

# Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?

By **Diego Saporta, MD; Alan McDaniel, MD;  
David Hurst, MD PhD; Brian Hasslinger, MD; Jenny Cross, MD**

## Introduction

The treatment of the allergic conditions, beyond medications and implementation of environmental modification maneuvers, is based on the administration of allergy immunotherapy. This is not a new technique, as by the early 1900s<sup>1,2</sup> immunotherapy was already being administered.

The authors of this paper are all board-certified otolaryngologists with an interest in clinical allergy. Since the beginning of the development of the specialty of allergy, there were two main schools for the management of allergic conditions:<sup>3</sup>

1. Otolaryngic allergy. Doctors practicing this approach are not exclusively otolaryngologists.
  - a) General Allergists. Today, affiliated with the American Academy of Asthma, Allergy & Immunology or AAAAI, that will be referred as “general or mainstream allergists”.

Since the inception of the specialty, this second group included the majority of allergy practitioners. A subgroup developed from the otolaryngic allergy group, the clinical ecologists. This group is today represented by the American Academy of Environmental Medicine. (For a detailed explanation of these differences see “A history of Otolaryngic Allergy.”<sup>3</sup>)

At the present time, there are strong economic and regulatory pressures that are adversely influencing the practice of allergy immunotherapy. The resultant difficulties affect the otolaryngic and environmental allergists more significantly than the general allergists.

The otolaryngic and environmental allergists treat their patients with all the allergens to which the patient was found to react during the allergy test. This is in alignment with the concept of the “Total Load” managed by the environmental practitioners: the disease is the result of multiple noxa, the more of the noxious elements that can be removed, the better the clinical results.<sup>4</sup> By this concept, the allergic disease is the result of exposure to multiple allergens. The more allergens that can be desensitized by allergy immunotherapy, the better the clinical result; therefore, including in the treatment vials all allergens to which the patient has reacted during testing is important.

The objective is to resolve as many of the symptoms as possible, attaining the resolution of the underlying inflammatory condition. This will eliminate or significantly reduce the need for controlling medications. If these objectives are attained the patient obviously benefits not only health wise—symptoms significantly or completely resolved—but also economically as less medication is required. The burden on the health care system also decreases as the affected people will consume less drugs, will have fewer hospital admissions (ex: asthma or sinusitis complications), and less surgical interventions (ex: sinus or ear surgery).

## Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?

Mainstream allergists use fewer allergens to treat their patients, according to the concept of the “most prevalent” or “most relevant allergen(s).”<sup>5,6</sup> Vials mixed in this fashion will carry only the few allergens considered to be the most relevant in the area, or the ones that are considered as the most important according to the patient’s history of exposure.

Abundant publications from the mainstream allergy community based on studies using a single allergen<sup>6</sup> and rarely using 2-4 allergens<sup>7,8</sup> suggest that allergy immunotherapy is effective, supporting the concept of “most relevant allergens.”

There is a paucity of published reports by the otolaryngic allergists<sup>3</sup> but their clinical experience is that when patients are treated with all or most of the reactive allergens, the patient benefits enormously.

### Present-Day Reality for the Administration of Allergy Immunotherapy

The practitioner treating a patient with allergy-immunotherapy in the 21<sup>st</sup> century will face several economic and regulatory difficulties. This effect will be more significant for the practitioner that treats patients according to the total allergy load concept.

- 1) **Allergen cost:** Cost of allergenic extracts has increased significantly more than the cost-of-living index.<sup>9</sup>
- 2) **Reimbursements:** The reimbursement for allergy services do not keep up with the sustained increase in the cost of allergy supplies and other allergy-related overhead costs.<sup>10</sup> The net result of these two opposing trends is the slow but steady decline in practitioner’s net income potential, which obviously interferes negatively with the practitioner’s ability to continue to provide allergy immunotherapy.
- 3) **Regulations:** In the last few years, insurance company guidelines and regulations are emerging that make the effective administration of immunotherapy even more difficult. Certainly, these regulations may not be the same for all states, therefore what will be discussed below may not necessarily apply to all allergy practitioners.

