**Prescription: Washington**

**Over-the-Counter Products**

**In Line for User Fee Program**

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After passing a Food and Drug Administration (FDA) user fee reauthorization last summer for prescription and generic drugs, plus a new one for biosimilars, 1 Congress is now ready to add another new user fee program to the FDA arsenal. That would be for over-the-counter (OTC) products, 2 almost all of which are governed by an archaic, tortoise-slow regulatory program developed in 1972 that has never been updated.

The FDA develops and publishes “monographs,” then final rules, for categories of OTC products, many of them containing multiple active ingredients. Those monographs take years to develop and are impossible to change quickly when safety problems come to the fore, impeding the issuance of safety warnings or product removal. Products that conform to the monograph rules and other relevant requirements do not have to be reviewed by the FDA before marketing. This is in contrast with the new drug application (NDA) system, where sponsors of prescription drugs must submit an application to the FDA and obtain approval prior to marketing.

Janet Woodcock, MD, Director of the FDA’s Center for Drug Evaluation and Research, painted a pretty unattractive picture of the OTC program as it exists today when she appeared before the House Committee on Energy and Commerce’s Subcommittee on Health on September 13, 2017. “FDA still has not been able to complete many monographs begun decades ago,” she explained. “Nor has it been able to make timely monograph modifications to account for evolving science and emerging safety issues, or to accommodate product innovation or marketing changes.” 3

Approximately one-third of the monographs are not yet final, and several hundred individual ingredients do not have a final determination of safety and effectiveness. In addition, a number of planned safety labeling changes for monograph ingredients have not yet taken place, while similar changes have already been made to prescription drugs containing the same ingredients.

Collectively, these monographs cover some 800 active ingredients for more than 1,400 different uses, ranging from antacids to diaper rash creams, and from analgesics to cough/cold products. There are many more OTC products than there are prescription drug categories. The FDA currently spends approximately 40 times as much budget authority on the process of reviewing Prescription Drug User Fee Act (PDUFA) products as it does on OTC monograph products. In fiscal year 2016, the agency spent $1.16 billion, including $837 million in user fees, on prescription drug regulation and $7.9 million reviewing OTC monograph products despite the fact that there are far more OTC monograph drug products than there are branded prescription drug products. 3

The monographs establish conditions (e.g., active ingredients, indications, dosage form, and labeled directions) under which an OTC drug is generally recognized as safe and effective (GRASE) for use. There are three categories for OTC products: category I includes products that are GRASE for the claimed therapeutic indication; category II includes products that are not GRASE or have unacceptable indications; and category III includes products that have insufficient data available to permit final classification. 4 The OTC Drug Review consists of approximately 88 simultaneous rulemakings in 26 broad therapeutic categories that encompass hundreds of thousands of OTC drug products marketed in the United States.

Kirsten Moore, director of the health care products project at the Pew Charitable Trusts, explained to the House subcommittee the challenges the FDA faces in addressing OTC products when their safety comes into question. In 2002, an FDA advisory committee recommended a specific liver toxicity warning and changes to OTC packages so that products containing acetaminophen could be more easily identified. It took the agency seven years to finalize a rule amending the labeling requirements. In contrast, it took the FDA only two years to convene an advisory committee and require a new boxed warning on all prescription drug products that contained acetaminophen. 3

More recently, in April 2017, the FDA required companies to add the strongest warning to children’s prescription cough and pain medications containing codeine, a controlled substance. The agency was responding to concerns that the drug can cause potentially fatal breathing problems, especially in children younger than 12 years of age. In 2015, an FDA advisory committee identified 24 deaths and 64 cases worldwide of serious breathing problems in the previous 50 years among children who took medications containing codeine. Despite the evidence, the FDA has not yet made the change to remove codeine from the monograph for OTC children’s cough and cold products.

As was the case with the other user fee programs either reauthorized or created earlier this year, the FDA met with a number of interest groups over the past few years to come up with a program that would suit all parties. Those talks morphed into a draft piece of legislation, which was aired at House hearings in September. The FDA estimates that the fees collected under the OTC Monograph User Fee program would start at $22 million in year 1 and gradually increase to a steady state of $34 million by year 4. In return for the new funds, the agency commits to meeting goals related to new hires, better communication with the industry, and more efficient completion of final GRASE determinations for category III drugs.

Moore of the Pew Charitable Trusts thinks the draft legislation is good,
though she advanced some potential tweaks that could be added in future years. Scott Melville, President and CEO of the Consumer Healthcare Products Association, the OTC trade group, had no reservations. “We believe the fee agreement strikes the right balance and will help to achieve a more nimble regulatory structure for monograph drugs that would be a win–win for consumers, manufacturers, and regulators.”

REFERENCES


