Use of Medication Guides to Distribute Drug Risk Information to Patients

Gerald K. McEvoy, Pharm.D.

Assistant Vice President, Drug Information

Editor in Chief, AHFS Drug Information

American Society of Health-System Pharmacists

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ASHP

- **30,000 member professional and scientific society**
- **Pharmacists helping people make the best use of medicines**
- **Core focus on promoting safe medication use through:**
  - **federally recognized evidence-based drug information publishing**
  - **mission and vision**
  - **policy positions**
  - **guidance documents for best practices**
  - **high-level participation in key national safety and quality initiatives**

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- 25 yrs of publishing consumer medication information (CMI)
- ASHP CMI is widely accessed via
  - National Library of Medicine's MedlinePlus consumer website
  - Consumer Reports Medical Guide website & Consumer Drug Reference
  - ASHP's safemedication.com website
- MedGuide safety information integrated into ASHP CMI
- Hyper-links to full MedGuides embedded in ASHP's electronic CMI; URL's and patient access instructions included in printed versions
- XML data structure can permit automatic generation of MedGuides with CMI without workflow disruption

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Issues with MedGuides

- **FDA's reliance on outmoded preprinted leaflets & cumbersome distribution mechanisms**

- **FDA's unwillingness to permit use of well-established electronic means for generation**

- **Resultant low levels of distribution**

- **Gross underestimates of burden relative to original (1998) estimates**

- **Consumer confusion from wide array of documents (CMI, MedGuides, PPIs PISs)**

- **Lack of research concerning the role, scope, and effects on patient understanding and behavior**

Problems - Distribution

- **MedGuides provided exclusively through PhRMA-supplied print (e.g., tear-pads)**
  - **Preprinted paper distribution is outmoded**
  - **Adequate supplies cannot be assured**
  - **Physical storage & retrieval of growing number of MedGuides**
  - **Impacts negatively on pharmacy workflow since outside the usual electronic prescription processes**

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Problems – Distribution (cont'd)

- **Low pharmacy compliance levels**
  - **2005 FDA National Assessment**
    - 5000 R.Ph.s surveyed (≈ 50% response rate)
    - Only **70% familiar** with **term MedGuide**
    - Only **30% of those** (20% total) **knew** MedGuides were **required** for *all* new and refill **Rxs**
    - Only **30% thought** that MedGuides were very **effective in communicating risks**
    - Only **35% knew** that FDA-approved **PPIs were always optional**

      Nourjah P, Lee L, Kortepeter C, Avigan M, FDA Office of Drug Safety. National Survey of Pharmacists to Assess Awareness of Drug Risk Communication Tools; 2005.

Gross Underestimates of Impact (1998 Regs)

- **1998: MedGuides issued with 1 million Rxs/yr**
  - 2006 estimate that required for 7% of Rxs, i.e., 280 million Rxs annually (NACDS Aug 28)
- **1998: Will take R.Ph. 5 sec to provide MedGuide to patient**
  - 2007: Substantial disruption of usual electronic workflow from mandated preprinted leaflets
  - Great inefficiencies and associated cost burden, especially in highly automated environments (e.g., VA mail-order pharmacies)
- **1998: PhRMAs must ensure adequate supplies**
  - FDA has failed to enforce
  - Undependable supplies and disarray in means to obtain
  - Great burden in dealing with multiple suppliers rather than single electronic source for generating print

Gross Underestimates of Impact (1998 Regs)

- **1998: ≤ 5–10 products per yr**
  - 33 products (Rx entities) per yr 2005–2006
  - 2007: Almost 10,000 NDCs affected (FDB 2007 May 4)
- **1998: 2-page limit as goal**
  - 2007: Average ≈ 8 pages long (range: 2–31 pages)
- **1998: Most will be required with initial FDA-approval of NDA; "rarely post-approval"**
  - 2007: Greatest impact from existing classes (e.g., antidepressants, NSAIDs, ADHD), i.e., post-approval
- **1998: Manufacturers would use 3rd-party info providers to ensure distribution via computerized systems**
  - 2007: Outmoded preprinted leaflet distribution
  - FDA inflexibility in accepting realistic alternatives that would foster greatly enhanced distribution to patients

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Problems – Pharmacies

- **Cost shift to pharmacies**
  - **Inefficient**
  - **Insufficient supplies to pharmacies**
    - pharmacies forced to incur costs associated with printing from FDA Web site and distributing to patient
  - **Additional cost shift with preferred electronic generation**

Problems - Content

- **Balanced description of both benefits and risks**
    - **Focus on risks of drug, usually a single risk**
    - **Little if any balance regarding benefits of treatment**
        - **Antidepressants and risk vs benefit on suicidality**
        - **Cardiovascular risk of NSAIDs vs benefit of aspirin**
        - **Amiodarone warning against use outside labeling vs standard of care recs in ACLS (AHA CPR guidelines)**
    - **Unintended consequences**
        - **E.g., is there a relationship between decreased antidepressant use after black box warning and increased suicide rates in adolescents?**

