The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion

NEWSLETTER

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Gray Matters

If you're anything like me, you may have a "to be read" list. And each January, you take a new look at how much of it you hope to tackle (and hope the stack doesn't tip over). Well, this January, OPDP has a lot to add to your TBR and, of course, we hope you put these at the top! We are excited to announce multiple scientific publications by our Research Team, including on consumer understanding of multiple indications in TV ads, a literature review on Emergency Use Authorizations, the promotional implications of proprietary prescription drug names, laypersons' interpretations of statistical concepts, and examining the modality used to communicate the drug's indication in DTC television ads. In a late-breaking update, FDA issued a guidance for industry entitled "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers," which finalizes the revised draft guidance of the same title issued in October 2023. If you're an audiobook or podcast person (my commuting survival trick), you can check out my new Q&A With FDA podcast focusing on the BadAd program. All this material posted just since our last issue.

You can browse the features later in this issue for more details and other announcements.

Looking back on 2024, we introduced you to the Office of Medical Policy and OPDP's home within it, and helped you get to know OMP senior leadership. Consider adding OMP's first publicly-available Annual Report to your TBR – it hosts a wealth of information about the accomplishments of our super superoffice.

This first issue of the 2025 *TBS* includes our usual January metrics roundup – we've made some updates to the metrics page to make it easier to read and more informative, so please check it out. One additional measurement I'm thrilled to share with you is that there are now over 70,000 subscribers to our listserv, receiving and reading this newsletter right along with you.

Wishing you good health, happiness, and success in 2025!

Best,

kbg

The "Q&A with FDA" podcast, hosted by FDA's Division of Drug Information, provides engaging conversation and discussion about the latest regulatory topics. The series aims to answer some of the most frequently asked questions received from the public. On December 4, 2024, OPDP Director Dr. Catherine Gray was interviewed for the episode "Recognizing and Reporting Potentially False or Misleading Prescription Drug Promotion". The episode explained OPDP's role in regulating prescription drug promotion; what OPDP is looking for when monitoring prescription drug promotion; and described OPDP's Bad Ad program, an outreach program designed to help healthcare providers recognize potentially false or misleading prescription drug promotion. Listen to the podcast here or read the transcript here.

On January 6, 2025, FDA issued a guidance for industry entitled "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers." This guidance describes FDA's enforcement policy regarding certain firm-initiated communications of scientific information on unapproved use(s) of the firm's approved/cleared medical products to health care providers (HCPs) engaged in prescribing or administering medical products to individual patients.

The guidance describes the characteristics of the specific source publications contained in firm-initiated communications that fall within the enforcement policy outlined in this guidance. Specifically, this guidance provides recommendations for firms initiating the sharing with HCPs of:

- Source publications that are:
  - Published scientific or medical journal articles (reprints)
  - Published clinical reference resources, as follows:
    - Clinical practice guidelines (CPGs)
    - Scientific or medical reference texts (reference texts)
    - Materials from digital clinical practice resources

- Firm-generated presentations of scientific information on unapproved use(s) provided with a source publication

For the purposes of this guidance, these specific types of firm-initiated communications to HCPs, in combination with the disclosures recommended in this guidance, are referred to as scientific information on unapproved use(s) of approved/cleared medical product communications (hereafter referred to as "SIUU communications"). FDA is issuing this guidance to provide reassurance to firms that, if they choose to provide communications consistent with the recommendations of this guidance, FDA does not intend to use the firm's dissemination of such communication standing alone as evidence of a new intended use. Additionally, FDA does not expect a firm to submit such a communication to the Agency at the time the communication is initially shared with HCPs. We acknowledge that firms communicate in other ways and with other audiences, and this guidance neither speaks to nor intends to convey any views on

communications that are not within the scope of the enforcement policy outlined in this guidance. The fact that a communication by a firm does not share all the characteristics of communications that are within the scope of this enforcement policy does not alone mean that FDA intends to rely on it to establish a new intended use.