In 1995 the Centers for Medicare & Medicaid Services (CMS) published a revised policy “Billing and Coding: Allergy Immunotherapy.”<sup>11</sup> At the present times other insurance companies have incorporated similar regulations.<sup>12-15</sup> An overview of those regulations follows:

#### a) **Definition of the volume of the weekly injected allergy dose:**

A usual maintenance dose is 0.5 mL. A vial with 5.0 mL will contain 10 doses enough to treat the patient for 10 weeks.

CMS arbitrarily decided that a dose of weekly allergy injections is 1.0 mL,<sup>11</sup> therefore a treatment vial of 5.0 mL would, by CMS calculations, contain only 5 doses so the reimbursement was cut in half.

The economic impact for the otolaryngic and environmental practitioners is more significant as the number of allergens included in a treatment vial is much larger. The production cost is therefore much higher, but the reimbursement is the same regardless of the number of allergens used.

#### b) **Number of allergens that can be tested.**

## Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?

An increasing number of insurance carriers are now limiting the number of allergens that can be tested, apparently using the concept that “the minimal number of necessary skin tests might deliver the diagnosis.”<sup>12</sup> The goal appears to be the confirmation of the allergy diagnosis (which can be done clinically) and not the formulation of a treatment vial for optimal immunotherapy.

The preparation of an effective allergy vaccine depends on performing a test with high diagnostic performance, able to diagnose all or most of the reactive allergens<sup>16</sup> so the test and the subsequent vial will include many more allergens. Unless allergy immunotherapy is considered, the role of the allergy test is limited for patient’s management.

- c) **How many vials can be used to treat a patient.** Some insurance carriers at this time do not allow using more than 12 vials in the first year of treatment and no more than six vials in each of the subsequent years.

The allergic patient has the ability to react to allergens present in the surrounding environment. The typical allergy sufferer is reactive to multiple allergens. These multiple allergens are best distributed in separate treatment vials for the following reasons:

- A large number of allergens may not fit in one vial
- Mold<sup>17</sup> and mite-allergen<sup>18</sup> contain proteolytic enzymes that can destroy pollen allergen
- Local arm reactions may interfere with dose advancement. These reactions are commonly encountered with mold allergens, so if mold is mixed with other allergens, their dose progression may be delayed.<sup>17,19</sup>

It is common practice to separate the allergens into separate vials<sup>20</sup> as mixing incompatible allergens may interfere with dose advancement. Twelve vials in the first year and 6 in the subsequent years may not be enough to administer all involved reactive allergens.

Compliance with this mandate faces the following potential problems:

- How to choose which allergens to include and which ones to exclude from the treatment vial? This may not be a problem for the general allergist that treats only with the “most significant allergen(s).” For the practitioner managing the total allergic load concept, the reality is that the patient may not attain a quality result.
- Attaining long lasting results after discontinuation of immunotherapy depends on attaining a high treatment dose<sup>21</sup> and maintaining the treatment for a prolonged period of time.<sup>22</sup> Not including mold is detrimental for the patient, but including mold, as explained above, is likely to interfere with dose advancement.

- d) **Duration of treatment.** These regulations establish that treatment cannot extend beyond three years, unless documentation of need is provided.<sup>12</sup> First year is for escalation and the two subsequent years for maintenance.

One year may not be enough to reach an effective maintenance dose. Maintenance is now “defined” as starting in the second year. During maintenance, the dose cannot be advanced because increasing doses at intervals longer than one week can trigger a severe reaction. The total length of immunotherapy cannot be arbitrarily defined. It is accepted that the “decision about continuation of effective immunotherapy should generally be made after the initial period of up to 5 years of treatment.”<sup>23</sup>

## **Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?**

Combined with the reduced number of allergens that the patient is receiving, limiting the length of treatment essentially prevent the patient from attaining a good quality result.

- e) **Definition of who is qualified to administer allergy-immunotherapy.** Some insurance carriers specify that only “Allergists, Immunologists or Otolaryngologists”<sup>12</sup> will be reimbursed for allergy services. This prevents any other physician interested in this field from working in this area or to continue to practice in this field if already established.

