Rediscovering FDA Websites

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My experience in plans, PBMs, and managed care consulting has shown that successful prescription drug benefit management requires integration of several critical components, including a membership-specific benefit design, distribution channels, claims and information systems, a drug formulary, clinical programs, and a pharmacy staff to execute the program. The pharmacy benefit exists to deliver the “best” medications to covered members to achieve desired clinical and economic outcomes. Prescriptions are the therapeutic connections that thread from physicians through pharmacists to patients, delivered within the framework of the benefit designs. A continuously flowing drug pipeline ensures that the search for the best drug is a Sisyphean task.

Formulary Information Sources
Selection of the best drug for a specific plan formulary is a subjective decision using objective clinical and economic data. Drug approval by the U.S. Food and Drug Administration (FDA) is the index event that triggers a pharmacy and therapeutics (P&T) committee review and decision, although information collection and review commenced months earlier. We expect the FDA Center for Drug Evaluation and Research (CDER) to fulfill its mission to ensure that drugs marketed in this country are safe and effective. We begin with FDA-approved labeling and pivotal studies as baseline data and greatly expand the drug information from sources described below.

Unique plan characteristics and independent P&T committee decisions often result in a specific drug being preferred in one plan and either not preferred or not covered in another. Through various market research projects, I often ask medical and pharmacy directors for the information sources that they include in drug reviews. Their responses include an exhaustive peer-reviewed literature search, the Academy of Managed Care Pharmacy (AMCP) dossier, commercial publications and references (e.g., Facts & Comparisons, American Hospital Formulary Service [AHFS] Drug Information), the FDA Drugs@FDA website, manufacturer websites, drug pipeline reports, local disease specialist recommendations, U.S. National Institutes of Health (NIH) Clinical Trials website, their internal drug utilization and cost experience, Cochrane Reviews, and, uncommonly, the United Kingdom’s National Institute for Health and Clinical Excellence (NICE) and the Canadian Agency for Drugs and Technologies in Health (CADTH) websites.

Rediscover FDA.gov/Drugs
Although the FDA Drugs@FDA website was frequently mentioned by pharmacists conducting drug reviews, many clinicians may not realize the extent of additional FDA information, often unavailable elsewhere. The article “The U.S. Food and Drug Administration: Drug Information Resource for Formulary Recommendations” by Marchand, Rose, Fine, and Kremzner in this issue of JMCP provides a summary of the information available at the FDA website, which does indeed provide “a vast amount of clinically useful and meaningful information.”

I encourage readers to explore the warren of FDA webpages that seem to have silently expanded over time. The article also provides useful definitions of terms we often use, perhaps incorrectly, such as priority versus standard drug reviews, accelerated drug approvals, Risk Evaluation and Mitigation Strategy (REMS) programs, the role of FDA advisory committees, and orphan drug designation.

Clinicians new to pharmacy benefit management will find that the FDA website provides information on a variety of useful topics, including generic equivalence (the “Orange Book”), drug shortages, MedWatch drug morbidity and mortality reports, market recalls and withdrawals, drug and biologic approval reports, drug approval timeline information (PDUFA), vaccine and device information, and much more.

Of course, the Drugs@FDA site provides unique information on approved brand, generic, and biological products unavailable elsewhere, often dating back to 1939.

Formulary Information Management Challenges
Pharmacy benefit and formulary management become more complicated as drug information expands exponentially; new drugs (especially specialty products) are launched; health care costs rise; patient cost sharing increases; and plan sponsor budgets shrink. Federal funding will result in more comparative effective research (CER) studies that formulary decisions makers must balance with real-world data. (See JMCP CER supplements.) The use of CER reports by pharmaceutical manufacturers and possible regulation of CER data by the FDA is a controversial topic.

In addition to commercial, Medicare, and Medicaid prescription drug programs, emerging plan sponsors—including risk-sharing Medicare Accountable Care Organizations (ACOs), other commercial accountable care entities, and austere drug benefits of Exchanges—may require custom formularies to satisfy unique benefit designs. Generation of more studies with economic outputs will require formulary decisions makers to improve their critical literature evaluation skills.

In the milieu of information overload, clinicians involved in formulary management should rediscover the rich information found within the FDA.gov website. The article by Marchand et al. published in this issue is an excellent place to begin this journey.
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**DISCLOSURE**

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**REFERENCES**


