increased in all SLIT regimens compared with controls. These results were statistically significant compared with controls in all but CD4+ IL-4–producing cells, and the results were similar across all treatment arms. All SLIT regimens resulted in an increase in Amba1-specific IgG4, and this increase was most impressive in the prolonged-SLIT treatment arm.

CONCLUSIONS. Although all SLIT regimens resulted in an improvement in clinical efficacy, prolonged SLIT was the most effective. The reduction in IL-4 and increase in IL-10 production is consistent with observations from subcutaneous immunotherapy studies and provides insight into the mechanism of SLIT. These cytokine changes might serve as an objective marker of efficacy of SLIT for patients on treatment.

REVIEWER COMMENTS. Further evaluation of SLIT is of particular importance in the pediatric population because of its less invasive method of administration compared with injection immunotherapy and its improved safety profile. However, more studies are needed before the therapy makes it to US practice.

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Efficacy and Safety of Timothy Grass Allergy Immunotherapy Tablets in North American Children and Adolescents

PURPOSE OF THE STUDY. To investigate the efficacy and safety of timothy grass allergen immunotherapy (AIT) treatment using sublingual tablets in children and adolescents with grass pollen–induced allergic rhinoconjunctivitis (ARC).

STUDY POPULATION. Three hundred forty-five subjects, aged 5 to 17 years, with a clinical history of physician-diagnosed grass pollen–induced ARC with or without asthma were studied.

METHODS. This was a double-blind, randomized, placebo-controlled, parallel-group, multicenter, phase III study. Subjects were randomly assigned (1:1) to once-daily sublingual grass AIT treatment (2800 bioequivalent allergen units; 15 µg of Phlp5) or placebo. Treatment began ~16 weeks before the grass pollen season (GPS) and continued through the entire GPS for a total treatment period of 23 weeks. The total combined score was a summation of the daily symptom score and daily medication score, which were predefined. Immune parame-
ters were measured over time. Safety was measured on the basis of reported adverse events.

RESULTS. The mean total combined scores for the entire GPS were significantly less in the grass-AIT group than in the placebo group by 26% (P = .001). The mean daily symptom score was significantly less in the grass-AIT group than the placebo group by 25% (P = .005). The improvements in scores for ocular and nasal symptoms were 28% and 23%, respectively, were noted in the AIT group (P = .003). The median daily medication score was significantly reduced in the grass-AIT group by 81% (P = .006). There was a significant improvement in quality of life in the AIT group that was greatest at the peak of the season (38%) when compared with the entire season (18%). Treatment with grass AIT did not significantly reduce asthma symptom scores. Levels of Phlp5–specific immunoglobulin G4 (IgG4)– and IgE-blocking factor were similar between the 2 groups at baseline and increased over time in the grass-AIT group (P < .001). Grass AIT was generally well tolerated, but 82% experienced some adverse events, primarily oral and throat pruritus and/or irritation. One subject in the AIT group received epinephrine for dose-related angioedema, dysphagia, and cough.

CONCLUSIONS. Allergen immunotherapy using sublingual grass pollen tablets is effective in the treatment of grass pollen–induced ARC with anticipated and acceptable adverse effects.

REVIEWER COMMENTS. This is the first North American study to show effective symptom control and an acceptable safety profile in children and adolescents with grass pollen–induced ARC by using a sublingual tablet for dose delivery. There was no increase in the outcome of asthma attacks, and there was improvement in quality of life at the peak of the allergy season. These results show promise for future therapy targeting children and adolescents for immunotherapy using an effective, safe, and easy-to-deliver alternative to traditional subcutaneous injection immunotherapy.

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Prevention of Allergy in Infants of Allergic Mothers by Probiotic Escherichia coli

PURPOSE OF THE STUDY. To study the effect of after-birth oral colonization by a probiotic Escherichia coli strain in infants of allergic mothers to reduce occurrence of allergy later in life.

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