

# The Role of Social Science in Prescription Drug Promotion at FDA and Preview of Upcoming Studies

**Kathryn J. Aikin, Ph.D.**

Senior Social Science Analyst, Research Team Lead  
Office of Prescription Drug Promotion | CDER | FDA

**DIA Advertising and Promotion Regulatory Affairs Conference  
Marriott Hotel and Conference Center | N. Bethesda, MD**

# Office of Prescription Drug Promotion's (OPDP) Mission



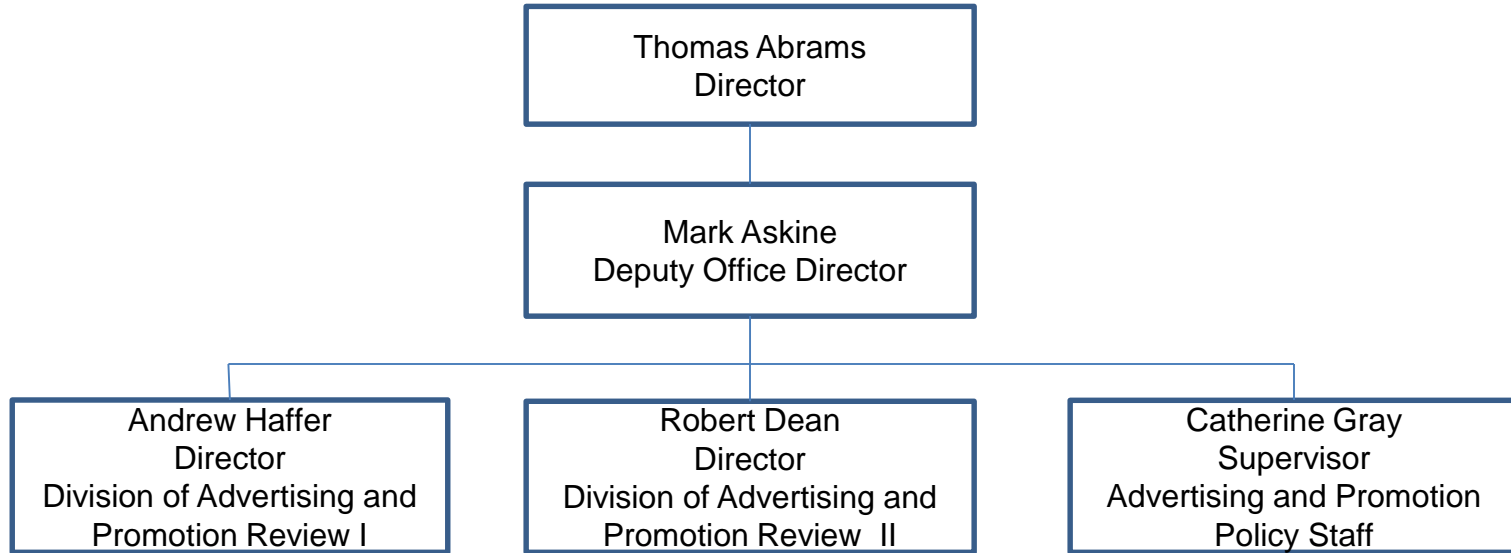
- Protect the public health by helping to ensure that prescription drug information is truthful, balanced, and accurately communicated
- Guard against false or misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs
- Foster better communication of information to help patients and healthcare providers make informed decisions about treatment options



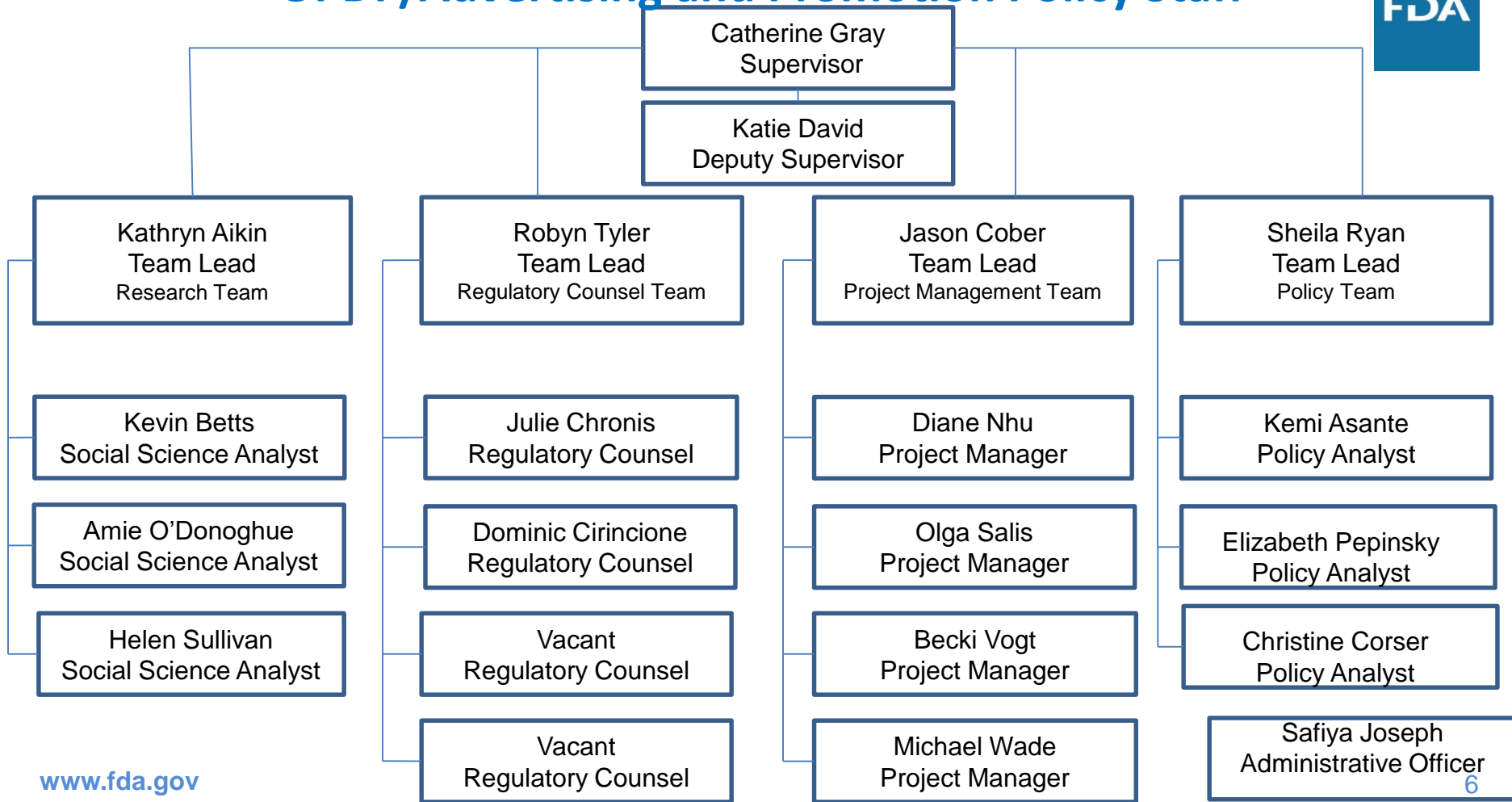
# Organizational Structure



# OPDP Organizational Structure



# OPDP/Advertising and Promotion Policy Staff





# OPDP Research Team

- Kathryn Aikin, Ph.D. (Team Lead)
- Kevin Betts, Ph.D.
- Amie O'Donoghue, Ph.D.
- Helen Sullivan, Ph.D., M.P.H.

# How Social Science Can Inform Approach to Problems



- Help identify goals
- Identify barriers to achieving goals
  - Cognitive barriers (capacity, motivation, attention)
  - Behavioral barriers (time, opportunity)
  - Others (literacy)
- Identify potential solutions
- Test and verify effectiveness of solutions



# Role of Research Team



## What we do

- Provide scientific evidence and advice to help ensure that OPDP's policies related to prescription drug promotion have the greatest benefit to public health
  - Investigate issues relevant to healthcare professional and patient/consumer usage of medical product information
  - Consider the audience's perception and comprehension of medical product information
  - Assess the accuracy and effectiveness of the informational messages

# Role of Research Team (cont.)



## How we do it

- Apply social science and communication principles to OPDP's:
  - Advice to industry, academia or internal FDA stakeholders
  - Guidance and policy development
  - Research
  - Surveillance and compliance activities

# OPDP's Research Agenda

- Provide science-based evidence and perspective
- Studies are proposed and selected to fulfill a number of purposes such as:
  - Congressional mandate
  - Help inform guidance and policy development
  - Enhance scientific literature base

# Application of Social Science Principles to Research



- Advertising Features
  - Content
  - Format
- Target Population(s)
- Research Quality

# Focus of OPDP's Research Studies

- Advertising Features
  - How do the features of the promotion impact the communication and understanding of prescription drug product risks and benefits?
  - Examples include:
    - Quantitative Information
    - Advertising and message elements
    - Disease characteristics
    - Product characteristics
    - Other elements

# Focus of OPDP's Research Studies (cont.)

- Target Population
  - How does understanding of prescription drug product risks and benefits vary as a function of audience?
  - Variables include:
    - Literacy
    - Education
    - Age

