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U.S. Food & Drug Administration
Dockets Management Branch
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Re: FDA Docket number 98P-0610/cp1.
Convert Allegra/Allegra-D, Claritin/Claritin-D, Zyrtec to OTC

Dear Sir or Madam:

This letter addresses the mandatory OTC switch of Zyrtec® described in the above referenced docket. In this regard, we have set forth in a previous filing with FDA, dated May 11, 2001, the reasons why a mandatory switch of a drug from Rx to OTC status would constitute a revocation of Pfizer's approved license (the NDA), why reliance on the NDA for a forced switch would violate the confidentiality provisions of the FD&C Act (as well as the Trade Secrets Act and the Takings clause of the U.S. Constitution) and why such an action, under the FD&C Act and the Due Process Clause of the 5th Amendment requires a formal evidentiary hearing pursuant to § 505(e) of the FD&C Act. Hank McKinnell previously outlined for the Department why a forced switch would not be in the public interest.[1] In this letter, I would like to elaborate on why such an initiative would represent bad public policy that the Administration should not undertake.

[1] Letter from Hank McKinnell to Secretary Thompson and Commissioner McClellan dated February 10, 2003.

There Is No Public Health Justification for A Government Mandated OTC Switch Of Zyrtec

Fundamentally, this is a commercial dispute between payors and innovators, not a public health issue warranting government intervention. The proponent of a mandated switch, WellPoint Health Networks, has argued that a switch would increase patient access and reduce patients' drug costs. It has not, however, presented any data or studies to support this contention, nor has it presented any scientific support for the assertion that this action will benefit public health. In fact, of the patient advocacy groups that participated in the May 2001 FDA Advisory Panel hearing on this issue, none supported a policy of a forced OTC switch.

Instead of mandating a forced OTC switch, based on unsupported assertions, the FDA has at hand an opportunity to test the claim that a forced switch will increase access and/or benefit patients. FDA could focus on studying the compliance and access of patients who now take OTC loratadine, instead of visiting their physician for treatment.[2] It would also be helpful for the FDA to look at how the OTC switch of loratadine is affecting the treatment of allergy patients with co-morbid conditions such as asthma, which can be triggered by allergies. Since the utilization of these drugs without a physician's evaluation can potentially mask or delay the appropriate diagnosis of asthma and other underlying disorders (such as sinusitis and otitis), the OTC switch of second-generation antihistamines can impact patient care.[3]

In any event, it is by no means clear that an OTC switch would improve patient access to these medicines. Prior to the OTC switch of loratadine, most patients with insurance or a prescription drug benefit were able to get a 30-day supply of the drug for as little as $10. Now, most loratadine users pay about two and one-half times more out-of-pocket for a 30-day supply, with no commensurate reduction in their insurance premiums.

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[2] See e.g, http://www.fda.gov/ohrms/dockets/dailys/00/Jul00/071800/tr00001.doc at p. 90 (Testimony of the National Consumers' League at the OTC Hearing sponsored by FDA's Center for Drug Evaluation and Research (Jan. 28, 2000): "*one in four people [surveyed] are having a problem with reading the OTC label and understanding it, and this increases with age.*" The Consumers' League survey goes on to note that approximately 14% of the consumers surveyed report that they ("always" or "most of the time") take more medication than is recommended and that 10% of the consumers surveyed said that they did not believe it was necessary to pay attention to OTC label directions. *Id.* at p. 91.

[3] *See e.g.* Comments of the *American Academy of Allergy, Asthma, and Immunology,* dated April 19, 2001, filed in FDA docket 98P-0610, posted at: http://www.fda.gov/ohrms/dockets/dockets/98p0610/98P-0610_emc-000005.doc

Managed care plans, on the other hand, have already realized significant cost savings with loratadine's OTC availability. Thus, the cost of the medicine would likely increase for most patients who rely on a prescription drug benefit, even if some patients may benefit from OTC access to the other second-generation products. For example, OTC Claritin now costs about $25 per month, while the typical co-pay for a "tier two" product like Zyrtec is now about $17. It is also unclear whether a forced switch by FDA of the remaining second-generation antihistamines will result in comparable access for the roughly three million medicaid patients who have, in the past, been taking a second-generation antihistamine.[4] Thus, adopting a "*one-size-fits-all*" approach, may in fact, actually *reduce* patient access and *increase* patient cost.

