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FDA schedules public hearing on solutions to drug shortages

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The U.S. Food and Drug Administration (FDA) has announced it will hold a public meeting on November 27 in Washington, D.C. to give stakeholders – including health care providers, patients, manufacturers, wholesalers, pharmacists, pharmacy benefit managers, veterinarians, public and private insurers, academic researchers, and the public – the opportunity to provide input on the underlying systemic causes of drug shortages and to make recommendations for actions to prevent or mitigate drug shortages.

Titled "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions," the meeting will result in a report to Congress by the drug shortages task force, focusing on

- the impact of drug shortages on patients, health care providers, and the supply chain;
- how additional data could more accurately capture the impact of different drug shortages;
- what factors affect the likelihood, severity, and duration of drug shortages;
- what government regulations could be modified to limit the impact of drug shortages;
- drug manufacturers' role in drug shortages, including what factors affect drug makers' decisions to make capital investments to expand manufacturing capacity;
- how to avoid production slowdowns when drug makers remediate or upgrade a facility;
- the features of drug supply contracts that may contribute to slowdowns; and
- how additional funding could provide incentives to remedy the root causes of drug shortages.

Drug shortages task force to consider financial incentives, manufacturing oversight for "critical drugs"

The FDA announced the formation of the drug shortages task force in July, citing concern over "ongoing shortages of medically necessary products." The task force's primary objective is to find lasting solutions to the drug shortages issue, including through consideration of changes to reimbursement policies and incentives aimed at encouraging investment in manufacturing facilities. The task force is comprised of leaders from the FDA, the Centers for Medicare & Medicaid Services (CMS), the Department of Veterans Affairs (VA), and the Department of Defense (DoD). FDA Commissioner Scott Gottlieb, M.D., said the drug shortage issue "can't be addressed by the FDA alone."

The FDA said in July it plans to take a hard look at its authority in the context of "expand[ing] the FDA's authority to require applicants of certain drugs to conduct a risk assessment to identify the vulnerabilities in their drug supply that could cause a shortage, and to establish risk mitigation plans to address those weaknesses proactively." The FDA is also considering creating an "essential drugs list," and will evaluate its authority to employ "significant interventions" to avert shortages of drugs on this list. The FDA also plans to assess the role of financial incentives to ensure that the agency isn't "discouraging investment for manufacturing drugs that are more likely to go into shortage."

Ongoing FDA efforts to prevent drug shortages

Dr. Gottlieb has previously discussed the FDA's efforts to advance long-term solutions to prevent shortages. One example is the Center for Drug Evaluation and Research (CDER) Office of Pharmaceutical Quality's Emerging Technology Program, which aims to promote the adoption of innovative approaches to pharmaceutical product design and manufacturing, as well as the FDA's Quality Metrics Feedback Program and 2018 Quality Metrics Site Visit Program, both intended to identify opportunities for manufacturing improvements. Proposals regarding these quality metrics programs have comment periods ending soon.

Dr. Gottlieb also made a statement in May on the FDA's work to mitigate shortages of intravenous drugs, shorten supply disruptions, and better predict vulnerabilities in the drug supply. CDER Deputy Director for Regulatory Programs Douglas Throckmorton, M.D., had provided updates in a June 19 statement on the FDA's work to address specific drug shortages. In addition, the FDA's Report on Drug Shortages for CY-2017 – the agency's fifth annual report of the type to Congress – expressed concern that the number of new drug shortages in the United States jumped to 39 in 2017 from 26 in the two preceding years. This announcement followed a June 15 letter by a bipartisan group of senators who relied on a February 2014 Government Accountability Office (GAO) report in urging Dr. Gottlieb to provide recommendations to Congress on how to address nationwide drug shortages; those senators applauded the new task force.

Next steps

The increased focus and activity create challenges and opportunities. Among the potential implications for drug manufacturers and distributors are

- the benefit of financial incentives made available for drugs at risk of being in short supply; and
- increased responsibilities to conduct risk assessments and report on potential vulnerabilities in their production processes.

Hogan Lovells lawyers will be attending the November meeting. The public comment period on the meeting will be open until January 2019 for clients who would like to submit comments.

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