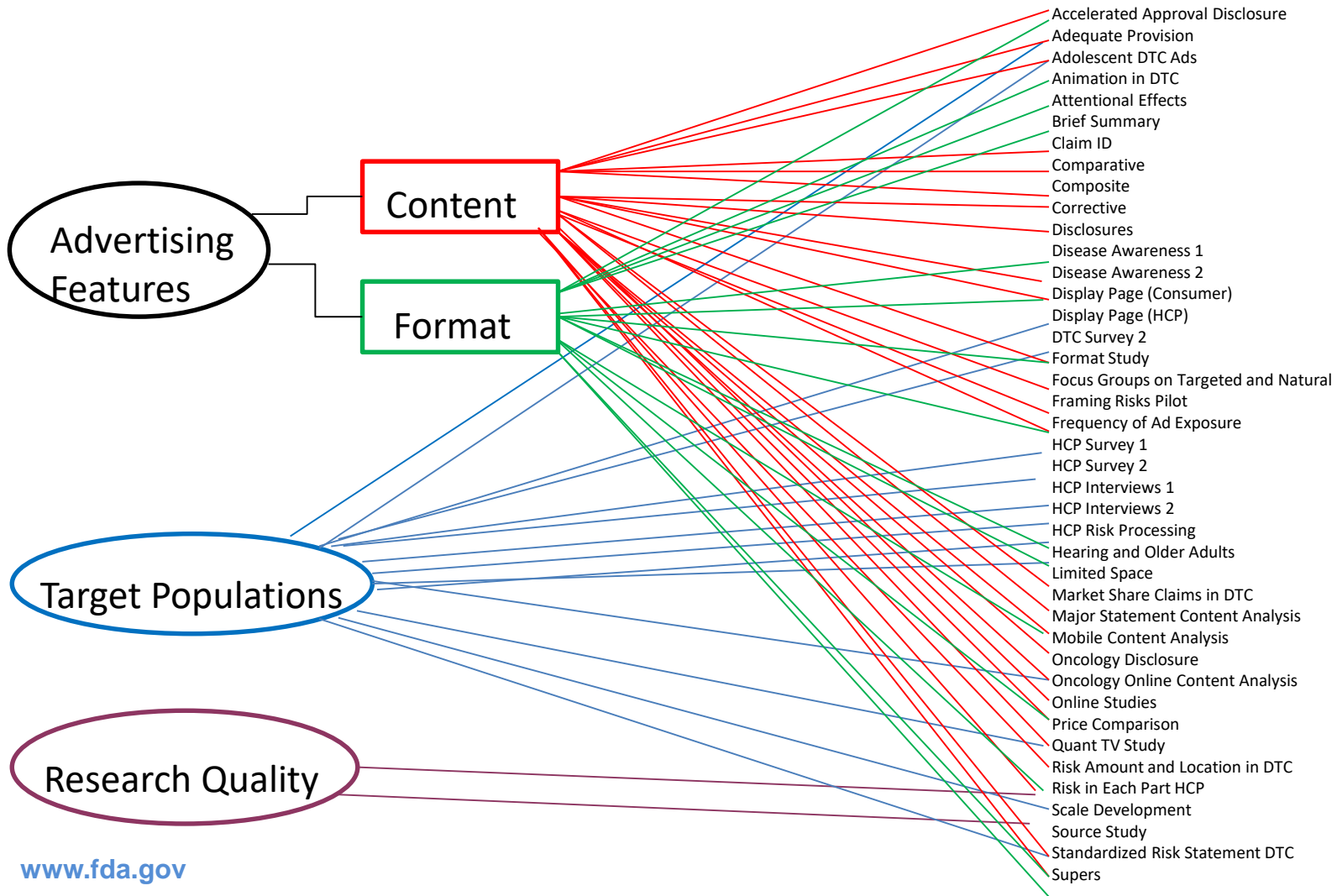
# Focus of OPDP's Research Studies (cont.)

- Research Quality
  - How can the quality of the research data be maximized to ensure the best possible return on investment for FDA?
  - Variables include:
    - Analytical methodology development
    - Sampling and response issues

# Research Design Choices

- Surveys
  - Survey of opinions of DTC promotion
- Experimental research
  - Studies that employ random assignment to condition in order to test causative hypotheses
- Qualitative research for development purposes
  - Smaller studies designed to efficiently focus future research priorities and considerations





# Public Comment Periods for OPDP Social Science Research



- Two statutory comment periods
- 60-day Federal Register Notice
  - Comments to FDA
- 30-day Federal Register Notice
  - Comments to OMB



# Additional Information About OPDP Research



## OPDP Research Website

- Completed projects
  - Link to publication
- Research in progress
  - Link to 60day FRN, 30day FRN
- <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm>



# An Examination of Superimposed Text in DTC TV Ads

Amie C. O'Donoghue, Ph.D.  
Center for Drug Evaluation and  
Research

October 17, 2018

# Collaborators

- **FDA**
  - Kevin R. Betts, Ph.D
  
- **RTI International**
  - Ryan Paquin, Ph.D.
  - Mihaela Johnson, Ph.D.
  - Bridget Kelly, Ph.D.

# Organization

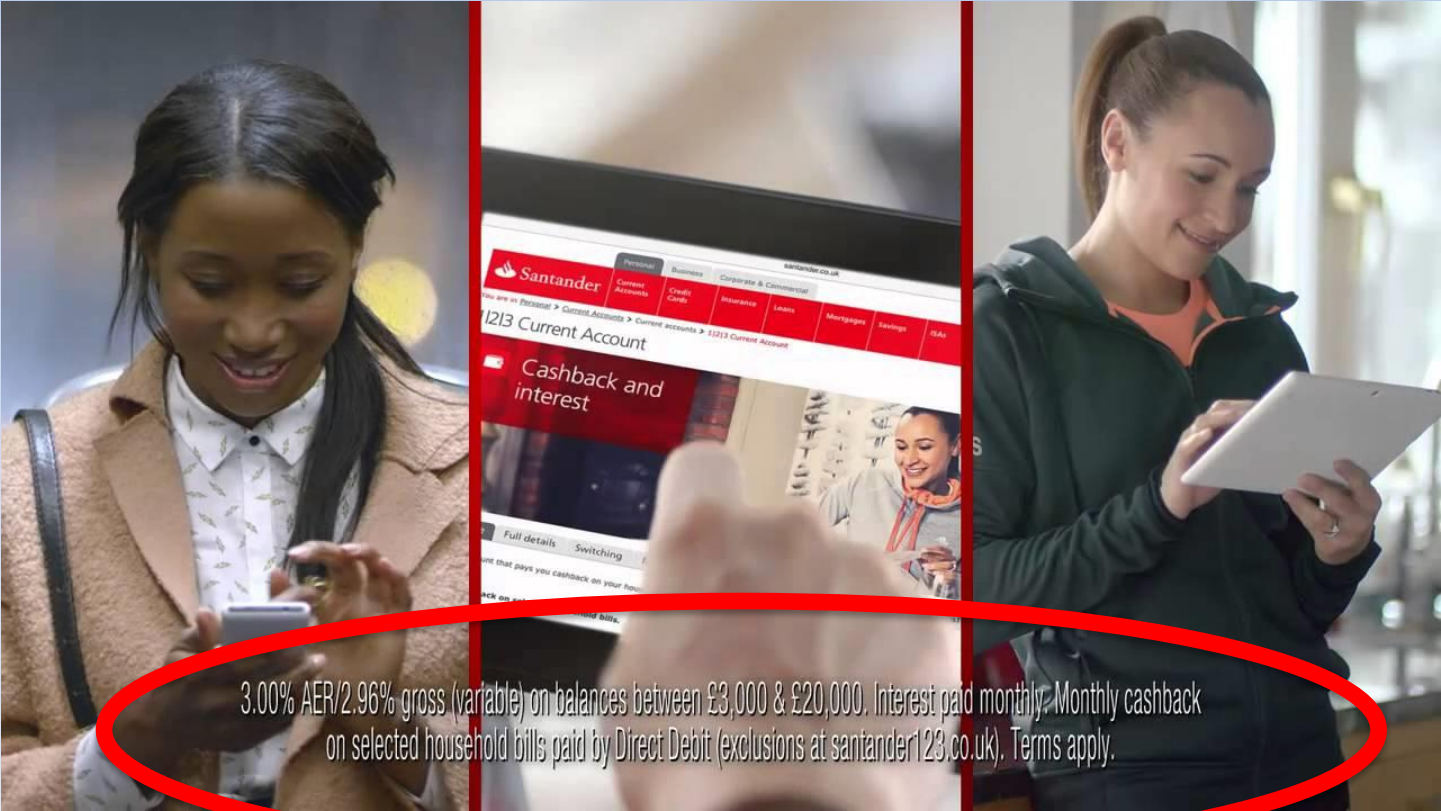
- Background
- Methodology
- Results
- Conclusions

Superimposed text = “Supers”





3.00% AER/2.96% gross (variable) on balances between £3,000 & £20,000. Interest paid monthly. Monthly cashback on selected household bills paid by Direct Debit (exclusions at [santander123.co.uk](http://santander123.co.uk)). Terms apply.



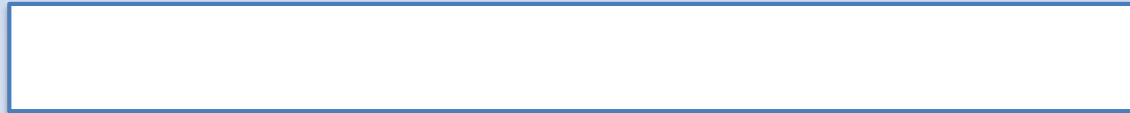
3.00% AER/2.96% gross (variable) on balances between £3,000 & £20,000. Interest paid monthly. Monthly cashback on selected household bills paid by Direct Debit (exclusions at [santander123.co.uk](http://santander123.co.uk)). Terms apply.

# Background

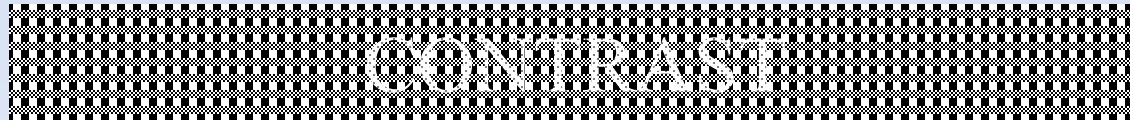
Factors that can influence consumer information processing:

TYPE SIZE

- ◊ ◻ • ◊ ◻ • ◊ ◻



**CPAFBIJFK** versus **CPA FBI JFK**



# Background

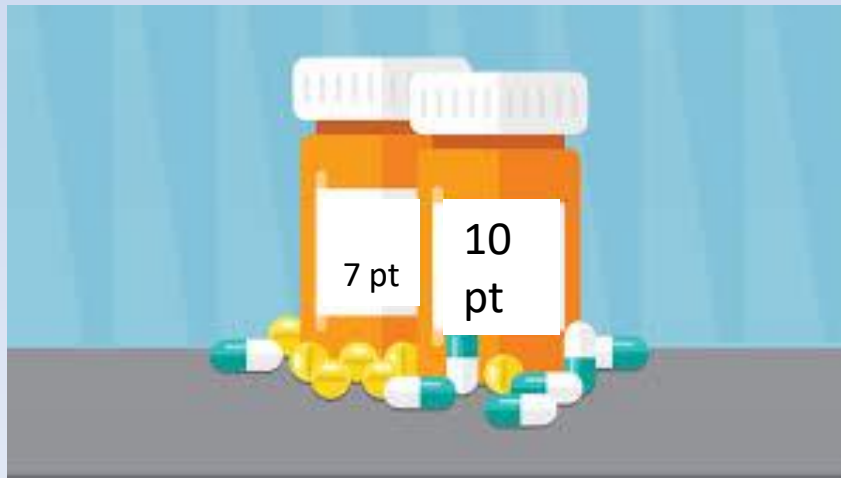
Factors that can influence consumer information processing:

**TYPE SIZE**

**CONTRAST**

# Background

- Wogalter & Vigilante, 2003:
- Older and Younger Adults
- 12 different OTC bottle displays



# Background

- Patients read more quickly and accurately when font is larger
- As font size increases, comprehension increases

**tiny small**

**smallish medium**

**bigger biggest**

# Background

- Contrast has had consistent but small effect
  - Black text on white background most readable
    - Tinker & Paterson, 1931
  - Contrast brightness has largest effect
    - Shieh & Lin, 2000
- Contrast may become more important as text size decreases
  - Legge et al., 1987
- No studies of text size and contrast in DTC prescription drug ads

# Background

- Most research conducted before 40+ inch TVs, tablets, even cell phones
- Average TV size today is 47-inches
- 58% of US homes had tablets in 2016
- 33% of Americans watch TV on cell phones



## Current Study

- Does super size, contrast, and/or device type influence noticeability, recall, and perceived importance of super information?
- Does super size, contrast and/or device type influence recall of and attitudes toward the promoted prescription drug?

