

The Role of Social Science in Prescription Drug Promotion at FDA

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Coalition for Healthcare Communication

This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

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, compliance, and educational programs
- Foster better communication of information to help patients and healthcare providers make informed decisions about treatment options

OPDP Social Science Research



- Active research program designed to investigate issues of relevance to direct-to-consumer (DTC) and professional promotional prescription drug materials.
- Utilize a number of different research methodologies.



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 Help Identify Issues and Solutions

- 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:
 - 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
 - Promotion and message elements
 - Description of disease characteristics
 - Product characteristics
 - Other elements

Focus of OPDP's Research Studies (cont.)



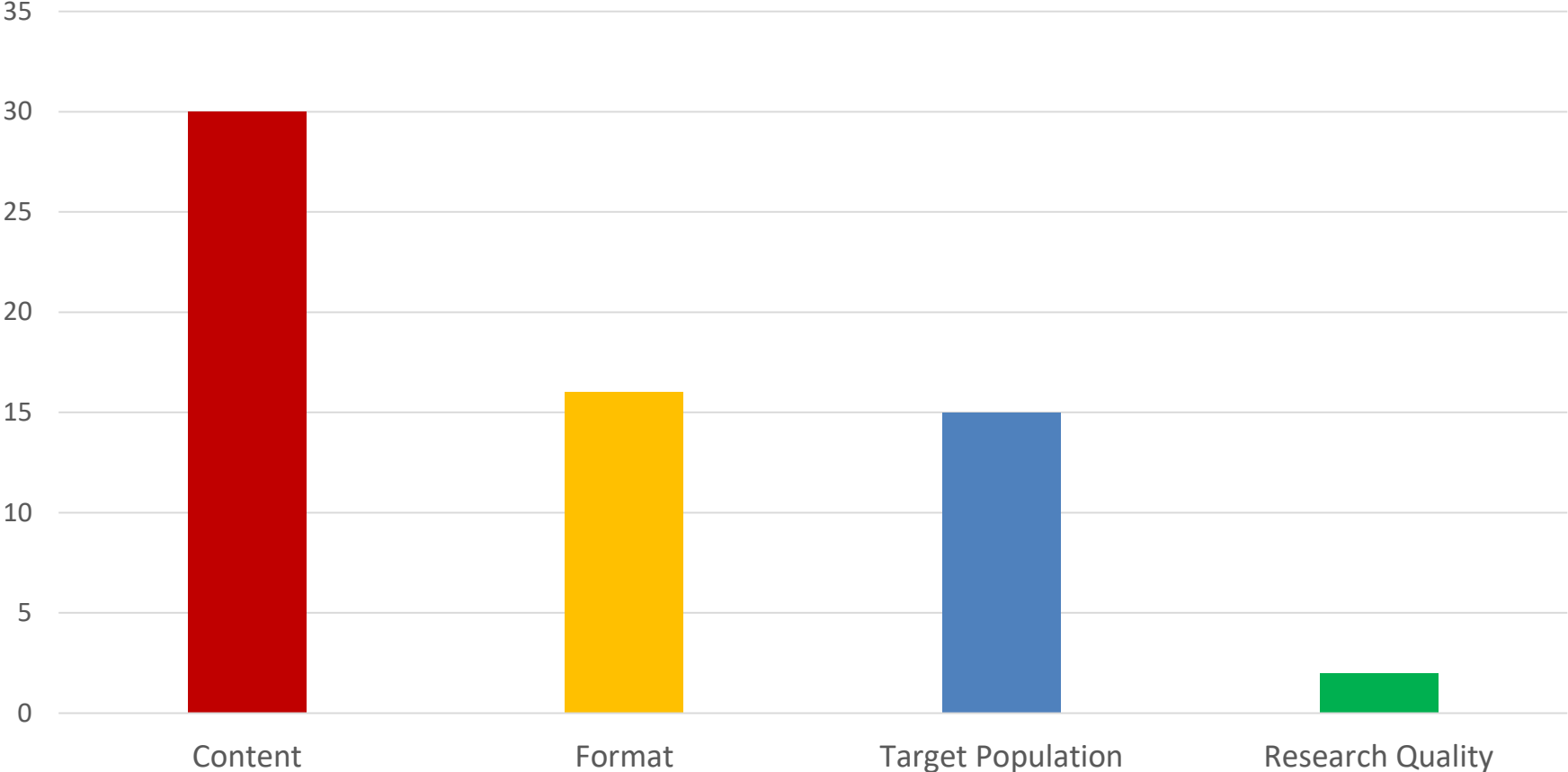
- Target Population
 - How does understanding of prescription drug product risks and benefits vary as a function of audience?
 - Variables include:
 - Literacy
 - Education
 - Age

