Unapproved Prescription Cough, Cold, and Allergy Medications

To the Editor:

In a recent issue of CHEST (August 2011), Irwin and Smith¹ wrote an editorial on a commentary about the recent US Food and Drug Administration (FDA) enforcement action² on marketed unapproved prescription cough, cold, and allergy medications.³ We appreciate the opportunity to provide insight into our action, which affects the American College of Chest Physicians cough guidelines.⁴ We also thank Irwin and Smith for their support of our action.

Irwin and Smith¹ suggested that extended-release products compounded by state-licensed compounding pharmacies represent an additional option to address the lack of extended-release, first-generation antihistamines and extended-release, first-generation antihistamine/pseudoephedrine combination products. They recommended that such products be compounded to meet United States Pharmacopeia–National Formulary standards.⁵

We would like to point out that the United States Pharmacopeia–National Formulary⁶ does not contain any standard or specification for any compounded extended-release drug product and, therefore, cannot by itself be a reference for the compounding of extended-release cough, cold, and allergy drug products. A compounding pharmacy would need to develop a drug formulation that had appropriate potency, purity, and performance characteristics to consistently yield a safe and effective product. Here, the compounding pharmacy would be faced with the same challenges but with fewer resources, as drug manufacturers have in developing and testing an extended-release drug product that could be relied upon by physicians and patients, while avoiding problems with safety, efficacy, dose dumping, and product-to-product variability. These are the same concerns that the FDA has with other unapproved compounded or manufactured extended-release drugs. For these reasons, the FDA recommends that practitioners not attempt to have pharmacists compound versions of the cough, cold, and allergy drug products as substitutes for those that were subject to the recent enforcement action of the FDA. Although the authors stress that it is important for clinicians to have an open dialogue with the compounding pharmacy regarding appropriate quality-control testing of compounded products, we have concerns that this option may not be a practical solution to the lack of availability of such products and recommend that practitioners instead rely on products of proven efficacy and safety, as recommended in Ostroff et al.³

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Other contributions: This article reflects the views of the authors and should not be construed to represent views or policies of the US Food and Drug Administration.

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2. Drugs for human use; unapproved and misbranded oral drugs labeled for prescription use and offered for relief of symptoms of cough, cold, or allergy; enforcement action dates. Fed Regist. 2011;76(42):11794-11798.
4. Irwin RS, Baumann MH, Bolser DC, et al; American College of Chest Physicians (ACCP). Diagnosis and management

Response

To the Editor:

We appreciate and wish to respond to the thoughtful comments of Dr Lee and colleagues concerning our editorial,1 in which we suggest that clinicians may potentially find the need to enlist the services of a licensed compounding pharmacy to make an extended-release product when other options have failed. We did not mean to imply that there was a United States Pharmacopeia-National Formulary monograph2 for specifically compounding an extended-release brompheniramine-pseudoephedrine medication that compounding pharmacies can follow; rather, we meant that compounding pharmacies can follow the guidelines in the general chapters “Dissolution”3 and “Uniformity of Dosage”4 that speak to the issue of dissolution and uniformity of dosage units. We thank Dr Lee and associates for allowing us the opportunity to better clarify this point and to reconfirm that we are in full agreement that clinicians should use US Food and Drug Administration (FDA)-approved cough, cold, and allergy medications whenever possible, and we believe that the alternative FDA-approved cough, cold, and allergy medications suggested by Ostroff et al5 will likely be sufficient to meet the needs of most adult patients.

When these FDA-approved products do not meet the needs of patients because of failure to achieve therapeutic end points, intolerance, and/or poor adherence, clinicians and patients may be faced with the dilemma of providing no treatment or seeking alternatives. In these situations, we believe that physicians may wish to take advantage of a compounded medication made by a licensed compounding pharmacy as an alternative.

Before recommending a compounded medication, we continue to recommend that clinicians speak with the compounding pharmacy to understand limitations of a compounded medication, ask for the data the pharmacist is using to support the compounding of a specific medication, inquire about what quality assurance methods are used, and determine what analytic methods are used by the compounding pharmacy to ensure the appropriateness of the compounded pharmaceutical preparation. If a compounding pharmacy lacks the equipment and/or expertise to perform such quality assurance tests, they should use an independent laboratory to perform such tests.

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