# Design

Device Type		TV			Tablet			Total
Super Size		Small	Medium	Large	Small	Medium	Large	
Contrast	High	106	106	106	106	106	106	636
	Low	106	106	106	106	106	106	636
Total		212	212	212	212	212	212	1,272

# Size determination

- Cap height relative to display height
- Pretested 5 sizes with 242 participants
- Cap heights set at:
  - Small »  $1/50^{\text{th}}$  of display height
  - Medium »  $1/30^{\text{th}}$  of display height
  - Large »  $1/20^{\text{th}}$  of display height

Superimposed Text Size

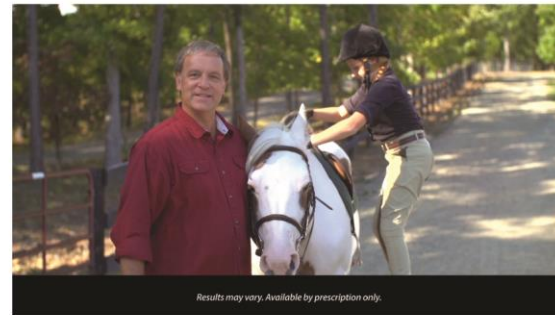
Large



Medium



Small

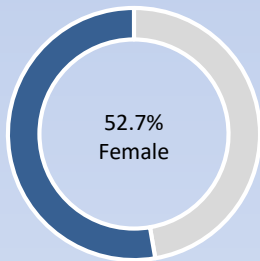


Low

High

Contrast

### Gender



### Mean Age

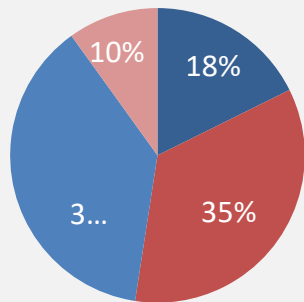


45

### Education



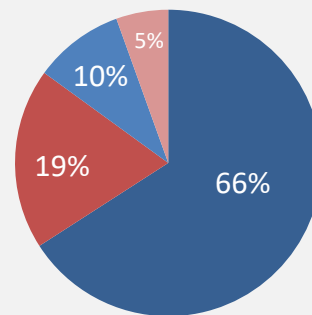
- <=High School
- Some college
- College degree
- Advanced degree



### Race/Ethnicity



- Non-Hispanic White
- Non-Hispanic Black
- Hispanic
- Other



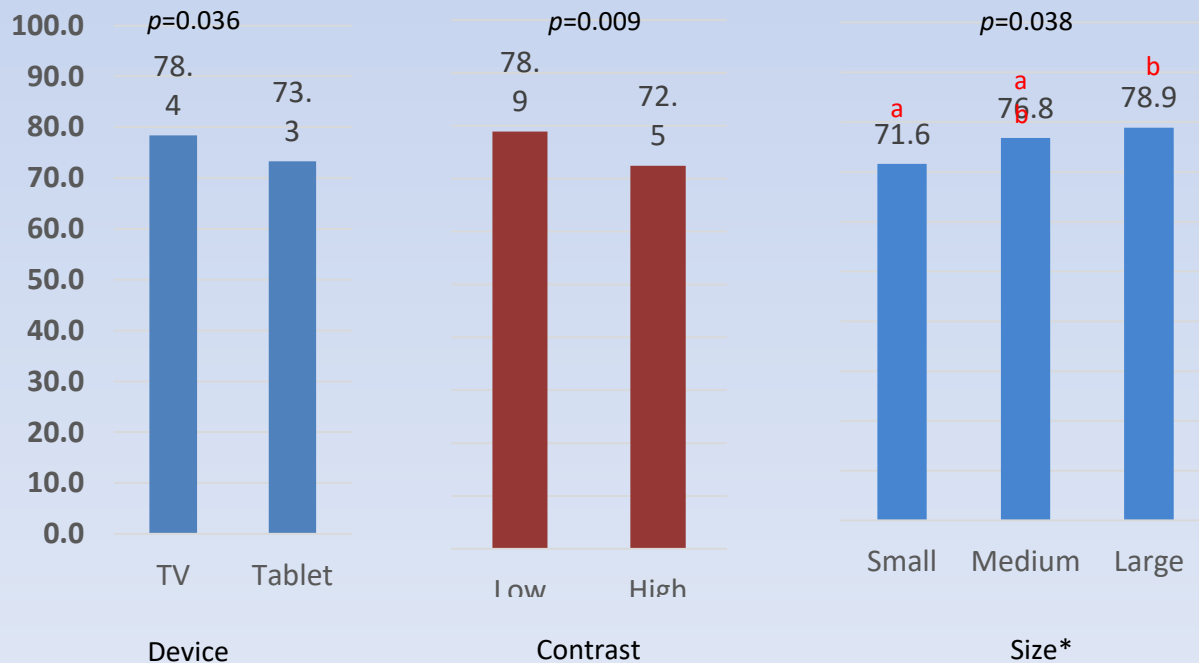
# Procedure

- In-person administration in
  - Tampa, FL
  - Cincinnati, OH
  - Los Angeles, CA
  
- Viewed one of 6 ads on either TV or tablet
  
- Completed questionnaire

# Outcome Variables

- Cognitive processing of super information
  - Awareness
  - Encoding
- Memory/interpretation of risk/benefits
  - Recall
  - Perceptions
- Attitudes

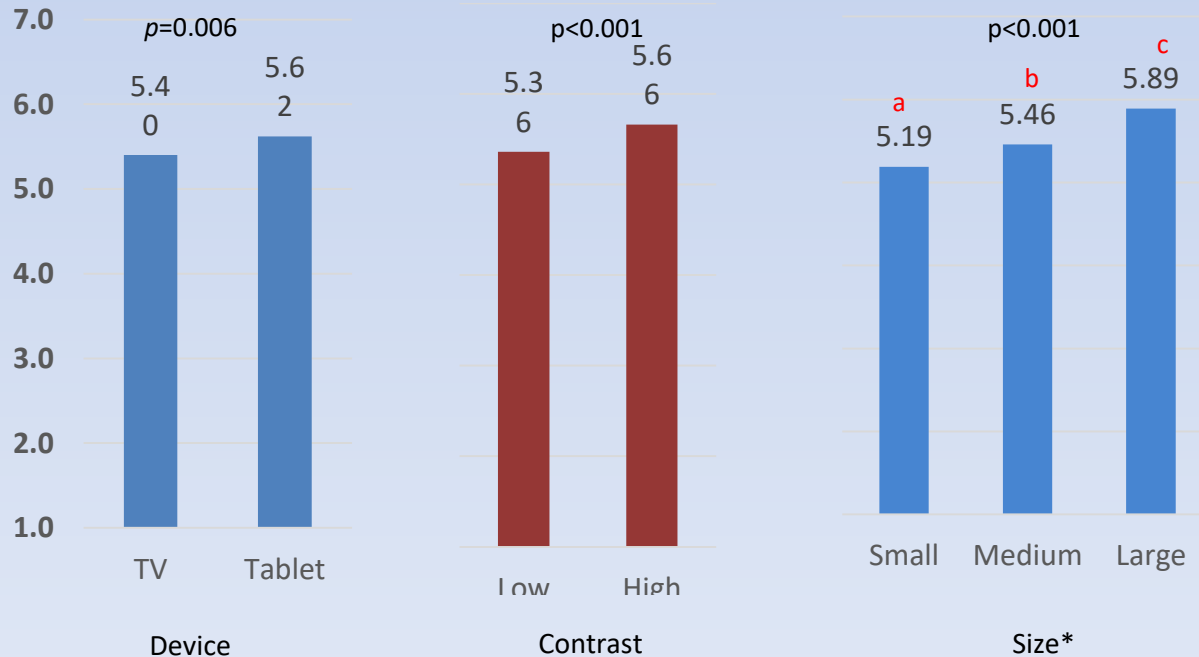
# Results - Awareness of Supers



\*Different superscripts indicate significant difference  $p < 0.0167$ .

