The impact of the rise in new drug rejections

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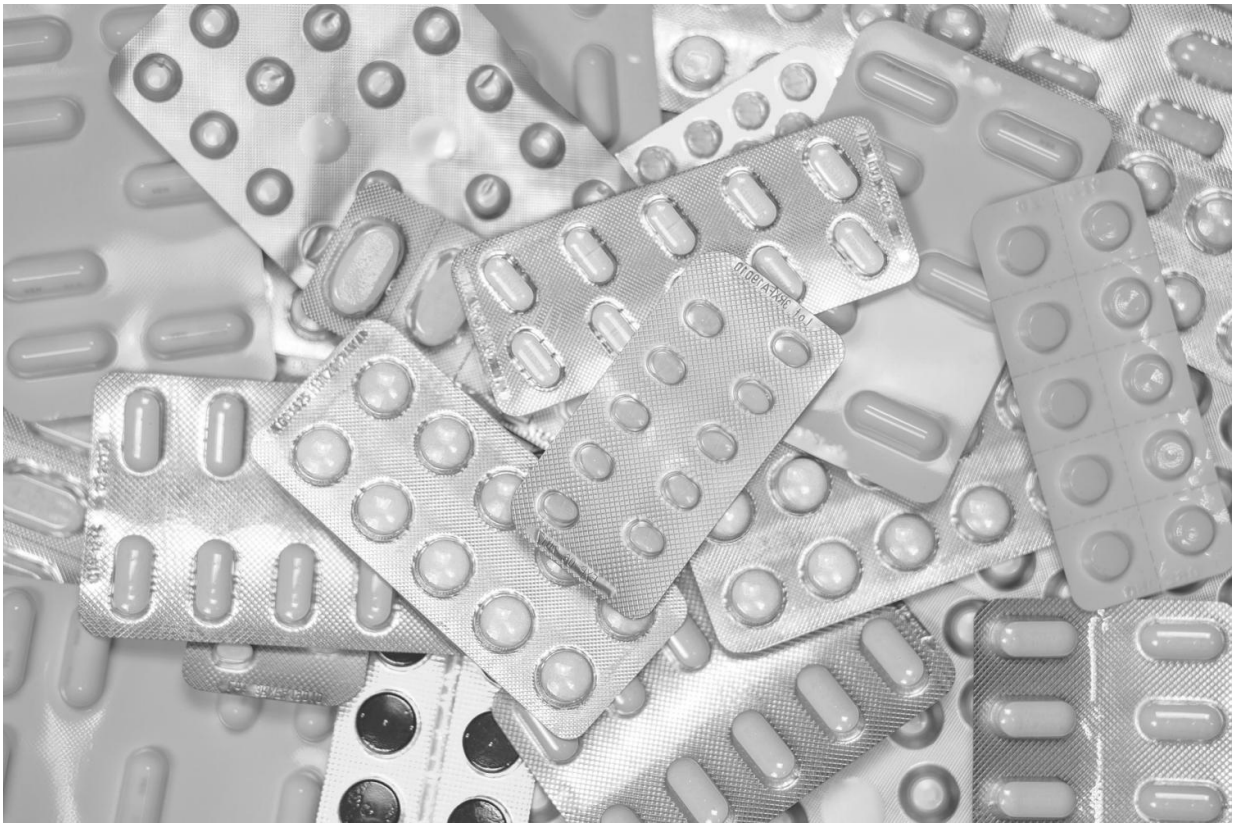

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The number of new drug applications rejected by the U.S. Food and Drug Administration has been on the rise. The cover story of *Chemical & Engineering News* (*C&EN*), the weekly newsmagazine of the American Chemical Society, explores why this is happening and what it means for patients.

Ann Thayer, a senior correspondent for C&EN, notes that in 2016, the FDA turned down 14 applications for novel drugs, more than the agency has rejected in recent years. Concurrent with this increase is a growing reliance on outside manufacturers. While outsourcing gives drug companies access to specialized manufacturing plants, it also opens them up to any problems those external firms might have. Often, drug rejections are due to these companies' failure to comply with good manufacturing practices.

Many drug companies and manufacturers eventually resolve the glitches and get their drugs approved. But the process can take a few months to a few years, which can leave patients with fewer treatment options while the snags get addressed. To help reduce delays, the FDA is providing guidance to drug companies for drawing up manufacturing-quality agreements with outside firms to help fix these problems before they have a chance to hold up applications.

More information: "The complete response letter: The mail no one wants to receive," cen.acs.org/articles/95/i20/co … letter-mail-one.html

Provided by American Chemical Society