Many decades ago, any physician interested in the management of the allergic conditions was able to take courses from any of the allergy societies offering such courses.<sup>3</sup> At this time, some main allergy societies do not allow doctors not belonging to their specialties to become a fellow of their societies.<sup>24</sup>

Smaller organizations like the American Academy of Environmental Medicine (AAEM) or the Pan American Allergy Society (PAAS)—now closed—never discriminated according to one’s area of specialty. This arbitrary policy lacks practicality as allergic conditions have attained an “epidemic” prevalence<sup>25,26</sup> considered a growing global concern.<sup>27</sup> This underlines the need to train more doctors rather than to restrict practitioners from managing allergic conditions.

### **What Are the Implications of These Regulations?**

From the insurance company’s point of view, preventing the practitioner from testing for a larger than allowed number of allergens, treating the patient with a smaller number of vials, not allowing more than a predetermined number of injections per year and treating for only three years could be interpreted as cost-savings interventions.

From the patient’s point of view, the difference comes down to attaining some improvement versus attaining a significant improvement.

Incomplete control of the allergic condition leads to the continued use of allergy medications, asthma inhalers, frequent need for antibiotics, the need for CTScans of the sinuses and other studies, the need for hospital admissions for respiratory or sinus conditions or the potential need for sinus surgery. In the long run, this will be more costly for the insurance companies.

Appropriate treatment should be determined by the clinical evaluation of the patient’s response and not from “one-size-fits-all” guidelines.

The cost savings for society when the patient receives an effective course of allergy immunotherapy is much more significant than the cost savings the insurance company gets by preventing the allergy practitioner from working freely. Of note is that the insurance companies’ guidelines are based on information provided by panels of experts that are mostly mainstream allergists.<sup>6,7,28,29</sup>

The real victim of these guidelines is the patient, as his/her health will not improve. Persistence of chronic disease ultimately becomes a burden for the society at large. The health care bill is huge and complex, allergy problems constitute just one of many chronic problems affecting us.

### **Who Benefits from a Weakened, Chronically Sick Society?**

It is difficult to answer this question. Why would insurance companies institute guidelines that in the long run may increase the cost of care therefore jeopardizing their objective: making money?

## **Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?**

Who benefits from the increased cost of caring for the chronically sick patient? One aspect of the answer is Big Pharma. This topic is not new.<sup>30</sup>

In this modern world the management of chronic conditions is usually based on medications rather than focusing on pathways or factors leading to health deterioration.

A present-day example of the role of pharmaceutical industries in the cost of allergy treatments is the relatively newly introduced group of medications known as “biologics,” that administer antibodies against IgE<sup>31</sup> or against mediators of the immune response.<sup>32</sup>

These treatments are extremely expensive.<sup>33</sup> They will not cure the patient; therefore a life-long treatment is a possibility. And they are not devoid of adverse effects; some of them potentially serious.<sup>31</sup>

As long as our society continues to allow interference from big business in the concepts of health, and ultimately in the way health care is provided, we will be victims of a system that rather than promoting health, promotes consumption of drugs.

### **Can Sublingual Immunotherapy Be Considered As a Viable Alternative?**

Usually known as SLIT, sublingual immunotherapy is probably the oldest allergy immunotherapy treatment modality.<sup>1</sup> It is extremely safe and highly efficacious.<sup>34</sup>

It does not require the patient to go weekly to the doctor’s office; therefore the overall cost of the treatment is much reduced. Young children and asthmatic patients can be treated with minimal risks. With SLIT, the same allergens that are diagnosed in the allergy test, instead of being mixed in a vial for weekly injections, are mixed in a dropper-bottle for oral administration. The potential problems with SLIT administration are minimal and usually of easy management.<sup>35</sup>

While this sounds ideal -safe and effective treatment administered at home- administration of sublingual immunotherapy in the 21<sup>st</sup> century will encounter the following difficulties:

- A good result is dependent on using a good quality test, able to diagnose all or most of the involved allergens.<sup>16</sup> With present day insurance-carrier restrictions, a complete intradermal test may not be fully covered, therefore adding an “out-of-pocket” expense.
- SLIT is not FDA approved. While it is widely used and covered by health plans in Europe, its use in the US is considered an off-label use of allergenic extracts. Not being approved by the FDA is the excuse for insurance companies to consider it an experimental treatment and therefore a non-covered service.

