

April 30, 2014

RE: Health Care Workshop, Project No. P13-1207

<http://ftcpublic.commentworks.com/ftc/healthcareworkshop>

To whom it may concern:

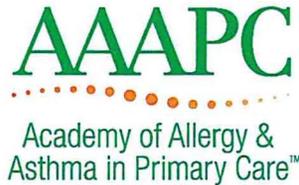
The Academy of Allergy and Asthma in Primary Care (AAAPC) appreciates the opportunity to provide comments to the Federal Trade Commission's Public Workshop, "Examining Health Care Competition." The Federal Trade Commission is seeking to better understand the competitive dynamics of evolving health care product and service markets.

The AAAPC supports innovative care models of allergy and asthma care in primary care, such as immunotherapy ancillary service models. In that role, AAAPC has been fighting to change outdated nonevidence-based government policy and breakdown anticompetitive activities in the health care market place that promote the ever-widening gap in the nation's largest health disparity – allergy and asthma care for minority children.

The mission of the AAAPC is to foster the ability of physicians to provide high quality, patient-accessible diagnostic and therapeutic allergy and asthma care. AAAPC is a voice for thousands of physicians and patients using allergy and asthma diagnostic and therapeutic services to raise awareness of the link between allergy care and asthma prevention, particularly in pediatric and family practice populations. AAAPC's membership practices across the nation.

In these comments, AAAPC will highlight government policies and commercial barriers in the health care marketplace that unnecessarily restrict the ability of primary care physicians to practice immunotherapy ancillary service models, thereby limiting access to care and supporting higher than necessary health care costs. The AAAPC is restricting its comments to discuss innovations in Health Care Delivery and to the question of:

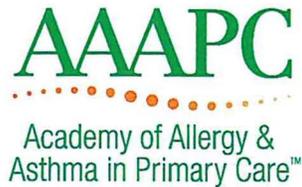
Are there regulatory or commercial barriers that may restrict the use of new models in health care, particularly immunotherapy under the care of a primary care physician utilizing home administration under appropriate clinical protocols.



As more fully discussed below there are two critical barriers to this new model in healthcare – these barriers are resulting in expanding the health disparities for allergy and asthma treatment:

1. ***While CMS permits primary care physicians to be reimbursed for providing immunotherapy under the new model of care using home administration, NIH NHLBI's Clinical Practice Guidelines for the Management of Asthma (2007) provide for only in office administration. NHLBI's Clinical Practice Guidelines need to be updated with current scientific evidence and need to contain evidence-based recommendations which include home-based administration models.***

The National Heart, Lung, and Blood Institute (NHLBI) National Asthma Education and Prevention Program (NAEPP) develops evidence-based clinical practice guidelines to translate research findings on asthma to improve asthma care and the health and quality of life for people who have asthma. These clinical practice guidelines serve as a foundation for numerous programs at the national, state, and local levels for clinicians, patients, their families and communities to improve asthma management.ⁱ The guidelines were last updated in 2007. In the guidelines, the panel recommended based on the review of the scientific evidence that immunotherapy should be considered as a treatment option when there is a clear connection between allergen exposure and asthma. However, the 2007 guidelines further state that allergen immunotherapy should only be performed in a physician's office so that rare life-threatening reactions can be immediately treated. To support this statement, the panel cited a recommendation made by an Allergist's Trade Association in 1994--no evidence or evidence ranking was provided to support the statement. Review of the literature that is now more than two decades old reveals that the risk of severe reactions is associated with uncontrolled asthma, severe cardiovascular disease and dosing errors that would not occur in home-based administration models as the clinical protocols would require such patients to be referred to an allergist. As more fully discussed below, in the home-based setting, the modern literature indicates that immunotherapy can be safe when patients are carefully screened and selected. Most recently, Schaffer et al. reported in 2012 on 24,000 patients treated under a home-based immunotherapy protocol that emphasizes careful patient selection and family education. The investigators found that the rate of severe adverse reactions was only 0.16 percent per patient and 0.002 percent per injection. The investigators selected patients to participate in this protocol based on a variety of criteria designed to ensure that home-based therapy was limited to those patients presenting the lowest risk for serious adverse reactions. Patient were trained and then demonstrated their ability to self-administer immunotherapy prior to physician approval to initiate home-based therapy.ⁱⁱ As more fully discussed below, not only are home-based administration models safe, they promote better compliance than in office administration and allow for greater access to care for underserved populations including



minority children. In January, NHLBI published a “Request for Information on Topics to be Considered for Systematic Reviews and a Possible Update to Clinical Practice Guidelines for the Management of Asthma.” We look forward for their determination to update their recommendation to permit home based administration under appropriate clinical protocols based on the scientific evidence.

