Docket # 03N-0168

FDA

FDA and Consumer Medication Information (CMI)

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August 24, 1995

- FDA publishes Medication Guide Proposed Rule for drugs with serious and significant side effects
- Proposal sets distribution targets of 75% and 95% by 2000 and 2006 for private sector
- FDA proposes broad criteria to judge written information as being useful

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1996 Events

- February 14 and 15 - FDA convenes workshop on the medication guide proposal, specifically related to defining useful information
- August 29 - Congress passed and President signed Public Law 104-180

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Public Law 104-180

- Directs Secretary of HHS to facilitate development of a long-range action plan that meets stated goals through private sector efforts
- Gives private sector opportunity to meet distribution and quality standards of plan
- Codifies FDA's distribution and quality goals of 75% by 2000 and 95% by 2006

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Keystone Center

- Secretary immediately contracts with the Keystone Center
  - non-profit consensus-building alternate dispute resolution organization
- There were 120 days under the statute to facilitate development of an action plan by interested stakeholders
- Keystone selected 34 private sector organizations to develop the Action Plan

Action Plan

- Collaboratively developed plan accepted by the Secretary in January 1997
- Criteria to determine usefulness
  - endorsed broad criteria in the public law
  - described specific criteria to be met
- Consistent with the public law, the plan called for periodic assessment of the quality of written information

Criteria for Useful Medication Information

1. Drug Names, indications for use
2. Contraindications, what to do
3. How to use, monitor, and get most benefit for drug
4. Precautions, how to avoid harm

Criteria for Useful Medication Information

5. Serious or frequent adverse reactions, what to do
6. General information, encouragement to ask questions
7. Scientifically accurate, not promotional, and up-to-date
8. Comprehensible (6-8th grade), legible

1998 - FDA Publishes Final Medication Guide Rule

- December 1 - Final Rule is published
- Rule estimates 5-10 products per year could have a Medication Guide
- Medication Guide reserved for drugs with serious and significant side effects
- To date, FDA has required 15 Medication Guides for prescription drug and biologics

June 2000 FDA Begins Plan for First Assessment

- FDA renews contract with NABP and University of Wisconsin School of Pharmacy for evaluation phase
- 384 pharmacies randomly selected from virtually every state
- Professional shopping service selected to buy four prescription drugs and collect data

2001 National Evaluation

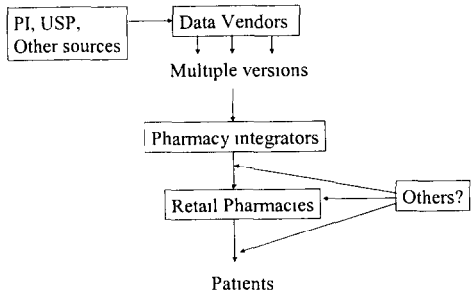
- Same evaluation methods as 1999 pilot study
- NABP and subcontractor sampled > 1300 CMI brochures
- Brochures evaluated by expert panel
  - Pharmacy
  - Medical Information
  - Drug Information

2001 National Evaluation

Endpoints:

- Distribution
- Usefulness of each material via eight criteria

Consumer Information Flow



FDA's Approach Post-AC

- AC asks FDA to take a more active role
- FDA defers decision on regulatory action
  - voluntary process can work if action begins now

Areas That Need Consensus/Action (I)

- Implementation
- Education
- Evaluation

Areas That Need Consensus/Action (II)

- Implementation
  - major quality improvements needed
  - identify procedures that will allow clear understanding of what is required
- Education
  - lack of awareness of Keystone criteria and legislative requirement for CMI

    educate "information developers," software vendors, prof'l associations, pharmacies, etc

Areas That Need Consensus/Action (III)

- Evaluation: clarification of how the Keystone criteria will be applied to specific drug products in the future

FDA Commissioner McClellan

- Very supportive of this effort
- Speech to National Consumer League February 28, 2003
  - communicating risk information about Rx medicines is one of his highest priorities

Next Steps

- Current need: plans for action to meet 2006 target
- Plans should include:
  - roles and responsibilities clearly articulated for all groups
  - identified barriers and what will be done to overcome them

Questions for Today's Meeting

- 1: What steps is the private sector taking to improve the usefulness of the written information patients receive with prescription drugs and to meet the Year 2006 goal?

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Questions for Today's Meeting

- 2: What barriers exist for the private sector to meet the Year 2006 goal, and what plans exist to overcome these barriers?
- 3: What should the role of FDA be in assuring full implementation of the Action Plan to meet the Year 2006 goal?

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Questions for Today's Meeting

- 4: What other initiatives should FDA consider for providing patients with useful written information about prescription drugs as endorsed by P.L. 104-180?