The FDA has recently approved immunotherapy allergy tablets. These are rapidly dissolving tablets that contain one or few allergens to be applied in the sublingual area. They are usually described and marketed as “SLIT.” These tablets have been developed by large allergen-extract manufacturers, in alliance with big pharmaceutical companies.

## Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?

Three allergy tablets were approved by the FDA in 2014,<sup>36,37,38</sup> and a fourth one in 2017.<sup>39</sup> These allergy tablets are Oralair<sup>®</sup> (Stallergenes Greer)<sup>36</sup> containing a mixture of five grass-pollens; Grastek<sup>®</sup> (ALK-Abello)<sup>37</sup> containing Timothy grass pollen; Ragwitek<sup>®</sup> (ALK-Abello)<sup>38</sup> containing short ragweed pollen; and Odactra<sup>™</sup> (ALK-Abello)<sup>39</sup> containing a mixture of the dust mites *Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*.

Policies of some insurance companies state that the use of “FDA approved sublingual extract tablets may be covered under applicable pharmacy benefits.”<sup>13</sup> In the same policy it is stated that the use of “sublingual immunotherapy prepared, administered, and delivered through a drop formulation is considered experimental/investigational and, therefore, not covered”<sup>13</sup> when actually the exact same allergens are used in both modalities.

The cost of these tablets could reach \$300.00 to \$600.00 per month.<sup>40</sup> Pollen tables are usually used pre-seasonally and continued throughout the season. For a minimum amount of a four-month period, the cost would be between \$1200.00 and \$2400.00 per season for each of the tablets considered. Using the dust-mite tablet for a year, would reach the staggering amount of \$4800.00 per year.<sup>40</sup>

The usual patient has reactivity to spring and/or fall pollen, often to grasses, and frequently to dust allergens (without considering reactivity to mold and/or animal dander). Managing the symptoms with allergy tablets would require 3 or 4 tablets (2 or 3 with pollen and one with dust mites). In this case scenario, the patient would undergo an incredibly expensive treatment of only partial benefit, failing to cover all trees, molds, animal dander, household insects and more. The huge cost could potentially be covered by the insurance company therefore at “no cost to the patient” but at a huge cost to the society; and the overall treatment result will be at best, mediocre.

These tablets also lack safety. They administer a dose found to work for most people but potentially too strong for some. The dose is not individually identified for each patient as is the case with SLIT (drops) rather the concept of “one size fits all” is applied. For this reason, their information leaflets carry a black box warning that says that the tablets “can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal edema,” and that an auto-injector of epinephrine should be prescribed in order to receive this treatment.<sup>36-39</sup>

When the treatment dose is individually prescribed, SLIT is a safe and effective treatment modality.<sup>41</sup> When properly administered, with a slow advancing protocol, SLIT is well tolerated, no serious adverse reactions develop beyond minor allergy symptoms or GI symptoms (which occur if the patient is intolerant to glycerin).<sup>35</sup>

Technically the tablets are administered sublingually, but in our opinion, SLIT should be reserved for the oral administration of a solution that is applied by a dropper or spray under the tongue. These drops contain a mixture of the allergens diagnosed by the test. These drops are mixed at the office by the practitioner and even if mixed by a general allergist, the content will usually go beyond one family of allergens.

## Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?

Probably the proper acronym for Allergy Immunotherapy Tablets should be AIT, reserving the acronym SLIT for allergens mixed by the allergy practitioner. This subtle issue is in our opinion important as the treatment results with SLIT, mixed with the concept of the total allergic load, versus the results of the treatment using AIT are completely different.

