

Presentation of the Pharmaceutical Research and
Manufacturers of America at FDA Part 15 Hearing on
Communication of Drug Safety Information

December 8, 2005

Alan Goldhammer, PhD

Pharmaceutical Research & Manufacturers of America

agoldhammer@phrma.org

WHAT THE PHARMACEUTICAL RESEARCH ENTERPRISE PROVIDES

- New therapeutics that provide positive patient health outcomes when used according to the drug label
- Goal of any therapeutic intervention is to maximize the treatment benefit while minimizing the risk to the patient
- Overwhelming majority of medicines are administered safely to tens of millions of patients each day and exhibit a favorable benefit/risk profile in accordance with the treating health care provider's expectations

BENEFIT & RISK ARE DIRECTLY LINKED

- FDA approves drugs based on an assessment of the benefit and risk
- Drug safety information cannot be communicated in the absence of benefit
- The definition of risk must extend to a patient who does not take the appropriate drug therapy or discontinues it

PhRMA's COMMITMENT TO BENEFIT/RISK COMMUNICATION

- National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP)
- National Council on Patient Information and Education (NCPIE)
- National Patient Safety Foundation (NPSF)
- SOS-Rx
- CERTs (Centers for Education and Research on Therapeutics)/FDA/PhRMA Workshop Series
- PhRMA Paperless Labeling Project

PRINCIPAL SOURCE OF INFORMATION IS THE DRUG LABEL

- FDA-approved synthesis of the critical prescribing information

BUT -

- No clinical program can be large enough or lengthy enough to understand all risks

AND

- new information on both benefit and risk will be acquired during the post market period

COMMUNICATION OF NEW SAFETY INFORMATION

1. Drug Label Outlining Current Safety Information →
2. Receipt of a Newly Generated Signal not in the Label →
3. Identification of the Signal as Relating to the Use of the Drug →
4. Verification/Validation of the Signal Attributable to the Drug →
5. Communication of the Signal to Healthcare Providers and Others

HOW TO COMMUNICATE SAFETY

- Drug Label (Package Insert)
- Patient Package Insert
- Medication Guide
- Consumer Medical Information
- DTC (Print, Broadcast, Internet)
- Other Sources (FDA & other third-party Internet sites)

FDA QUESTION #1

What are the strengths and weaknesses of the communication tools listed previously in this section of the document?

PhRMA RESPONSE

- Lack of Access to the Tools
- Confusing Messages
- Uncertain Utility

FDA QUESTION #2

What information is available about awareness, use, and perceptions of effectiveness of these communication tools by health care professionals and by the public in general?

PhRMA RESPONSE

PhRMA is unaware of any comprehensive studies that have been done regarding these Internet sites. An assessment of these sites will necessarily be complicated by the difference in content and prospective audience. For example, CDER Educational Campaigns are focused on classes of drugs and may cover dramatically different types of issues from sites that deal with a specific drug. The healthcare practitioner has different needs than that of the patient.

FDA QUESTION #3

Do these tools provide the right kind and amount of risk and other information that health care professionals need to make informed decisions about whether to prescribe drug products, and that the public needs to make informed decisions about whether to use those products?

PhRMA RESPONSE

- Tools focus on risk communication in the absence of benefit
- Tools principally discuss risk issues on a population basis and may be inappropriate for patient-specific prescribing decisions
- Tools are not validated

FDA QUESTION #4

*How easily accessible and understandable are
FDA's Internet-based sources of drug information?*

PhRMA RESPONSE

- Information not Presented in a Coherent Manner (spread out over numerous webpages without a common link)
- Inconsistent Presentation (lack of drug label)
- Too many sites that imply patient/prescriber information is located there

FDA QUESTION #5

To what extent do CDER's patient-focused communication tools provide useful information for people with low health literacy skills?

PhRMA RESPONSE

- Tools assume Internet access and familiarity
- Unclear whether Tools have been appropriately tested for such individuals
- Isn't this the purpose of the Consumer Medicine Information (CMI) initiative?

FDA QUESTION #6

What mechanisms should CDER consider to convey risk information to special populations (e.g., elderly, non-English speaking)?

PhRMA RESPONSE

- Over 170 languages are spoken in the United States
- Is the generation of multi-lingual websites a good use of FDA resources?
- For the elderly poly-pharmacy is a real concern
 - drug-drug interactions (need for personal medication record)
 - over/under dosing because of confusion

PhRMA RECOMMENDATIONS

- PhRMA supports FDA's efforts in communicating benefit/risk
- Evaluation of Internet-based tools must be carried out:
 - Ease of use
 - Impact
 - Comprehension
- FDA should develop a single portal (entry point)
 - Perhaps DailyMed???

PhRMA RECOMMENDATIONS (continued)

- Communicating benefit/risk is not just a job for the FDA; it is a job for all stakeholders
- PhRMA has proposed to the CERTs a workshop on patient focused benefit/risk communication where these and other ideas can be discussed. This should be viewed as an important first step and not a final resolution of the issue as there is much that all stakeholders can do.

ONE SMALL (or VERY BIG) STEP

Let's all work to insure that every patient has realistic expectations about the medicine they are prescribed.