risk information is entirely appropriate and necessary. Distribution of the professional labeling to selected patients at the discretion of the pharmacist is appropriate. However, not

at the expense of medication quality of life/ benefit information. And I am not speaking about the "benefit" noted in the survey criterion, which deals with maximizing drug effectiveness, not quality of life. A majority of patients in my experience, and informally corroborated by conversations with colleagues including David Blair R.Ph. (a NCPIC Communicator of the Year honoree), do not have either the formal education or the medical knowledge to put risk information into proper perspective without direct assistance from a healthcare professional. For example, these patients, upon reading of the risk of death due to rhabdomyolysis from the cholesterol-lowering "statin" drugs, frequently will refuse to take the medication. This may result in a significant negative impact on quality of life. The patient may suffer a premature or preventable major cardiovascular event, such as a myocardial infarction. This insidious problem of noncompliance is frequently not adequately addressed, given the difficulty of characterizing or tracking it. Studies show medication compliance rates are already in the 50% range, an unacceptably low number.

The risk information needs to be communicated, but along with the "benefit" information. For example, in our monographs, we explicitly state that statins help prevent heart attacks and strokes. When we indicate the possibility of a fatal outcome for a drug, we note the incidence to put it into perspective (e.g., rare). This gives the patient a more balanced picture of risk and benefit. Non-clinicians or ex-clinicians tend to lose sight of these critical issues in their zeal to "fully inform" patients.

First DataBank's clinical pharmacist staff is solely interested in assisting our healthcare customers in improving patient care. Furthermore, we believe that no written document can ever fully substitute for a personal interaction with a professional. Every patient is unique, and each has their own knowledge base, misconceptions, biases, etc. The healthcare professional lends crucial perspective and individualized advice to the patient which cannot be capsulized in the leaflet. The written patient education material is an essential component of this process, but inherently never can stand alone if the goal is a fully educated patient. Efforts must be made to utilize the proven methods of freeing-up pharmacist time to counsel patients, such as automation aids, and use of certified pharmacy technicians.

In conclusion, I reiterate our proposal to FDA for ongoing, periodic dialogue and feedback related to our written patient education information. The purpose would be to address any quality issues. I suggest this would best be accomplished in cooperation with some of the clinician members of Dr. Svarstad's group, whereby constructive interchange would occur regarding content and format of monographs. Perhaps as appropriate, the Action Plan or Scoring Guideline/Evaluation sheet criteria may be revisited in the future. Other drug information providers and various stakeholders would be welcome as well.