Session Report

The Promotional Review Process (and Pitfalls) for Beginner Medical Writers

Speaker

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By Kaley Wilburn, PhD

As consumers, we are all familiar with pharmaceutical drug advertisements, but what should beginner medical writers know about the process, and pitfalls, of creating promotional pieces? During the afternoon session of the AMWA Carolinas 2024 Spring Conference, Sendra Yang, PharmD, MBA presented a behind-the-scenes look at the review process used by pharmaceutical companies to prepare effective promotional materials that also meet FDA standards.

Drawing on over six years of experience as a medical information and review professional at two pharmaceutical companies, Dr. Yang outlined the steps and strategies that drive the promotional review process, described the collaborative decision-making process of the Promotional Review Committee, and demonstrated how writers can tailor their work to fit the requirements of various promotional pieces.

The Promotional Review Process:
To introduce the concept, Dr. Yang defined the goal of the promotional review process: "It ensures that materials created for use in advertising and promotion of a prescription drug are compliant, medically appropriate, factually accurate, truthful, non-misleading, and well-balanced," she explained. This process is designed to ensure that every piece complies not only with internal company policies but also with external laws, regulations, and guidance documents. On the external side, the FDA's **Office of Prescription Drug Promotion** (OPDP) oversees the majority of drug promotion activities in the United States, and enforces rules set out by the Federal Food, Drug, and Cosmetic Act and Title 21 of the Code of Federal Regulations.

The Promotional Review Committee:
Distributing non-compliant promotional materials can result in serious consequences for a pharmaceutical company. This motivates the internal **Promotional Review Committee**—a cross-departmental team whose members have medical, legal, and regulatory expertise—to complete a comprehensive review at multiple stages during the development of all materials (print or commercial ads, digital marketing products, sales team presentations, and more). Their feedback (communicated via "**outcome designations**") begins before a draft is even created, which is especially important for new concepts or materials that are expensive to produce. Following additional internal reviews at the midpoint and final stages, a piece is ultimately submitted to OPDP for approval and distribution by the company.

Avoiding Pitfalls when Writing Promotional Pieces:
For writers working on promotional pieces, it is important to be aware of the requirements Promotional Review Committee members focus on during their

reviews. According to Dr. Yang, the medical reviewer looks for every piece to meet **six key standards**: it must "be truthful and accurate, not misleading, fair and balanced in how it presents efficacy and risks, avoid promoting information that is inconsistent with the drug label, substantiate product claims with evidence, and match claims to the trial questions without extrapolating from them."

To avoid **common regulatory pitfalls**, she suggested writers pay careful attention to how claims are adapted from references, selecting the highest quality primary sources available and adapting information from them carefully. For instance, she "would never recommend referencing a previously approved piece in case something becomes altered about it." She also encouraged writers to ensure all benefit and risk information is presented in its appropriate medical and scientific context and to check that all graphics match the approved target population. For more information, new writers can review correct and incorrect examples of three major ad types on the FDA's website.

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