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Problems – Content (cont'd)

- **Highly variable content despite general requirements**
  - Regulatory exemption permits omission of all but 2 content items:
    - 208.20(a)(2): must be "scientifically accurate" (i.e., does not conflict with professional labeling)
    - 208.20(a)(6): must include prominently the title "Medication Guide" and that MedGuide was "approved by US FDA"
  - Will contain information that is "necessary for safe and effective use"
    - Too narrowly focused to cover what is "necessary"
  - FDA also can exempt format
    - E.g., MedGuides appended to professional labeling need not meet font requirements

Problems - Consumer

- **Issues for the consumer**
  - **MedGuides are too long**
    - **FDA 1998: "Lengthy information could result in unnecessary or even dangerous barriers to the effective communication of important concepts." Goal: 2-page limit**
  - **Emphasis is on risk; little if any balance for benefit**
  - **Consumer confusion, CMI vs. MedGuide vs. PIS vs. PPI**
  - **The "usefulness" of the information (e.g., per Keystone guidelines) and affect on patient behavior/outcomes have not been adequately tested**

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Recommend – Revisit Regulations

- **If current MedGuide regulations would not permit needed improvements, then revise them to address existing problems with effective dissemination and use by consumers**
  - **Encourage FDA to conduct stakeholder forums**
  - **Recommend FDA allow the format of MedGuides to be changed so PDF format would no longer be necessary, allowing pharmacies and consumers to access and print MedGuides electronically if PDF technology is not available**
  - **Allow flexibility in formatting so pharmacies can integrate printing of MedGuides into their current systems, and append to CMI**
  - **Address cost shifts from manufacturers to pharmacies that print MedGuides from pharmacy computer systems**

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Recommend – Electronic Distribution

- **Recommend support of innovative solutions focusing on electronic rather than print distribution**
  - Allow integration with existing pharmacy information systems
  - Allow pharmacies to e-mail MedGuides to certain patients as an alternative
  - Permit merging of MedGuide and private-sector CMI so less consumer confusion and better integration into pharmacy workflow

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Recommend - Content

- **Recommend FDA carefully evaluate content**
  - **Review current content exemptions relative to providing "necessary information for safe and effective use"**
    - **Review current disparities**
    - **Hold adequate stakeholder forums**

Recommend - Research

- **Recommend adequate, well-designed research to assess usefulness and effectiveness of MedGuides**
  - **Evaluate alone**
  - **Evaluate in context of other patient drug information (e.g. CMI)**
  - **Scientifically determine whether verbatim appendage of MedGuides to CMI greatly enhances effectiveness in communicating risk compared with contextual content integration into private-sector CMI**

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Recommend – Risk vs. Benefit

- **Recommend careful assessment of risk vs. benefit balance of existing MedGuides**
  - **Establish (e.g., through expert review) whether balance is provided regarding potential benefits of therapy in existing CMI**
  - **Change FDA policy as appropriate to correct current imbalance and ensure future balance**
  - **Encourage appropriate inclusion of description of treatment benefits as currently permitted in the regulations**

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Recommend – Page Length

- **Recommend careful assessment of failure to meet page length goals and effects on patients**

Recommend – Assessment

- **Recommend careful assessment of advantages and disadvantages of MedGuides**

Recommend – Assess Consistency

- **FDA requirement in Final Rule: "The Medication Guide shall be scientifically accurate and shall be based on, and shall <u>not conflict with</u>, the approved professional labeling for the drug product…"**

- **Requirement not always followed**
  - **Example: Inconsistency in risk emphasis in MedGuide vs. professional labeling for Ritalin**

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Recommend – Reassess Burden

- **Recommend recalculating burden on pharmacists**
  - **Original assumptions were incorrect**
    - **R.Ph. time**
    - **Number of drugs and prescriptions affected by MedGuides**
    - **Paper and other cost considerations**
    - **Cost shifts from manufacturers to pharmacies**

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Recommend - Refills

- **Recommend reassessment of need to provide with every refill**

Recommend – Web Access

- **Recommend clear, up-to-date posting of all MedGuides on MedlinePlus and DailyMed for easy web access**

- **Ensure timely web posting of current versions and use of a stable identifier (URL) that does not change over time for current version**
  - **Older versions should adopt a new identifier for archival purposes**
  - **Develop electronic systems that will ensure that the current version is always retrieved when a stable URL is embedded into related documents (e.g., CMI)**
  - **Develop easy, timely, and dependable notification/distribution mechanisms for stakeholders to obtain revised documents**

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