

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

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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



FDA Organization

Office of the
Commissioner



**Center for
Food
Safety &
Applied
Nutrition**

**Center for
Drug
Evaluation &
Research**

**Center for
Biologics
Evaluation &
Research**

**Center for
Devices &
Radiological
Health**

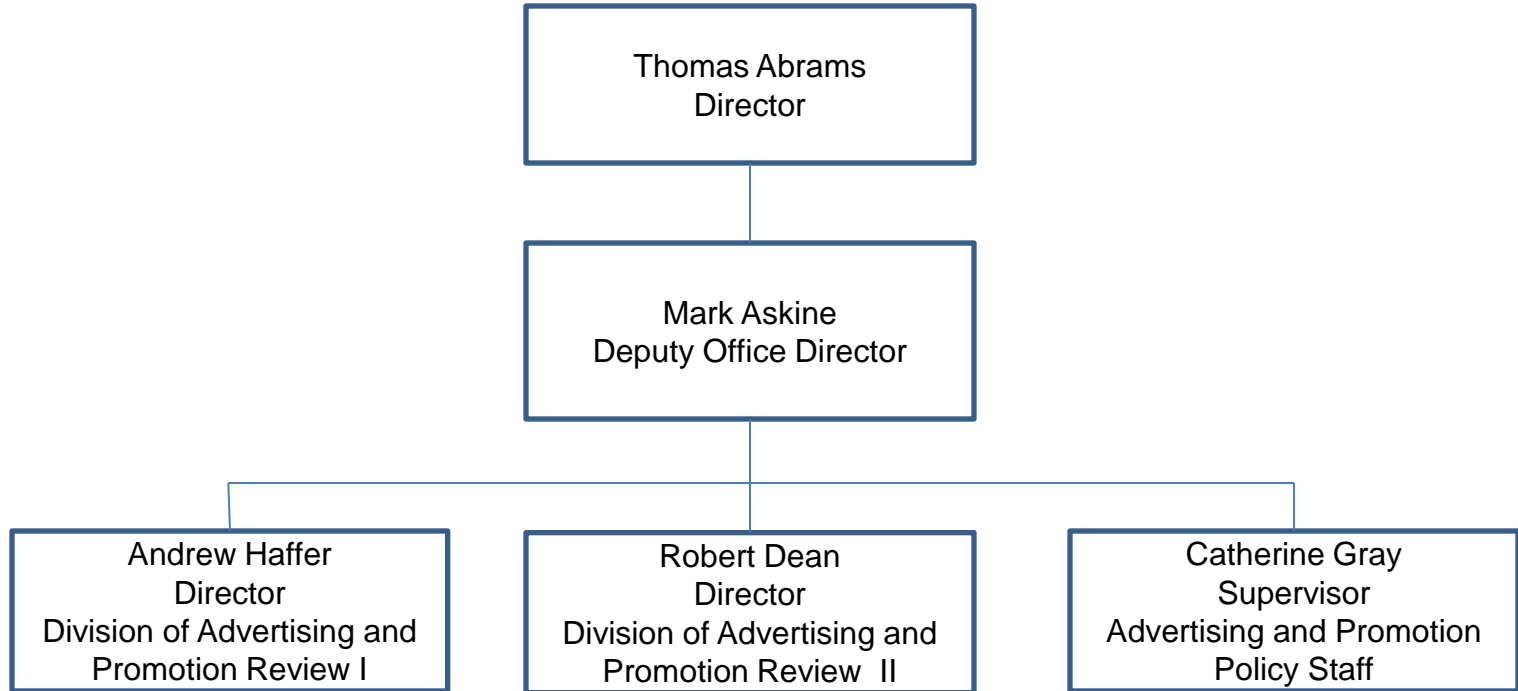
**Center for
Veterinary
Medicine**

**National
Center for
Toxicological
Research**

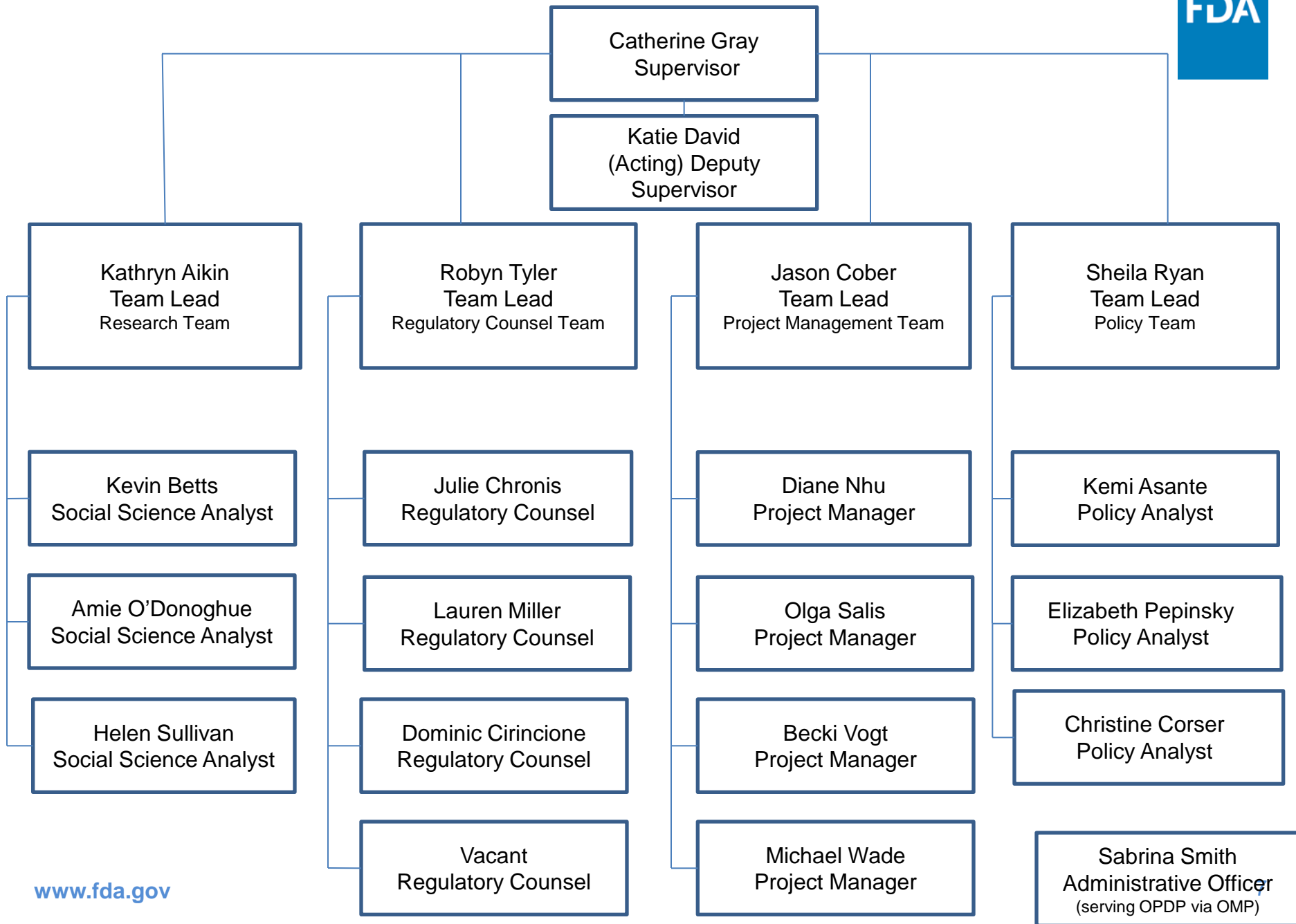
**Center for
Tobacco
Products**

**Office of
Regulatory
Affairs**

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, such as cost or comparative information

Focus of OPDP's Research Studies (cont.)