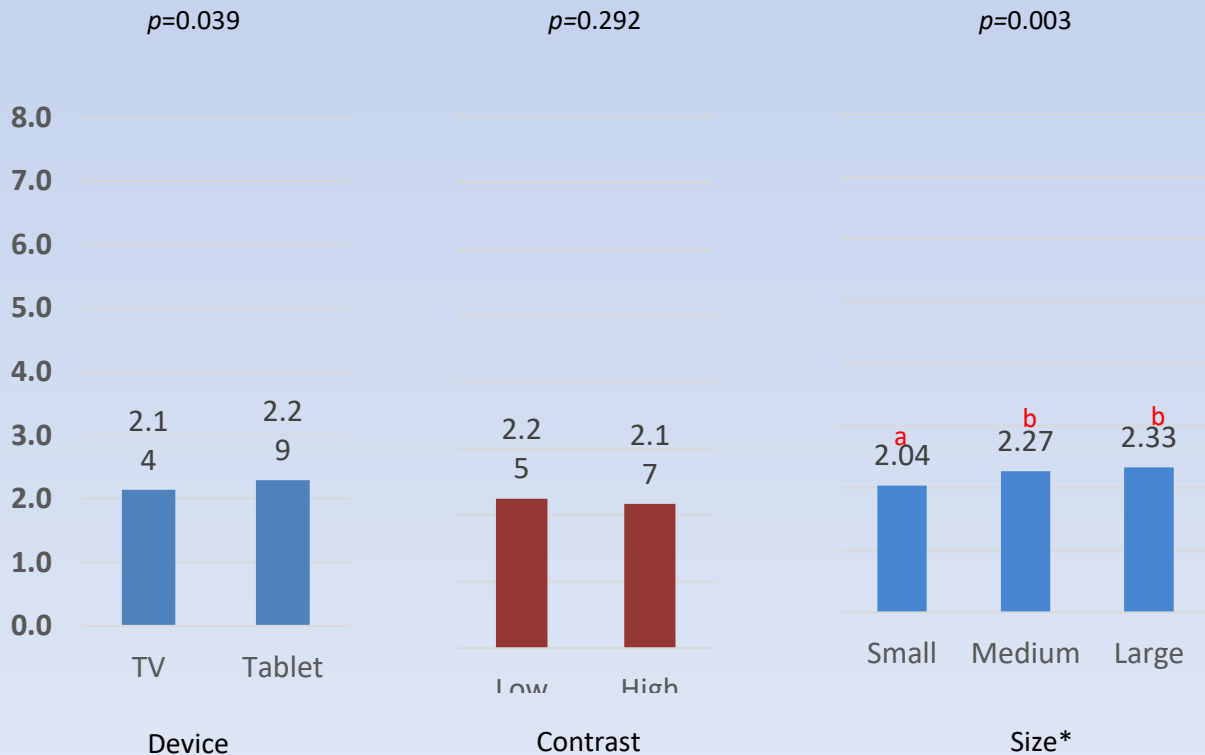


# Results – Perceived prominence among those who noticed



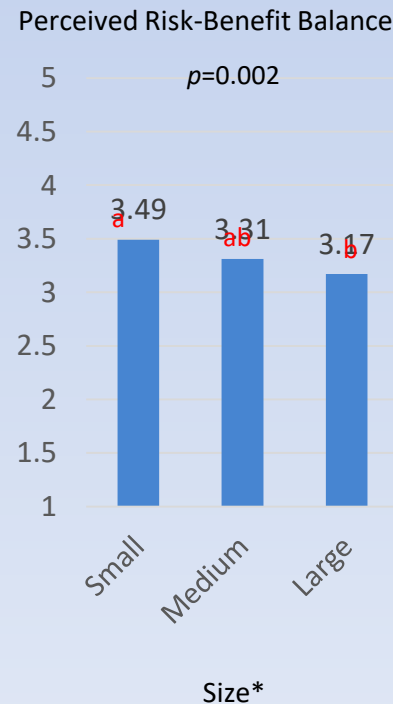
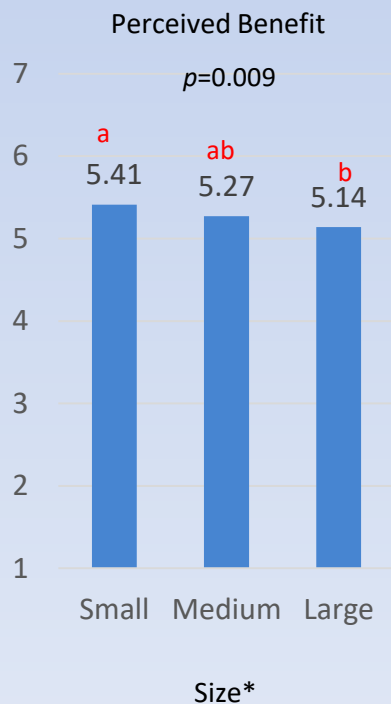
\*Different superscripts indicate significant difference  $p<0.0167$ .

# Results – Risk Recall



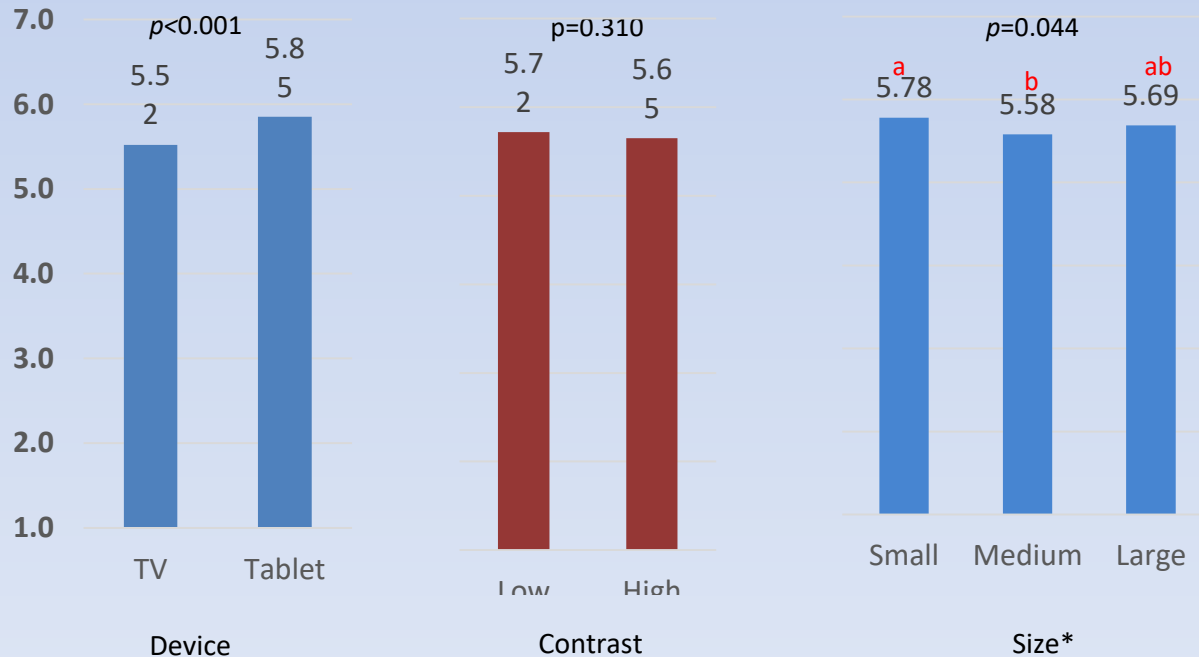
\*Different superscripts indicate significant difference  $p < 0.0167$ .

# Results – Perceived Benefit



\*Different superscripts indicate significant difference  $p<0.0167$ .

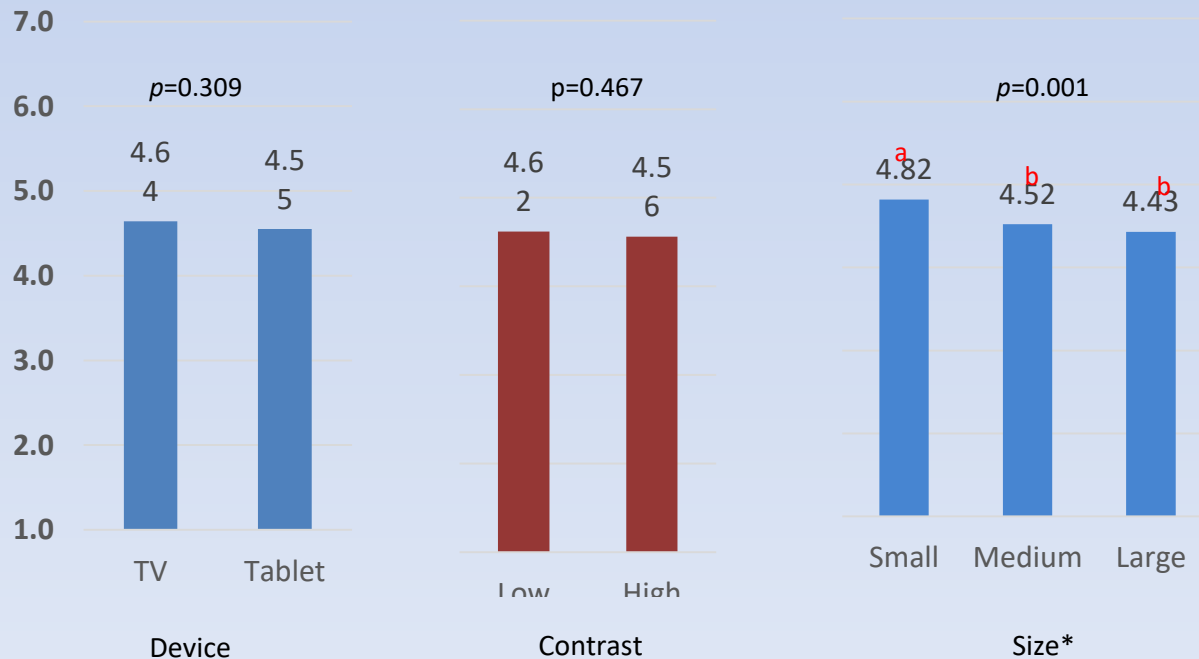
# Results – Attitude toward the ad



Note: General perceptions of advertising was included in the model as covariate; it was significantly associated with attitude toward the ad.

\*Different superscripts indicate significant difference  $p < 0.0167$ .

# Results – Attitude toward the drug



\*Different superscripts indicate significant difference  $p < 0.0167$ .

# Summary

Super size had expected effects

- Larger supers more noticeable, prominent
- Almost everyone recalled the indication; but participants who saw the small supers:
  - Recalled fewer risks/side effects
  - Had more positive risk-benefit balance perceptions
  - Had higher benefit perceptions
  - Had more favorable attitudes toward the drug.

# Summary

- People noticed low contrast super (in scene) more than high contrast super (black bar)
- Those who did notice supers thought black bar was more visually clear
- Contrast did not affect risk/benefit recall or perceptions

# Summary

- TV watchers more aware of supers than tablet users
- Of those who noticed supers, tablet users thought they were more visually clear
- Tablet users:
  - Had greater risk recall
  - Had more positive attitudes toward the ad; no differences on attitudes toward drug



## Limitations & Future Research

- One medication – could be different in others
- Only examined two devices – what about phones with even smaller screens?
- Two examples of contrast – many ways to show supers

# Conclusions

- Size matters!
  - Important information is best presented in larger fonts, regardless of contrast
- Tablet usage may be more engaging with regard to risk information
- Black bar format may not be the best way to present supers



Amie O'Donoghue, Ph.D.

