

From: Michael Kaliner, MD

Re: Paper presenting my position regarding the switch of non-sedating antihistamines OTC

Dear Members of the NDAC and PADAC Panels:

You are being asked to consider the extremely complex issue of whether to recommend that safe and effective medications used for the treatment of allergic rhinitis be switched to OTC status against the wishes of their manufacturers. This issue has been precipitated by the desires of WellPoint Insurance Company to switch the cost of providing these medications from their pocket to the pockets of their members. I won't address the costs of such a switch and who would actually bear these costs as I am certain that others have and will do so.

Instead I want to address the position in which this petition and the FDA's decision to address it have placed you. Over the years, the legislatively mandated patent protection laws have allowed pharmaceutical manufacturers a period of time to market their successful products in order to pay for the research and development of new products.

Many of the ethical pharmaceutical companies are not equipped to market products OTC, and the costs and profit margins in the OTC market differ from the prescription market.

Moreover, it is possible that you are not aware of the potential consequences of forcing companies to switch products OTC against their wishes. Let me ask, if a company develops a safe and effective product, does that mean that it should automatically go OTC? Does that ruling apply to all products in the class and at what point do you determine that a product should be forced OTC? Will you automatically review all products, including the dozens of sedating antihistamines, the decongestants, mucoevacuents, and anticholinergic products currently sold for the treatment of allergic rhinitis by prescription only, or will you limit this ruling to the top products only?

Besides the issues of incorrect self-diagnosis and inappropriate use of OTC products, please look at this issue from the industry's perspective. If companies anticipated that safe and effective products in an area like allergy risked limited time in the prescription-only marketplace, then why would companies continue to develop such products? I believe that they would stop development of allergy products immediately, and that there would be no future products developed in this area until there was additional legislative protection of patented products.

I have some doubts that this panel should be involved in an issue that infringes on patent rights, and guess that this issue should be considered in the legislative, not regulatory, arena. Notwithstanding, forcing companies to move their prescription products to OTC against their will would establish a powerful precedent which would have enormous effects on the future of all prescription medications. It is one thing when a company petitions you to allow a safe and effective product, at appropriate doses, to go OTC, but it is quite another for you to force them to abort the revenue stream of an effective product prematurely. As this ruling would cause predictable losses in their revenue stream, are you prepared to recommend compensation to the companies?

In summary, allow me to ask, are you prepared to create havoc in the patent protection of pharmaceutical products, are you prepared to stop new product development in fields like allergy, and are you prepared to compensate these companies for their loss of revenue? If I were in your seat, I would avoid this issue entirely and recuse myself from any decision. In my opinion, this is an inappropriate use of your time and forces you into a decision-making process outside of your areas of expertise and which might have huge consequences far beyond the regulatory roles for which you volunteered.

In my opinion, the petition by WellPoint is flawed for many reasons, but the most critical aspects of this issue are the consequences of this ruling and its effect on new drug development. As an allergist, I look to these companies to develop new and more effective products for my patients. If you continue this review and rule in favor of WellPoint, you might just have stopped new drug development in allergy forever. I hope that you take my advice, reject the petition and avoid making any ruling.

Michael Kaliner, MD

Dr. Michael Kaliner is the Medical Director of the Institute for Asthma and Allergy, PC., a center providing medical care, research and education in asthma and allergic diseases. Dr. Kaliner was the Chief of the Allergic Diseases Section of the NIAID, NIH from 1975-1993, the president of the American Academy of Asthma, Allergy and Immunology, the Chairman of the American Board of Allergy and Immunology, and is currently the Vice-President of the World Allergy Organization.

Dr. Kaliner has published more than 450 articles, books and monographs on allergy and asthma. He has consulted with every company in the allergy-asthma community, has worked with Schering on the development of Claritin, and with Aventis on the development of Allegra. He has also consulted with Pfizer. Dr Kaliner also advises the companies which make the major OTC antihistamines, and has worked with several companies on OTC switches of antihistamines.

The Institute for Asthma and Allergy does research with every company who has allergy and asthma products, including the 3 companies in question. Dr. Kaliner's primary occupation is the care of allergy and asthma patients and the Institute for Asthma and Allergy is the largest allergy provider in the Washington DC area. Dr. Kaliner does not own stock in Aventis or Schering but does own stock in Warner-Lambert, which was purchased by Pfizer, and also owns stock in Johnson and Johnson and Merck. (All stocks are valued at less than \$15000 each). There are no expenses or fees associated with his presentation.