



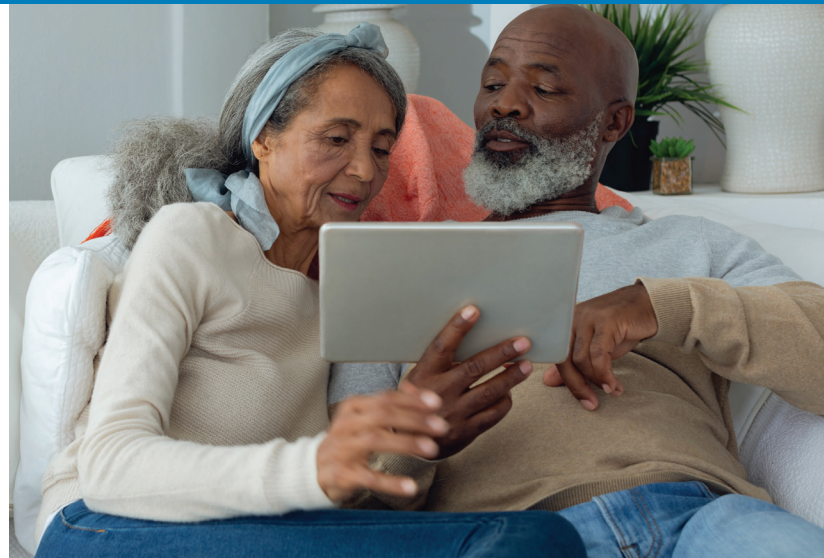
THE SOCIAL SCIENCE RESEARCH TEAM

IN THE OFFICE OF PRESCRIPTION
DRUG PROMOTION (OPDP)

RIGOROUS RESEARCH IN
SERVICE OF PUBLIC HEALTH

THE MISSION OF OPDP

Protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated



Guard against false or misleading prescription drug promotion through comprehensive surveillance, compliance, and educational programs



Foster better communication of labeling and promotional information to both healthcare providers and consumers



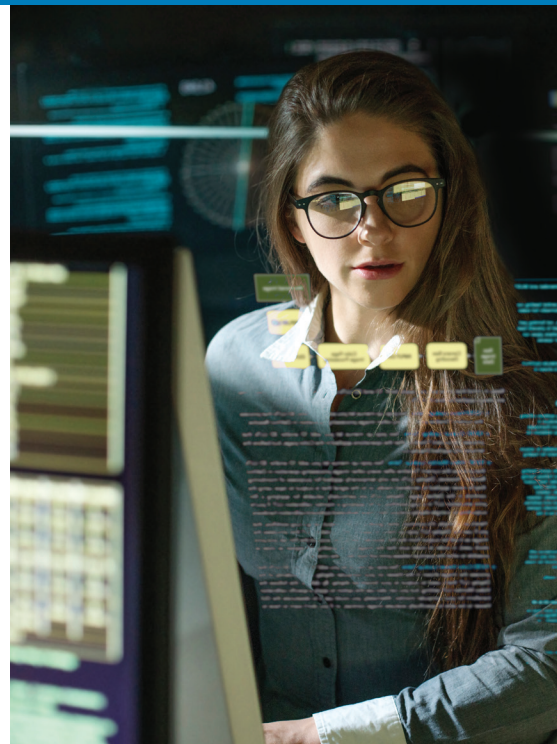
OUTCOMES OF OUR RESEARCH

1. PEER-REVIEWED PUBLICATIONS
2. GUIDANCE AND POLICY DEVELOPMENT
3. RULEMAKING
4. OTHER REGULATORY ACTIONS

ROLE OF THE RESEARCH TEAM IN THIS MISSION

I. PROVIDE SCIENTIFIC EVIDENCE AND ADVICE TO HELP ENSURE THAT OPDP'S POLICIES HAVE THE GREATEST BENEFIT TO PUBLIC HEALTH

- Investigate issues relevant to healthcare provider 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



II. APPLY SOCIAL SCIENCE AND COMMUNICATION PRINCIPLES TO OPDP'S:

- Guidance and policy development
- Rulemaking
- Surveillance and compliance activities
- Research
- Advice to FDA stakeholders:
 - The OPDP research team provides technical assistance on the design and implementation of studies concerning prescription drug promotion.



