

# **Use of Medication Guides to Distribute Drug Risk Information to Patients**

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# Disclosures

- No current industry affiliation
- No industry sponsorship
- Primary care physician
- 20+ years pharmaceutical industry experience
  - Clinical drug safety
  - Product labeling
  - Clinical trial design and conduct

# Medication Guides

- Intended to provide information that FDA has determined is necessary to patients' safe and effective use of drug products that pose a serious and significant public health concern
- Medication guides inform patients about known risk and are intended to make patients aware of information concerning the risk(s) that could affect the patients' decision to use or continue to use a product

# Implementation of the Medication Guide Program

- Inquiry at local pharmacies suggests that implementation of the Program has been inconsistent
  - Knowledge of the program
  - Availability of the Guides
  - Distribution of the Guides
  - Content of Medication Guides

# The Best Way to be Informed

- There is probably no one best way to inform consumers about serious medication risk
  - Consumers are heterogeneous and they access and comprehend risk information in varying ways
  - It is essential to have information standards but the delivery of that “authentic” information must be adapted, through multiple vehicles, to the diverse population it serves
  - Multiple information “documents” describing prescription drug risk from a range of sources should be available to address patients’ and healthcare professionals’ disparate needs

# The Best Time to Provide Medication Risk Information

- The need for current medication risk information begins before a treatment decision is made and continues after the medication has been discontinued
  - Exposure risk information is a decision-making tool i.e. known potential risks, should be available prior to the initial treatment decision and whenever the patient is able to comprehend it
  - Emergent risk information i.e. newly recognized adverse effects or product recalls/withdrawals, should guide patients in their decisions to discontinue treatment and/or seek medical assistance

# Good Information Practices

- The precise nature, content and distribution channels for risk identification documents should be the subject of additional systematic research involving all stakeholders
- Information should be product specific
- Information should be understandable i.e. include aids like a Glossary of Terms with simple definitions
- An FDA-approved information “source document” should provide comprehensive information
- Derivative documents/sources should conform with the intent of the source document
- Sources that comply with the spirit and content of the FDA’s source should be identified (logo) as ‘reliable’

# Good Information Distribution Practices

- Provide multiple sources of information targeted at differing levels of education and understanding
- Educate consumers and healthcare providers about the the need to be informed and consider risk when making treatment decisions
- Publicize the availability and sources of “FDA-approved” risk information
- Provide assurance that information complies with FDA standards (logo)
- Maintain an oversight program with regulatory powers to assure distribution of reliable risk information from key sources like pharmacies



# Promoting Good Decision-Making

- Guide the general public in their decisions about prescription medication use through education
  - Start the process in primary school
  - Teach the fundamentals of drug development
    - What is drug safety?
    - What is the risk when taking a prescription medication?
    - How are decisions involving risk made?
  - Get other governmental and educational agencies involved

# A Gap

- There appears to be a gap in communication when emergent risks associated with prescription medications are discovered and there is need for prompt dissemination of reliable information
  - Product recalls/withdrawals
  - Newly identified safety risks
- Modern communication techniques now make prompt notification possible
  - E-mail/cell phones
  - Text messaging/IM
  - Automated phone dialing
- It is time to consider expanding distribution of risk information to include emergent risks