Office of Prescription Drug Promotion

Center for Drug Evaluation and Research

10903 New Hampshire Ave., Bldg. 51

Silver Spring, MD 20993-0002

[amie.odonoghue@fda.hhs.gov](mailto:amie.odonoghue@fda.hhs.gov)

301-796-0574





# **TAKING REPEATED EXPOSURE INTO ACCOUNT**

## **AN EXPERIMENTAL STUDY OF DIRECT-TO-CONSUMER PRESCRIPTION DRUG TELEVISION AD EFFECTS**

**Kevin R. Betts, Ph.D., Social Science Analyst**

Office of Prescription Drug Promotion | CDER | FDA

FDLI Advertising and Promotion Conference, Washington, DC

October 2018

# Some Observations

In a recent content analysis, Sullivan et al. (2017) found that major statements of risk in DTC prescription drug television ads often “included long and complex sentences...were often accompanied by competing non-risk information in the visual images, presented with moderately fast-paced music, and read at a faster pace than benefit information.”

The major risk statement—as currently formatted—tends to be poorly processed by consumers (Betts et al., 2018).

But also...

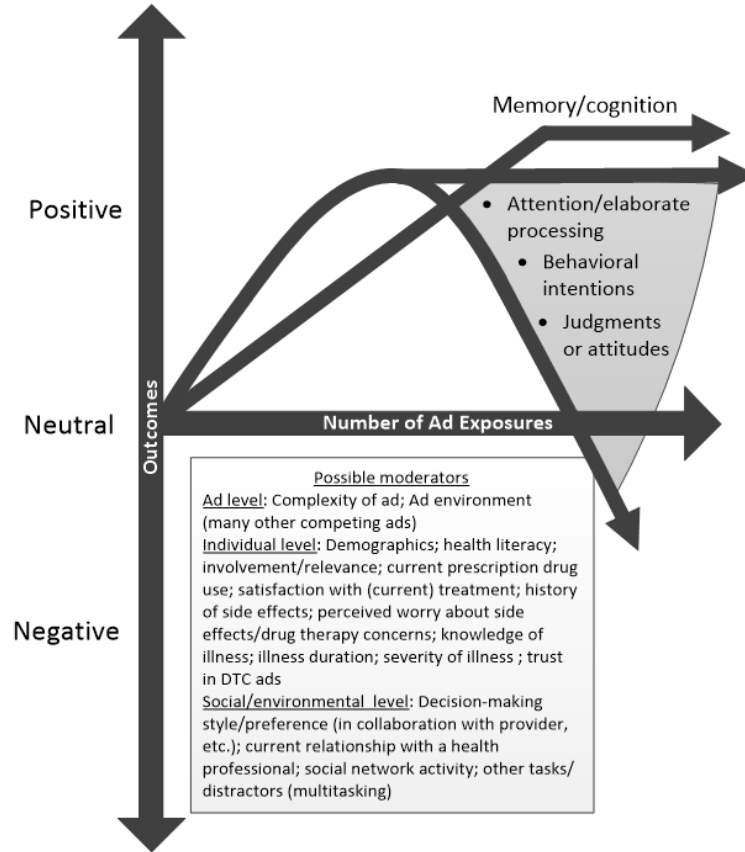
Consumers are exposed to a particular DTC ad multiple times which together could promote adequate or at least improved processing of the major risk statement.

# Ad Exposure Frequency Conceptual Framework

Our conceptual framework depicts potential effects of repeated DTC ad exposure.

Outcomes such as attention and attitudes are expected to follow an inverted-U curve, though the exact pattern may vary up to a leveling off.

Memory, in contrast, is expected to rise and then level off with repeated exposures.



# Research Questions

Hypothesis (H1): As ad exposure frequency increases, recall and recognition of risks and benefits will increase.

Research Question 1 (RQ1): Will risk and benefit information be recalled or recognized differently (e.g., benefits recalled/recognized more easily than risks)?

Research Question 2 (RQ2): Will ad exposure frequency affect risk and efficacy perceptions?

Research Question 3 (RQ3): Will ad exposure frequency affect behavioral intentions (specifically intentions to seek information about the drug or take the drug if prescribed)?

Research Question 4 (RQ4): Are effects of ad exposure frequency on recall and recognition mediated by increased elaborate processing or counterarguing?

Research Question 5 (RQ5): Will attention be affected by ad exposure frequency?



# Drug Profile

**Trinase**  
treats and helps prevent nasal allergy symptoms.

Don't let nasal allergy symptoms prevent you from enjoying your home or garden. Prescription **Trinase** is clinically proven to help relieve both seasonal (outdoor) and year-round (indoor) nasal allergy symptoms.

**Trinase** is a tablet that treats and helps prevent nasal allergy symptoms. Talk to your doctor about trying **Trinase** and visit [Trinase.com](http://Trinase.com).

It is important that you take **Trinase** regularly as recommended by your doctor since its effectiveness depends on regular use.

Used once a day, **Trinase** can provide maximum treatment benefits in as little as 1 to 2 weeks.

**Trinase**  
200 mg tablets

**Important Risk Information**

- Some people who take TRINASE may experience eye problems, including glaucoma and cataracts. You should have regular eye exams when taking TRINASE.
- Infections of the nose and throat may occur.
- TRINASE may cause slow wound healing. Do not use TRINASE until your nose is healed if you have a sore in your nose, if you have had surgery on your nose, or if your nose has been injured.
- A condition in which the adrenal glands do not make enough steroid hormones may occur. Symptoms can include tiredness, weakness, nausea, vomiting, and low blood pressure.
- The most common side effects include headache, viral infection, sore throat, nosebleeds, and coughing.

**Trinase** is

- Scent free and alcohol free
- Non-habit forming
- Non-drowsy

[Trinase.com](http://Trinase.com)

Please see Important Information about Trinase on the next page. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**MILLER**  
pharmaceuticals

Manufactured by Miller Pharmaceuticals, St. Louis, Missouri  
©2013 Miller Pharmaceuticals. All rights reserved.

**Important Information**

**Trinase** (TRF-nase)  
tricamasona furoate 200 mg tablets

**What is TRINASE?**

TRINASE is a prescription medicine approved for adults and children aged 2 years and older. Used once a day, TRINASE is clinically proven to help relieve both seasonal (outdoor) and year-round (indoor) nasal allergy symptoms. It is important that you take TRINASE regularly as recommended by your doctor because its effectiveness depends on regular use. Maximum treatment benefit is usually achieved in 1 to 2 weeks.

**Who should take TRINASE?**

TRINASE is available only by prescription for:

- Adults and children aged 2 years and older for treatment of nasal allergy symptoms

**Who should NOT take TRINASE?**

- Those who are allergic to TRINASE or any of its ingredients

**Talk to your doctor**

Before you start taking TRINASE, tell your doctor:

- About all of your prescription and over-the-counter medications as well as vitamins and herbal supplements. Certain medicines may affect the way TRINASE works.
- If you have any of the following:
  - Recent or unhealed nasal sores, nasal surgery, or nasal injury
  - Eye or vision problems including glaucoma and cataracts
  - Tuberculosis or any untreated fungal, bacterial, viral, or eye infections
  - Exposure to chickenpox or measles

**Or:**

- Are pregnant, or plan to become pregnant. It is not known if TRINASE can harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if TRINASE passes into breast milk and may harm your baby.

**Possible side effects of TRINASE**

- Eye problems including glaucoma and cataracts
- Infections of the nose and throat
- Slow wound healing
- Immune system problems that may increase the risk of infection
- Adrenal insufficiency, a condition in which the adrenal glands do not make enough steroid hormones

**Call your doctor right away if you:**

- develop any signs of infection such as fever, pain, aches and chills
- Feel tired or weak
- Experience nausea, vomiting or low blood pressure

**The most common side effects of TRINASE include:**

- Headache
- Sore throat
- Viral infection
- Nosebleeds
- Cough

Tell your doctor if these side effects do not go away.

**How should I take TRINASE?**

- Take TRINASE exactly as prescribed by your doctor.
- If you miss a dose of TRINASE, take it as soon as you remember.
- Do not take TRINASE more often than prescribed.

**Need more information?**

- Talk to your doctor or health care provider.
- Talk to your pharmacist.
- Call 1-866-TRINASE.

[Trinase.com](http://Trinase.com)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**MILLER**  
pharmaceuticals

Manufactured by Miller Pharmaceuticals, St. Louis, Missouri  
©2013 Miller Pharmaceuticals. All rights reserved.

# DTC Television Ad



Our fictitious DTC television ad was embedded alongside filler ads in a clutter reel, or commercial break.

# Television Program



The two television programs lasted 60 minutes in total and presentation order was counterbalanced.

# Study Design

Number of Ad Exposures	Clutter Reel Number					
	1	2	3	4	5	6
Low (1 exposure)						Mock DTC ad
Medium (2 exposures)				Mock DTC ad		Mock DTC ad
High (4 exposures)	Mock DTC ad		Mock DTC ad	Mock DTC ad		Mock DTC ad

- Participants were randomly assigned to low, medium, or high exposure experimental conditions.
- The clutter reel (commercial break) number shows placement of the DTC ad within the television programming.

