The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion

NEWSLETTER

IN THIS EDITION

Subscribe to *The Brief Summary*

Office Director
Dr. Catherine (Katie) Gray

Gray Matters

OPDP in Context

FDA can sometimes seem like a black box. Studying org charts doesn't always reveal how different FDA components work together. In this issue, I'd like to pull back the curtain a little bit and tell you about where OPDP sits within FDA and how we work with our colleagues.

OPDP is part of the Office of Medical Policy (OMP), which is led by Khair ElZarrad, Ph.D., M.P.H., and his deputy Karen Hicks, M.D., FACC. Khair and Karen lead the development, coordination, and implementation of medical policy programs and strategic initiatives. This includes policy considerations for issues such as real-world evidence, novel clinical trial designs, the use of new technologies including artificial intelligence, and issues related to human subject protection and good clinical practices. Sitting within the Center for Drug Evaluation and Research (CDER), OMP works collaboratively with other CDER program areas, FDA centers, and stakeholders to enhance policies to improve drug development and regulatory review processes.

OMP includes the Office of Medical Policy Initiatives (OMPI) and the Office of Prescription Drug Promotion. Hopefully, this newsletter has already helped you get to know OPDP better. Our sister office, OMPI, provides oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas. One key area where OPDP and OMPI work together is to provide scientific and regulatory leadership in ensuring accurate and effective communication of medical information to health care professionals and patients in compliance with applicable regulations - think patient-directed FDA-approved labeling, for example. We also regularly contribute to each other's policy projects and research, and we collaborate on best practices to address challenging issues as well as holding office-wide enrichment activities.

Prior to joining FDA, Khair served at NIH, and as a fellow on both the FDA's Interagency Oncology Taskforce and the National Cancer Institute's Cancer Prevention Fellowship Program. Khair is ably assisted by Deputy Office Director Karen Hicks, an interventional cardiologist who joined FDA in 2003 and OMP in 2022. Prior to coming to OMP, Karen served as a Team Leader in the Division of Cardiovascular and Renal Products (now the Division of Cardiology and Nephrology) and a Deputy Director in the Division of Nonprescription Drugs II. Karen has experience leading large multi-stakeholder initiatives to standardize data collection for cardiovascular trials.

On a final note, Khair was recently awarded the 2023 Arthur S. Flemming Award for his work on policy development in areas such as digital technology, decentralized clinical trials, artificial intelligence, and modernizing clinical trial conduct. This work continues to propel the FDA's cutting-edge regulatory policies in emerging areas. The award honors outstanding federal employees and you can read more about Khair and the award here.

I hope this helps you better understand OPDP's place in OMP and CDER. I am perpetually thankful to be surrounded by such smart, thoughtful, and accomplished colleagues!

Best,

kbg

On April 24, FDA announced a revised draft guidance to answer questions biologics companies may have when developing promotional communications for prescription biologics including reference products, biosimilars, and interchangeable biosimilars.

The revised draft guidance, "Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers," discusses considerations for presenting data and information about reference products or biosimilar products, including interchangeable biosimilars, in promotional communications to help ensure they are accurate, truthful, and non-misleading.

This revised draft guidance fulfills the Biosimilar User Fee Amendments of 2022 commitment to publish draft guidance on promotional labeling and advertising considerations for interchangeable biosimilar products and replaces the 2020 draft guidance, "Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products: Questions and Answers."

Changes from the 2020 draft guidance include additional recommendations, an example of an interchangeable biosimilar product, and clarifying editorial changes.

FDA is committed to supporting adoption of biosimilars and identifying false or misleading statements about biologics. Biosimilars and interchangeable biosimilars are as safe and effective as their reference product.

In Case You Missed It

On November 20, 2023, the U.S. Food and Drug Administration issued a final rule to amend its prescription drug advertising regulations, entitled "Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format" (CCN Final Rule). The rulemaking implements a requirement of the Food, Drug, and Cosmetic Act (the FD&C Act), added by the Food and Drug Administration Amendments Act of 2007 (FDAAA, P.L. 110-85), that in human prescription drug ads presented directly to consumers in television or radio format stating the name of the drug and its conditions of use, the statement relating to major side effects and contraindications ("major statement") must be presented in a clear, conspicuous, and neutral manner. As directed by FDAAA, FDA is establishing standards to help ensure that the major statement in these advertisements is presented in the manner required.

