


NCPiE Consumer Medicine Information Initiative: The Road Ahead and Conclusion


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- Goals
- Letter of the Law
 - Fulfill promise of the Keystone process
- Spirit of the Law
 - Provide useful information for low literate patients




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Question 1

- What is the private sector doing to improve the usefulness of written information regarding prescription medicines?
 - Much has already been done
 - We propose a three-function process represented by the three Committees

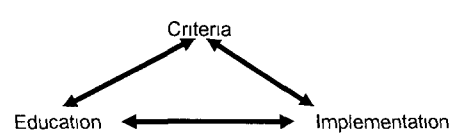



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Process

- Each Committee provides essential processes, each must coordinate with the others

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Question 2

- What barriers exist, how can they be overcome?
- 95% success rate is a very high standard
- Logistics/resources in small pharmacies
 - Lack of technological support
- How to apply Keystone criteria for certain medicines?
- Additional evolving barriers



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Question 3

- What role should FDA have?
- Primary
 - Oversight and evaluation to determine if Keystone goals are met
- Additional
 - Work with private sector to aid process
 - Criteria – how will FDA interpret/apply Keystone criteria
 - Education – share views of success and ramifications of not meeting goals
 - Implementation - how will FDA evaluate success?



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Question 4

- What other FDA initiatives are needed?
 - Usefulness of information for Low Literacy patients
 - Additional interventions are needed
 - Research program to learn how to influence behavior
 - Regulatory Role
 - Medication Guides
 - Coordinate with risk management initiatives



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