# Measurement

- Brand recognition
- Risk recall & recognition
- Benefit recall & recognition
- Perceived risk
- Perceived efficacy
- Elaborate processing
- Counterargument
- Self-reported attention
- Number of times viewed the ad
- Attitudes toward the drug
- Risk/benefit balance
- Length of time since diagnosis
- Current prescription drug use
- Satisfaction with current treatment

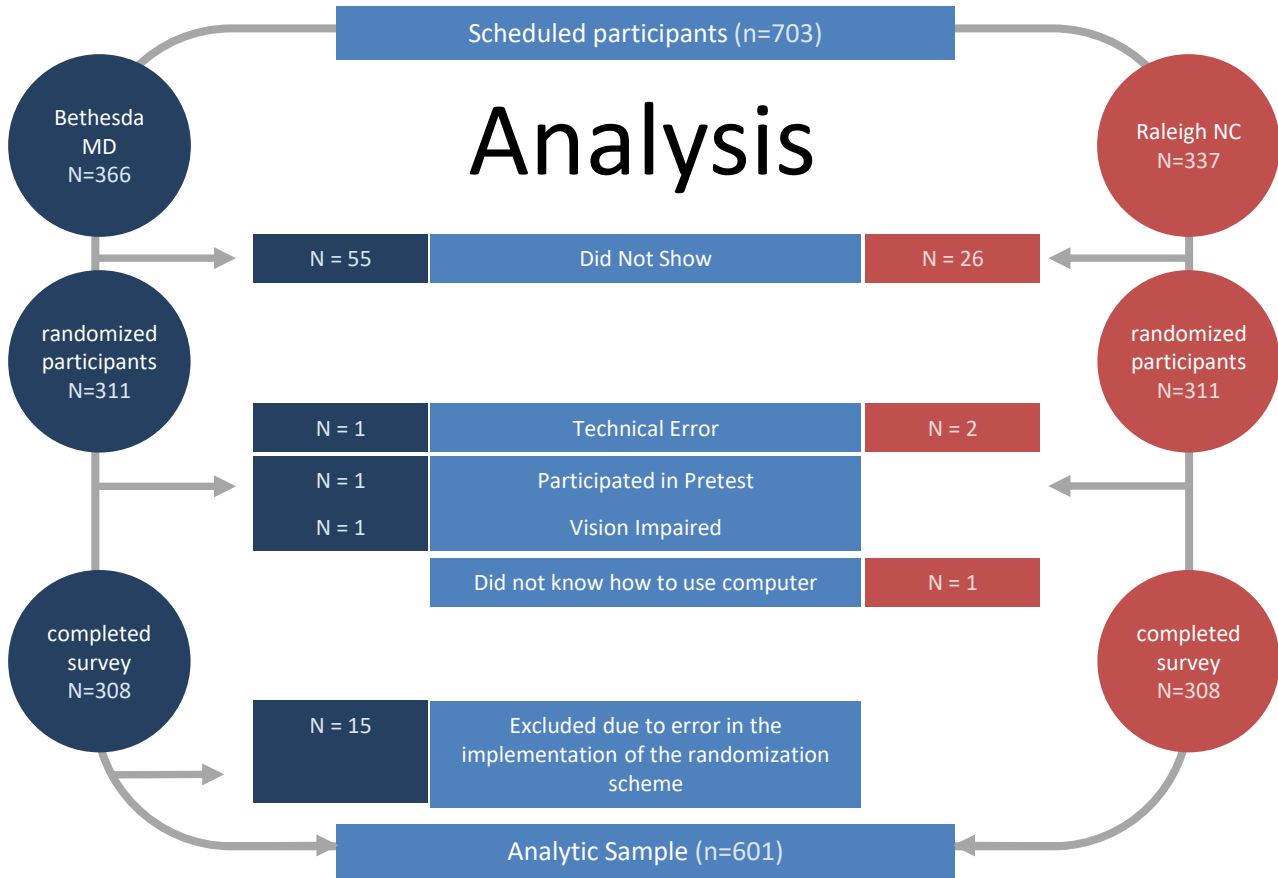
# Sample

The sample consisted of adults with seasonal allergies identified through opinion research recruitment firm databases.

Individuals with healthcare or marketing backgrounds, or who had participated in the study's pretest were excluded from participation.

All participants could read and speak English.

Sample	Overall	1 exposure	2 exposures	4 exposures
	%	%	%	%
<b>Gender</b>				
Male	252 (43.5%)	91 (47.4%)	81 (40.9%)	80 (42.3%)
Female	327 (56.5%)	101 (52.6%)	117 (59.1%)	109 (57.7%)
<b>Age</b>				
<b>Mean Age (SD)</b>	47 (13.7)	49 (13.2)	47 (13.9)	46 (13.8)
<b>Race/Ethnicity</b>				
Non-Hispanic White	394 (73.4%)	137 (77.4%)	135 (72.2%)	122 (70.5%)
Non-Hispanic Black	105 (19.6%)	29 (16.4%)	42 (22.5%)	34 (19.7%)
Hispanic	15 (2.8%)	3 (1.7%)	6 (3.2%)	6 (3.5%)
Other	23 (4.3%)	8 (4.5%)	4 (2.1%)	11 (6.4%)
<b>Education</b>				
Less than high school	6 (1.0%)	4 (2.0%)	2 (1.0%)	0 (0%)
High school	95 (16.0%)	26 (13.1%)	36 (18.0%)	33 (16.8%)
Some college	104 (17.5%)	36 (18.2%)	34 (17.0%)	34 (17.3%)
College degree	389 (65.5%)	132 (66.7%)	128 (64.0%)	129 (65.8%)





# Analysis

ANOVA models were used to test effects of exposure on continuous outcomes.

- When main effects observed, we conducted planned contrasts to identify differences between experimental groups.

For categorical outcomes, we conducted ordinal logistic regressions.

- When main effects observed, differences between experimental groups were examined using odds ratios and Wald chi-square stats.

In both cases, Holm-Bonferroni corrections were applied to control for inflation of error rates.

To examine whether participants recalled risk and benefit information differently at various ad exposure frequencies we compared regression coefficients using z-tests for the relationships between ad exposure and recall/recognition of risk and benefit information.

Consult forthcoming publication for details on approach to testing differences in regression coefficients, mediation testing, etc.

# Results

Nearly all (99%) participants were able to recognize the name of the promoted drug.

Most (74%) were able to accurately recall the number of times they had seen the DTC ad.

Participants reported positive opinions about the drug.

- 65% said the benefits outweigh the risks.
- 72% reported positive attitudes toward the drug.

# Results: Recall and Recognition

Risk and benefit recall was low overall.

- Participants on average recalled 1.09 risks ( $SD = 1.10$ ) out of 7, and 1.44 benefits ( $SD = 1.03$ ) out of 8.
- About 30% of participants recalled two or more risks; and about 41% of participants recalled two or more benefits.

On average, participants accurately recognized 4.61 risks ( $SD = 1.27$ ) out of 7 as real or bogus claims, and 5.07 benefits ( $SD = 1.17$ ) out of 7 as real or bogus claims.

# Results: Risk and Benefit Recall

Ad exposure frequency was significantly related to risk recall ( $X^2 = 20.93, p < .001$ ).

- Those who saw the ad four times were more likely to recall more risks compared to those who saw the ad only once (Odds Ratio [OR] = 2.36,  $p < .001$ ) or twice (OR = 1.59,  $p < .012$ ).

Ad exposure frequency was also significantly related to benefit recall ( $X^2 = 9.34, p < .009$ ).

- Those who saw the ad twice (OR = 1.70,  $p = .005$ ) and four times (OR = 1.59,  $p = .014$ ) were more likely to recall more benefits compared to those who saw the ad only once.

# Results: Risk and Benefit Recognition

We also found that ad exposure frequency was significantly related to risk recognition ( $F(2, 597) = 11.89, p = .001$ ).

- Those who saw the ad four times ( $M = 4.91, SE = .09, p < .001$ ) and those who saw the ad two times ( $M = 4.61, SE = .09, p = .012$ ) had higher risk recognition than those who saw the ad only once ( $M = 4.30, SE = .09$ ).

We also found a significant relationship between ad exposure frequency and benefit recognition ( $F(2, 597) = 3.17, p = .043$ ).

- Planned comparisons show that those who saw the ad four times ( $M = 5.23, SE = 0.08, p = .017$ ) had higher benefit recognition than those who saw the ad only once ( $M = 4.95, SE = .08$ ).

# Results: Differential Retention

When comparing those exposed to the ad two and four times, the slope of the relationship between ad exposure frequency and recall of risk information was statistically different than the slope of the relationship between ad exposure frequency and recall of benefit information,  $B_{\text{risk}} = .47$ ,  $SE_{\text{risk}} = .18$ ,  $B_{\text{benefit}} = -.07$ ,  $SE_{\text{benefit}} = .19$ ,  $z = 2.01$ ,  $p = .044$ .

The difference in slopes for the relationship between ad exposure frequency and recognition of risks and ad exposure frequency and recognition of benefits was not significant,  $p = .0143$  for one vs. two exposures;  $p = .635$  for two vs. four exposures.

# Results: Risk and Benefit Perceptions



Outcome	Overall	Experimental Condition				χ <sup>2</sup> -value, p-value
		1 Exposure	2 Exposures	4 Exposures		
	n (%)	n (%)	n (%)	n (%)		
Perceived risk likelihood (% >median = slightly likely-extremely likely)	158 (26.3%)	49 (24.6%)	61 (30.2%)	48 (24.0%)	2.41, .230	
Perceived risk magnitude (% >median = somewhat serious-extremely serious)	125 (20.8%)	38 (19.1%)	48 (23.8%)	39 (19.5%)	1.63, .443	
	<b>Mean (SD)</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	<b>F-value, p-value</b>	
Perceived efficacy likelihood	3.41 (.84)	3.39 (.83)	3.42 (.87)	3.43 (.84)	.11, .896	
Perceived efficacy magnitude	3.45 (.84)	3.40 (.85)	3.49 (.82)	3.48 (.84)	.71, .490	

No significant differences were detected.

# Recap: Key Findings

Retention of risks and benefits was low across experimental conditions, but did improve with ad repetition.

Ad repetition affected recall of risks more than benefits (that is, risk recall continued to improve with additional exposures whereas benefit recall tended to level off).

Risk and efficacy perceptions were not impacted by ad exposure frequency.



# Limitations and Future Research

The number of repetitions may have been too low to detect more effects.

- Does risk recall plateau at some point after four ad exposures?
- Does greater ad exposure impact other outcomes?

Future research should assess memory, perceptions, and judgment outcomes after more than four ad exposures.

# Practical Considerations

A key problem is that most DTC prescription drug television ads include a substantial amount of information despite known limitations to human memory capacity (Sullivan et al., 2017), with research showing that consumers recall only about one or two risks after viewing a DTC TV ad (Betts et al., 2018), which is not substantially improved after multiple exposures (Betts et al., in preparation).

A likely solution is to simplify DTC TV ad presentations! Consider health literacy, utilize consumer friendly language, implement best practices for ad design, etc.

# Acknowledgments



**Thank you** to my collaborators!

## FDA

Kathryn Aikin, PhD

Kevin Betts, PhD

## RTI International

Carla Bann, PhD

John Bollenbacher, BA

Alex Breslav, BA

Kate Ferriola, BA

Ryan Gordon, BA

Mihaela Johnson, PhD

Bridget Kelly, PhD, MPH

Molly Lynch, MPH

Nicole Mack, MS

Sarah Parvanta, PhD

Alex Rabre, MPH, MS

Chris Smith-Naill, BA

Amanda Smith, MA

Brian Southwell, PhD

Janice Tzeng, MPH

Natasha Vazquez, BS

Peyton Williams, BA



**U.S. FOOD & DRUG**  
ADMINISTRATION

# *Quantitative Risk Information in Direct-to-Consumer Television Ads*

**Helen Sullivan, Ph.D., MPH**  
Social Science Analyst

Office of Prescription Drug Promotion | CDER | FDA

**FDLI Advertising and Promotion Conference**  
**Renaissance Downtown Hotel | Washington, DC**

# Collaborators

## FDA

Amie O'Donoghue, Ph.D.

