

Why GAO Did This Study

To manage the risks posed by some drugs, FDA requires drug companies to establish risk evaluation and mitigation strategies. Companies developing generic drugs generally need samples of the reference standard drug to conduct bioequivalence testing. Generic companies may also have to negotiate a shared system with the reference drug company, when that company's drug is subject to certain REMS requirements.

FDA and FTC officials acknowledge that some drug companies have used certain practices that prevent or delay the development of generic drugs. The practices include limiting access to samples of reference standard drugs with and without REMS and delaying negotiations for creating required shared systems. GAO was asked to review drugs subject to REMS and drug companies' experience with these practices. This report describes (1) the drugs subject to REMS, and (2) FDA and FTC's efforts to address these practices, and stakeholders' views on agencies' efforts.

GAO analyzed FDA data on the conditions these drugs treat and the REMS requirements that apply to the drugs. GAO also interviewed FDA and FTC officials and representatives from five reference drug companies and four generic drug companies, which GAO selected based on a variety of factors, including the companies' experiences with drugs subject to REMS. GAO also reviewed public comments and related documents from FDA and FTC.

HHS and FTC provided technical comments on a draft of this report, which GAO incorporated as appropriate.

GENERIC DRUG DEVELOPMENT

Stakeholders' Views of Risk Evaluation and Mitigation Strategies Differ

What GAO Found

The Food and Drug Administration (FDA) can require drug companies to establish risk evaluation and mitigation strategies (REMS) for drugs with serious safety concerns to ensure that a drug's benefits outweigh its risks. As of March 18, 2019, FDA approved 74 active REMS that cover 523 drugs that treat various conditions. One hundred forty-three of the drugs are reference standard drugs, which are drugs generic drug companies must use to conduct bioequivalence testing. Of these 143, 64 have at least one approved generic that is also subject to REMS. Ten of the REMS are shared systems that allow health care providers to obtain information from multiple companies on a drug's risks and satisfy other administrative requirements through one REMS system.

According to FDA and the Federal Trade Commission (FTC), drugs with and without REMS have been the subject of practices that can delay or prevent generic drug development and marketing. FDA and FTC have taken actions designed to address some of these practices. According to FDA officials, they are more limited in what actions they can take when drugs without REMS are involved. Drug company officials that GAO interviewed had different views on these actions. To address practices that may limit access to samples of reference standard drugs and keep generic drugs from the market:

- FDA issued draft guidance in 2014 on how generic companies could obtain a letter stating that the agency would not consider it a REMS violation to provide reference standard drug samples to the generic company requesting the letter. Three of the four generic companies GAO interviewed said these letters were not useful because they do not require drug companies to share samples. In contrast, officials from three of five reference drug companies said the letters addressed their safety concerns about providing samples to generic companies. FDA does not issue such letters for drugs without REMS.
- In February 2019, FDA published a list of drug companies whose reference standard drugs were the subject of access inquiries made to FDA by generic drug companies. One of the four generic companies GAO spoke with said FDA's list was helpful, and one reference drug company said it was uncertain why it was included on the list.
- FTC has reviewed inquiries it received from FDA and generic companies, and has filed amicus briefs in two cases involving drugs with REMS. According to FTC, to date, the agency has not brought a case charging a drug company with violating federal antitrust law for refusing to provide samples to a generic drug company.
- To address practices that may delay negotiations between reference drug and generic drug companies for creating required shared systems, FDA issued waivers and related guidance that allowed generic companies to develop a separate, but comparable, REMS shared system. One generic drug company said the guidance on waivers was helpful; however, one drug company said the waivers put added burden on health care providers who have to use multiple REMS systems.