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

Number of Studies by Topic Area, 1999-2018



OPDP Social Science Research Methods

Research Methods

Cognitive
interviews

Pretesting

Literature
reviews

Content
analyses

Interviews
& focus groups

Surveys

Experiments

Cognitive Interviews

- Cognitive interviews involve “administration of draft survey questions while collecting additional verbal information about the survey responses, which is used to evaluate the quality of the response or to help determine whether the question is generating the information that its author intends.”¹
- Cognitive interviews inform later stages of the research, particularly the development of measures and stimuli.

Cognitive Interviews

Sample findings from **Betts et al., 2018**¹ cognitive interviews:

Challenge: “Many participants struggled with the idea of basing their responses on their *impression* from the ad. Some based their responses on exactly what the ad said, meaning that if the ad did not directly address the answer to the question, they did not know how to answer it. Others did not know how to answer because they had no personal experience with the advertised drug.”²

Proposed solution: “We have recommended several revisions to the script throughout the annotated survey that will make the directions more explicit and address possible barriers to answering questions.”

Result: “Most people do not know how a prescription drug will affect them until they have taken the drug. But we would like you to make your **best guess** based on the [name of drug] ad you just saw.”

¹ Betts, K.R., Boudewyns, V., Aikin, K.J., Squire, C., Dolina, S., Hayes, J.J., & Southwell, B.G. (2018). **Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements.** *Research in Social and Administrative Pharmacy, 14*, 951-963.

²Quoted material on slides 14 - 16 is from a cognitive interview report drafted by RTI International.

Pretesting

- Pretesting involves experimenting with (varying) different components of the questionnaire, stimuli, or survey design prior to full-scale implementation.
- Like cognitive interviews, pretesting informs later stages of the research, particularly the development of measures, stimuli, and procedures.

Pretesting

- Sample findings from **Betts et al., in press**¹ pretesting:
 - “...both locations had difficulty finding participants with lower levels of education. In RTP, the recruiter has begun working with her marketing team to develop the database of lower education respondents so they are prepared for the main study round. In addition, they will attempt to recruit those individuals first in order to have more flexibility in the schedule (more open time slots) with which to accommodate them. We will be asking that DC implement similar strategies.”²

¹ Betts, K.R., Aikin, K.J., Kelly, B.J., Johnson, M., Parvanta, S., Southwell, B.G., Mack, N., Tzeng, J., & Cameron, L. (in press). **Taking repeated exposure into account: An experimental study of direct-to-consumer prescription drug television ad effects.** *Journal of Health Communication.*

² Quoted material drawn from the pretest report drafted by RTI International.

Literature Reviews



- “A critical evaluation of material that has already been published.”¹
- Used to...
 - inform development of hypotheses, stimuli, measures, etc.
 - sometimes serve as a research outcome in their own right

¹ APA Manual, 6th Edition

Content Analyses

- Critical evaluation of promotional materials in the marketplace.
- Inform both our general understanding of what happens in the marketplace as well as stimuli development for future research projects.

Interviews and Focus Groups

- Provide in-depth, qualitative data about knowledge and perceptions.
 - Questionnaires are typically semi-structured.¹
 - Used to inform our thinking and approaches to later survey and experimental research.

¹ Harrell, M.C., & Bradley, M.A. (2009). *Training manual: Data collection methods: Semi-structured interviews and focus groups*. RAND: National Defense Research Institute.

