Controversial and Unproven Techniques
Position Statement from the ACCP Section on Allergy and Clinical Immunology*

Allergic diseases are common, and the economic impact of medical care for these patients is great. It is often difficult for physicians from multiple subspecialties to keep current regarding the validity of effectiveness of techniques to diagnose or treat allergic and immunologic disorders. It is, therefore, incumbent upon physicians to understand those procedures based on sound, scientific foundation vs those that are unproven or controversial so as to provide competent and appropriate advice to patients. The validity of all of the following have been questioned:

**CYTOTOXIC LEUKOCYTE TEST (Bryan’s test)**

Leukocytotoxic testing is based on the observed reduction in white cell count or the death of leukocytes after the addition of a specific allergen such as foods, pollens, or animal danders in vitro to whole blood or serum leukocyte suspension. It has most popularly been used for the diagnosis of food allergy, but the validity of the results has not been supported in controlled, double-blind studies, and there is lack of correlation with clinical evidence of food allergy. The test is time consuming, requires well-trained, and supervised technicians and is dependent on subjective interpretations. It lacks specificity and sensitivity as well as an acceptable rationale based on current knowledge of allergy and immunology. Although cytotoxic leukocyte testing has been incorporated into the medical practice of many otolaryngologic allergists and clinical ecologists, most medical subspecialty societies suggest that cytotoxic leukocyte testing be considered experimental at this time.

**SUBLINGUAL PROVOCATIVE TESTING AND NEUTRALIZATION THERAPY FOR FOOD ALLERGIES**

This method, adopted for the diagnosis and treatment of food allergies, consists of the administration of a few drops of food antigens sublingually and the observation of the patient for clinical symptoms over a period of 10 to 20 minutes. If a reaction is provoked, a more dilute solution of the same antigen is applied sublingually in an attempt to “neutralize these symptoms.” If the responsible food cannot be easily eliminated from the diet, drops of the same dilution that neutralized the provoked symptoms are prescribed to the patients regularly before or after a meal containing the offending food, thereby avoiding or ameliorating this food allergy symptom. Controlled, double-blind, multicenter studies revealed that sublingual, provocative food testing did not discriminate between placebo controls and food extracts. As a result, various investigators and committees have recommended that sublingual, provocative techniques are unreliable as indicators of food allergy. Since no known immunologic mechanism can account for the neutralization of provoked symptoms by dilute solutions and there is lack of scientific evidence for effectiveness, neutralization therapy for food allergy should be considered experimental at this time.

**INTRACUTANEOUS (INTRADERMAL) AND SUBCUTANEOUS, PROVOCATIVE AND NEUTRALIZATION TESTING AND NEUTRALIZATION THERAPY FOR FOOD ALLERGIES**

The procedure involves intracutaneous or subcutaneous injection of antigen of sufficient quantity to elicit symptoms corresponding to the patient’s complaints. This is followed by the immediate injection of a weaker or stronger dilution of the same antigen to relieve the provoked symptoms. The symptoms are quite extensive and include the following: headache, nasal symptoms, chest symptoms, ear reactions, gastrointestinal reactions, skin eruptions or itching, or general reactions such as fatigue, chills, muscle pain, or drowsiness.

Neutralization therapy for food allergies involves regular intracutaneous or subcutaneous injections of the “neutralizing dose” either before or after meals containing the offensive food. Although one double-blind crossover study supported the validity of these
procedures, it relied on a symptom-scoring system of questioned validity. At least four other controlled clinical studies have shown this method of diagnosis and treatment to be ineffective. Since subcutaneous provocation and neutralization as a method of treatment and diagnosis of allergic disease has no plausible rationale nor scientific evidence of effectiveness, these procedures should be considered experimental at this time and a consideration for controlled experiments.

**Urinary auto injection (autogenous urine immunization)**

The concept of autogenous urine injection for allergic disease was introduced in 1947 by Plesch. Apparently, there has been no subsequent article advocating the benefit. Fresh urine is sterilized by filtration and/or boiling in volumes of 0.25 to 5 ml and injected intramuscularly in the same patient who had excreted that urine. Relief of a myriad of symptoms was reported in 12 patients. The treatment has not been proven safe and is potentially dangerous in that injections of kidney protein (glomerular basement membrane in particular) might induce nephritis. There is no rationale from an immunologic basis, so such treatment should be reserved for experimental use in well-designed trials.

**Conclusion**

A search of the medical literature and statements of investigations by many subspecialty groups, including the American Academy of Allergy, the American College of Allergists, the American College of Physicians, the Joint Council of Allergy and Immunology, have not supported the use of the above-mentioned techniques. The details of the available literature have been summarized below in review articles and other publications. It has been proposed that Medicare exclude these from coverage.) The steering Committee of the Allergy and Immunology Section of the American College of Chest Physicians has adopted the recommendation that these procedures are not acceptable medical practice until well-controlled investigations prove otherwise.

**References**