A Forced Switch Will Reduce Incentives To Invest In Research

As you know, an NDA is the result of a large investment in research over a long period of time. The odds against success are astronomical. By mandating an OTC reclassification of a prescription drug, the government would be increasing the uncertainty of product lifecycles and undermining incentives to invest in the research required to develop *more* effective and safer products. A forced switch will not only result directly in reduced returns to research, but will increase concerns within the drug discovery, research, and investment sectors as to the likelihood that other, yet undiscovered, products could be subject to similar unilateral actions by the government, at the urging of third party payors or others.

In this case, Zyrtec is an improved, second-generation antihistamine. In order to obtain marketing approval, Zyrtec underwent years of extensive clinical testing before submission to the FDA and almost eight additional years of FDA review, while additional safety studies and analysis requested by the agency were undertaken. The proposed policy, if adopted, would in effect penalize Pfizer and our partner, UCB Pharma, for developing a product that is now "*too safe*" for prescription use.

Pfizer will spend $20 million every day this year (over $7 billion annually) in our search to discover and develop new medicines. The research-based pharmaceutical/biotech industry spends more on drug research (over $30 billion annually) than the NIH ($20 billion in 2001) or any other public or private initiative. In the case of Zyrtec, for example, Pfizer has conducted or sponsored over 100

[4] Many states don't provide coverage, under their medicaid programs, for OTC drugs. Other states, including New York, have begun using formulary incentives to encourage the use of OTC products. *See e g.*, April 2003 New York Department of Health letter (enclosed).

clinical studies (in addition to numerous clinical and pre-clinical studies commissioned by UCB Pharma). Continued commitments of capital for drug discovery and testing will be threatened if the Administration undermines insurance reimbursements for new drugs like Zyrtec. Presently, for example, there are few ongoing programs for developing new products to treat allergic rhinitis. Indeed, our partner, UCB Pharma, has already seen its market capitalization drop 20% this year on continued rumors that the FDA might reclassify all second-generation, prescription antihistamines. Their research program, like ours, is funded by current product sales.

A Mandatory OTC Switch Would Amount To The Government Taking Sides In A Commercial Dispute

In light of the absence of any evidence that a forced switch will result in a health benefit to patients, there is no policy justification for the government to take such an action. Indeed, as the identity of those proposing the switch demonstrates, a switch would primarily benefit private economic interests - particularly managed care organizations. The private health plans have various means for avoiding the costs of reimbursing particular pharmaceutical products - from tiered formularies to prior authorization requirements to revising their policies to exclude coverage for certain classes of drugs (like Rx antihistamines).

But, instead of taking direct actions to limit patient access to popular medications like Zyrtec directly and accepting accountability for such actions in the marketplace, these companies are asking the government to intervene on their behalf. Ironically, some plans appear to be trying to avoid reimbursing patients for these drugs in the name of advancing patient interests. The government should not accept the invitation to intervene in the marketplace by putting its thumb on one side of an essentially commercial dispute.

A Mandatory OTC Switch Would Divert Scarce Agency Resources And Invite Numerous New Similar Petitions

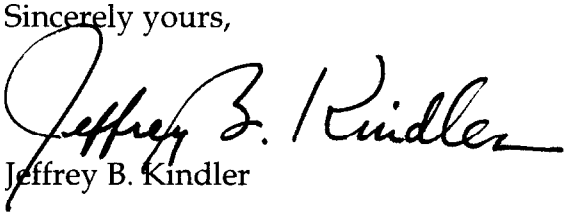
We understand that there are currently a substantial number of sponsor-initiated OTC switch submissions at FDA. Should the agency begin the practice of forcing OTC switches, it would add to the staff's already considerable workload. Moreover, it would inevitably lead to third-party insurers and others filing additional forced switch petitions. Indeed, that already appears to be happening. For example, the Center for Reproductive Rights has a petition pending at FDA, on behalf of 76 public interest and public health organizations, to switch two FDA-approved emergency contraceptive drugs, and any equivalent new drugs, to OTC status.[5]

Conclusion

The Department should not undertake an unprecedented, unnecessary, and illegal action to help payors deny patients access to individual drugs. We urge you to avoid this big government approach and allow the marketplace to work. The significance of preserving incentives for drug development is real and important to maintaining public health over the long-term.

Thank you for your consideration of our views.

Sincerely yours,



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Enclosure

[5] http://www.fda.gov/ohrms/dockets/dailys/01/Feb01/021401/cp00001.pdf.