

**Consumer Comprehension & Outcomes Research
Risk Communication Advisory Committee
5.1.09**

**Julie L. Aker
President & CEO
Concentrics Research**

Highlights: Concentrics Research

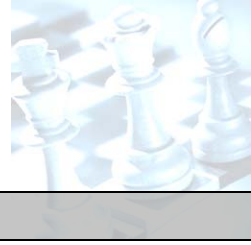
- Privately held research company specializing in consumer and patient focused research; Nearly 25 years old (1985)
- OTC and Rx drugs and devices
- Consult on labeling and program development
- Design and conduct consumer, patient and HCP research
- Conducted nearly 700 studies
- 76% of past successful Rx-to-OTC Switches
- Well known for comprehension research with labeling for consumers/patients/HCPs (>120 studies)
- Very active in industry and FDA-sponsored initiatives
- Currently involved in key projects with CDC, FDA, HHS, NIH

REMS



- 6 programs that we are working on or discussing with clients
- Focus my discussion today, on programs necessitating labeling or communications, in particular.
- Challenges
 - REMS expectations are variable
 - Little or no comprehension testing in programs involving changes to labeling/medication guides/communications
 - Recruitment and study population expectations may not result in the best overall insights and efficiency.
 - Same expectations applied for recruitment of new drugs (smaller available populations) and established drugs (larger available populations).
 - Labeling assessments of medication guides are largely based on subject recall vs. comprehension.

REMS Expectations



- Develop materials based on consumer and HCP input.

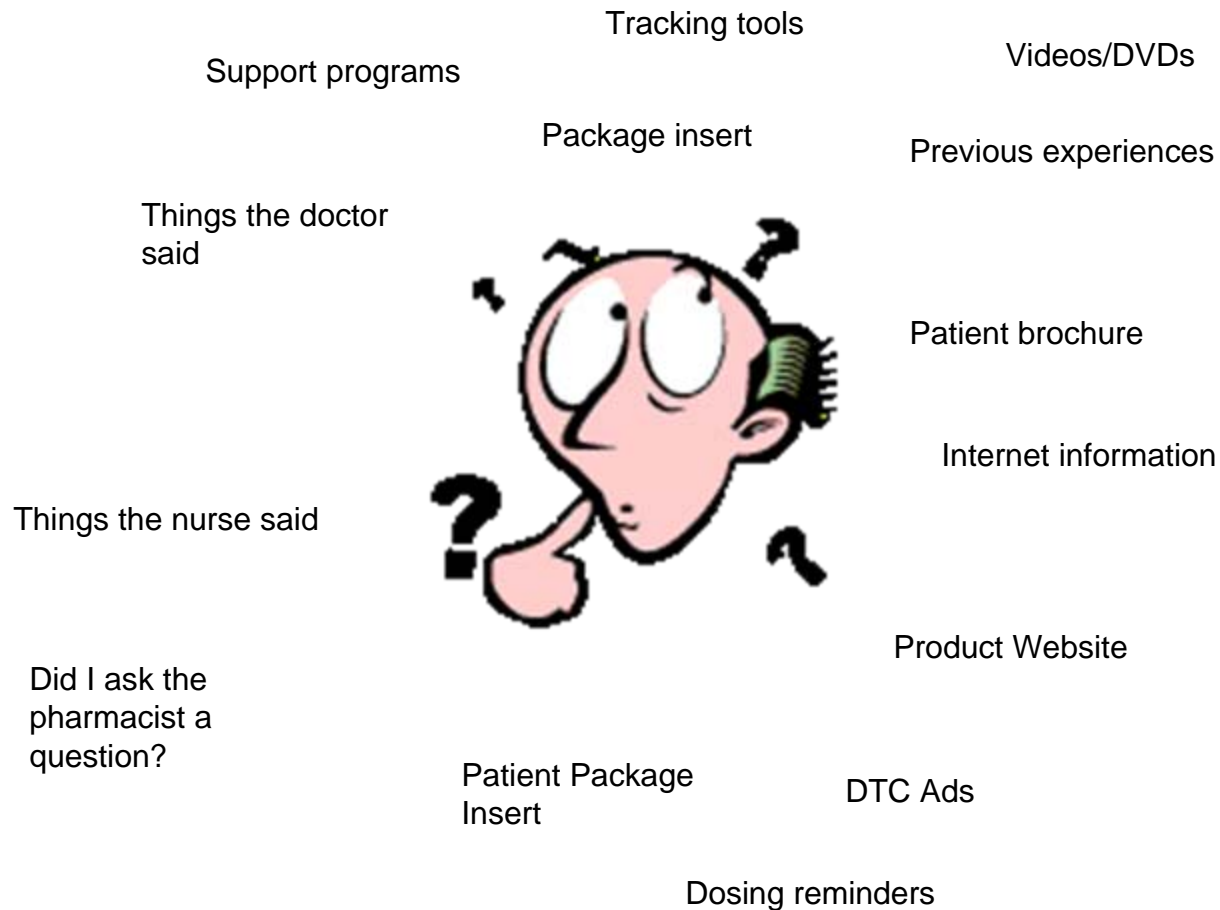
- Test and iteratively improve

- Assure access to clear information

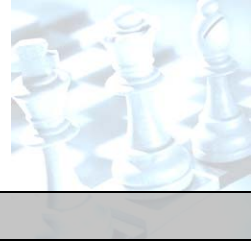
- Create awareness
- Cause behavior to change such that the desired outcome(s) occur.

- Consumer safety
- Adherence to warnings and instructions

Keeping it Simple & Targeted



Who should be tested?