## RTI International

Douglas Rupert, MPH

Molly Lynch, MPH

Mihaela Johnson, PhD

Christine Davis, BA

# Background

- One way to improve consumers' understanding of medical information is to include quantitative, or numerical, information.<sup>1</sup>
- One study found that adding simple quantitative information about drug *benefits* to DTC TV ads can help improve consumer understanding of benefits.<sup>2</sup>

1. West et al. (2013). Communicating quantitative risks and benefits in promotional prescription drug labeling or print advertising. *Pharmacoepidemiology and Drug Safety*, 22(5), 447-557.

2. O'Donoghue, et al. (2014). Presenting efficacy information in direct-to-consumer prescription drug advertisements. *Patient Education and Counseling*, 95(2), 271-280.

## Research Questions

- Can adding quantitative *risk* information to DTC TV ads help improve consumer understanding?
- How much quantitative risk information can consumers process?



# Study Design

		Risk Presentation		
		No quantitative	General	Specific
Benefit presentation	No quantitative			
	Single outcome			
	Multiple outcome			

# Study Design

Risk Presentation		
No quantitative	General	Specific

# Risk Presentations

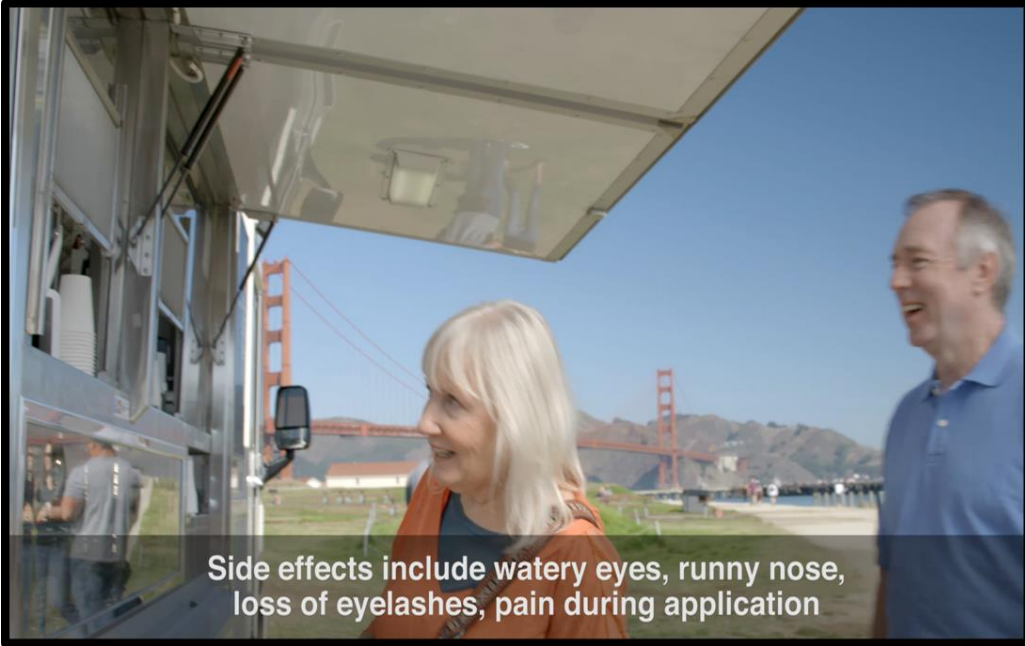
Quantitative	General	Specific
<ul style="list-style-type: none"> <li>• Side effects of Vistasin include watery eyes, runny nose, loss of eyelashes, pain or stinging during application,</li> <li>• fever, light flashes at the outer edges of vision, loss of depth perception,</li> <li>• sensitivity to light, double vision, and detached retina.</li> </ul>		

# Risk Presentations

Quantitative	General	Specific
<ul style="list-style-type: none"> <li>• Side effects of Vistasin include watery eyes, runny nose, loss of eyelashes, pain or stinging during application,</li> <li>• fever, light flashes at the outer edges of vision, loss of depth perception,</li> <li>• sensitivity to light, double vision, and detached retina.</li> </ul>	<ul style="list-style-type: none"> <li>• Side effects that occur in 10% or less of people who take Vistasin include watery eyes, runny nose, loss of eyelashes, pain or stinging during application,</li> <li>• fever, light flashes at the outer edges of vision, loss of depth perception,</li> <li>• sensitivity to light, double vision, and detached retina.</li> </ul>	Empty content for Specific column

# Risk Presentations

Quantitative	General	Specific
<ul style="list-style-type: none"> <li>• Side effects of Vistasin include watery eyes, runny nose, loss of eyelashes, pain or stinging during application,</li> <li>• fever, light flashes at the outer edges of vision, loss of depth perception,</li> <li>• sensitivity to light, double vision, and detached retina.</li> </ul>	<ul style="list-style-type: none"> <li>• Side effects that occur in 10% or less of people who take Vistasin include watery eyes, runny nose, loss of eyelashes, pain or stinging during application,</li> <li>• fever, light flashes at the outer edges of vision, loss of depth perception,</li> <li>• sensitivity to light, double vision, and detached retina.</li> </ul>	<ul style="list-style-type: none"> <li>• Side effects that occur in 6-10% of people who take Vistasin include watery eyes, runny nose, loss of eyelashes, and pain or stinging during application.</li> <li>• Side effects that occur in 1-5% of people who take Vistasin include fever, light flashes at the outer edges of vision, and loss of depth perception.</li> <li>• Side effects that occur in less than 1% of people who take Vistasin include sensitivity to light, double vision, and detached retina.</li> </ul>



Side effects include watery eyes, runny nose, loss of eyelashes, pain during application



Side effects in 10% or less of people: Watery eyes, runny nose, loss of eyelashes, pain during application



Side effects in 6-10% of people: Watery eyes, runny nose, loss of eyelashes, pain during application

# Procedure

- 20-minute study online
- Ad for fictitious prescription drug for cataracts

Participants were:

- Randomly assigned to view 1 of 9 TV ads
- Shown ad twice, then asked questions

# Participants

- 945 US adults 60 years of age or older
- Internet panel



# Participants

- 44% Currently or previously had cataracts
- 50% High school education or less
- 50% Male
- 83% White, 14% Black

# Results

# Two Kinds of Memory

## Verbatim Memory

- For example, knowing the exact numbers in the ad

## Gist Memory

- For example, knowing the idea the number conveyed, even if you don't remember the exact numbers

## Gist Memory

Almost everyone who takes Vistasin will experience at least one side effect.

- Correct answer: False

Some of Vistasin's side effects are more likely to occur than others.

- Correct answer: True

## Gist Memory

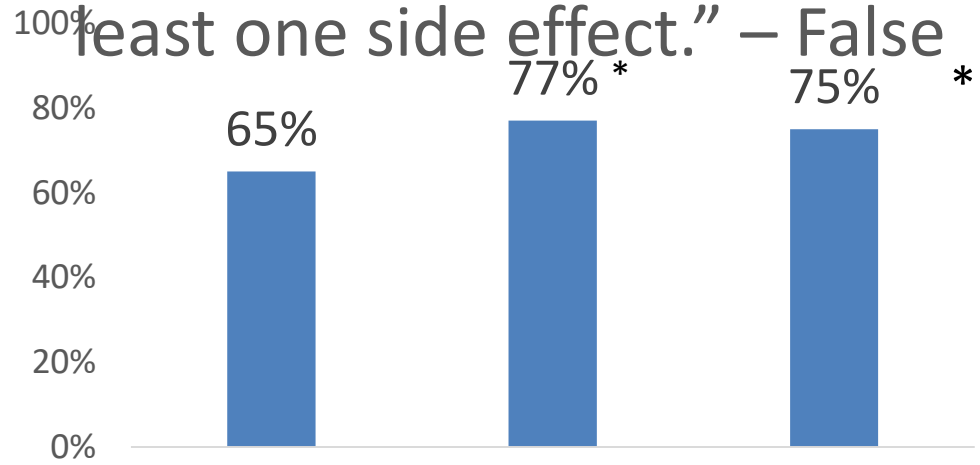
Vistasin’s most common side effects occur in what percent of people who take it?”

- Correct answer: 6-10%

Vistasin’s least common side effects occur in what percent of people who take it?”

- Correct answer: < 1%

“Almost everyone who takes Vistasin will experience at least one side effect.” – False



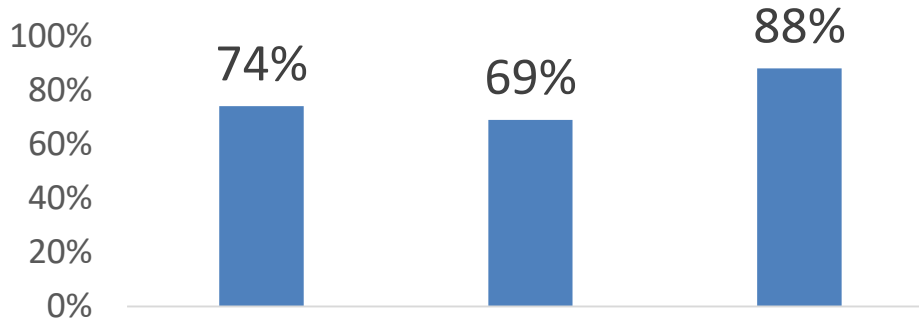
o quantitative representation of general risk  
 o quantitative representation of specific risk  
 o quantitative representation of specific presentation

\* =  $p < .017$

“Some of Vistasin’s side effects are more likely to occur than others.”