### Summary

The authors have summarized the difficulties that the practice of allergy immunotherapy is facing at the present time due to the implementation of guidelines adopted by many insurance companies. These regulations do not help the patients, rather they prevent the administration of effective allergy immunotherapy, ultimately determining that the patient will only attain a mediocre result.

The impact is clearly stronger for the practitioners managing the concept of the total allergy load—the otolaryngic and environmental allergists—than for the general allergists.

These guidelines may provide a short-term economic benefit for the insurance carrier. In the opinion of the authors these same guidelines, by preventing the administration of an effective treatment, will in the long run increase the cost of caring for the allergy patient. This will have a negative economic impact not only for the patient but for the society at large. Even the operative cost of the insurance companies may increase due to these policies.

The difficulties here described, for the proper administration of allergy immunotherapy, constitute only a narrow view of a very large problem that involves all areas of medicine and health.

These regulations have a synergistic effect with the rising cost of the allergen extracts, and other aspects of the overhead.

Published March 25, 2023

### References

- 1) Curtis HH. The immunizing cure of hay fever. Med News, New York 77:16, 1900.
- 2) Noon L. Prophylactic inoculation against hay fever. Lancet. 1911; 1: 1572-1573
- 3) King HC. A history of Otolaryngic Allergy, in: Allergy and Immunology: An Otolaryngic Approach. Editors: Krouse JH, Chadwick SJ, Gordon BR, Derebery, MJ. Published by Lippincott Williams & Wilkins, 2002. ISBN 10: 078172628X ISBN 13: 9780781726283 (Chapter 1)

### The Townsend e-Letter

Following the history and goals of the *Townsend Letter*  
- Examining the world of  
'Alternative' Medicine since 1983

**The Townsend e-Letter - publishing regular  
articles on the topics that help keep us healthy.**

nutrition - politics - supplements - health - science - brain  
health - exercise - homeopathy - acupuncture - kidney  
health - heart health - cancer - covid - alzheimers & more!

Click [HERE](#) to make sure you get the Townsend e-Letter!

## Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?

- 4) Chemical Sensitivity: Sources of Total Body Load, Volume II. William J Rea, M.D. CRC Press, Boca Raton, FL. ISBN-13: 9780873719636
- 5) Bernstein IL, Li JT, Bernstein DI et al. Allergy diagnostic testing: an updated practice parameter. *Ann Allergy Asthma Immunol.* 2008 Mar;100(3 Suppl 3):S1-148. doi: 10.1016/s1081-1206(10)60305-5. PMID: 18431959. Page S27, S28, S32
- 6) Cox L, Nelson H, Lockey R et al. Allergen immunotherapy: A practice parameter third update. *J Allergy Clin Immunol.* 2011 Jan;127(1 Suppl):S1-55. doi: 10.1016/j.jaci.2010.09.034. (pages S33-S34).
- 7) Calderón MA, Cox L, Casale TB, Moingeon P, Demoly P. Multiple-allergen and single-allergen immunotherapy strategies in polysensitized patients: looking at the published evidence. *J Allergy Clin Immunol.* 2012 Apr;129(4):929-34. doi: 10.1016/j.jaci.2011.11.019. Epub 2012 Jan 11. PMID: 22244595.
- 8) Nelson HS. Multiallergen immunotherapy for allergic rhinitis and asthma. *J Allergy Clin Immunol.* 2009 Apr;123(4):763-9. doi: 10.1016/j.jaci.2008.12.013. Epub 2009 Feb 13. PMID: 19217653.
- 9) The Cost-of-Living index has increased an average of 5.3% per year between 2019 and 2022 (<https://www.officialdata.org/us/inflation/2019?amount=40>). Accessed 11/4/2022.  
  