The effective date of the final rule is May 20, 2024 and the compliance date is November 20, 2024. To help you get ready for November 20th, please see the feature on OPDP's CCN webinar later in this issue!

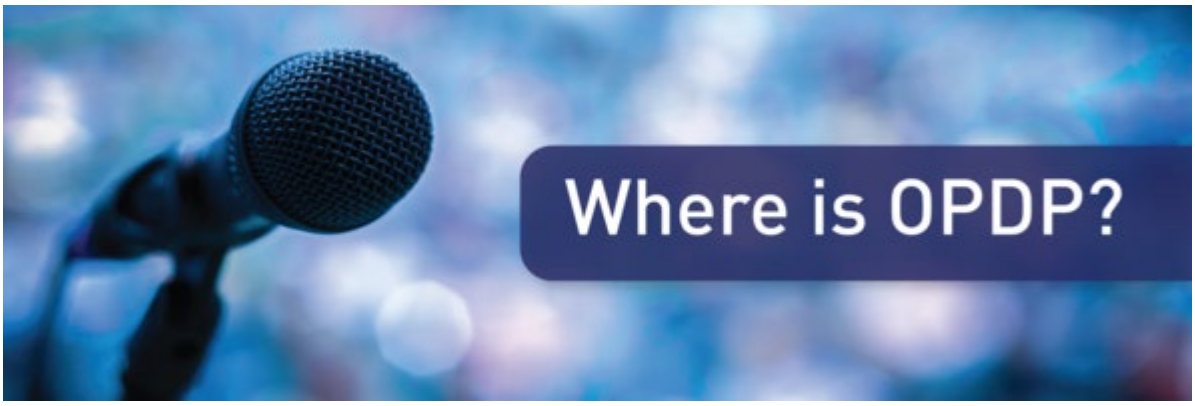
Focus on Research

CDER's Regulatory Science Impact Stories describe recent advances by FDA researchers and the impacts of these discoveries on drug development and the public health. A recent Impact Story highlights research from OPDP's own Kathryn (Kit) Aikin and Amie O'Donoghue. This new story "How does the source and quality of medical product information impact physician perceptions?" discusses a study conducted among primary care physicians to better understand how physicians process and interpret information that could guide prescribing decisions, and how such factors as time pressure, whether the information source is promotional in nature, and indicators of methodological rigor (e.g., sample size or duration) may influence physician's perceptions of a drug product and prescribing.

As they make decisions about which drug products should be prescribed to their patients, physicians must process a great deal of relevant information in a limited

amount of time. This information is from a wide range of sources, including but not limited to, FDA-approved labeling, peer-reviewed research published in scientific journals, continuing medical education, discussions with colleagues, and clinical practice guidelines. Physicians may also obtain information from drug advertising and promotion, including materials such as sales aids provided in person by sales representatives.

The results of this study suggest that prominently disclosing methodological rigor helps the audience form a more accurate perception of the presented information. Furthermore, promotional communications without graphics that appear to be more closely related to study reprints or summaries may be approached and interpreted with less caution by physicians than promotional communications that fit the classic expectation of "promotion." This highlights the importance that any promotional communications should be truthful and non-misleading. You can read more about the study here.



On June 26, 2024, OPDP's Suzanna Boyle presented a webinar on the recently published final rule: "Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format" (CCN). The webinar provided background information on prescription drug promotion, including different categories and types of promotion, as well as regulatory requirements for each. Stakeholders learned about the CCN final rule, including the five standards associated with the rule and the rule's compliance date. Finally, the webinar noted available FDA resources to assist firms in complying with the CCN final rule and applicable requirements for prescription drug promotion.

For more information, see this webpage, which will also host a recording of the webinar,

---

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