\*^

– True

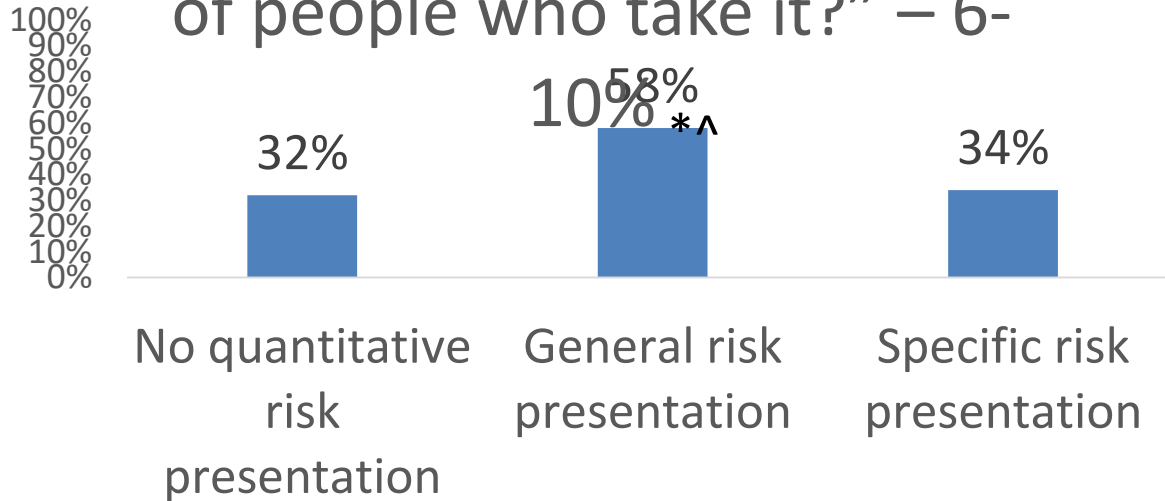


↓ quantitative comparison

\* =  $p < .017$

^ =  $p < .017$

“Vistasin’s most common side effects occur in what percent of people who take it?” – 6-

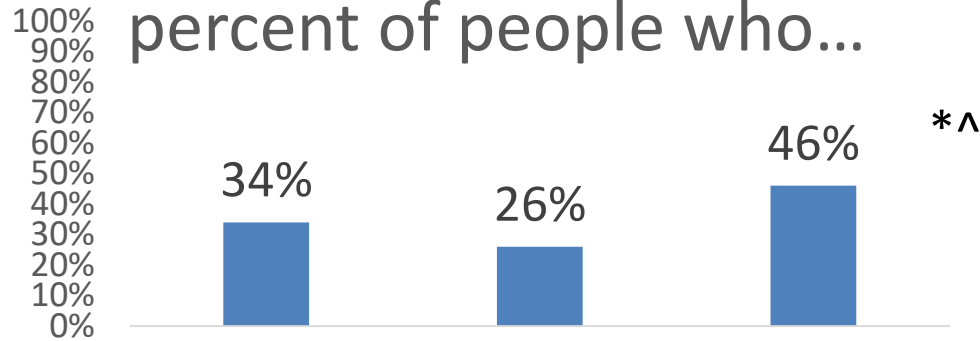


\* =  $p < .017$

^ =  $p < .017$



# “Vistasin’s least common side effects occur in what percent of people who...



o quantitative    general risk    specific risk presentation

\* =  $p < .017$

^ =  $p < .017$

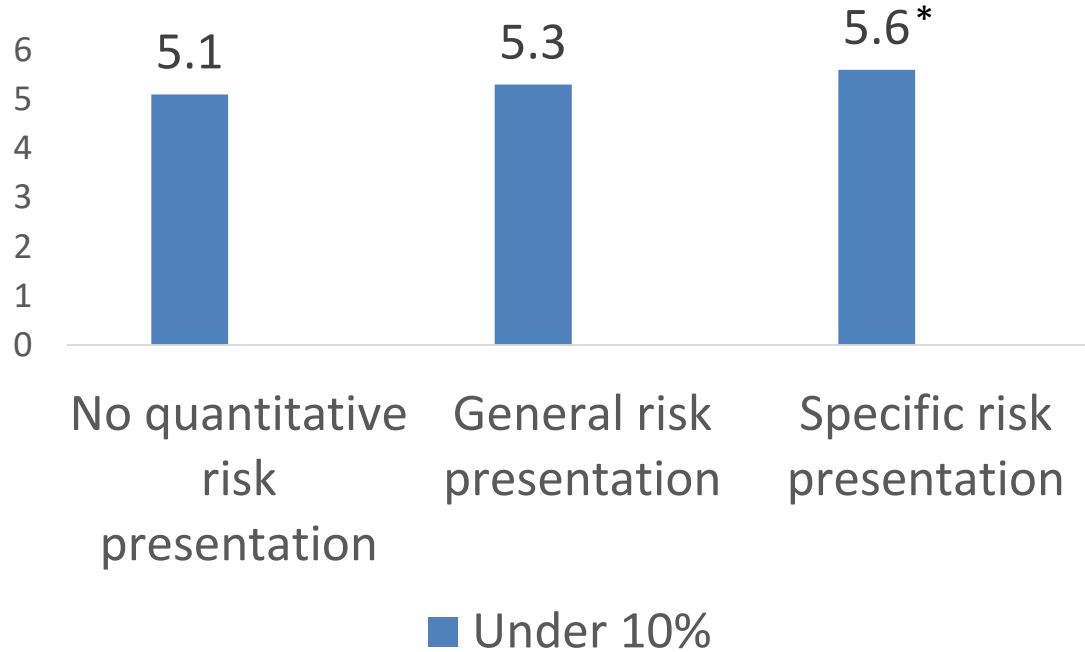
# Verbatim Memory



Side effect occurs in \_\_\_\_ of people who take Vistasin.

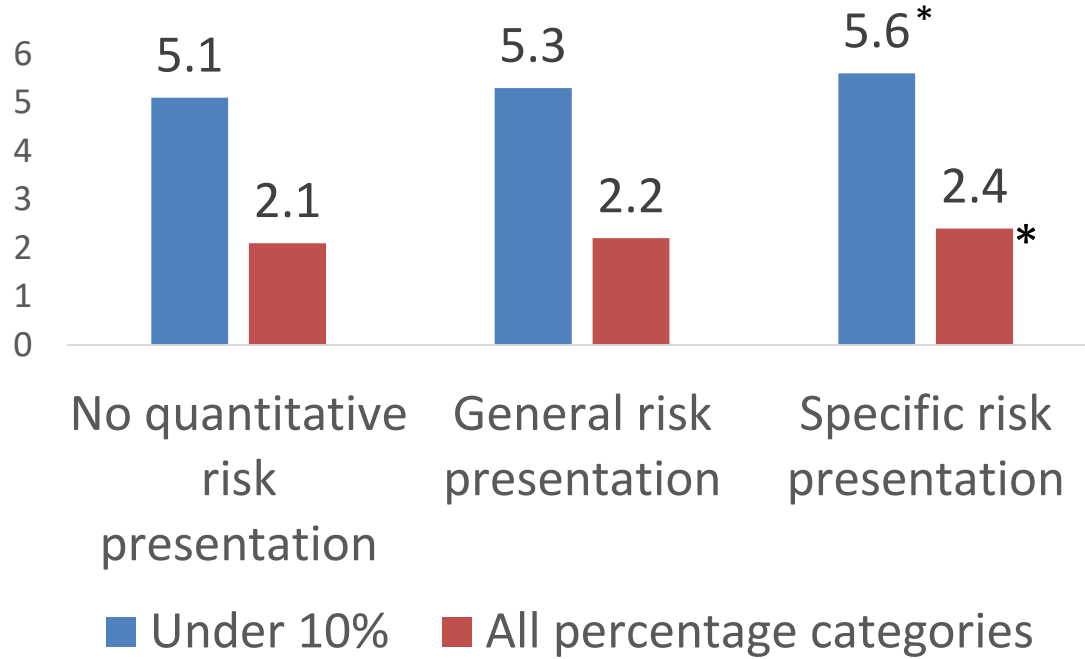
<b>Side Effect</b> %	<b>Less than 1%</b>	<b>1%-5%</b>	<b>6-10%</b>	<b>11-15%</b>	<b>16-20%</b>
Watery Eyes			X		
Runny Nose			X		
Fever		X			
Loss of Depth Perception		X			
Double Vision	X				
Detached Retina	X				

# Verbatim Memory



\* =  $p < .017$

# Verbatim Memory



\* =  $p < .017$

# Perceived Risk

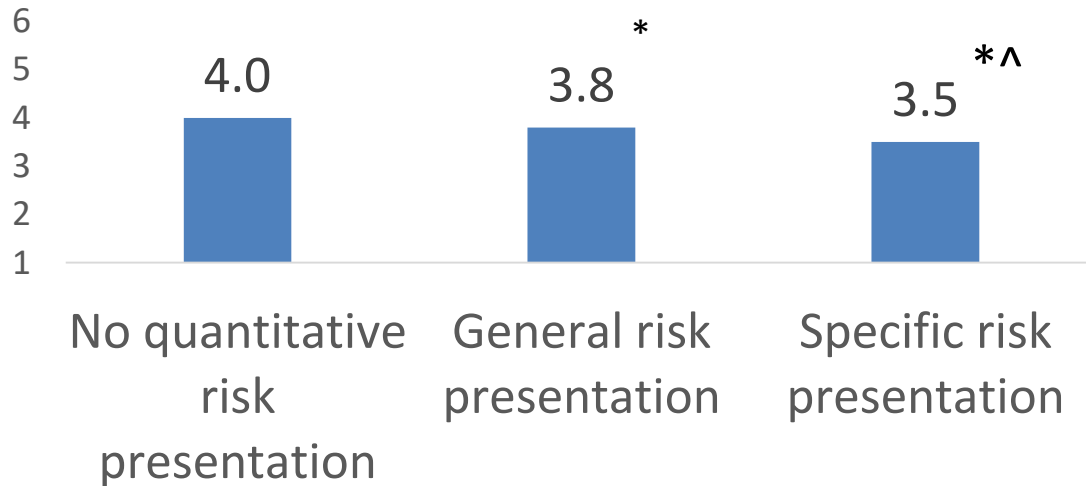
Vistasin is riskier than other treatments for cataracts.

How serious are Vistasin's side effects?

How bothersome would Vistasin's side effects be?

1      2      3      4      5      6  
← Less risky      more risky →

# Perceived risk (1 = lower risk, 6 = higher risk)



\* =  $p < .017$

^ =  $p < .017$

# Limitations

- One ad
- One medical condition
- Participants were at-risk, but did not all have the medical condition

# Summary

- Consumers can process quantitative information about a drug's risks in DTC TV ads.
- Specific risk information may help consumers have a better understanding of a drug's safety profile.



