

New study points to supply chain disruptions if the FDA removes ineffective decongestant from the market

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Credit: Andrea Piacquadio from Pexels

In a new study of nasal decongestant purchasing patterns, researchers at the University of Pittsburgh School of Medicine found that

phenylephrine remained the most popular choice year after year, despite decades of concerns over a lack of evidence supporting its effectiveness.

Published in [JAMA](#), the research letter points to a coming wave of supply chain disturbances if the Food and Drug Administration (FDA) moves to pull oral phenylephrine from the shelves, as [recommended by an FDA advisory panel](#) in 2023 that found the medication ineffective.

The researchers analyzed purchases of phenylephrine and [pseudoephedrine](#)—the only two nasal decongestants currently approved by the FDA—by pharmacies and major retail outlets. Between 2012 and 2021, American pharmacies purchased 19.8 billion units of phenylephrine products, compared to 13.2 billion units of pseudoephedrine products.

The researchers showed that pseudoephedrine is usually sold as a stand-alone product; phenylephrine, however, tends to be combined with several drugs and packaged as multi-symptom products. If the FDA opts to follow the [advisory panel](#)'s recommendation, most multi-symptom products will be pulled from the shelves, as there are still few pseudoephedrine-based alternatives on the market.

The study points to a need for continued reform of the over-the-counter drug review process, said lead author Timothy Anderson, M.D., M.A.S., a [primary care physician](#), health services researcher and assistant professor of medicine at Pitt.

"The FDA needs to hold over-the-counter drugs to a standard of effectiveness similar to that of prescription drugs," Anderson said. "A comparable pathway is needed for drugs that are sold over the counter as exists for post-approval monitoring of the risks and efficacy of [prescription drugs](#). This will require a substantial investment in infrastructure to expand capacity."

Other authors on the study were Katie J. Suda, Pharm.D., M.S. and Walid F. Gellad, M.D., M.P.H., both of Pitt; and Mina Tadrous, Pharm.D., Ph.D., of the University of Toronto.

More information: Trends in Phenylephrine and Pseudoephedrine Sales in the US, *JAMA* (2024). [DOI: 10.1001/jama.2023.27932](https://doi.org/10.1001/jama.2023.27932)

Provided by University of Pittsburgh

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