2. Allergists trade associations have conspired to push primary care physicians including members of AAAPC out of the market for allergen immunotherapy through various means, which has resulted in severely limiting the care for minority populations and increasing health disparities.

AAAPC filed for a preliminary injunction against various board-certified allergists, their businesses, and the trade associations they lead alleging that they have conspired to push primary care physicians who are members of AAAPC out of the market for allergy testing and allergen immunotherapy, including by contacting insurance companies and health plans in an effort to convince those payors for immunotherapy services not to pay primary care physicians or to adopt pricing and reimbursement policies to disadvantage primary care physicians while protecting their inflated prices. As more fully discussed below, these practices also serve to disadvantage minority children who have limited access to allergy and asthma care. A copy of the current complaint in this action is attached.

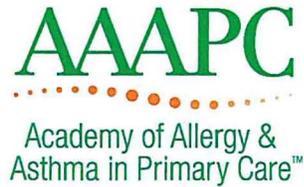
Chronic Conditions: The Burden of Asthma and Allergic Rhinitis

The rapidly-growing prevalence of chronic conditions in the U.S. places a staggering cost burden on the healthcare system. Two of the more common chronic conditions affecting both children and adults are asthma and allergic rhinitis. Today, approximately 60 million Americans are affected by asthma and allergic rhinitis,ⁱⁱⁱ and the prevalence is increasing.^{iv v vi} Not only do these conditions negatively impact sufferers’ quality of life, but also account for lost time from work or school, added cost to patients and, ultimately, a significant financial burden on the health system.

Allergic Rhinitis

Specifically, allergic rhinitis is ranked the third-leading chronic disease in the U.S. among individuals younger than 45 and the fifth leading chronic disease among all Americans.^{vii viii} Up to 30 percent of all adults and 40 percent of all children suffer from allergic rhinitis.^{ix x xi}

Allergic rhinitis has been found to precede other chronic medical conditions, including asthma, upper respiratory tract infections, sleep disorders, and depression.^{xii} For most patients, this



impacts everything from job to academic performance and leads to lost time from work, school and leisure activities.^{xiii xiv xv} In fact, in 2010 the prevalence of allergic rhinitis in the United States alone resulted in more than six million missed work and school days.^{xvi}

Allergic rhinitis-related expenses cost patients \$6.1 billion in 2000, and, annually, average costs for someone with allergic rhinitis-related expenses increased from \$253 to \$434 for those under age 18 from 2000 to 2005, and for those ages 18 to 64 from \$381 to \$566.^{xvii}

Asthma

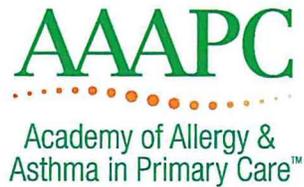
Imposing as the burden of allergic rhinitis is, perhaps the greatest strain it puts on healthcare results from its association with asthma.

The link between allergic rhinitis and asthma is clear. With recurrent allergen exposure, pediatric and adult individuals with allergic rhinitis can develop allergic asthma, and some allergies have even been defined as risk factors for the development of asthma.^{xviii xix xx xxi xxii} Sixty percent of people with asthma have allergic asthma, in which asthmatic complications are triggered by allergen exposure. Additionally, asthma is present in 20 to 50 percent of patients with allergic rhinitis.^{xxiii}

The impact of asthma on the healthcare system is far-reaching and dramatic. According to the CDC, nearly 19 million adults and 7.1 million children currently have asthma—representing 8.2 and 9.5 percent of the populations, respectively.^{xxiv} A Gallup poll published in 2012 named asthma the fourth most common chronic condition in the U.S.—more prevalent than diabetes, cancer, depression and obesity.^{xxv}

