IN THIS EDITION

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OPDP Fun Facts: OPDP was originally comprised of two Divisions: Division of Professional Drug Promotion and Division of DTC Promotion.


Office Director
Dr. Catherine (Katie) Gray

Gray Matters

May hosts a variety of celebrations and recognitions. Perhaps you have a graduate? If you have a graduate, you certainly have some teachers to thank that were part of the journey. I suspect many will have a teacher, a coach, a caregiver, or other nurturing individual to thank during Teacher Appreciation Week. We all have a mother or mother figure to celebrate or remember.

While I am lucky to have a few such folks to celebrate this week, I want to gratefully recognize all public servants – particularly my fellow OPDPers – during Public Service Recognition Week. OPDP's team of smart, dedicated, talented and selfless professionals work together to be part of something bigger than the individual.

This month's *TBS* introduces you to OPDP's tireless review staff in the Divisions of Advertising and Promotion Review. These public health servants focus on the *now*, touching on a broad range of activities that foster truthful, non-misleading and high-quality promotional communications, and support the development of FDA-approved labeling. You may have worked with one or several of these OPDPers during your career as you

prepped for a launch or labeling revision. Just like our Division of Promotion Policy, Research and Operations (DPPRO) and Immediate Office staff, these professionals embody an altruistic spirit that drives public health forward toward a better future for all. For that, we can all be thankful and celebrate their dedication.

Best,

kbg

Duobrii Untitled Letter

On March 31, 2022, OPDP issued an Untitled Letter (UL) to Bausch Health Companies Incorporated regarding the company's product Duobrii. The UL is posted on the OPDP Untitled Letters 2022 webpage. A copy of the UL can be downloaded at this link.

Federal Register Notice

FDA Announced a 60-day information collection titled "Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider Promotion." The Federal Register Notice can be downloaded here.

Staff Spotlight

Charuni Shah - Regulatory Reviewer

I joined OPDP in 2014 as a regulatory reviewer and initially worked with dermatology products. Currently, I am a reviewer for cardiology, nephrology, and general endocrinology products. I enjoy these dockets because I have the opportunity to work across a variety of products in general endocrinology as well as work with cardiology products which impact such a large patient population.

I earned my degree from the University of the Sciences in Philadelphia, Philadelphia College of Pharmacy in 2009. Prior to joining OPDP in 2014, I worked in pharmaceutical marketing in New York City.

When I was a student in Pharmacy school, I did a rotation at FDA and I recall the OPDP presentation being one of the most memorable and remarkable with regard to my career interest. I feel very fortunate to have had the opportunity to join OPDP several years later.

One interesting fact about myself is that I was born and grew up in New Jersey but have lived in a total of 7 other states, including Ohio, North Dakota, Pennsylvania, New York, Maryland, Virginia, and Tennessee. I love traveling (pre-pandemic), spending time outdoors with my family and friends, as well as trying out new recipes and cuisines.

Getting to Know OPDP - DAPR-1 and DAPR-2

Since OPDP restructured as an Office in 2011, OPDP Reviewers have been organized into two Review Divisions. Over the years, various drug classes have shifted between the two Divisions of Advertising and Promotion Review (DAPR 1 & 2, pronounced “dapper”), but overall, the DAPRs have generally been aligned with CDER’s Office of New Drugs (OND).

DAPR-1 is led by Andy Haffer, who has served as the Division Director since 2013. Katie Klemm, an OPDPer since 2008, has served as Deputy Division Director since 2021. DAPR-1 is comprised of four Review Teams. Ray Conklin and Emily Dvorsky lead Teams 1 and 2, respectively, and these teams are responsible for the review of solid tumor oncology products. Aline Moukhtara leads Team 3 and her team covers the neurology and psychiatry dockets. Team 4 is led by Sam Skariah whose team covers anesthesiology, addiction medicine, pain medicine, antivirals, and anti-infectives.

Finally, Susannah O'Donnell oversees special projects, mentoring, and new Team Lead development.

DAPR-2 is led by Twyla Thompson who was promoted to Division Director in 2021 after serving as Deputy Division Director for 7 years. Another OPDP veteran since 2011, Matt Falter has served as Deputy Division Director since 2021. Like DAPR-1, DAPR-2 is also comprised of four Review Teams. Team 5 is led by Jina Kwak and covers the hematology docket. Jim Dvorsky leads Team 6 and his team is responsible for the dermatology, dentistry, urology, obstetrics, gynecology, ophthalmology, imaging & radiation medicine, and rare disease dockets. Team 7 is led by Melinda Wilson and her team reviews cardiology, renal, endocrine, and diabetes products. Finally, Team 8 is led by Wale Adeleye whose team covers rheumatology, transplant medicine, pulmonary, allergy, gastroenterology, hepatology, and nutrition.

If you have any questions about the reviewer currently assigned to your product, please contact the OPDP RPM mailbox at CDER-OPDP-RPM@fda.hhs.gov.

Getting to Know OPDP – Reviewer Background

While most OPDP Reviewers are pharmacists with either a Doctor of Pharmacy (PharmD) or Bachelor of Science in Pharmacy (BS Pharm) degree, OPDP Reviewers come from a variety of backgrounds and experiences. OPDP Reviewers also hold degrees in Nursing (RN or MSN), Public Health (MPH), and Business Administration (MBA). All OPDP Reviewers have a strong science background, and many have completed post-graduate residencies or fellowships and have prior experience in various healthcare settings, including direct patient care in hospital and community settings. Several Reviewers bring industry experience from their former work as sales representatives, medical science liaisons, or regulatory affairs professionals. Some Reviewers have also previously served as faculty at Colleges of Pharmacy. The diversity of the Review Teams is the foundation for OPDP's culture of innovation, collegiality, and leadership.

OPDP Electronic Submissions Update

A revised Final Guidance for industry titled "Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs" was posted on April 11, 2022. The Final Guidance was previously posted on June 21, 2019.

The following changes related to regulatory submissions in electronic and non-electronic format are included in the Final Guidance:

- Footnote 12 has been updated to include the link to the FDA Forms webpage.
- Footnote 14 has been updated to include directions for requesting the current OPDP reviewer assignment through the OPDP Regulatory Project Manager Mailbox (CDER-OPDP-RPM@fda.hhs.gov).
- References to Box 14 on the Form FDA-2253 have been removed. The box numbering on the Form FDA-2253 was updated during the April 2021 revision of the Form and Box 14 was renumbered to Box 13. All references to the box numbering have been removed and the box is now referenced by title – "For CBER Products Only."

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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