U.S. FOOD & DRUG ADMINISTRATION

The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion

NEWSLETTER

IN THIS EDITION

Office Director
Dr. Catherine (Katie) Gray

Gray Matters

I have mentioned in prior editions that OPDP benefits from a team of smart, committed and kind individuals. Over the last year, we have gratefully welcomed new staff to this stellar OPDP team. As I watch the OPDP veterans mentor these bright and talented new colleagues, the engagement highlights the incredible dedication and resiliency of the people who continue to serve in and grow this office. While our growth this year has me feeling very optimistic about the future, it also reminds me of OPDP's past - of its legacy of service and excellence. Our future would not shine so brightly without those who have dedicated so much to OPDP. Perhaps no one is more to thank for the caliber of our staff and the culture of this office than our former director, Tom Abrams. With excitement for the future, and in honor of this office's storied past, I am taking the present to share a note from

Subscribe to *The Brief Summary*

Tom. Although he is almost two years into his retirement, he remains, still, an OPDPer at heart.

Best,

kbg

Tom writes:

While I will be retired two years at the end of this month and am enjoying retirement immensely with all the additional free time, I miss the interactions with my colleagues in both the public and private sectors. I've been so pleased to see OPDP's ongoing focus on fulfilling its mission under Katie Gray's and Mark Askine's leadership, helping to ensure that communications about prescription drugs are truthful and not misleading. With my understanding of the critical role OPDP plays in serving public health, I eagerly follow OPDP's activities. I was encouraged to see the office's focus on critical and emerging issues through its compliance actions, including letters concerning treatments for COVID-19, the opioid epidemic, and prescription drug promotion on social media.

I have also appreciated Katie's focus on increasing transparency and collaboration with stakeholders to jointly advance public health and to address important issues. The office's public workshop with Duke Margolis last fall, focusing on the development of digital health tools and novel digital marketing strategies, was innovative and informative. I've noted OPDP's increased participation in conferences, seeing both familiar and new OPDP staff members taking the time to speak and engage with stakeholders. And along with the rest of you, I've been delighted to read The Brief Summary each time it appears in my inbox.

I feel honored to have been asked for this contribution in The Brief Summary. It gives me a chance to communicate with many of you whom I interacted with during my FDA career. I learned a lot from folks in both the public and the private sectors, which made my career more interesting. I also appreciated the personal interactions and mutual respect that we had for each other, and that made my career more enjoyable. It brings me great satisfaction (and no surprises) to see OPDP's

continued focus on protecting public health and addressing misinformation. I share Katie's excitement for the future and am so proud to have been a part of its past.

Thank you!

Tom

FDA Announced a 30-day information collection titled "Targeted Mechanism of Action Presentations in Prescription Drug Promotion." The Federal Register Notice can be downloaded here.

FDA Announced a 60-day information collection titled "Perceptions of Prescription Drug Products With Medication Tracking Capabilities." The Federal Register Notice can be downloaded here.

FDA Announced a 60-day information collection titled "Endorser Status and Actual Use in Direct-to-Consumer Television Ads." The Federal Register Notice can be downloaded here.

Staff Spotlight

Emily Dvorsky - Lead Consumer Safety Officer

I joined OPDP in 2018 as a regulatory review officer covering an oncology review docket. In February 2022, I became the Team Lead of one of the two Solid Tumor Oncology Teams in OPDP. I enjoy working in this docket as the field of oncology is fast-paced and constantly evolving. It is exciting to see the advances being made in the field.

I earned my PharmD from Duquesne University in Pittsburgh in 2008. Prior to coming to OPDP, I worked in the pharmaceutical industry as a sales representative and a pharmacy account specialist. I also spent several years behind the counter as a retail pharmacist.

My husband and I have two young daughters. We enjoy spending time outdoors as a family and love to travel together.