Asthma is the most common chronic disease in childhood, impacting an estimated 6.5 million Americans under the age of 18. It is the primary reason children miss school and the leading cause of childhood hospitalization. Furthermore, the CDC recently reported that not only has the prevalence of asthma increased from 7.3 percent in 2001 to 8.4 percent in 2010, but minority and lower income populations are being hit hardest. African Americans and Hispanics manifest the highest asthma prevalence (11.2 percent and 16.1 percent respectively) in contrast to that of Caucasians (7.7 percent) and Asian Americans (5.2 percent). Today, 11.2 percent of individuals living below the poverty line have asthma.^{xxvi}

Not surprisingly, asthma is associated with high rates of healthcare utilization. Recently, in one year alone, asthma was responsible for 1.3 million visits to hospital outpatient departments and 1.8 million emergency department visits, with the average length of stay for inpatient care for asthma patients being 3.6 days. Sadly, the condition is associated with thousands of deaths each year.^{xxvii}



With high healthcare utilization, associated comorbidities and medication expenditures, the annual cost of asthma –estimated to be nearly \$56 billion, according to the CDC—is staggering.

The burden of asthma today, both in terms of cost as well as impact on vulnerable patient populations, is heavy and continuing to grow. Increasing access to high quality care for allergic asthma, as well as allergic rhinitis, is critical.

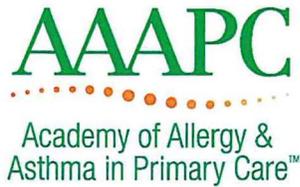
Furthermore, the strong association between allergic rhinitis and the subsequent development of asthma underscores an opportunity to better address this healthcare issue. Volumes of clinical data show that this link could be decreased through a treatment shown not only to reduce allergic rhinitis symptoms, but to *actually prevent the onset of new allergies and allergic asthma*: immunotherapy.^{xxviii xxix xxx xxxi xxxii xxxiii} Increasing access to immunotherapy is an opportunity for healthcare change that is real and significant.

In order to improve U.S. healthcare and to meet the human and economic challenges presented by the rise in chronic conditions such as asthma and allergic rhinitis, new delivery models that strengthen and support primary care have been developed. Care focused on early diagnosis of patient symptoms and increased preventive, holistic treatment, rather than siloed or inaccessible care models, is imperative.

Innovations in Health Care Delivery: A Patient Centered Model for Immunotherapy in Primary Care

Primary care is the only entity charged with the continuum of care for the whole patient, and represents an opportunity to better coordinate early diagnosis, disease management and access to appropriate treatment. Many physicians have turned to healthcare businesses with supportive expertise in numerous areas of specialty care to increase their scope of services and to expand patient access to much-needed therapies for chronic conditions such as asthma and allergic rhinitis.

More than 100 years of scientific research and medical practice^{xxxiv xxxv xxxvi} have proven that the only lasting relief from allergies is immunotherapy, also known as allergen-specific subcutaneous immunotherapy (SCIT). SCIT is a disease-modifying therapeutic treatment which reduces the need for long-term medical care and halts the progression of allergic rhinitis to asthma^{xxxvii xxxviii} and the development of new allergies.^{xi xli xlii} The therapy induces immunologic tolerance by introducing the patient to safely increased doses of an allergen(s) through a series of customized single-injections. The purpose of SCIT is to desensitize the patient to the allergen that triggers the symptoms, standing in stark contrast to OTC and prescription drugs, which only temporarily mask allergy symptoms and doesn't treat the actual disease.^{xliii xliv xlv xlvi xlvii xlviii}

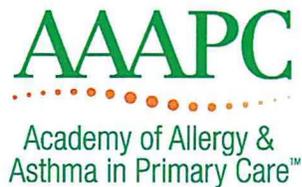


Ultimately, effective SCIT treatment allows the patient to be exposed to sensitizing allergens in everyday life without any reaction. Up to 85 percent of patients receive a significant long-term reduction in allergy symptoms using immunotherapy.^{xlix} Immunotherapy, aside from diminishing the symptoms of pre-existing allergic rhino conjunctivitis,^l ^{li} ^{lii} ^{liii} also decreases the severity of pre-existing allergic asthma^{liii} ^{liv} ^{lv} ^{lvi} ^{lvii} and prevents the onset of new allergies and allergic asthma.^{lviii} ^{lix} ^{lx} ^{lxi} ^{lxii} ^{lxiii} Logically and ethically, such a treatment—one that not only effectively reduces symptoms, but also may prevent the development of new, related illnesses—should be made widely available to patients as a first-line option rather than a secondary, highly-specialized and often inaccessible therapy.