Interviews and Focus Groups



- Shown above is a sample interview room with one-way mirror at Shugoll Research in Bethesda, MD.
- Interviews and focus groups may also be conducted remotely.

Surveys

- Provide insights on consumer and healthcare professional knowledge, attitudes, and perceptions.
- Often allow for nationally representative estimates.¹

¹ Heeringa, S.G., West, B.T., & Berglund, P.A. (2017). *Applied Survey Data Analysis: Second Edition*. Boca Raton, FL: CRC Press.

Experiments

- Use random assignment to condition to test causative hypotheses.
- Objective is to estimate causal effects of experimental manipulations rather than to provide descriptive estimates for populations.

Potential Outcomes

Publications

Guidance

Rulemaking

Other
Regulatory
Actions

Selected Study Results: Risk Information in DTC

Revised risk statement (serious and actionable risks only) in TV ads improved risk recall and recognition and improved benefit recognition. Presence of a disclosure did not adversely affect consumers' processing of drug risk and benefit information.(1)

Distracting elements during the major statement in TV ads decreased attention (as measured by eye tracking) to the superimposed risk text, which led to lower retention of the drug risk information. (2)

Location of risk information on prescription drug websites affected consumers' risk knowledge, suggesting that risk information is more effective when located on the homepage. No significant effects for including a signal to the risk information or for paragraphs versus bulleted lists of risks.(3)

In an analysis of data across studies, we found that some consumers interpreted precautions on prescription drug websites as potential side effects.(5)

Framing the summary of risks as "Important Safety Information" or "Important Risk Information" does not differentially affect consumer risk perception. (12)

Selected Study Results: Risk Information in DTC (con't.)



The addition of a serious risk to the display page of an ad and the addition of frequency and duration information about side effects in the brief summary did not negatively affect the understanding of the risk information as a whole, including the most serious warnings and precautions. (15)



Selected Study Results:

Quantitative Efficacy Information in DTC

Consumers are not familiar with the concept of composite scores but informing them about composite scores increases their understanding of them and influenced perceptions. (9)

The majority of participants who viewed numeric data were able to accurately report it. People provided with absolute frequencies and percentages were able to use this numeric data to report benefit and risk information regardless of whether they also saw absolute differences or qualitative information. (10)

Adding placebo rates to DTC ads may be useful for consumers, whereas the evidence does not support the use of mixed frames. (11)

Providing quantitative benefit information in DTC ads increased participants' ability to accurately report the benefits of the drug in quantitative terms. Further, adding visual aids, in particular bar charts and tables, increased participants' ability to accurately report the drug's benefits. (13,14)

Selected Study Results: Websites and Social Media

Analysis of content and format of mobile communications indicates while risks and benefits are both represented in mobile communications and their associated landing pages, they are not equally prominent and accessible. (4)

Analysis of inclusion and presentation of quantitative information about drug benefits and risks on oncology drug websites for consumers and healthcare professionals indicates both website types include quantitative information about oncology drugs and, in particular, about the benefits of these drugs. (5)

Individuals use online health communities to obtain more information about their health in addition to their communication with, and reliance on, their healthcare providers. These findings suggest that individuals use peer-generated health information (PGHI) in much the same way they use traditional online health information; PGHI facilitates, rather than obstructs, shared decision making with health care providers. (6, 7)

Consumers who saw a prescription drug website with a link to a disease information website confused drug benefits and disease information, even when disclosures explained that the disease information website was external. (8)

Recap

- OPDP's social science research program includes survey research and experimental research, as well as qualitative research for development purposes.
- OPDP research priorities are:
 - Factors that affect communication of risk and benefit information
 - Target populations
 - Research quality
- For more information, including details about methods implemented, consult our webpage at:
<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm>



