3Qs: Analyzing why sudden drug shortages occur

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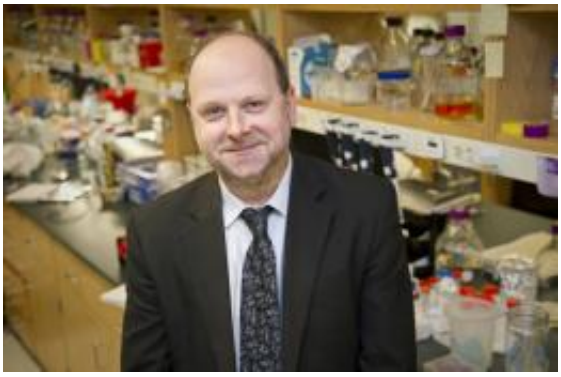

Graham Jones, chair of the chemistry and chemical biology department, says tough FDA standards and slim profit margins for certain pharmaceuticals mean drug shortages are likely, and the global market may worsen the problem. Photo by Mary Knox Merrill.

Drug manufacturers and the Food and Drug Administration (FDA) scrambled earlier this month to address a sudden shortage of methotrexate, a 60-year-old drug that treats children with severe cases of leukemia and sarcoma. Graham Jones, the chair of the chemistry and chemical biology department in the College of Science, said the problem is likely to continue as fewer pharmaceutical companies produce drugs with slim profit margins and a small patient base.

Why did the FDA shutdown of one factory cause a crisis for doctors and the patients who rely on

methotrexate?

The company that was contracted by the FDA to make this drug — Ben Venue Laboratories in Ohio — had a problem with an inspection. The FDA found some violations, contamination and housekeeping issues, so they suspended the approval process, creating a backlog for the drug.

With these drugs with very low profit margins, one company agrees to take on production for a couple years, so it factors in how much it can produce in that time while still making a profit. It's a way to continue making these vital drugs, but it also puts all the eggs in one basket. If you wanted to prevent this from happening, you have to have more labs making this drug on very short notice, which is what is happening now: more labs coming up online to produce this molecule that's in very short supply.

What factors can prompt the FDA to shut down the production of live-saving medications, which often are produced at just one site?

If you produce drugs for patients in the United States, it has to be done to FDA specifications under what is referred to as Good Manufacturing Practice or 'GMP,' the standards of which are high — and with good reason. If you look at the reports, for example, of the Ben Venue plant, there are reports that suggest there was mold on the walls and rust falling into the vials, which is the kind of thing that could happen anywhere. The standards have to be very high and it is also difficult to routinely monitor those standards outside the United States, making it problematic to outsource to drug producers overseas.

There are common things that come into play in these cases that we must be conscious of. There is the potential for contamination in

pharmaceutical and biological drugs and there are safety and plant violations that can happen anywhere. The bigger issues are outsourcing and relying on individual plants and plants in countries abroad as sole suppliers — you need to have an inventory of companies that can come online very quickly so the entire stocks of a particular drug isn't suddenly at risk.

What lessons have we learned from previous shortages and what issues can be expected to emerge in the future?

A few years back, we were no long producing the flu vaccine in the United States, instead outsourcing it to a company in the United Kingdom, where a virus spread through the plant, shutting down production. There was an acute shortage for a few months that caused an immediate problem here in the United States as our stockpiles of the vaccine had run low.

It is also increasingly dangerous to rely on outsourced companies. What if there is a trade war? What if the drug can no longer be produced up to our standards? National security is at risk, and these are issues that will need to get more and more attention as we move into this global economy.

Provided by Northeastern University

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