This guidance finalizes the revised draft guidance of the same title issued in October 2023 (88 FR 73031). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include (1) reorganizing the guidance to include dedicated glossary and policy sections; (2) revising the recommendations for source publications to provide additional specificity and examples to illustrate the recommendations; (3) refining language around presentational considerations to provide additional clarity and an additional example; and (4) updating the section on firm-generated presentations to specify that the recommendations apply to firm-generated presentations of scientific information from any of the source publications addressed in the guidance. In addition, editorial changes were made for clarity.

OPDP Data Digest

2024 Metrics

2024 marked another busy year for OPDP. Some notable trends and metrics include:

- Form FDA 2253 submissions increased by 5.0% over 2023 submissions. OPDP received over 70,000 Form FDA 2253 submissions in 2024.
- The number of individual promotional pieces submitted to OPDP increased by 7.9%. OPDP received over 150,000 individual promotional pieces in 2024.
- OPDP issued five Compliance Letters in 2024. Links to Untitled Letters can be found here and Warning Letters can be found here.
- OPDP staff and leadership gave six presentations at five different conferences.

Federal Register Notices

On October 2, 2024, FDA announced a 60-day information collection titled “Promotion of Prescription Drugs Within a Talk Show Format.” The Federal Register Notice can be viewed here.

On October 24, 2024, FDA announced a 30-day information collection titled “Adherence Potential and Patient Preference in Prescription Drug Promotion.” The Federal Register Notice can be viewed here.

Focus on Research

The Social Science team published FIVE new manuscripts:

1. Sullivan, H.W., Aikin, K.J., Johnson, M., & Ferriola-Bruckenstein, K. (2024). Consumer understanding of prescription drug indications in direct-to-consumer television advertisements. *Therapeutic Innovation and Regulatory Science*. Advance online publication. https://link.springer.com/article/10.1007/s43441-024-00732-4 (subscription required)

2. Rains, C., Aikin, K.J., Sullivan, H., Kelly, B., Liu, S., Wooten, C., Brophy, J., Peinado, S., McCormack, L., & Crouse Quinn, S. (2024) Public and Health Care Provider Attitudes, Understanding, and Behaviors Regarding Emergency Use Authorizations: A Scoping Literature Review. *BMC Public Health*. 24, 2791. Advance online publication. https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-024-20234-0

3. Peinado, S.; O’Donoghue, A.C.; Betts, K.R.; Paquin, R.S.; Giombi, K.; Arnold, J.E.; Kelly, B.J.; & Davis, C. (2024). Experimental study of the promotional implications of proprietary prescription drug names. *Therapeutic Innovation and Regulatory Science.* Sep 28. Advance online publication. https://link.springer.com/article/10.1007/s43441-024-00704-8 (subscription required)

4. Yount, N.D., Osafo-Darko, B., Burns, W., Johnson, M., Betts, K., & Sullivan, H.W. (2024). Laypersons’ understanding of statistical concepts commonly used in prescription drug promotion: A review of the research literature. *Research in Social & Administrative Pharmacy*. Dec;20(12 Pt A):1075-1088. Advance online publication. https://www.sciencedirect.com/science/article/pii/S1551741124003486 (subscription required)

5. Boudewyns, V., Paquin, R.S., O’Donoghue, A.C., & Sullivan, H.W. (2024). Communicating Therapeutic Indication Information in Direct-to-Consumer

Television Ads for Prescription Cancer Drugs: Exploring the Effect of Dual-Modality Presentations. *Patient Education and Counseling*. Advance online publication. https://www.sciencedirect.com/science/article/abs/pii/S0738399124004658

In Case You Missed It

On September 25, 2024, The Second Annual Future of Prescription Drug Promotion and Digital Marketing Meeting The Duke-Margolis Institute for Health Policy was convened under a cooperative agreement with the FDA. This second annual virtual workshop explored the state of digital prescription drug promotion, including the marketing technologies and strategies currently available and commonly used by marketers, and insights on the future direction of marketing in this space. The objective of this convening was to understand how recent and emerging trends in this space may have bearing on public health. This event explored new formats and strategies that have emerged since the September 2023 convening on Prescription Drug Digital Promotion as well as expanded upon discussions from the prior convening. The agenda and participant list are available here: https://healthpolicy.duke.edu/events/future-prescription-drug-promotion-and-digital-marketing-0 A summary report will be added in the coming weeks.

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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