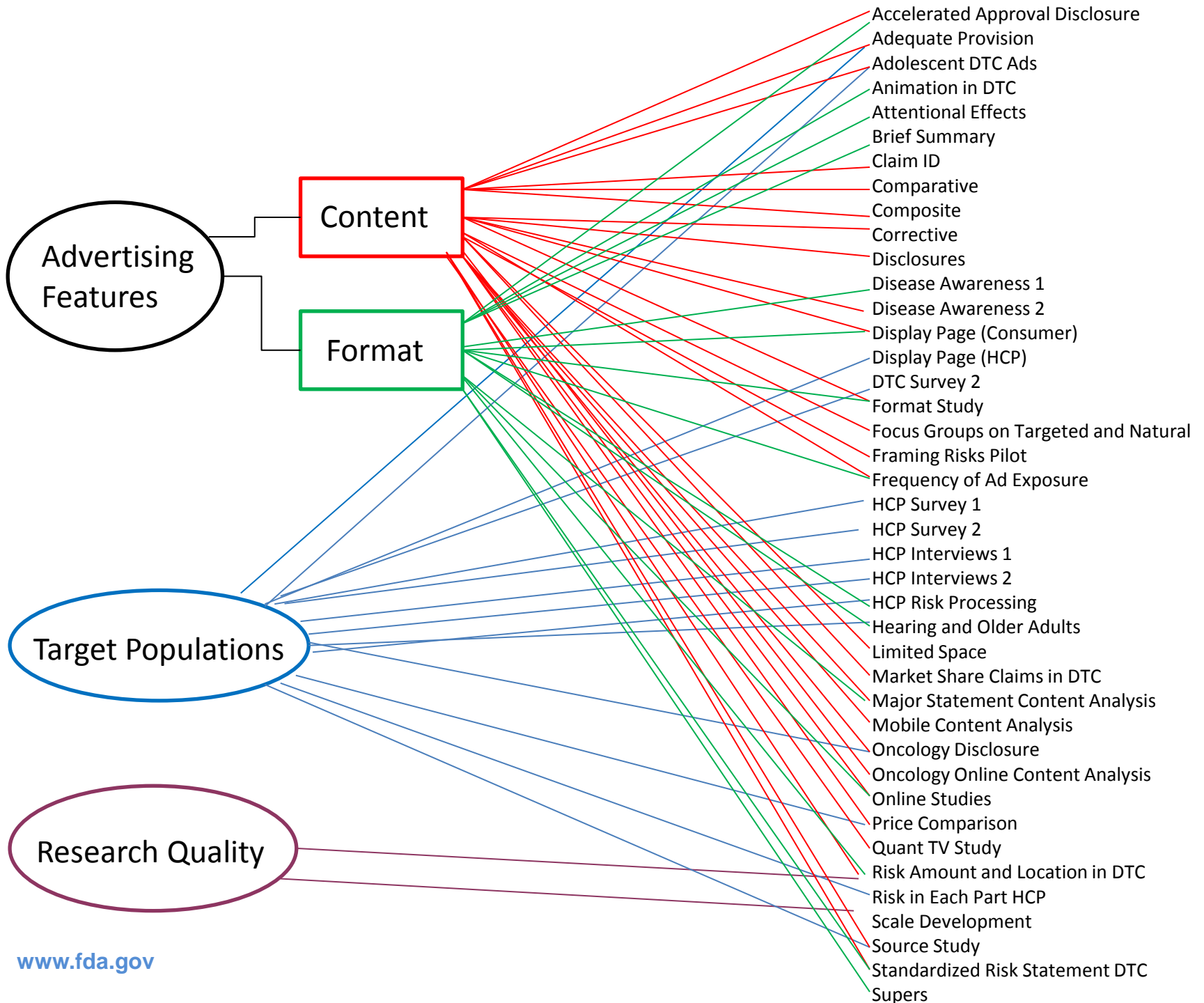
- Target Population
 - How does understanding of prescription drug product risks and benefits vary as a function of audience?
 - Variables include:
 - Literacy
 - Education
 - Age

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





Sneak Peek at Upcoming Research

- Focus groups
- Surveys
- Experimental studies

Interpretation of Claims in Scientific Publications vs. Promotional Pieces

- Subject matter: Investigate the impact of information context, information quality, and presentation of FDA approval status in healthcare professional prescription drug promotion.
- Description:
 - Three types of context (medical journal, sales aid without graphic design elements, sales aid with graphic design elements)
 - Two types of study quality (classified as high or low)
 - Presence of a sentence saying the product is approved by FDA (present, absent).
- We will test promotional (sales aid) and non-promotional (journal) sources to examine the potential differences in perception that may arise by presenting the same information in different contexts.

Disease Awareness and Product



Promotion in DTC Television Ad Contexts

- Subject matter: Test the effects of similarity, positioning, and timing of disease awareness ads on consumer perception and understanding of direct-to-consumer (DTC) product ads.
- Description: In two studies, we will examine the impact of –
 - Perceptual similarity between target ads (disease awareness and product promotion)
 - Distance between target ads over the course of programming
 - Exposure frequency and delay.

Healthcare Professional Survey of Prescription Drug Promotion



- Subject matter: Healthcare professional promotion of prescription drugs
- Description: A nationally representative sample of HCPs will be recruited online to answer questions about their opinions, attitudes, beliefs, and intentions regarding pharmaceutical promotion directed at them.



Focus Groups Examining Accelerated Approval Information

- Subject matter: Consumer understanding of information about the accelerated approval process.
- Description:
 - Eight focus groups
 - Focus group moderator will explain the accelerated approval process to participants and ask for their perceptions and reactions.
 - Focus groups will explore the types of information participants would like to have when making decisions about prescription drugs.

Experimental Study of an Accelerated Approval Disclosure

- Subject matter: Examine utility and consumer comprehensibility of a disclosure explaining the drug's accelerated approval
- Description:
 - Participants will view a website for a fictional oncology prescription drug and then complete a questionnaire that assesses their attention to and understanding of the product's accelerated approval information.
 - Websites will vary the presence, prominence, and readability of an accelerated approval disclosure.

Healthcare Professional Interviews: Risk Processing for Newly Promoted Drugs



- Subject matter: Healthcare professional promotion of prescription drugs
- Description:
 - Study how HCPs process risk information for newly promoted prescription drug products, including any impact of typical time constraints.
 - The research methodology will involve in-person, semi-structured interviews with practicing HCPs.
 - The study will assess attention to risk information in a mock promotional piece using eye-tracking technology.



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>

