



The Brief Summary

FDA | CDER | Office of Prescription Drug Promotion
NEWSLETTER

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Office Director
Dr. Catherine (Katie) Gray

Gray Matters

I hope the holiday weekend brought you family, friends, fun and fireworks. Annual Fourth of July celebrations tend to coincide with some of my favorite memories. As a kid, I always looked forward to ending the day with a fantastic firework show, my body nearly levitating with excitement. Once the first thump sounded on the far side of the lake, I was fixed on my corner of the blanket with my eyes staring up. The night sky danced in light and color, and my young mind filled with wonder and delight. As the years passed, I still anticipated the thrill of the show, but I found myself imagining what innovative firework might appear. What new display would follow the thump of the launch, the climbing ember, and the explosion of sound, color and light? I was rarely disappointed by the results.

So it is with science. I have always loved the field but grew to wonder about specific questions and distinct disciplines. What display would follow the hypothesis, the conduct of the trial, and the analysis of the data? Would it

be the display I anticipated, or would it be an innovative firework? Would I be delighted or disappointed? This month's *TBS* brings more of OPDP's science to your summer evening. Will it be what you anticipated, or will it be an unexpected read?

One final note to share. With seven issues posted, and the dog days of summer closing in, *TBS* will shift to a quarterly publication schedule. We look forward to continuing to share helpful tips and brief updates in October, January, April and July.

Have a wonderful, restful summer!

Best,

kgb

Staff Spotlight

Kevin Betts Ph.D. - Social Science Analyst

Kevin R. Betts, Ph.D., is a Social Science Analyst in OPDP's Division of Promotion Policy, Research, and Operations (DPPRO), where he plans and directs social science research studies and provides consultation pertaining to promotional prescription drug communications. His research has covered topics such as misinformation detection and reporting capabilities among both consumers and healthcare providers, and strategies for improving the communication of prescription drug risks and side effects. Dr. Betts received his Ph.D. in Health/Social Psychology from North Dakota State University.



A few recent publications from Dr. Betts are provided below:

- Betts, K. R., O'Donoghue, A. C., Johnson, M., Boudewyns, V., & Paquin, R. (2021). Detecting and reporting deceptive prescription drug promotion: Differences across consumer and physician audiences and by number and type of deceptive claims and tactics. *Health Communication*. <https://doi.org/10.1080/10410236.2021.1909264>

- Betts, K. R., Aikin, K. J., Burke, P. B., Miles, S., & Mannis, S. (2021). Utilization of adequate provision in prescription drug broadcast ads among low- and non-Internet users. *Health Marketing Quarterly*, 39(1), 4-22. <https://doi.org/10.1080/07359683.2021.1989747>
- Betts, K. R., Aikin, K. J., Kelly, B. J., Johnson, M., Parvanta, S., Southwell, B. Mack, N., Tzeng, J. & Cameron, L. (2019). Taking repeated exposure into account: An experimental study of direct-to-consumer prescription drug television ad effects. *Journal of Health Communication*, 24, 503-511. <https://doi.org/10.1080/10810730.2019.1609139>



Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug Television Advertisements

In July 2017, the OPDP Social Science Research Team published an [article](#) titled “Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug Television Advertisements¹.” The article appeared in the journal *Research in Social and Administrative Pharmacy*.

Direct-to-consumer (DTC) prescription drug ads on television that include representations or suggestions about the drug product are required to also present the major side effects and contraindications of the drug product (the major statement). Debate exists regarding how much risk information should be included in these major statements. Some argue that such statements expose people to unnecessary amounts of information, which may result in reduced comprehension, minimization of important risk information and, potentially, therapeutic non-compliance due to fear of side effects. Others argue that the statements leave out important information. This research examined the amount and type of risk information presented in the major statement of DTC television ads. Specifically, this research varied the type of risk presentation (a traditional statement of risks versus serious and actionable risks only) and the inclusion of a disclosure indicating that not all risks are presented in the ad to see what impact this would have on consumers’ ability to remember the important risks and benefits of a drug following exposure to the television ad. Risk and benefit perceptions, ad-prompted actions, recognition of the disclosure statement, and evaluations of both the disclosure and risk statement were also examined. The research found that the risk statement with only serious and actionable risks improved overall processing of the television ad as compared to the traditional full statement of risks, as evidenced by improved risk recall and recognition and improved benefit recognition. Further, the presence of the disclosure did not adversely affect consumers’ processing of drug risk and benefit information.

