The Brief Summary

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NEWSLETTER

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Gray Matters

Spring has finally sprung! Since our last issue, we have celebrated the Lunar New Year, Black History Month, Mardi Gras, Holi, Passover and Easter, to name a few. While it's a bit late to officially observe Pi Day (March 14th) together, with a nod to math and "dad" joke fans, you can still get a piece of the PIE Act(ion). This notable legislation was signed into law late last year and partially supersedes OPDP's 2018 Payor guidance. Read on for a feature article about this law.

While the pandemic isn't quite finished with us, like crocuses peeking through the snow and cherry blossoms announcing spring, we are emerging from some pandemic-era patterns. Part of OPDP's "new normal" includes a return to the White Oak campus on a regular basis for some staff. It's been wonderfully refreshing to meet our many new OPDPers in person and reconnect with long-time colleagues at the same conference (or lunch!) table. We've entered yet another phase of new meeting norms, pushing the limits of technology and facilitation with both on-line and in-person attendees. (I haven't yet decided if the pandemic is keeping me young or aging me prematurely.) All that said, with these changes in mind, we are resuming activities such as

attending conferences in-person and visiting the exhibit halls.

I look forward to the busy months ahead and hope to cross paths with many of you at a conference this year. Enjoy the warming weather and the colorful palette that is spring.

Best,

kbg

Congress passes PIE Act; Allows certain pre-approval communications between prescription drug and device manufacturers and insurance payors

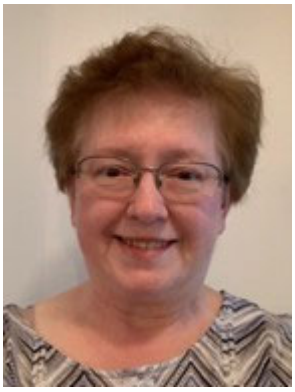
As part of the Consolidated Appropriations Act of 2023, signed into law in late December 2022, Congress enacted Section 3630, entitled "Facilitating Exchange of Product Information Prior to Approval" (also known as the PIE Act). This provision amended section 502 of the Federal Food, Drug, and Cosmetic Act, and is important for the Office of Prescription Drug Promotion (OPDP).

The new law is consistent with Section C of FDA's 2018 guidance document, "Drug and Device Manufacturer Communications with Payors, Formulary Committees and Similar Entities—Questions and Answers" (aka the Payor Guidance) that was drafted to provide additional flexibility for drug and device manufacturers to share truthful and not misleading product information about investigational products or investigational uses of approved, cleared, authorized, or licensed products to payors, formulary committees, and other similar entities with knowledge and expertise in the area of health care economic analysis ("payors"). The 2018 Payor Guidance clarified to stakeholders the types of information and circumstances under which FDA did not intend to object under FDA's statutory and regulatory authorities to pre-approval communications to payors for unapproved drugs and biologics or unapproved uses.

The PIE Act supports and bolsters the recommendations conveyed in the 2018 Payor Guidance and provides additional information for stakeholders about the communication of product information to payors, which may help expedite patient access to treatments. FDA

encourages manufacturers with questions about their product information communications to contact OPDP.

Staff Spotlight



GET TO KNOW JANET DALY

I graduated from Maine Maritime Academy in April 1983 with a bachelor's degree in Marine Engineering with a minor in Naval Engineering along with an engineer's license as a third engineer in the Merchant Marine and my Commission as an Officer is the US Navy.

I have two wonderful grandchildren who live with me. My son is in the US Air Force, stationed at the Little Rock Air Force Base in Jacksonville, Arkansas. We have three loving cats who were all rescued from the Fort Bragg Army Base in North Carolina and thankful that they now have a forever home. I like to spend time with my son, grandchildren, hike, read, and work in my gardens.

After graduating from college, I served as an Officer in the US Navy where I was stationed at the Philadelphia Naval Shipyard. While stationed at the Shipyard, I was an Assistant Project Manager assigned to the flight deck on the USS Forrestal and later as the Project Manager on the USS Lexington in charge of the flight deck and communications overhaul. Later in my Naval career, I worked as the Environmental Control Officer at the Shipyard where I developed a recycling program, a reclamation facility for solvents, and a hazardous material/waste tracking system for the shipyard. I then worked for a property management company for about 10 years, both in their corporate office on the financial side and then as a Community Manager. Finally, I joined the FDA as a Technical Information Specialist, Program Specialist and now an Administrative Officer servicing OPDP.

Recent OPDP Publications

The Social Science team published two new manuscripts:

- A scoping review of empirical research on prescription drug promotion
- Implied claims in drug advertising: A review of recent literature and regulatory actions

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In February, OPDP Director Catherine (Katie) Gray led a session at the Drug Information Association (DIA) Advertising and Promotion Regulatory Affairs Conference. The session featured updates from Katie as well as from senior CBER and CDRH representatives on recent FDA advertising and promotion activities, including compliance actions, process modifications, program areas and goals for 2023.

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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