



# Development and Testing of Health Literate Patient Labeling

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# Objective

- Purpose
  - Maximize comprehension of patient labeling for all audiences, including those with limited health literacy
- New process developed by an innovative industry-academia partnership
  - Merck:
    - Legal, Health Literacy, Regulatory Policy, Marketing, Marketing Research, Chief Medical Officer
  - Academia: National health literacy experts and teams
    - Dr. Ruth Parker (Emory)
    - Dr. Michael Wolf (Northwestern)

# Merck's Past Approach to Testing

- Historically, Merck has done comprehension testing of patient labeling
- Merck's past approach included conducting research across a broad range of education levels; however, few respondents presented with limited health literacy
  - Harder to locate and less likely to participate
  - Directionally, limited health literacy respondents had lower comprehension scores than those with adequate health literacy

# Updated Approach to Testing

- Elimination of requirement for desktop computer
- Recruitment at literacy centers, senior centers
- Inclusion of health literacy assessment
  - One question phone screener (*How confident are you filling out medical forms by yourself?*)
  - Newest Vital Sign assessment done at the end of the interview
  - Schlesinger database began to add health literacy assessment
- In-person research to increase likelihood of participation by respondents with limited health literacy
  - Moderators who are knowledgeable of and sensitive to health literacy
- Combination of open and closed book assessment
- Aim for 25% of respondents with limited health literacy

# Process Overview: Patient Labeling Development and Testing

## Health Literacy Review

- ❖ Merck creates draft of patient labeling
- ❖ Northwestern/Emory apply best practices
- ❖ Merck reviews, with few changes

## Focus Groups

- ❖ Focus groups in Chicago and Atlanta
- ❖ Patient labeling revised and sent to Merck
- ❖ Merck reviews, with few changes

## Comprehension Testing

- ❖ Qualitative research with limited and adequate health literacy respondents
- ❖ Debrief with Merck, Northwestern, and Emory
- ❖ Labeling revised as necessary

# Results

- High comprehension by respondents with both adequate and limited health literacy

<b>Average Comprehension Scores Across Literacy Levels (n=548)*</b>				
	<b>Patients (n=249)</b>	<b>Caregivers (n=145)</b>	<b>Gen Pop (n=154)</b>	<b>Overall (n=548)</b>
<b>Limited Health Literacy</b>	88%	94%	87%	89%
<b>Adequate Health Literacy</b>	94%	96%	92%	95%
<b>Overall</b>	92%	96%	90%	93%

# Positive Patient Feedback

Both adequate and limited health literacy respondents stated they would be likely to:



Read the information



Keep information as a reference



Have a clear understanding of how to correctly use medication



Have a clear understanding of risks



Ask questions of their providers

# Contact Information

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