OPDP Social Science Web Updates

As part of OPDP's commitment to transparency, the Social Science Research Team seeks publication of all its research. In order to share the most current OPDP research with stakeholders, the OPDP Social Science Research webpage is updated three times a year. In the March Edition of *The Brief Summary,* we discussed the organization of the OPDP Research Website and the posting criteria for each webpage. The most recent updates were completed in September 2022. The following updates were made to each webpage:

Completed Research Projects

- Two new entries and corresponding publications have been added:
    - Character-Space-Limited Online Prescription Drug Communications
    - Risk Information Amount and Location in Direct-to-Consumer Print Ads
- The new entries bring the total number of completed research projects to 50

Research Pending Peer Review and Publication

- Two projects were moved from this webpage to the Completed Research Projects webpage:
    - Character-Space-Limited Online Prescription Drug Communications
    - Risk Information Amount and Location in Direct-to-Consumer Print Ads
- There are now 3 projects Pending Peer Review and Publication

Research in Progress

- There were no changes to the Research in Progress webpage during this round of updates
- There are currently 13 research projects actively in progress.

Recent OPDP Publications

As described in the website updates section, the Social Science team published two new manuscripts:

- Attention to risk information in direct-to-consumer prescription drug print ads: An eye-tracking study[1]
- Character-space-limited online prescription drug communications: Four experimental studies[2]

In addition, DAPR Reviewers Domenic D'Alessandro, PharmD, MBA, BCPS, CDCES, and Sapna Shah, PharmD, in collaboration with staff from FDA's Office of New Drugs, published an article in Pharmacy Times Journal online entitled, "The Pharmacist's Role: Opioid-related Risks With a Psychiatric Drug." The article highlights some key drug features pharmacists should consider when counseling patients taking Lybalvi (olanzapine and samidorphan) and includes important recommendations related to the life-threatening consequences that can occur if opioids are taken concurrently with Lybalvi. The article can be accessed here.

[1] Aikin, KJ, Sullivan, HW, Caporaso, A, et al. Attention to risk information in direct-to-consumer prescription drug print ads: An eye-tracking study. Pharmacoepidemiol Drug Saf. 2022; 1- 9.

[2] Helen W. Sullivan, Amie O'Donoghue, Shane Mannis, Amanda M. Carpenter, Character-space-limited online prescription drug communications: Four experimental studies, Research in Social and Administrative Pharmacy, 2022, in press

3 Reasons to Read the "Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements" Guidance for Industry

- This guidance clarifies the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertisements for prescription drugs.
- The placement, size, prominence, and frequency of the proprietary and established names for prescription drugs are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h) and 202.1(b), (c) and (d)). These regulations are applicable to prescription drugs that contain one or more active ingredient(s). The guidance provides recommendations for products with one active ingredient and products with two or more active ingredients.

- The guidance includes recommendations and FDA considerations on juxtaposition of proprietary and established names, size of proprietary and established names, prominence of proprietary and established names, and frequency of disclosure of proprietary and established names.

Read the full "Product Name Placement, Size and Prominence in Promotional Labeling and Advertisements" Guidance for Industry to learn more!

OPDP speakers participated in the RAPS virtual conference "US Regulation of Advertising and Promotion for Drugs and Biologics" on August 11th and 12th. Amy Muhlberg, Deputy Director of the Division of Policy, Research, and Operations (DPPRO) gave an overview of prescription drug advertising and promotional labeling regulations, FDA and OPDP's roles, and covered some recent developments. Kathleen Klemm, Deputy Director of the Division of Advertising and Promotion Review I (DAPRI) discussed the current FDA environment for prescription drug promotion, giving an update on OPDP oversight of prescription drug advertising and promotional labeling, including examples of recent compliance actions and process considerations. The conference is available to view here (Day 1, Day 2). OPDP speakers gave the first session each day.

Kathryn Aikin, Senior Social Science Analyst and Research Team Lead, presented at the National Advertising Division (NAD) Annual Conference on September 20th as part of a panel entitled, "Emerging Issues: Influencers, Dark Patterns, Review." Panelists discussed how to spot thorny issues brands may face when using influencers, consumer reviews, or other promotional strategies that are attracting scrutiny from the NAD, FTC, and other regulators, including FDA.

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

OPDP RPM Mailbox: CDER-OPDP-RPM@fda.hhs.gov

OPDP eCTD Mailbox: OPDPeCTD@fda.hhs.gov

Bad Ad Mailbox: BadAd@fda.gov

OPDP Homepage

Previous Editions of *The Brief Summary* are available on the OPDP News webpage