The cost of allergy supplies increased much more. Ex: the yearly office expenses for all allergy supplies (DS office) increased 11% per year between the years 2016 and 2019. Based on information provided to DS by one vendor of allergy supplies, the cost of allergenic extracts by the 3 main allergenic extracts manufacturers (Greer, Alk-Abello & Hollister), has increased an average of 13.8% per year between 2018 and 2022.
- 10) Reimbursements for allergy services have essentially not changed, rather showed a mild but steady decrease over the years. Example (from DS's office): the average reimbursement from all insurance companies for the following 5 CPT codes: CPT 95165 (preparation of a vial for weekly shots); CPT 95004 (prick test); CPT 95027 (intradermal dilutional test); CPT 95024 (intradermal test, single dilution) and CPT 95117 (administration of allergy shots), has decreased 0.9 % per year between 2010 and 2019
- 11) [www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57472](http://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57472). Accessed 11/4/2022.
- 12) [www.horizonnjhealth.com/for-providers/resources/policies/reimbursement-policies-guidelines/allergy-services](http://www.horizonnjhealth.com/for-providers/resources/policies/reimbursement-policies-guidelines/allergy-services). Accessed 11/4/2022.

## Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?

- 13) <https://medpolicy.amerihealth.com/ah/Commercial/Pages/Policy/5bebbba01-0b42-45ed-ae07-f386ffcf954.aspx>. Accessed 11/4/2022.
- 14) [http://www.aetna.com/cpb/medical/data/1\\_99/0038.html](http://www.aetna.com/cpb/medical/data/1_99/0038.html). Accessed 11/4/2022.
- 15) [https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm\\_0070\\_coveragepositioncriteria\\_allergy\\_testing.pdf](https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0070_coveragepositioncriteria_allergy_testing.pdf). Accessed 11/4/2022.
- 16) Saporta D and Hurst D. Management of the allergic patient: The role of different diagnostic tests. *Townsend Letter April* 2018:52-55.
- 17) Kordash TR, Amend MJ, Williamson SL et al. Effect of mixing allergenic extracts containing *Helminthosporium*, *D. farinae*, and cockroach with perennial ryegrass. *Ann Allergy*. 1993 Sep;71(3):240-6. PMID: 8372997.
- 18) Gough L, Schulz O, Sewell HF, Shakib F. The cysteine protease activity of the major dust mite allergen Der p 1 selectively enhances the immunoglobulin E antibody response. *J Exp Med*. 1999 Dec 20;190(12):1897-902. doi: 10.1084/jem.190.12.1897. PMID: 10601364; PMCID: PMC2195724.
- 19) Nelson HS, Iklé D, Buchmeier A. Studies of allergen extract stability: the effects of dilution and mixing. *J Allergy Clin Immunol*. 1996; Aug;98(2):382-8. doi: 10.1016/s0091-6749(96)70162-8. PMID: 8757215.
- 20) Young A and Wu Y. Immunotherapy - Vaccines for allergic diseases. *J Thorac Dis*. 2012 Apr 1; 4(2): 198–202. doi: [10.3978/j.issn.2072-1439.2011.07.03](https://doi.org/10.3978/j.issn.2072-1439.2011.07.03)
- 21) Reference #6, page S7
- 22) Jacobsen L, Wahn U, Bilo MB. Allergen-specific immunotherapy provides immediate, long-term and preventive clinical effects in children and adults. *Clin Transl Allergy*. 2012;2:8. Published 2012 Apr 13. doi:10.1186/2045-7022-2-8
- 23) Reference #6, page S18
- 24) <https://www.aaallergy.org/wp-content/uploads/2021/06/AAOA-Membership-Application-Fillable.pdf> (Aspiring member needs to complete an Otolaryngology residency) Accessed 10/30/2022.
- 25) Small et al. *Allergy Asthma Clin Immunol* 2018, 14(Suppl 2):51  
<https://doi.org/10.1186/s13223-018-0280-7>
- 26) Czarnobilska E, Klimaszewska-Rembiesz M, Gaweł B et al. Występowanie chorób alergicznych u dzieci w szkołach podstawowych Krakowa i okolic--próba określenia

## Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?

głównych czynników ryzyka [Prevalence of allergic diseases in primary school children in Cracow and surroundings--risk factors]. *Przeegl Lek.* 2002;59(6):422-6. Polish. PMID: 12418278. (Abstract in English)

