



## The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion  
NEWSLETTER

### IN THIS EDITION

- [Gray Matters](#)
- [Getting to Know OPDP - The Social Science Research Team](#)
- [Staff Spotlight - Amie O'Donoghue](#)
- [Informing and Refining the Prescription Drug Promotion Research Agenda](#)
- [The OPDP Research Team Website](#)
- [Where is OPDP](#)

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Office Director  
Dr. Catherine (Katie) Gray

### Gray Matters

Middle school. Throwing out those two words probably conjures a spectrum of memories, and I venture to say not all will be amazing ones. Mixed in with all that social awkwardness, I was lucky enough to have a middle school experience full of science. Science experiments, science classes, science-based field trips and the all-engrossing science projects. It was the scientific method on repeat. And it was fabulous. I discovered the power of the organized and structured investigation. I learned how to narrow queries and control variables, always striving for clean and clear results. Part of the learning process was discovering that results weren't always clean and clear. But the results always offered something – a confirmation, a prompt for more work, a new question.

My twelve-year-old self never imagined that my dream job would include the privilege of working with an entire team of social scientists that harnesses the scientific method to advance public health. OPDP's highly skilled social science team pursues answers to many questions about how to communicate truthful and non-misleading

**OPDP Facts:** The Social Science Research Team has 75 years combined experience in the Office of Prescription Drug Promotion.

prescription drug information to healthcare providers and consumers. This edition of *TBS* will take a deeper dive into the team and their work and connect the dots between their scientific findings and OPDP's mission.

You may have also noticed that OPDP's structure has officially changed. OPDP now includes a third division, the Division of Promotion Policy, Research and Operations (DPPRO). The Division will allow our staff to better organize and align their efforts in pursuing a research and policy development pipeline to address and investigate issues critical to stakeholders in the field of prescription drug promotion. FDA is a science-based organization. This reorganization and OPDP's long-established social science program underscore that science is a guiding principle for OPDP. Enjoy learning more about the role of social science at OPDP as you peruse this month's *TBS*.

Best,

kgb



On February 11, 2022, OPDP issued a Warning Letter (WL) to Cytodyn Incorporated regarding the company's Investigational New Drug (IND) for leronlimab. The WL is posted on the FDA Warning Letter [webpage](#). A copy of the WL can be found [here](#).



**THE SOCIAL SCIENCE  
RESEARCH TEAM**



**Getting to Know OPDP - The Social Science Research Team**

The OPDP Social Science Research Team and their collaborators develop and apply rigorous experimental methods to advance the Agency's understanding of how consumers and health care providers perceive and respond to prescription drug promotion. The insight gained by this research can help inform policy development, enhance review of drug promotion, and ultimately help consumers and health care providers make informed health decisions.

The Social Science Research Team is led by Senior Social Scientist Kathryn (Kit) Aikin, PhD and is comprised of three Social Scientists: Kevin Betts, PhD, Amie O'Donoghue, PhD, and Helen Sullivan, PhD, MPH. The Team utilizes several different research methodologies, including survey and experimental research, as well as qualitative research for development purposes.

The Social Science Research Team has published several outreach pieces highlighting their ongoing research efforts:

- In 2021, OPDP published a Social Science Research [brochure](#) which provides an overview of the OPDP Research Mission, the role of the Social Science Research Team in service of this mission, and the outcomes of the team's research projects. The brochure also discusses the Social Science Research Team's methods, focus, and research topics. The brochure serves as an introduction to the OPDP Social Science Research Team and is intended to provide OPDP stakeholders with insight into the methods, objectives, and results of the team's research.
  - In 2017, Dr. Aikin was featured in CDER's "Scientists in Their Own Words." Dr. Aikin's [video](#) discusses how social scientists ensure that communications about prescription drugs are truthful, balanced, and not misleading.
  - In August 2021, FDA published an [article](#) titled "Advancing Our Understanding of How Drug Promotion Influences Consumers and Health Care Providers" which provided an overview of three OPDP Social Science Studies.
  - In February 2022, FDA published a "CDER Conversation" [article](#) highlighting the OPDP Social Science Research Team.
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## **Staff Spotlight**

### **Amie O'Donoghue - Social Science Analyst**

I had a choice when I graduated from college: attempt to make a living as an artist or pursue my passion for understanding human behavior. As you can see, I chose the latter. In graduate school I specialized in social and lifespan development psychology, with a focus on older adults. This set the stage for my position at OPDP, where I could influence the lives of millions of older adults – a population that is particularly vulnerable given their increased reliance on prescription drugs.



Before joining FDA, I was a Visiting Assistant Professor of psychology at St. Mary's College of Maryland. Again, faced with a choice, I left their bucolic campus and began my career at FDA. I continue to conduct research on the communication of risks and benefits of prescription drugs, accumulating over 40 publications so far. It is an honor to work for an Agency whose people care so much for improving the health and lives of Americans.

I joined OPDP (then DDMAC) in 2003 as a Social Science Analyst, the same position I hold today. This position was magically and exactly perfect for me, as it has allowed me to apply my training in social, cognitive, and health psychology as well as my firm desire to serve the public in a positive way. I continue to research fascinating topics and communicate them to colleagues in the office and outside FDA. I enjoy working with my social science colleagues, who share my passion for rigorous and meaningful research.