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>

Referenced OPDP Studies

1. Betts, K. R., Boudewyns, V., Aikin, K. J., Squire, C., Dolina, S., Hayes, J. J., & Southwell, B. G. (2018). Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements. *Research in Social and Administrative Pharmacy, 14*(10), 951-963.
2. Sullivan, H. W., Boudewyns, V., O'Donoghue, A., Marshall, S., & Williams, P. A. (2017). Attention to and distraction from risk information in prescription drug advertising: An eye-tracking study. *Journal of Public Policy & Marketing, 36*(2), 236-245.
3. Sullivan, H.W., O'Donoghue, A.C., Rupert, D.J., Fitts Willoughby, J., & Aikin, K.J. (2017) Placement and Format of Risk Information on Direct-to-Consumer Prescription Drug Websites, *Journal of Health Communication, 22*(2), 171-181,
4. Aikin, K. J., Sullivan, H. W., Dolina, S., Lynch, M., & Squiers, L. B. (2017). Direct-to-consumer promotion of prescription drugs on mobile devices: Content analysis. *Journal of medical Internet research, 19*(7), e225.
5. Sullivan, H. W., Aikin, K. J., & Squiers, L. B. (2018). Quantitative information on oncology prescription drug websites. *Journal of Cancer Education, 33*(2), 371-374.
6. Rupert, D. J., Moultrie, R. R., Read, J. G., Amoozegar, J. B., Bornkessel, A. S., O'Donoghue, A. C., & Sullivan, H. W. (2014). Perceived healthcare provider reactions to patient and caregiver use of online health communities. *Patient education and counseling, 96*(3), 320-326.
7. Rupert, D.J., Gard Read, J., Amoozegar, J.B., Moultrie, R.R., Taylor, O.M., O'Donoghue, A.C., & Sullivan, H.W. (2016) Peer-Generated Health Information: The Role of Online Communities in Patient and Caregiver Health Decisions. *Journal of Health Communication, 21*(11), 1187-1197.

Referenced OPDP Studies (con't.)



8. Sullivan, H.W., O'Donoghue, A.C., Rupert, D.J., Fitts Willoughby, J., Amoozegar, J.B. & Aikin, K.J. (2016) Are Disease Awareness Links on Prescription Drug Websites Misleading? A Randomized Study. *Journal of Health Communication*, 21(11), 1198-1207.
9. Williams, P.A., O'Donoghue, A.C., Sullivan, H.W., Fitts Willoughby, J., Squire, C., Parvanta, S., Betts, K.R. (2016). Communicating efficacy information based on composite scores in direct-to-consumer prescription drug advertising. *Patient Education and Counseling*, 99(4), 583-590
10. Sullivan, H.W., O'Donoghue, A.C. & Aikin, K.J. (2015). Communicating Benefit and Risk Information in Direct-to-Consumer Print Advertisements: A Randomized Study. *Therapeutic Innovations and Regulatory Science*, 49(4), 493-502.
11. O'Donoghue, A.C., Sullivan, H.W., & Aikin, K.J. (2014). Randomized Study of Placebo and Framing Information in Direct-to-Consumer Print Advertisements for Prescription Drugs. *Annals of Behavioral Medicine*, 48(3), 311-322.
12. O'Donoghue, A.C., Sullivan, H.W., Aikin, K.J., & Betts, K.R. (2013). Important Safety Information or Important Risk Information? A Question of Framing in Prescription Drug Advertisements. *Therapeutic Innovations and Regulatory Science*, 48(3), 305-307.
13. O'Donoghue, A. C., Sullivan, H. W., Aikin, K. J., Chowdhury, D., Moultrie, R. R., & Rupert, D. J. (2014). Presenting efficacy information in direct-to-consumer prescription drug advertisements. *Patient Education and Counseling*, 95(2), 271-280.
14. Sullivan, H. W., O'Donoghue, A. C., Aikin, K. J., Chowdhury, D., Moultrie, R. R., & Rupert, D. J. (2016). Visual presentations of efficacy data in direct-to-consumer prescription drug print and television advertisements: A randomized study. *Patient Education and Counseling*, 99(5), 790-799.



Referenced OPDP Studies (con't.)

15. Aikin, K.J., O'Donoghue, A.C., Swasy, J.L., & Sullivan, H.W. (2011). Randomized Trial of Risk Information Formats in Direct-to-Consumer Prescription Drug Advertisements. *Medical Decision Making*, 31(6), E23-E33.

