

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

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<https://oversight.house.gov>

December 3, 2023

The Honorable Robert M. Califf  
Commissioner of Food and Drugs  
U. S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Commissioner Califf:

The Subcommittee on Health Care and Financial Services is investigating the efficacy of over the counter (OTC) drugs after a recent advisory committee meeting concluded that a commonly used decongestant, known as phenylephrine, is ineffective.<sup>1</sup> Oral OTC decongestants have a large share of the retail drug market and it is estimated that Americans spend an average of \$1.8 billion per year on these products.<sup>2</sup> Since 2006, phenylephrine has been branded as an oral decongestant ingredient in popular OTC drugs branded as Sudafed, Theraflu, and Vicks DayQuil and NyQuil.<sup>3</sup> We are concerned that phenylephrine has remained approved by the Food and Drug Administration (FDA) as an OTC drug “generally recognized as safe and effective” (GRASE) for nearly fifty years despite strong scientific evidence supporting the contrary.<sup>4</sup> Due to these concerns, we ask that you provide a staff-level briefing to assist the Subcommittee’s oversight of this matter.

The Code of Federal Regulations standard for OTC drugs GRASE defines effectiveness as “a reasonable expectation that, in a significant portion of the target population, the pharmacological effect of the drug... will provide clinically significant relief of the type claimed.”<sup>5</sup> Although phenylephrine has been GRASE since the OTC monograph was established in 1976,<sup>6</sup> it became a more popular decongestant ingredient beginning in 2005, when

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<sup>1</sup> News Release, FDA clarifies results of recent advisory committee meeting on oral phenylephrine, U. S. Food & Drug Admin. (Sept. 14, 2023).

<sup>2</sup> U. S. Food & Drug Admin., NDAC briefing document: Oral phenylephrine in the CCABA monograph, 68 (Sept. 11-12, 2023), *available at*

[https://www.fda.gov/media/171915/download?utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=newsletter\\_axiosvitals&stream=top#\\_ga=2.33449853.2106642016.1694473699-1778585207.1686244675](https://www.fda.gov/media/171915/download?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top#_ga=2.33449853.2106642016.1694473699-1778585207.1686244675).

<sup>3</sup> Megan Cerullo, *Ineffective ingredient could make Dayquil, Sudafed and others disappear from store shelves*, CBS NEWS (Sept. 12, 2023).

<sup>4</sup> Nidhi Subbaraman, *These are the two scientists taking down cold medicines that don’t work*, WALL ST. J. (Oct. 20, 2023; *Supra* n. 2).

<sup>5</sup> 21 C. F. R. 330.10(a)(ii) – Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

<sup>6</sup> 21 C. F. R. 341.20(a)(1) – Cold, cough, allergy, bronchodilator, and antiasthmatic drug products for over-the-counter human use.

a law required pseudoephedrine to be removed from OTC products.<sup>7</sup> Prior to and since phenylephrine became the preferred alternative to pseudoephedrine, scientific support for the effectiveness of phenylephrine has been consistently weak, showing that the drug administered orally provides no better symptom relief than a placebo.<sup>8</sup>

In the last two decades, pharmaceutical researchers, skeptical that phenylephrine met FDA's effectiveness standard, performed a meta-analysis of over fifty years of clinical research and concluded that these drugs provide no relief for nasal congestion when administered orally.<sup>9</sup> In 2015 and 2022, these researchers authored citizen's petitions to the FDA's Non-Prescription Drug Advisory Committee (NPDAC), requesting that oral phenylephrine be removed from the OTC monograph based upon these conclusions.<sup>10</sup> In 2023, the NPDAC agreed to review the available evidence and found inadequate efficacy data to support retaining phenylephrine as a drug GRASE.<sup>11</sup>

It is concerning that the NPDAC, and thereby the FDA, relied upon outdated and insufficient evidence regarding phenylephrine's use as a decongestant for so many years, despite numerous appeals by the scientific community.<sup>12</sup> Americans seeking OTC relief should not have to worry whether they are wasting their hard-earned money on ineffective drugs.<sup>13</sup> As the FDA takes the NPDAC recommendation into consideration, we urge you to consider the evidentiary standard of drugs GRASE and evaluate the effectiveness of the OTC medications that Americans rely upon.<sup>14</sup> It is important that the American people have confidence in the FDA's approvals and trust that the drugs they purchase are not only safe, but also effective.

To assist the Subcommittee's oversight of this matter, please make arrangements to schedule a briefing with Committee staff no later than December 11, 2023.

To schedule the briefing please contact Committee on Oversight and Accountability staff at (202) 225-5074. The Committee on Oversight and Accountability is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. Thank you in advance for your cooperation with this inquiry.

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<sup>7</sup> Combat Methamphetamine Epidemic Act of 2005, Pub. L. No. 109-177, 120 Stat. 192.

<sup>8</sup> Randy C. Hatton & Leslie Hendeles, *We've known for 20 years this cold medicine doesn't work*, N. Y. TIMES (Sept. 29, 2023).

<sup>9</sup> *Supra*, n. 5.

<sup>10</sup> Nidhi Subbaraman, *These are the two scientists taking down cold medicines that don't work*, WALL ST. J. (Oct. 20, 2023); Leslie Hendeles, Pharm. D. & Randy C. Hatton, Pharm. D., *Oral Phenylephrine Citizen's Petitions from Nov. 2015 & May 2022* (on file with the Comm.).

<sup>11</sup> News Release, FDA clarifies results of recent advisory committee meeting on oral phenylephrine, U. S. Food & Drug Admin. (Sept. 14, 2023).

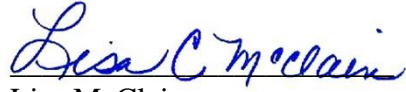
<sup>12</sup> Randy C. Hatton & Leslie Hendeles, *Why is oral phenylephrine on the market after compelling evidence of its ineffectiveness as a decongestant?* 56 ANNALS OF PHARMACOTHERAPY (Mar. 25, 2022); Nidhi Subbaraman, *These are the two scientists taking down cold medicines that don't work*, WALL ST. J. (Oct. 20, 2023).

<sup>13</sup> Matthew Perrone, *Popular nasal decongestant doesn't actually relieve congestion, FDA advisers say*, A. P. (Sept. 12, 2023).

<sup>14</sup> Alvin Powell, *Why are ineffective oral decongestants still on store shelves?* THE HARV. GAZETTE (Sept. 20, 2023).

The Hon. Robert M. Califf  
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Sincerely,

A handwritten signature in blue ink that reads "Lisa C. McClain". The signature is written in a cursive style with a horizontal line underneath the name.

Lisa McClain  
Chairwoman  
Subcommittee on Health Care and Financial Services

cc: The Honorable Katie Porter, Ranking Member  
Subcommittee on Health Care and Financial Services