### **Informing and Refining the Prescription Drug Promotion Research Agenda**

On November 19, 2021, OPDP and the Duke-Margolis Center for Health Policy hosted a meeting titled “Informing and Refining the Prescription Drug Promotion Research Agenda.” The event featured opening remarks from Dr. M. Khair ElZarrad, Super Office Director for the Office of Medical Products, comments from Dr. Kit Aikin, OPDP’s Senior Social Scientist, and multiple presentations from an array of experts whose research is focused on prescription drug promotion and digital marketing. Presenters and panel members explored both current and emerging trends in drug promotion, how drug promotion can affect patient and health care provider thinking and decision making, and how to best support research at the FDA that is both impactful and actionable. A recap of the meeting is available [here](#).

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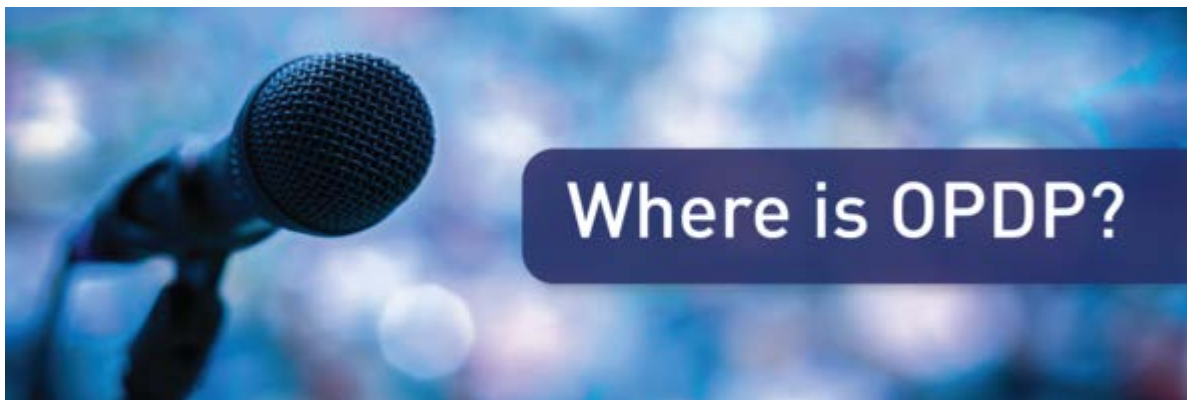
## The OPDP Research Team Website

The OPDP Research Team develops, conducts, and publishes numerous research projects each year. In 2021, OPDP restructured the Research Team website and added new search functionality to assist stakeholders. The OPDP Research [website](#) is the one-stop hub that provides stakeholders with an overview of the research team in addition to links to recent FDA publications related to OPDP research. Our research projects are displayed on the Research Team website and are separated into three categories: Completed Research, Research Pending Peer Review and Publication, and Research in Progress. Research projects under each category are grouped under separate webpages that can be accessed from the OPDP Research Team website.



OPDP research projects are added to the [Research in Progress](#) webpage in conjunction with the public availability of a 60 Day Federal Register Notice announcing the planned study and inviting public comment. Research projects will remain on the Research in Progress webpage until the completion of the study. Once a project is complete and submitted for Peer Review, the project description is moved to the [Research Pending Peer Review and Publication](#) webpage. Finally, after a research project has been peer reviewed and published, the project description is moved to the [Completed Research](#) page. This page is the largest of the three pages and includes descriptions and links to publications completed by the OPDP Research Team.

To make searching easier, especially when viewing the Completed Research page, a searchable table of contents has been added to each Research webpage. The table of contents can be filtered by entering a keyword or phrase from the Research Study Title. The table of contents will automatically filter as a user enters keywords and the user can jump to the research project by clicking on the link in the table of contents.



Be on the look-out for OPDP at the following conference sessions this month:

- **DIA Advertising and Promotion Regulatory Affairs Conference**
  - March 8, 2022 8:00 AM
  - **Katie Gray** – Welcome, Opening Remarks and Session 1: FDA Updates
- **DIA Advertising and Promotion Regulatory Affairs Conference**
  - March 8, 2022 11:55 AM-12:55 PM
  - **Jean-Ah Kang** – Pro Tip! Effective Engagement between FDA’s OPDP/APLB and Industry Leaders
- **DIA Advertising and Promotion Regulatory Affairs Conference**
  - March 9, 2022 8:45 AM-9:45 AM
  - **Kit Aikin** – Research Status Update
  - **Helen Sullivan** – Character-space-limited Online Prescription Drug Communications: Four Experimental Studies
  - **Kevin Betts** – Disease Awareness and Prescription Drug Communications on Television: Evidence for Conflation and Misleading Product Impressions
  - **Amie O’Donoghue** – How Physicians View Data of Uncertain Clinical Utility in Oncology Prescription Drug Promotion
- **DIA Advertising and Promotion Regulatory Affairs Conference**
  - March 9, 2022 11:25 AM-12:25 PM
  - **Katie Klemm** – Intersection of Labeling and AdPromo – OPDP and Industry Perspectives
- **DIA Advertising and Promotion Regulatory Affairs Conference**
  - March 9, 2022 1:30 PM-2:30 PM
  - **Multiple OPDP Staff** – Meet and Greet with OPDP/APLB/CDRH

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The Office of Prescription Drug Promotion (OPDP) resides in the Office of Medical Policy (OMP) in the Center for Drug Evaluation and Research (CDER).

### **OPDP Contacts**

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[OPDP Homepage](#)

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March 2022