

## Why GAO Did This Study

OTC drugs prevent and treat a variety of conditions; for example, sunscreen is used to help prevent sunburn. FDA officials and stakeholders, such as industry representatives and patient and provider groups, have questioned whether the monograph process used to regulate most OTC drugs has been overly burdensome and has limited FDA's ability to quickly update and finalize monographs in response to potential safety issues for consumers. Enacted in March 2020, the CARES Act changed how FDA regulates OTC drugs.

The Sunscreen Innovation Act included a provision for GAO to review FDA's regulation of OTC drugs. This report describes, among other issues, (1) the factors that affected FDA's ability to regulate OTC drugs and (2) how FDA identified and responded to safety issues associated with these drugs.

GAO reviewed federal statutes and agency documents and interviewed FDA officials and stakeholders familiar with the monograph process. These stakeholders included representatives from the OTC drug industry, health care provider and consumer groups, and researchers.

The Department of Health and Human Services provided technical comments on this report, which GAO incorporated as appropriate.

## OVER-THE-COUNTER DRUGS

### Information on FDA's Regulation of Most OTC Drugs

## What GAO Found

The Food and Drug Administration (FDA) has regulated most over-the-counter (OTC) drugs—that is, drugs available without a prescription—through the OTC monograph process. FDA has described an OTC monograph as a "rulebook" for marketing safe and effective OTC drugs, such as aspirin, cough and cold medicine, and hand sanitizer. OTC monographs established conditions—such as active ingredients, indications for use, dosage forms, and product labeling—under which an OTC drug was generally recognized as safe and effective.

According to FDA officials, before the CARES Act, which was enacted in March 2020, the agency's ability to update and finalize monographs in response to safety issues and to reflect new scientific information was limited by the rulemaking process the agency was required to follow, as well as insufficient resources. Agency officials estimated that it took at least 6 years to complete the required rulemaking process. Additionally, the agency reported it was critically under-resourced to regulate the estimated 100,000 OTC drugs marketed through the monograph process. However, the CARES Act provided for a new process to regulate these OTC drugs rather than the rulemaking process. FDA officials expect it will take less time to update and finalize requirements for OTC drugs using the new process. The CARES Act also authorized FDA to assess user fees to provide additional resources to regulate OTC drugs. Although FDA officials said this new process and user fees should improve its regulation of OTC drugs, the agency's analysis of the effect of the CARES Act is still ongoing.

FDA officials told GAO that prior to the CARES Act, they used various methods to identify and respond to safety issues related to OTC drugs. For example, to identify these issues, FDA officials said they read medical literature related to safety issues and reviewed reports submitted to the agency's adverse event reporting system. To respond to these issues, FDA took steps such as issuing drug safety communications to consumers and requesting that manufacturers make changes to a drug's labeling. For example, in 2015, two FDA advisory committees recommended that cough and cold drugs with codeine be removed from the relevant OTC monograph for use in drugs in children. In 2018, FDA also issued a drug safety communication stating the risks outweighed the benefits for the use of these drugs in children. However, FDA officials said these methods were not a substitute for rulemaking because manufacturers could legally market their OTC drugs without making requested safety changes until the rulemaking process was completed.

According to FDA officials, the new process for regulating OTC drugs included in the CARES Act could improve FDA's ability to address identified safety risks in a more timely and efficient manner in the future. The act established an expedited process to address safety issues that pose an imminent hazard to public health or to change a drug's labeling to mitigate a significant or unreasonable risk of a serious adverse event.