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June 29, 2000  
1:30 P.M.

My name is Dr. Robert C. Seidman, and I am Vice President of Pharmacy for WellPoint Health Networks Inc. based in Thousand Oaks, CA. WellPoint Health Networks Inc. is one of the nation's largest publicly traded managed care companies serving the health care needs of 7.5 million medical and approximately 31 million specialty members nationally.

Given our limited time today, I would like to take the opportunity to respond to the questions outlined by the FDA in the April 27, 2000 Federal Register Notice of this hearing. In responding to these questions, I want to focus on the documented safety and effectiveness of the prescription non-sedating (loratadine/Claritin, fexofenadine/Allegra) and minimally sedating (cetirizine/Zyrtec) antihistamines. Through our prescription drug benefits, WellPoint Health Networks Inc. currently provides access to these drugs at a copayment paid by the member.

**A. Criteria**

There are three criteria that the FDA should consider in rendering decisions on over-the-counter (OTC) availability of drug products: ease of self diagnosis, ease of compliance with a treatment regimen, and drug safety. In applying these three criteria to the second-generation antihistamines referenced above, we have found that the average lay person can easily self diagnose allergic rhinitis and treat the condition with relative ease. This self-diagnosis and treatment is performed by millions of Americans daily, with the current complement of OTC antihistamines available. The third criteria, safety, is also satisfied since hundreds of randomized controlled studies in the peer reviewed medical literature clearly show that these agents are safer than the currently available OTC antihistamine alternatives. To support our claim of second generation antihistamine safety, we have contracted with the University of Southern California School of Pharmacy to perform a meta-analysis on all peer-reviewed articles on antihistamines. Our preliminary analysis of 84 peer-reviewed articles clearly shows that the second generation antihistamines (Claritin, Allegra and Zyrtec) are safer than those antihistamines that are currently available without a prescription. The complete results of this analysis will be provided to the FDA as an amendment to our existing petition to convert these drugs to OTC status.

The majority of Americans seek to self-medicate with OTC drugs, and it is incumbent upon the FDA to ensure access through OTC status of drugs that have documented safety, efficacy and ease of use. Regarding the treatment of chronic conditions, two interests must be balanced: potential harm of self-treatment versus the value of early diagnosis of a debilitating chronic disease. It would also be beneficial for a portion of the close to 2 billion dollars that are currently being allocated to direct-to-consumer (DTC) advertising to be redirected to efforts to help patients with the early diagnosis and treatment of disease states where our current medical interventions have been inefficient in improving the lives of Americans. Diseases such as diabetes, asthma and hypertension are particularly amenable to greater health education. Drugs like antibiotics should not

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be available OTC because the current system of medical management has not succeeded in stemming the inappropriate prescribing of antibiotics and the resultant danger of increase in antimicrobial resistance.

#### **B. Classes of Products**

Again, I want to focus on the safety and efficacy of the second-generation antihistamines and not venture into the other, more complicated classes of drugs. The second-generation antihistamines clearly meet the criteria utilized by the FDA in determining whether a drug should be available OTC. Consequently, they can be used as a model for other classes of drugs.

#### **C. Consumer Understanding**

When the marketplace, through DTC advertising, converts a drug into a "virtual OTC" product, consumers can easily understand the benefits and risks of the products. There is documented evidence demonstrating that DTC advertising of second generation antihistamines has increased physician office visits to request prescriptions for these drugs and that physicians are uncomfortable declining these requests. As a result of this phenomenon, second generation antihistamines are "virtual OTC" drugs today.

#### **D. Selection of Treatment**

Even today, we have examples of OTC and prescription versions of drugs in the same milligram and delivery system, so the issue of coexisting products is not new or novel. Again, with the second-generation antihistamines, there is no clinical controversy about converting these drugs to OTC status. When prescription drugs do go OTC, which I hope the second generation antihistamines will shortly do, the first drug converted is not necessarily the "gold standard", although it would be difficult to imagine drugs safer and more efficacious than the currently available second generation antihistamines. Personal consumer experience will determine which is the better drug. The question here is whether the pharmaceutical manufacturer has sole discretionary power to decide what is in the best interest of society. It is my belief that this important decision making process should be vested in the clinical merits of these drugs and supported by the FDA.

#### **E. OTC Marketing System**

The current structure for marketing OTC products in the United States is flawed. Currently, no safe and effective drug has ever gone OTC without the pharmaceutical industry initiating the request for the conversion. In areas where controversy is non-existent, as in second generation antihistamines, the FDA should be proactive in providing easier consumer access to these drugs. Maintaining Claritin, Allegra and Zyrtec as prescription drugs deprives a majority of patients ready access to the highest quality pharmaceutical care and trivializes the patient-physician relationship.

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**F. FDA's Role in Switches**

When there is no toxicity associated with a drug and a lay person can easily diagnose and treat a condition or disease, the FDA should take an activist role in converting those identified prescription drugs to OTC. As I indicated in my petition to the FDA, patients are seeking greater ownership of their health care and often prefer to self medicate when feasible. Of all the therapeutic classes of drugs available, the discrepancy in safety between the current antihistamines available OTC compared to prescription second generation antihistamines is most pronounced. The health care system should not be burdened with the increased costs and patient inconvenience associated with these drugs remaining prescription only. The millions of allergy sufferers should have unimpeded access to these drugs. Accordingly, I request that the FDA review our petition and expedite the conversion of prescription Claritin, Allegra and Zyrtec to OTC medication status.

Thank you.