



Correspondence

Capsaicin not homeopathic

To the Editor: We were interested in the recent article by Bernstein et al¹ on the therapeutic effect of capsaicin in nonallergic rhinitis as demonstrated in other studies.^{2,3} Although not disputing the results of the study, we are concerned about use of the term *homeopathic* to describe the capsaicin solution (ICX72, Sinus Buster; Buster Brands, SciCap, LLC, Schenectady, New York) used in this trial.

Homeopathy is a form of alternative medicine based on the premise that a substance that causes symptoms, when diluted to an extreme degree, may relieve the condition. Traditional homeopathic compounds are typically diluted by 10^{-24} to 10^{-60} to, the point where no molecules of the original substance are present, and therefore lack measurable biological effect and scientific plausibility.⁴ ICX72 is a dilution of 10^{-4} to 10^{-5} ($4\times/5\times$) according to the product label, although the concentration of the solution from which the dilution is made is described neither on the product label nor in this article. Capsaicin is an extremely potent substance with biological activity at very low concentrations. The local irritation described by the authors and information from the manufacturer (SiCap, LLC; email communication, September 22, 2011) indicate that ICX72 contains a sufficient pharmacologically active concentration of capsaicin to explain the benefit observed. Incidentally this local irritant effect

creates an obvious risk of unblinding of the active compound compared with the placebo.

We understand that the US Food and Drug Administration requires the product to be labeled as *homeopathic* to enable nonprescription sales in the United States,⁵ but this is a significant redefinition of the traditional use of the word. To describe ICX72 as a *homeopathic* preparation is inappropriate, and it is important that this article not be used as evidence for the efficacy of traditional homeopathy.

William B. Smith, MBBS, PhD*

Raymond J. Mullins, MBBS, PhD†

*Clinical Immunology and Allergy

Royal Adelaide Hospital

North Terrace, Adelaide, South Australia

†Faculty of Health

University of Canberra

Canberra, Australian Capital Territory

william.smith@health.sa.gov.au

References

- [1] Bernstein JA, Davis BP, Picard JK, Cooper JP, Zheng S, Levin LS. A randomized, double-blind, parallel trial comparing capsaicin nasal spray with placebo in subjects with a significant component of nonallergic rhinitis. *Ann Allergy Asthma Immunol*. 2011;107:171–178.
- [2] Blom HM, Van Rijswijk JB, Garredts IM, Mulder PG, Timmermans T, Gerth van Wijk R. Intranasal capsaicin is efficacious in non-allergic, non-infectious perennial rhinitis: a placebo-controlled study. *Clin Exp Allergy*. 1997;27:796–801.
- [3] Van Rijswijk JB, Boeke EL, Keizer JM, Mulder PG, Blom HM, Fokkens WJ. Intranasal capsaicin reduces nasal hyperreactivity in idiopathic rhinitis: a double-blind randomized application regimen study. *Allergy*. 2003;58:754–761.
- [4] Shang A, Huwiler-Müntener K, Nartey L, et al. Are the clinical effects of homeopathy placebo effects? comparative study of placebo-controlled trials of homeopathy and allopathy. *Lancet*. 2005;366:726–732.
- [5] US Food and Drug Administration. CPG Sec. 400.400 Conditions Under Which Homeopathic Drugs May Be Marketed. Revised March 1995. <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm>. Accessed September 24, 2011.

Disclosures: In the last 5 years, Dr Mullins has received unrestricted investigator-initiated grants from Commonwealth Serum Laboratories Australia and Alphapharm Australia (the past and current Australian distributors of EpiPen), Abbott Nutrition Australia, and the Ilhan Food Allergy Foundation. Dr Smith has participated in an advisory board meeting for iNova Pharmaceuticals, distributor of Rinair (a topical capsaicin nasal spray containing 4 µg of capsaicin per metered dose). He has no other interests relevant to this article.

Author response

ICX72 in the referenced manuscript is compliant with the FDA requirements for homeopathic preparations. *Capsicum annum* has a monograph in the United States Homeopathic Pharmacopoeia that states that dilution factors in the range of $3\times$ to $5\times$ are appropriate for over-the counter applications.¹ Additionally, *Capsicum* is also described at these levels in the common homeo-

pathic material medicas for the treatment of congestion and related symptoms. As the authors note, the nature of capsicum is such that at the dilution permitted in the monograph, its sensory effects are not completely eliminated. No requirement based on the homeopathic monograph (United States Homeopathic Pharmacopoeia) or Material Medica for *Capsicum annum* calls for it to be diluted to 10^{-24} to 10^{-60} .^{1,2}

Similar to what has been encountered in other intranasal medication studies, formulating a placebo that caused a mild transient sensation similar to the ICX72 formulation was not

Disclosures: The corresponding author and lead investigator is a consultant for Dynova Laboratories.

Financial Support: This study was funded by Dynova Laboratories.