The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion

NEWSLETTER

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OPDP Fun Facts: Prior to being elevated from a Division to an Office in 2011, OPDP was known as the Division of Drug Marketing, Advertising, and Communications (DDMAC).

Office Director
Dr. Catherine (Katie) Gray

Gray Matters

***"April hath put a spirit of youth in everything."* William Shakespeare**

Welcome to the April edition of *TBS*. Spring has officially arrived here in the National Capital Region, and with its arrival we celebrate the return of more daylight, warmer weather, blooming flowers and trees (the cherry blossoms at the Tidal Basin reached peak bloom on March 25!). Spring is a hopeful season that brings transformation and change. It is a time to launch exciting things, and in this edition of *TBS* you will see that OPDP has definitely launched an exciting thing!

In last month's Gray Matters, I briefly mentioned the establishment of OPDP's new Division of Promotion Policy, Research and Operations (DPPRO). We are thrilled to share additional details about this new Division. This month's *TBS* includes a spotlight on DPPRO Director Katie David and a feature article on the DPPRO structure and leadership. The Division's focus on guidance and policy development, as well as legal, research, and project management activities, will enhance

the office's ability to respond to the rapidly evolving landscape of prescription drug promotion. Katie David and her talented team of professionals are committed to supporting their OPDP colleagues and resolutely dedicated to helping to ensure that prescription drug promotional communications are truthful and non-misleading.

We welcome this season of change with a bright outlook. Wishing you all the best as you shed your winter gear and embrace the sunshine.

Best,

kbg

FDA Announced a 30-day information collection titled "Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites." The Federal Register Notice can be viewed and downloaded here.

Staff Spotlight

Katie David - DPPRO Director

I joined OPDP in 2012 after spending two years in FDA's CBER, following prior careers in oncology nursing and corporate intelligence. My first role in OPDP was as a regulatory reviewer for oncology products, later moving into a Team Lead role in 2014. In 2017, I became the deputy staff supervisor for the Advertising Promotion Policy Staff, now known as the Division of Promotion Policy, Research, and Operations (DPPRO), and I currently serve as the Division Director for DPPRO. It is an incredible privilege and an exciting challenge to lead this Division and help to steer the operations, and research and policy agenda of OPDP to meet the needs of our stakeholders. I have a passion for science, for service, and for communication. These passions find ample outlet in my work here in OPDP. My colleagues are brilliant, dedicated, innovative, driven professionals who rise to every challenge, lift each other up, and are constantly striving to fulfill our mission to protect

the public health. They inspire me daily and it is an honor to serve the American public with them.

When not stretching my brain with my FDA colleagues, you will find me doing my best to entertain my children or grabbing a good book and joining my dog in hiding from the children.

Getting to Know OPDP - Division of Promotion Policy, Research, and Operations (DPPRO)

OPDP is pleased to announce the establishment of the Division of Promotion Policy, Research, and Operations (DPPRO). DPPRO is dedicated to policy development, research, and program support. Staff assigned to the new division previously resided in the Advertising and Promotion Policy Staff (APPS) within OPDP's Immediate Office. This change allows DPPRO staff to organize and align their efforts to pursue a research and policy development pipeline that addresses and investigates issues critical to stakeholders in the field of prescription drug promotion.

The new Division is led by Division Director Katie David and is comprised of four teams. The Policy Analyst Team is led by Christine Bradshaw. This team focuses on policy development initiatives, including the drafting and publication of guidance documents related to prescription drug promotion. The Regulatory Counsel team is led by Dominic (Dom) Cirincione. This team is responsible for legal analysis and regulatory initiatives across OPDP. The OPDP Research Team, which was featured in the March Edition of *The Brief Summary*, is led by Kathryn (Kit) Aikin. This team conducts original research in support of OPDP's mission. And finally, the Project Management Team is led by Jason Cober. This team provides operations and program support to all of OPDP. They keep the trains running, the lights on, and the gateway open for all promotional submissions.

DIA Recap

On March 8th and 9th 2022, OPDP staff participated in multiple sessions of the Drug Information Association (DIA) Advertising and Regulatory Affairs Conference.

- Katie Gray presented opening remarks, an overview of recent OPDP compliance actions, and a few OPDP updates.
- Kit Aikin provided an update on the status of the OPDP Research Program and the OPDP Research Team provided an overview of recent publications.

- Several OPDP staff participated on DIA panels and provided insights and best practices for interacting with OPDP.
- Multiple OPDP staff participated in a Meet & Greet session on the final day of the conference.

Be on the look-out for the "Where is OPDP" feature in upcoming editions of *The Brief Summary* for advance notice of OPDP presentations and engagement opportunities.

OPDP Electronic Submissions News

The OPDP eCTD webpage was updated in February 2022 to include the following content:

- Links to Form FDA 2253 and the Instructions Supplement have been added to the OPDP eCTD webpage. Form FDA 2253 was revised in October 2021 to include an Application Type option of "CDER IND".
- A link to the August 2021 "OPDP Electronic Submissions – Grouped Promotional Submissions" webinar has been added. The webinar provides an overview of Grouped Promotional submissions in eCTD format along with commonly observed errors related to these submission types and how to avoid them. The webinar was previously available on FDA's Small Business and Industry Assistance (SBIA) webpage.

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

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OPDP Homepage

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