FDA RISK COMMUNICATION MEETING Dec 7-8, 2005

ABSTRACT

Medwatch safety updates are useful sources for database providers to capture safety-related labeling changes. However, FDA does not review the entire label, and hence all relevant safety data is not necessarily identified (example given).
Patient Information Sheets (PIS) present "emerging safety information", which is useful information provided it is not premature and/or incorrect. Agency decisions regarding if/when/how to release preliminary information should be driven strictly by science. Consumers may incorrectly assume the PIS is a complete patient education document because 1) FDA patient education materials are posted on different pages/sites, and 2) consumers may expect that FDA patient education materials are all Keystone Guideline-compliant.
FDA risk communication strategies result in exclusion of relevant drug benefit/QOL information. In order for consumers to participate fully in decisions regarding their healthcare, they must be presented with an accurate representation of medication risks and benefits in the context of the available drug or non-drug treatment options.

BRIEF CV summary

Dr. Ratto earned his Doctor of Pharmacy degree at the University of California San Francisco in 1984. He completed a one-year postgraduate clinical pharmacy residency at the VA Medical Center, San Francisco CA. He served as Pharmacy Supervisor/Clinical Pharmacist at the VA Oakland Clinic, then Assistant Director of Pharmacy/Residency Director for the VA Northern California Health Care System. He has held clinical faculty appointments at UOP and UCSF Schools of Pharmacy. Dr Ratto joined First DataBank, Inc in August 1996. He currently is the Manager of the Consumer Drug Information Group.