- Consumers
 - Broad and diverse population
 - Sufferers: Taking the medication (today's consumers)
 - Sufferers: Not currently taking the medication (tomorrow's consumers)
 - Those of normal and low literacy (REALM)
 - Not previously involved in research in past 3 months
 - Not currently working for a healthcare, marketing or regulatory organization
- HCPs
 - Those who order the medications
 - Doctors (primary care + specialists as applicable), NPs, PAs
 - Those who educate/support consumers
 - Doctors, NPs, PAs, RNs, Pharmacists

What do consumers tell us?



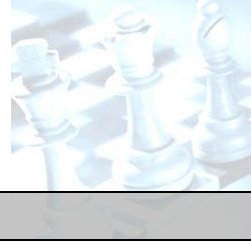
- “My doctor will tell me anything I need to know.”
- “The pharmacist will tell me what I need to know.”
- “Important warnings are on the medication package/bottle.”
- “I throw away all the information with my prescription.”
 - “There is too much paper.”
 - “It is all too repetitive, not sure what is REALLY important.”
 - “It is not for me—it is written by lawyers.”
 - “It’s too complicated.”
 - “It’s not for the patient—it’s for doctors.”
- “I use my own judgment.”
- “What’s a medication guide?”
- “What’s consumer information?”
 - “Where is it?”

What have consumers taught us?



- Tune in when:
 - They are in a caregiver role
 - A doctor or nurse emphasizes or educates them
 - Women > men
 - New product > existing
- They are overwhelmed with information
 - They can't absorb everything—too much
 - They can't discern what's important from what's not
 - Normal and low literacy consumers don't always do well on the same messages.

What HCPs tell us:



- In terms of training/counseling:
 - “I don’t have time.”
 - “I refer the patient to the labeling.”
 - “The patient can call with questions or ask the pharmacist.”
 - “Every product is different; don’t have time for every variation.”

5 Core REMS Questions



- Do all stakeholders clearly know their role and how to perform it?
 - What do we expect?
- Are we asking the right research questions?
 - “Evaluate patient understanding, not comprehension.”
 - “Evaluate usefulness of medication guide.”
 - Comprehension?
 - Dissemination?
 - Usefulness as a tool?
 - Usefulness in driving good outcomes?
- Are we going to the source (consumers and HCPs that will be involved) too late?
- Are we keeping it simple and targeted?
- Are we involving the right experts at the right time?

Comprehension guidance exists

- CDER
 - Office of Non-Prescription Products (ONP)
 - Nearly 20 years of experience in consumer research
 - Drugs are much more complex in directions and warnings
 - New Guidance out TODAY!
 - <http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm>
 - DRAFT has 90 day review period

Goals of Consumer Research



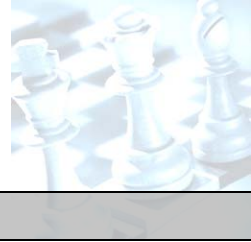
- **Label Comprehension (Focus=label)**
 - Exterior label, PI, PPI, Brochure, Med Guide, Tools
- **Warnings/Dosing (Focus=decisions/judgment)**
 - Who the product is for, Who the product is NOT for, What to do, What NOT to do, when to get medical assistance
- **In-Use (Focus=real-world behavior and outcomes)**
 - Safety: Through compliance with label
 - Undesired events are minimized
 - Outcomes: Obtain a health benefit that exceeds the risk
 - Desired outcomes are maximized

Consumer Studies are Rigorous



Study Procedures	Clinical Trial	Label Comp	Outcomes/In-Use
Protocol	Yes	Yes	Yes
IRB	Yes	N/A	Yes
Select Sites	Yes	Yes	Yes
Screen subjects	Yes	Yes	Yes
Informed Consent	Yes	Confidentiality/HIPAA	Yes
Medical History or procedures	Yes	No	Minimal
Enroll subjects	Yes	Sufferers using/not using the medication	Sufferers using/not using the medication
Use drug/device at home	Yes	No	Yes
Monitor safety and outcomes	Yes	1-day interview	Yes
Gain Information about labeling & Use	Partial	Yes	Yes
Collect data and analyze data	Yes	Yes	Yes
Improve labeling & processes	Yes	Yes	Yes
Send data/report to FDA	Phase IV: Yes	Yes	Yes

Comprehension Methods



- Proven methods
- 1:1 interviews
- Diverse population
 - Consumers
 - Sufferers and taking the medication
 - Sufferers and not currently taking the medication
 - Low literacy
 - HCPs
 - Diagnosing and writing Rx:
 - Physicians: Primary care, specialists, NPs, PAs
 - Training/Teaching/Counseling:
 - MDs, RNs, NPs, PAs
 - Pharmacists
- Scenario-based: comprehension and judgment (sometimes simulations, especially with HCPs)
- Open-ended
 - Probes: reason for answers
 - Verbatims responses coded
- NOT a recall test

Final Thoughts



- Communications and especially warnings must be tested in advance.
 - Tested iteratively and improved
 - Tested with consumers of normal and low literacy
 - Tested in populations that:
 - Take the drug
 - Do not take the drug
- Use well established comprehension methods used for OTC drugs.
- Partner with companies that are experienced in consumer/patient and HCP research and have access to large and diverse populations.
- Keep it simple
 - Industry-driven initiatives
 - Drive consistency in core tools, methods and approaches (familiar constructs are helpful)
 - Product-specific initiatives
 - Customize to meet the product needs, but within a consistent process
- Listen to consumers
 - From the theoretical to reality
 - Consumers and HCPs will lead the way, if we listen...
- All things are possible when you bring the right group of people together.



Concentrics Research
www.concentricsresearch.com
1.800.800.5525