- 27) Seidman MD, Gurgel RK, Lin SY, et al. Clinical Practice Guideline: Allergic Rhinitis. *Otolaryngology–Head and Neck Surgery.* 2015;152(1\_suppl):S1-S43. doi:10.1177/0194599814561600
- 28) Larenas-Linnemann DE, Gupta P, Mithani S, Ponda P. Survey on immunotherapy practice patterns: dose, dose adjustments, and duration. *Ann Allergy Asthma Immunol.* 2012 May;108(5):373-378.e3. doi: 10.1016/j.anai.2012.03.009. PMID: 22541411.
- 29) Krouse JH, Mabry RL. Skin testing for inhalant allergy 2003: Current strategies. *Otolaryngol Head Neck Surg.* 2003;129(4):S33-S49.
- 30) The Truth About the Drug Companies, by Marcia Angell. HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT Random House Trade Paperbacks, Aug 09, 2005. ISBN 9780375760945
- 31) [www.gene.com/download/pdf/xolair\\_prescribing.pdf](http://www.gene.com/download/pdf/xolair_prescribing.pdf). Accessed November 3, 2022.
- 32) [www.regeneron.com/downloads/dupixent\\_fpi.pdf](http://www.regeneron.com/downloads/dupixent_fpi.pdf). Accessed November 3, 2022.
- 33) <https://www.goodrx.com/dupixent>. Accessed November 22, 2022. Two pens with 300 mg of Dupixent are advertised at a discounted price of \$ 3,692.72. The same page mentions a program called “The DUPIXENT MyWay® Copay Card” that has an annual maximum of \$13,000. The cost of treating a patient with subcutaneous injectable immunotherapy with 2 vials of weekly shots will not reach \$ 2000.00 per year (DS).
- 34) Saporta D. Sublingual Immunotherapy: A Novel, Albeit Not So New, Immunotherapy Treatment Modality, *Am J Rhinology* 22,1-00,2008; doi: 10.2500/ajr.2008.22.3131
- 35) Saporta D. Reactions to Sublingual Immunotherapy: An Analysis of a Group of Patients Who Developed Adverse Events over a Period of 5 Years. *Townsend letter – August/September 2014:78-79.* NOTE: Discussion about the role of Glycerin in the on-line version.
- 36) Oralair®: <https://www.fda.gov/media/87935/download>. Accessed November 3, 2022
- 37) Grastek®: <https://www.fda.gov/media/88510/download>. Accessed November 3, 2022
- 38) Ragwitek®: <https://www.fda.gov/media/88712/download>. Accessed November 3, 2022
- 39) Odactra™: <https://www.fda.gov/media/103380/download>. Accessed November 3, 2022

## Are We Approaching the End of Allergy Immunotherapy As We Practiced It Until Now?

40) <https://www.goodrx.com/odactra?dosage=30-sublingual-tablets-of-12-sq-hdm&form=dose-pack&quantity=1>. Accessed November 3, 2022

41) Saporta D and McDaniel A. Efficacy Comparison of Multiple-Antigen Subcutaneous Injection Immunotherapy and Multiple-Antigen Sublingual Immunotherapy. *ENT Journal* 2007; 86(8):493-497.

Published March 25, 2023

### About the Authors

The authors are all board-certified otolaryngologists who were able to successfully incorporate Allergy Immunotherapy into their practice. DS (from NJ) wrote the paper. AMcD and DH edited and contributed to the manuscript. BH (from Maryland) and JC (from West Virginia) read the manuscript and agreed that their practices are also being similarly affected.

DH and AMcD are now retired from the practice of allergy. DS, BH and JC are actively providing these services.

DH, AMcD and DS have published in peer reviewed journals and also in *Townsend Letter* about topics related to the field of allergy and allergy immunotherapy.

DH is a past research chairman of the AAOA. He has taught instructional courses on allergy and otitis media with effusion, and on mold allergies for several years at such organization.

DH, AMcD and DS have presented on the topic of mold allergy and other topics of allergy at the AAOA and AAEM.

DS, DH, BH and JC have presented papers at the PAAS on the topics of allergy and allergy immunotherapy.

DS, BH and JC have taught about allergy management and immunotherapy at the PAAS for many years.