III. HELP IDENTIFY ISSUES AND SOLUTIONS:

- Help identify goals (for example, improved consumer understanding of drug benefits and risks, improved health outcomes) and barriers to achieving goals
 - Cognitive barriers (capacity, motivation, attention)
 - Behavioral barriers (time, opportunity)
- Identify potential solutions
- Test and verify effectiveness of solutions



OUR RESEARCH FOCUS

The OPDP Social Science Research Team conducts research to evaluate the aspects of prescription drug promotion most central to OPDP's mission, focusing in particular on three main topic areas: Advertising Features, including content and format; Target Populations; and Research Quality.

1. ADVERTISING FEATURES: Through the evaluation of advertising features, including content and format, we assess how elements such as graphics, layout, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits.



2. TARGET POPULATIONS: Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience.

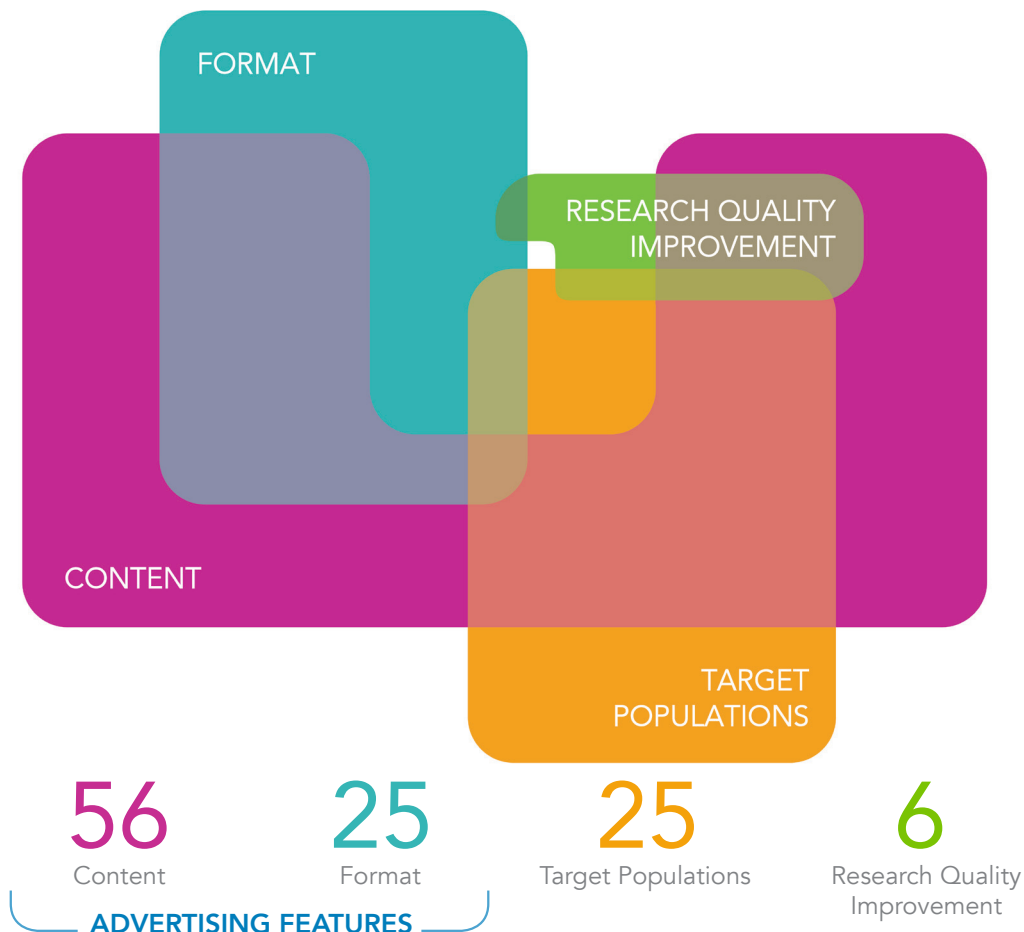


3. RESEARCH QUALITY: Our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues.



NUMBER OF OPDP RESEARCH PROJECTS BY TOPIC AREA

Between 1999 and 2021, OPDP led 74 research projects. Many of these research projects address more than one topic area. The visual below is an approximation of the overlap between topic areas.



