FDA Statement on Drug Shortages

Even shortages of a small number of key drugs can place a serious burden on patients and providers.

July 12, 2018 By Food and Drug Administration (FDA)

Statement by FDA Commissioner Scott Gottlieb, M.D., on formation of a new drug shortages task force and FDA's efforts to advance long-term solutions to prevent shortages

We've seen the number of new drug shortages steadily decline since a peak in 2011 owing to the work of the Food and Drug Administration, industry and other groups. Despite these efforts, we continue to see ongoing shortages of medically necessary products. Even shortages of a small number of key drugs can place a serious burden on providers. While we've made progress to mitigate individual shortages, we haven't firmly impacted the underlying structural concerns that give rise to these recurring challenges. When shortages occur, practitioners are forced to ration supplies or substitute alternate drugs that in some cases compromise patient care. We need to pursue more enduring solutions.

We've been providing updates and information about the FDA's efforts to prevent or mitigate drug shortages—both actions to address specific shortages and efforts that target the root causes of drug shortages in general.

At the same time, I believe that more can and must be done across our health care system to achieve more enduring solutions. We've recommitted ourselves to expanding our efforts to identify additional actions to prevent and address shortages and look forward to continuing to work with Congress on these efforts.

Lawmakers have recently urged us to develop new proposals for the actions that we believe could have a more enduring impact on solving these vulnerabilities. In that spirit, they've asked us to consider whether the FDA or other federal agencies may need additional authorities to help ensure that patients have continued access to their medicine. They have also asked us for recommendations on the policy steps we can implement to address the root causes that give rise to shortages. We are taking up this cause.

Today, I'm announcing the formation of a new Drug Shortages Task Force. It will be led by Keagan Lenihan, the FDA's associate commissioner for strategic initiatives. I'm charging the shortages task force to delve more deeply into the reasons why some shortages remain a persistent challenge. The charge to this new task force is to look for holistic solutions to addressing the

underlying causes for these shortages.

The task force will expand upon the work of a group that was created by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). FDASIA gave the FDA new authorities to address drug shortages. This includes broadening the requirements that manufacturers notify us of a permanent discontinuation or temporary interruption in manufacturing, which might lead to a shortage of prescription drugs for serious illnesses. Being notified of these issues has been critically important. It has allowed the FDA to work with manufacturers to address and prevent hundreds of shortages in the past few years. Recently, we submitted our annual drug shortages report to Congress that discusses this important work. However, challenges around drug shortages persist. We must work to find new and creative ways to tackle the issue.

We believe lasting solutions to this issue can't be addressed by the FDA alone. Historically, many drugs in short supply have been low-profit margin generic medicines. Many are sterile, parenteral drugs, which can be challenging to manufacture. The low-profit margins, and the significant cost of manufacturing these complex drugs, has resulted in consolidation in the industry. The only way to produce these low-margin products profitably is to manufacture them at tremendous scale. This has resulted in fewer and fewer manufacturers for certain key products. The result is very little margin for error in this space.

It has also resulted in an under-investment in manufacturing. Manufacturing sterile, injectable drugs is not a trivial endeavor. Unless drug makers are investing in their manufacturing facilities, it can create conditions that give rise to production stoppages in order to fix manufacturing problems. With few manufacturers operating at tremendous scale, if even one of the suppliers faces manufacturing challenges, shortages can occur. I believe long-term solutions must include those that encourage companies to invest in more capacity to make these important medicines, and to produce them with robust manufacturing processes that ensure consistently available quality products. This is one area we'll explore. But we also need to look more broadly across the entire pharmaceutical industry, health care providers, payors and government regulators for structural solutions that keep these shortages from happening.

To ensure we aren't overlooking any solutions, our task force will include not only senior leaders from the FDA, but also leaders from the Centers for Medicare and Medicaid Services (CMS) and the Department of Veterans Affairs. Collectively, they provide or pay for prescription medicine for millions of Americans.

