

Whitehall-Robins Speaking Points for May 11, 2001 Advisory Committee Meeting

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1. The first generation antihistamines have a long history of safe and effective use and are widely recommended by pediatricians and family practitioners.

2. The Blue Cross Evidence Report on the discussion of first generation antihistamines is incomplete and not fully representative of their safety and efficacy. The Evidence Reports suggests that second generation antihistamines are more effective than first generation antihistamines. There are at least three studies not included in the discussion that refute this assertion:

a) Brompheniramine, Terfenadine, and Placebo in Allergic Rhinitis. Klein GL, Littlejohn T, Lockharte, et al. Ann Allergy Asthma Immunol 1996;77:365-70.

b) Brompheniramine Maleate: A Double Blind, Placebo-Controlled Comparison with Terfenadine for Symptoms of Allergic Rhinitis. Thoden WR, Druce HM, Furey SA, et al. Am J Rhinol 1998;12, 293-299

c) Brompheniramine, Loratidine, and Placebo in Allergic Rhinitis: A Placebo Controlled Comparative Clinical Trial. Druce HM, Thoden WR, Mure P, et al. J Clin Pharmacol 1998;38:382-389.

All three studies show that the brompheniramine was more effective for SAR than the second generation antihistamines.

In some people, therefore, the first generation antihistamines actually have greater efficacy than second generation antihistamines even for the allergy indication. The first generation antihistamines did cause mild sedation; but it is important to note that not all patients who received them got sedated and those who got sedated usually developed a tolerance with continued use.

Sedation is not always a negative effect in patients-especially young patients where their ability to treat allergic symptoms and promotion of sleep is viewed as positive effect as in children with viral illnesses

3. Even among the second generation antihistamines, cetirizine cannot be considered totally non-sedating. In fact, it is not labeled as such. In essence, sedation caused by antihistamines is a continuum:

Sedation decreases as follows:

DPH>Brom/Chlor>Cetirizine (10mg sedation 13.7%) >Loratidine(somnolence 8%)/Fexofenadine (somnolence 1.3%)

(Figures obtained from package insert)

4. Unlike the second generation antihistamines, the first generation antihistamines are indicated for colds in addition to allergies. Their anticholinergic action is critical to this therapeutic effect.

5. From a medicoeconomic perspective, the first generation antihistamines are far more cost effective