Testimony Before the Food and Drug Administration's Nonprescription Drugs Advisory Committee Regarding the Efficacy of Oral Phenylephrine as a Nasal Decongestant

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I note that in the context of oral congestion, we petitioned the Food and Drug Administration (FDA) in 2000 to ban phenylpropanolamine[1] due to safety concerns before the agency removed it from the market.[2]

We believe that even when safety is not a concern, ineffective drugs should not be on the market. We concur with the conclusion of the FDA briefing document that the current collective evidence strongly demonstrates that oral phenylephrine hydrochloride is not effective for *temporary* relief of nasal congestion at the monographed dose of 10 milligrams (mg) and at the monographed dosing interval of every four hours, nor at larger potentially safe doses (up to 40 mg) given at the same frequency.[3]

Mainly, the FDA's clinical pharmacologists have confirmed that based on updated technological methods, the bioavailability of phenylephrine when taken orally is less than 1% because the drug is broken down during absorption.[4] These scientists also have concluded that the half-life of oral phenylephrine is significantly shorter than the four-hour dosing interval.[5]

Additionally, the FDA's new analysis of the original efficacy studies of oral phenylephrine uncovered many methodological and statistical problems that make these studies equivalent to phase 1 studies by current standards.[6] Notably, two of these original

[1] Public Citizen. Petition requesting OTC ban of PPA. October 19, 2000. https://www.citizen.org/article/petition-requesting-otc-ban-of-ppa/. Accessed September 8, 2023.
[2] Food and Drug Administration. FDA issues public warning on phenylpropanolamine. November 6, 2000. https://www.fda.gov/drugs/information-drug-class/fda-issues-public-health-warning-phenylpropanolamine. Accessed September 8, 2023.
[3] Food and Drug Administration. FDA briefing document, efficacy of oral phenylephrine as a nasal congestion; Nonprescription Drug Advisory Committee Meeting. September 11 and 12, 2023. https://www.fda.gov/media/171915/download. Accessed September 8, 2023. PDF p. 9.
[4] *Ibid*. PDF pp. 55-56.
[5] *Ibid*. PDF p. 31.
[6] *Ibid*. PDF pp. 37, 60.

studies generated unbelievable "near textbook perfect results" that were not duplicated in other similar studies by the same sponsor, according to the agency's scientists.[7]

Furthermore, the FDA clinical reviewers examined publicly available data from three adequately controlled, industry-sponsored clinical trials conducted since the 2007 Nonprescription Drugs Advisory Committee meeting. These trials represent the largest and most well-designed available studies evaluating the efficacy of oral phenylephrine for nasal congestion.[8] They illustrated the lack of efficacy of oral immediate-release phenylephrine at doses up to 40 mg and extended-release doses of 30 mg.

Based on this current credible and consistent evidence, the FDA scientists concluded that orally administered phenylephrine is not effective at any dose that can be administered with a reasonable margin of safety.[9]

As discussed in the FDA's briefing document, the benefits of removing oral over-the-counter phenylephrine from the U.S. market are numerous.[10] These include avoiding unnecessary costs and possible delay in care or missed opportunities for using effective treatments when needed, avoiding potential allergic reactions or other adverse events caused by taking multiple products containing oral phenylephrine, avoiding the risks of the drug's accidental use in children, and decreasing overall health care costs. These benefits outweigh any industry-related consequences of removing this ineffective drug from the market.

Therefore, we urge the committee to vote "No" on the questions regarding whether the current evidence supports the effectiveness of orally administered phenylephrine for nasal congestion and whether a higher dosage of the drug would be safe and effective.[11]

In conclusion, oral phenylephrine salts should no longer be classified as Generally Recognized as Safe and Effective. Consumers would not be served by leaving these placebo-like products on the market.

To allay potential concerns, it is imperative for the FDA to couple the removal of oral phenylephrine from the market with disseminating education materials for consumer and health care professionals about the lack of efficacy of these products and the availability of effective treatment alternatives for nasal congestion that requires treatment.[12]

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[7] *Ibid*. PDF p. 32.
[8] *Ibid*. PDF p. 32.
[9] *Ibid*. PDF p. 32.
[10] *Ibid*. PDF p. 9.
[11] Food and Drug Administration. Draft questions, efficacy of oral phenylephrine as a nasal congestion; Nonprescription Drug Advisory Committee Meeting. September 11 and 12, 2023. https://www.fda.gov/media/171912/download. Accessed September 8, 2023.
[12] Treatment for nasal allergies: An updated review. April 2016. *Worst Pills, Best Pills News*. https://www.worstpills.org/newsletters/view/1027. Accessed September 8, 2023.