U.S. FOOD & DRUG ADMINISTRATION

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

Time seems to move differently during the pandemic. It's hard to believe one year has passed since the launch of this newsletter as well as the reorganization of OPDP. Notably, it is also the 60th anniversary of the 1963 regulations stemming from the prior year's Kefauver-Harris amendments (P.L. 87-781). While the 1962 changes to the law are usually associated with the requirement to demonstrate drug efficacy, they also required that drug advertisements include increased information on a drug's risks and effectiveness, and the agency quickly issued regulations implementing these provisions.

These regulations and their anniversary have been on my mind lately. The pandemic years have shown us how quickly technologies can develop and change information sharing practices, including how prescription drugs are advertised, leading to situations the drafters of 1963 could not have imagined.

We don't know what the next 60 years will hold, but OPDP's responsibility to protect the public health by helping to ensure that prescription drug promotional communications are truthful, balanced and accurately communicated remains the same. With the help of our dedicated team, OPDP is more than up to the task.

Happy New Year,

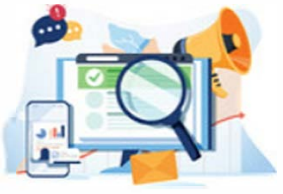
kbg

President Kennedy signing the 1962 amendments. Courtesy of The FDA History Office

Focus on Research

The latest issue of the CDER Regulatory Science newsletter, a compendium of news updates about regulatory science activities in CDER, highlights research from OPDP's own Helen Sullivan and Amie O'Donoghue. The rise of online communications that have character space limitations (CSL), such as tweets and Google sponsored links, has led to questions about how to use these communications for prescription drug promotion while complying with applicable requirements for risk information. OPDP researchers examined the effects of (1) including substantive risk information in the CSL communication itself versus only providing a link to risk information, and (2) including both risks and benefits versus describing only risks on the landing page to which the promotional communication links. The results provide a first look at the tradeoffs for consumer understanding of drug risks and benefits when drugs are promoted in CSL communications. Read all about the study here.

Metrics Update



2022 Milestones

2022 marked another busy year for OPDP. Some notable trends and milestones include the following:

- Form FDA 2253 submissions decreased by 5% over 2021 submissions. OPDP received over 64,000 Form FDA 2253 submissions in 2022.

- The number of individual promotional communications submitted to OPDP decreased by 5.5%. OPDP received over 140,000 individual promotional

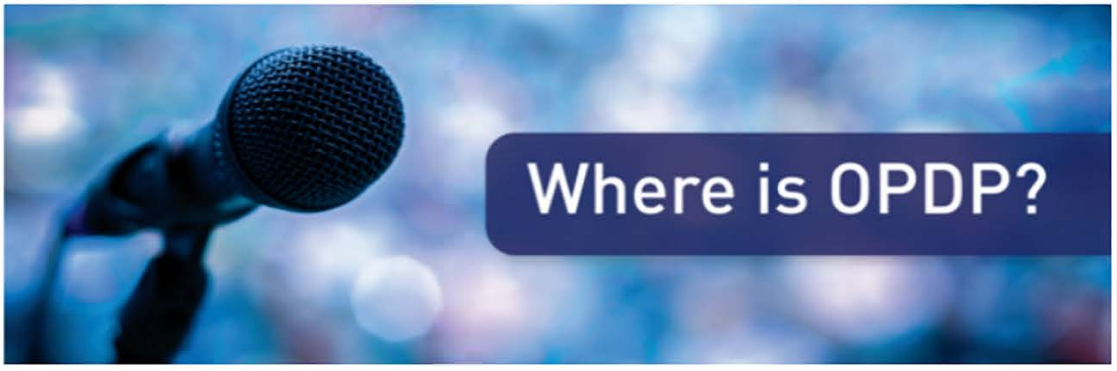
communications in 2022.

- OPDP issued four compliance letters in 2022. Six compliance letters were issued in 2021. Links to the 2022 untitled letters can be found on OPDP's website and warning letters can be found here.

- OPDP continued its outreach efforts by providing over 13 presentations at 9 conferences in 2022.

Federal Register Notices

FDA published a 30-day notice for an information collection titled "Targeted Mechanism of Action Presentations in Prescription Drug Promotion." The Federal Register Notice can be viewed and downloaded here.



Each year, on National Wreaths Across America Day (https://www.wreathsacrossamerica.org/), the mission to Remember, Honor and Teach is carried out by coordinating wreath-laying ceremonies at Arlington National Cemetery, as well as at more than 3,400 additional locations in all 50 U.S. states, at sea and abroad. On December 17th 2022, OPDP staff volunteered at Wreaths Across America sites in Virginia and Maryland.

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