




NCPIE Consumer Medicine Information Initiative: Criteria Committee

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Presented on behalf of NCPIE
by David Blair, R.Ph.
Medical Care & Outcomes, Inc.




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Criteria Committee Members

- American Society of Health-System Pharmacists
- Catalina Marketing
- Cerner Multum
- First DataBank
- Medical Care & Outcomes
- National Community Pharmacists Assn.
- National Consumers League
- WoltersKluwer Health Clinical Tools Div.




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Criteria Committee

Unless Consumer Medicine Information helps patients use medicine safely and effectively, the information is of little value. This committee's role is to ensure that patients receive truly "useful" CMI.




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Criteria Cmte. Role & Mission

- Provide advice on what's considered "useful" based on Keystone criteria
- Translate Keystone criteria into concrete requirements:
 - (1) Develop/apply principles to help apply criteria to specific medicines;
 - (2) Develop therapeutic-class prototypes



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Challenge: “Clash of Criteria”

- Fully comprehensive CMI may not be easily understood by patients
- Rely on consumer research to assess variety of CMI formats’ effect on consumer understanding, appropriate utilization of medicines, etc.



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Practical Issues to Overcome

- Professional sources of information (beyond package insert) to determine scientific accuracy
- Legibility (font size) vs. pharmacy system integrators’ “single pass” technology



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Development of Scoring Method

- Criteria Cmte. will address what constitutes a “passing grade” for individual criteria, and/or collectively for all criteria?
- Use objective consumer research to better understand how CMI criteria influence “usefulness”



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Criteria Committee Process

- **Balanced makeup**
- **Study translational principles – applied to all medicines**



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Criteria Cmte. & FDA Input

- Whatever criteria applications are developed must be acceptable to FDA
- FDA input into design and acceptability of criteria will be invited
- FDA advice on specific info to include in CMI leaflet, and on information sources to develop clinically-accurate information, will also be sought



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