

Open Public Hearing of the Nonprescription Drugs
Advisory Committee and the Pulmonary-Allergy
Drugs Advisory Committee of the Food and Drug
Administration

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Statement prepared by:

Daniel A. Hussar, Ph.D.
Remington Professor of Pharmacy
Philadelphia College of Pharmacy
University of the Sciences in Philadelphia
600 S. 43rd Street
Philadelphia, PA 19104
Telephone – (215) 596-8880

My name is Daniel Hussar and I am a pharmacist and a Professor of Pharmacy at the Philadelphia College of Pharmacy at the University of the Sciences in Philadelphia. I have reviewed the guidelines regarding this open public hearing and declare that I have no conflict of interest with respect to the subject being addressed and my comments. I am receiving no compensation or reimbursement of expenses relative to my participation in this hearing.

Six hundred deaths and 47,000 injuries each year – these are the estimates of the deaths and injuries occurring each year in the United States as a consequence of motor vehicle accidents related to the sedative or other central nervous system effects associated with the use of nonprescription antihistamines. It is well known that nonprescription antihistamines such as diphenhydramine and chlorpheniramine may cause sedation. Indeed, the sedative action of diphenhydramine is so pronounced that this agent is often used in the treatment of insomnia as well as in the management of allergic disorders.

Fexofenadine (Allegra) and loratidine (Claritin) are not likely to cause sedation and are often designated as nonsedating antihistamines. I recognize that this hearing is also addressing the status of cetirizine (Zyrtec), an agent that is considered to be a low-sedating antihistamine. Although I can support nonprescription status for cetirizine, my comments are limited to fexofenadine and loratidine because I do not want a debate about the safety of cetirizine to delay a decision to transfer fexofenadine and loratidine to nonprescription status.

I am not aware of any studies that demonstrate that there is a greater risk associated with the use of fexofenadine and loratidine than there is with the nonprescription antihistamines. In fact, the studies and expert opinions with which I am familiar say the opposite – that these two antihistamines that are restricted to prescription use in the United States are safer than the antihistamines that are currently available for nonprescription use in this country. The safety of fexofenadine and loratidine has been thoroughly evaluated – using dosages in some studies that are much higher than the recommended therapeutic dosage – to rule out an association with the occurrence of cardiac arrhythmias that resulted in the withdrawal of terfenadine (Seldane) and astemizole (Hismanal) from the market.

I consider the matter we are addressing today to be a very serious public safety issue. Many individuals who experience allergy and/or cold symptoms self-treat their conditions with a nonprescription product without visiting a physician. Many of the deaths and injuries mentioned earlier could be avoided if these individuals could use products containing the antihistamines that are associated with the least risk, instead of those that cause sedation. Products containing fexofenadine and loratidine are available without a prescription in certain other countries including Canada, and I am not aware of any problems that are related to their use without a prescription.

During the last several years there has been unprecedented publicity regarding medical errors, drug-related problems, and the safety of medications. In many of these situations, it is difficult to identify a positive course of action that will effectively address the problem. However, there is a course of action that will reduce the risk of deaths and injuries resulting from antihistamine-related accidents, and that is to transfer fexofenadine and loratidine from prescription-only to nonprescription status.

Unlike most, if not all, previous decisions to switch medications from prescription-only to nonprescription status, the issue we are now addressing has life or death implications for some individuals. This was not the case, for example, when the histamine H₂-receptor antagonists were switched to nonprescription status.

The need to take action is urgent. We do not need more studies, and we will miss the opportunity to immediately reduce the number of victims of antihistamine-related accidents if there are further delays in making this decision and implementing it. Appropriate labeling for nonprescription use can be quickly developed using as resources for pertinent information the labeling for the prescription products of fexofenadine and loratidine, the labeling for the nonprescription antihistamine-containing products available in the United States, as well as the labeling for the nonprescription fexofenadine and loratidine products that are available in Canada.

I strongly urge the Food and Drug Administration (FDA) to take immediate action that will permit the availability of fexofenadine and loratidine without a prescription. Because the manufacturers of these agents have not initiated this action, and may actually oppose it, the FDA should be prepared to exercise its full authority to take and implement this action as soon as possible in the interest of the safety of the public.

I recognize that some have suggested that the FDA does not have the authority to transfer medications to nonprescription status if the manufacturers do not wish to do so, and that the companies may pursue legal action if the FDA takes such an action. In my opinion, such a step on the part of the companies would be a serious mistake for an industry that does not need any more negative publicity. When such legal actions are reported in the press, I expect that there will be public outrage regarding efforts to continue to restrict access to medications that are recognized to be safer than those available in nonprescription products now, as well as an increase in the number of lawsuits filed on behalf of victims of antihistamine-related accidents.

If there is a determination that the FDA does not have the authority to transfer fexofenadine and loratidine to nonprescription status, legislative action must be pursued to provide FDA with this authority and/or to specifically authorize the nonprescription availability of these two antihistamines. If legislative action can not be accomplished at the federal level on a timely basis, such action should be pursued in the individual states. However, it is my hope that these steps will not be necessary as it is my belief that the FDA currently has authority to take action on matters that will reduce the risk of drug-related problems for the purpose of increasing the safety of the public.

Thank you for the opportunity to address you and for your consideration of these comments.