The article was posted in *Research in Social and Administrative Pharmacy* in digital format in July 2017 and later published in print in Volume 14, Issue 10 of the journal in October 2018. Additional information regarding the project can be found on the OPDP Completed Research [page](#) under the heading title “Disclosure Regarding Additional Risks in DTC Prescription Drug Ads (Completed 2017).”

¹Betts K.R., Boudewyns V., Aikin K.J., Squire C., Dolina S., Hayes J.J., & Southwell B.G. (2017). Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements, *Research in Social & Administrative Pharmacy*, 14(10), 951-963. doi: 10.1016/j.sapharm.2017.07.015

2022 OPDP Social Science Publications



The Social Science Research Team continues its mission to advance the understanding of how consumers and health care providers perceive and respond to prescription drug promotion. The team has published the following articles through the first half of 2022 :

- [The Impact of Interactive Advertising on Consumer Engagement, Recall, and Understanding: A Scoping Systematic Review for Informing Regulatory Science](#)¹
- [Physicians' use of and preferences for FDA-approved prescribing information](#)² (Now available in print)
- [Influence of data disclosures on physician decisions about off-label uses: Findings from a qualitative study](#)³
- [Physician perceptions of the FDA's Breakthrough Therapy designation: An update](#)⁴

¹Giombi, K., Viator, C., Hoover, J., Tzeng, J., Sullivan, H.W., O'Donoghue, A.C., Southwell, B.G., & Kahwati, L.C. (2022). The impact of interactive advertising on consumer engagement, recall, and understanding: A scoping systematic review for informing regulatory science. *PLoS ONE*, 17, e0263339.

²Sullivan, H.W., Squire, C., Aikin, K.J., Tzeng, J., Ferriola-Bruckenstein, K., Brodsky, E., Trentacosti, A.M., & Johnson, M. (2022). Physicians' use of and preferences for FDA-approved prescribing information. *Research in Social and Administrative Pharmacy*, 18(6), 3027-3037.

³ Chansky, M.C., Price, S.M., Aikin, K.J., & O'Donoghue, A.C. (2022). Influence of data disclosures on physician decisions about off-label uses: Findings from a qualitative study. *BMC Primary Care*, 23(87).

⁴ Paquin, R.S., Boudewyns, V., O'Donoghue, A.C., & Aikin, K.J. (2022). Physician perceptions of the FDA's Breakthrough Therapy designation: An update, *The Oncologist*, 27(1), e85–e88.



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 June 2022. The following updates were made to each webpage:

Completed Research Projects

- A new entry has been added for the *Interactive Advertising Literature Review*. The entry outlines the project objectives and briefly describes the outcomes. A link to the corresponding article titled [The Impact of Interactive Advertising on Consumer Engagement, Recall, and Understanding: A Scoping Systematic Review for Informing Regulatory Science](#) has also been added.
- The new entry brings the total number of completed research projects to 48.

Research Pending Peer Review and Publication

- The project titled *Study of Oncology Indications in Direct-to-Consumer Television Advertising* is now pending Peer Review and Publication and has been transferred from the "Research in Progress" webpage.
- There are now 5 projects Pending Peer Review and Publication.

Research in Progress

- A new entry has been added for the *Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider Promotion* project. The entry includes a link to the 60-Day FRN posted on April 25, 2022.

- A link to the March 24, 2022, 30-Day FRN for the *Experimental Study of an Accelerated Approval Disclosure* has been added to the project's description.
- There are currently 13 research projects actively in progress.

Informing and Refining the Prescription Drug Promotion Research Agenda - Update



The Duke-Margolis Center for Health Policy has published the final report from the virtual public meeting titled *Informing and Refining the Prescription Drug Promotion Research Agenda*. The report provides an executive summary and overview of the November 19, 2021, virtual public meeting. The meeting included a discussion of current research topics on prescription drug promotion in the digital space before turning to emerging trends and gaps in research. The meeting concluded with a discussion of future research needs and topics for further study. The report is available on the Duke-Margolis website on the *Informing and Refining the Prescription Drug Promotion Research Agenda* [page](#).

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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Previous Editions of *The Brief Summary* are available on the OPDP News [webpage](#)

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