

Drug shortages pose a public health crisis in the US

June 18 2018, by Sharona Hoffman



Credit: Karolina Grabowska from Pexels

On June 12, the American Medical Association <u>announced that drug</u> <u>shortages</u> pose an urgent public health crisis. This crisis should be of concern to all Americans.



The Food and Drug Administration <u>defines a drug shortage</u> as a "period of time when the demand or projected demand for a medically necessary drug in the U.S. exceeds its supply." All too often, a shortage means that doctors cannot give the right drugs to <u>patients</u> when needed.

Serious drug shortages are not a new phenomenon. The FDA recognized their prevalence and established a <u>Drug Shortage Program</u> back in 1999. The problem, however, persists.

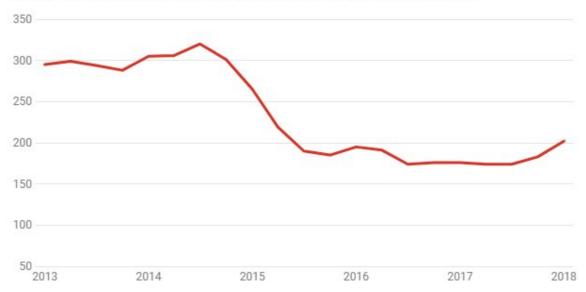
In short supply

Currently, the U.S. is short on <u>182 drugs and medical supplies</u>, according to the American Society of Health-System Pharmacists. The list includes <u>IV bags</u>, <u>injectable morphine</u> and other powerful painkillers, <u>anesthetics</u>, <u>antibiotics</u>, <u>electrolytes</u>, <u>cancer drugs</u> and much more. All of these are of critical importance to patients with serious illnesses.

Why do drug shortages occur? The AMA <u>blames the current crisis</u> in part on the damage caused to production facilities in Puerto Rico by <u>hurricanes Irma and Maria in 2017</u>. Furthermore, <u>the government's</u> <u>efforts</u> to combat the opioid crisis by reducing the availability of opioids has hampered the ability for hospitals to obtain necessary painkillers. <u>Production delays</u> at manufacturing plants or delays in procuring raw materials from suppliers can also contribute to shortages.



Active drug shortages



In the first quarter of 2018, there were 202 active drug shortages across the U.S.

Credit: The Conversation, CC-BY-ND Source: American Society of Health-System Pharmacists

Some companies <u>choose to stop</u> manufacturing a drug in order to focus on newer, more lucrative medicines. If a manufacturer is one of only a few producers or the primary producer, even a temporary stoppage can have harmful market effects. For example, <u>only seven companies</u> make most of the sterile injectable drugs sold in the U.S. If one of these has difficulty or discontinues production, it would be very hard for the others to make up the difference.

Dangerous outcomes

Drug shortages have serious consequences. Most importantly, they often endanger patients' lives. When <u>health care providers</u> cannot administer



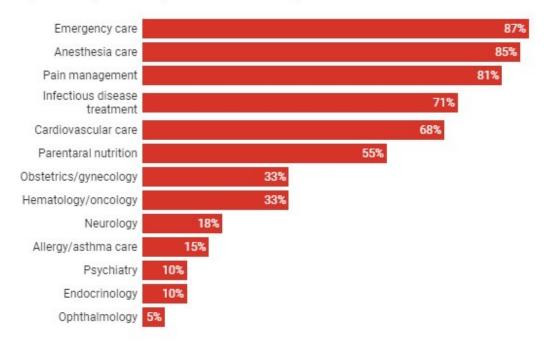
needed drugs, they cannot provide proper treatment.

The Institute for Safe Medication Practices conducted a <u>survey</u> of almost 300 health care providers in 2017. A majority of participants felt that drug shortages had affected their patients. Seven in 10 stated shortages made them unable to provide some patients with recommended treatments. Almost half believed that as a result, their patients received less effective therapies.

In addition, 75 percent of participants stated that they were forced to delay patient treatments because of shortages. In one case, a delay in treating sepsis with sodium bicarbonate may have contributed to a patient's death. Other poor outcomes included more pain or discomfort during procedures because appropriate drugs were unavailable.

Drug shortages

In a survey of 300 U.S. health care workers, over half reported that more than 20 drugs were involved in shortages during the six months prior to the survey. Emergency care, anesthesia care and pain management drugs were the most likely to be affected.





Credit: The Conversation

Drug shortages also contribute to increased health care costs. Medical staff must spend time <u>managing</u> drug shortages. They must track inventory, identify alternatives and make decisions about rationing scarce resources.

In addition, some vendors engage in price gouging when selling drugs in short supply. The cost of this deplorable practice may reach <u>over</u> <u>US\$400 million</u> a year.

Drug shortages can have <u>other consequences</u> for doctors and patients. Physicians face the unenviable task of explaining to patients that they cannot receive needed drugs. This can be demoralizing for patients and make them lose trust in the medical profession. Additionally, insurers may refuse to pay for a treatment that is substituted for a drug in shortage. They may insist the alternative medication is not standard therapy and therefore will not be covered.

Finally, drug shortages can adversely affect medical research. If drugs that are being studied are unavailable, research projects may have to be postponed, suspended or canceled.



Reasons for drug shortages

In 2017, in 30 percent of situations, manufacturers cited manufacturing issues as the cause of a shortage.

Manufacturing	30%		
Supply/demand	8%		
Natural disaster	3%		
Raw material	2%		
Discontinuation	2%		
Unknown	53%		

Credit: The Conversation

Tackling the problem

By law, manufacturers are required to report the expected duration of shortages and the reasons for them to the FDA. They must also provide notifications of production discontinuances and temporary interruptions.

FDA states that it posts information about <u>drug shortages</u> on its <u>website</u>. However, it is not clear where on the website this data is placed. Indeed, many health care providers indicate that they do <u>not consistently</u> receive information that could help them prepare for shortages.

The FDA states that it <u>works</u> with manufacturers to <u>resolve drug</u> <u>shortages</u> as quickly as possible.

Fortunately, in recent years, there have been <u>fewer drug shortages</u> than earlier in the decade. However, the number still hovers around 200 annually. In my view, this figure remains unacceptably high and all too



often compromises patient care. The <u>drug</u> shortage crisis must remain a priority for the government, the health care industry and the public at large.

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