As we stand up the task force, we intend to establish several dedicated workgroups to look at various aspects of this issue. These will include an examination of the FDA's current authorities. It will also evaluate the reimbursement policies from CMS and other payors that could be making it difficult for companies to manufacture certain drugs profitably. I also want the task force to explore possible incentives to encourage expansion of manufacturing capacity and enhanced quality. We'll be looking at whether it makes sense to develop a critical drugs list, or a list of essential drugs. These are medicines where it would be especially important, from a clinical perspective, to ensure an uninterrupted drug supply. For these medicines, we may want to

consider more significant interventions than we currently employ to avert shortages.

One possibility might be to look at regulations coupled with additional financial incentives to market these critical access drugs. We want to make sure we aren't discouraging investment for manufacturing drugs that are more likely to go into shortage, and thus working against our own goals. Among some of the steps that could potentially be considered, and coupled with additional incentives, are requirements for sharing additional key information from industry when they notify the agency about a possible shortage. Another consideration might be to look at whether it could help address shortages to expand 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.

As it seeks new solutions, the task force will not be operating in a vacuum. Addressing shortages and devising new, practical solutions will require input from the pharmaceutical and health care industries, patient representatives, our federal partners and Congress. We intend to engage the public and hold a meeting with stakeholders in the next several months to provide an opportunity for everyone with a stake in addressing drug shortages to come to the table. We appreciate that lawmakers are also considering this issue. As part of the task force's work, we'll consider how additional authorities from Congress might help better address shortages. This engagement will be critical to informing these considerations.

The task force will also be exploring manufacturing issues. The FDA is already taking steps to support new technologies that can improve manufacturing and help reduce the chance that supply disruptions will occur.

Patients expect and deserve high-quality drug products. It is the manufacturer's responsibility to ensure that its drug products are safe, effective and of high quality. While preventing drug shortages is a top priority for the agency, we also must make sure that quality standards are not compromised. This is why we are committed to working with manufacturers to resolve quality or manufacturing problems in a sustainable way that will help ensure continued patient access to vital safe and effective drugs.

I've previously noted that the FDA has implemented an emerging technology program and established an emerging technology team to engage with companies about new production technologies that could, in the long run, prevent drug shortages caused by product quality and manufacturing problems. We recently announced two new initiatives regarding quality metrics, which are used in a variety of industries to monitor the quality control systems and processes that ensure quality standards are met, and to identify opportunities for manufacturing improvements. These scientific and regulatory advances can help address some of the conditions that can give rise to drug shortages.

In the meantime, the FDA's dedicated groups of employees will continue working diligently behind-the-scenes to anticipate and help mitigate shortages. Our drug shortages staff at the FDA's Center for Drug Evaluation and Research, who are also U.S. Public Health Service Commissioned Corps

officers, worked with manufacturers to prevent 145 drug shortages in 2017. That work was on top of a nearly around-the-clock effort, along with other FDA employees, to cope with the aftermath of the 2017 Atlantic hurricanes, which initially shut down several important medical product manufacturing facilities in Puerto Rico, exacerbating shortages of IV saline and other fluids. These dedicated Commissioned Corps officers, collaborating with other colleagues in CDER and across the FDA, worked with pharmaceutical companies to address the shortages by temporarily providing discretion to import products from other facilities and to expedite approval of new manufacturing facilities. They also worked to help expedite the review and approval of similar products from other companies. The important work they do cannot be understated.

Given the tremendous impact it had on drug shortages over the last year, I'd be remiss if I didn't mention this year's hurricane season, which is already upon us. The FDA's Emergency Operations Center routinely monitors storms, in conjunction with other federal agencies. Part of the FDA's monitoring is identifying FDA-regulated facilities that could be impacted by any storms. If and when storms hit, that planning enables the agency to begin responding quickly in conjunction with other partners. Staff across the FDA stand ready to work with manufacturers to prevent and mitigate any potential storm-related drug shortages.

We look forward to continuing our collaborative efforts with industry, patients, health care professionals, Congress and other stakeholders to address this vital public health issue. Our mission is to ensure that patients have access to the drugs they need. The task force will report regularly on its progress. We'll keep the public informed about current drug shortages and our efforts to prevent and mitigate new ones.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

This statement was originally published on the Food and Drug Administration website on July 12, 2018.

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http://beta.docker.cancerhealth.com/blog/statement-new-drug-shortages-task-force-longterm-solutions-prevent-shortages