OUR RESEARCH METHODS



The research team uses a variety of methodological approaches to address research questions. These range from qualitative, formative research methods, such as cognitive interviews and focus groups, to rigorous experimental studies with random assignment that provide the ability to determine causality. These methods are briefly described below.

We often conduct qualitative research before investing in quantitative research. Qualitative research involves obtaining more in-depth responses from individuals, including how and why they feel a certain way about something. A small number of participants are questioned in these studies and we are able to get a fuller picture of how people may respond to prescription drug issues. They provide essential information for the development of research questions, methodologies, and approaches.



Examples of qualitative research include “cognitive interviews” in which participants are often asked to think aloud and describe their thought process as they view study materials and answer a draft questionnaire. These interviews are used to determine whether concepts and items are understood by study participants in the same way that the researchers intend. Sometimes a study involves a series of one-on-one interviews, such as with physicians, to obtain in-depth information about a topic that FDA may want to pursue in future research. We also conduct focus groups, where we bring a small group of

of people together in a room or online to discuss a particular topic. These groups are helpful in assessing the way individuals think about topics that regulators are evaluating, and in some cases, the group format can facilitate new research ideas.

After qualitative research has been conducted, we may move into quantitative research which allows us to make some conclusions about larger numbers of people. We may use a variety of quantitative methods. Surveys provide insights on consumer and healthcare provider knowledge, attitudes, and perceptions and often allow for nationally representative estimates. In most cases, however, surveys only provide us with information on the state of current opinion and some correlations. In order to make cause and effect conclusions about why something occurs, we conduct research employing the experimental method. By randomly assigning participants to different test conditions, we can estimate causal effects of experimental manipulations. For example, we may show participants the same ad except for one statement about side effects, which differs in three ways. In that case, by keeping all other aspects of the ad the same, and by randomly assigning participants to see one of the three statements, we could conclude that any findings are likely a result of the difference in the statement.



We also use a variety of other research methods, including literature reviews, which are a critical evaluation of material that has already been published, and content analyses, which are critical evaluations of promotional materials in the marketplace.

MEET THE TEAM



KATHRYN J. AIKIN, PhD, is a Senior Social Science Analyst and Research Team Lead. Dr. Aikin's research focuses on communication of information in prescription drug promotional messages directed to consumers and healthcare providers, and the development of FDA guidance and regulation. A graduate of Oberlin College (BA, Psychology) and Penn State University (PhD, Social Psychology), she is a frequent speaker at academic and professional conferences and has authored numerous publications on prescription drug promotion-related topics.



KEVIN R. BETTS, PhD, is a Social Science Analyst. Dr. Betts plans and directs social science research studies and provides consultation pertaining to promotional prescription drug communications. His research has covered topics such as misinformation detection and reporting capabilities among both consumers and healthcare providers, and strategies for improving the communication of prescription drug risks and side effects. Dr. Betts received his PhD in Health/Social Psychology from North Dakota State University.



AMIE C. O'DONOGHUE, PhD, is a Social Science Analyst. She has published over 40 articles on professional and direct-to-consumer (DTC) advertising and the communication of information to physicians and consumers. She also provides technical assistance on research and communication issues to FDA staff and external organizations. Before joining OPDP, Dr. O'Donoghue taught psychology at St. Mary's College of Maryland. She received her doctorate in Psychology from Washington University in St. Louis.



HELEN SULLIVAN, PhD, MPH is a Social Science Analyst. Dr. Sullivan's research examines the communication of prescription drug information to consumers and healthcare providers. Major research topics include online prescription drug promotion and communicating quantitative drug efficacy and risk information. Prior to joining FDA, she was a Cancer Prevention Fellow at the National Cancer Institute. She received her BA from Yale University; her PhD in Social Psychology from the University of Minnesota, Twin Cities; and her Master of Public Health from Johns Hopkins Bloomberg School of Public Health.



For more information on our current and past research projects, please visit:

<https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research>