In addition to allergic rhinitis, immunotherapy's potential for asthma care is critical. A 2010 published review of 88 randomized controlled trials showed that immunotherapy is associated with a significant reduction in asthma symptoms, improvement in bronchial hyper-reactivity and reduced need for asthma medication.^{lxiv}

In a recent meta-analysis of 24 prospective, randomized, double-blind studies published in *Clinical Therapeutics*, showed that immunotherapy was an effective treatment for patients with allergen-triggered asthma in 71 percent of the studies, independent of the age of the study population. Symptoms improved in 62 percent of patients receiving immunotherapy versus 23 percent of comparison patients treated with a placebo, with results remaining comparable for adults and children. The analysis found immunotherapy was also associated with clinical improvements in pulmonary function in 70 percent of patients receiving the treatment, as well as overall reduced need for medications.^{lxv}

Another study of 147 allergy patients concluded that immunotherapy should be recognized not only as a first-line therapeutic treatment for allergic rhinitis, but also as a secondary preventive option for asthma. Patients with allergic rhinitis and without asthma before the start of immunotherapy were analyzed for the development of asthma after a 10 year period. The number of patients who developed asthma among controls was 45 percent. Among the group actively treated with allergen-specific subcutaneous immunotherapy (SCIT), 25 percent developed asthma. The study concluded that immunotherapy for three years shows a persistent long-term effect on clinical symptoms after termination of treatment and a long-term, preventive effect on later development of asthma in children with seasonal rhino conjunctivitis.^{lxvi} Recently, the authors of this study released additional data showing significant reduction in outpatient services for chronic URIs, nasal polyps, influenza, allergic reactions and emphysema. According to the results, immunotherapy may mitigate the development and severity of other allergic and respiratory diseases.^{lxvii} The ability to halt the progression of asthma, a condition that lowers patient quality of life and health, drains healthcare dollars and is even associated with loss of life, shows that the benefits of immunotherapy reach far beyond reducing allergy



symptoms alone.

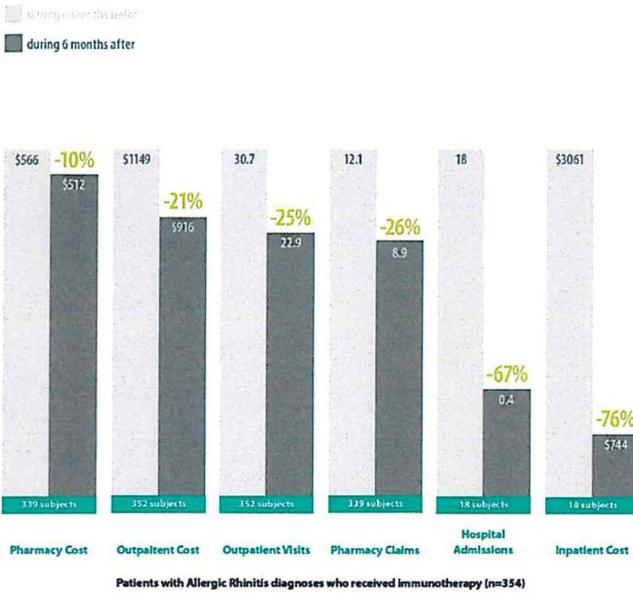
Disparities and Cost of Asthma and Allergic Rhinitis Treatments

Because patients benefit for many years after finishing SCIT, it is clear that immunotherapy offers not only a health benefit, but an economic one as well.^{lxxviii}

Unlike most chronic medical conditions, the majority of allergy sufferers spend their entire lives battling symptoms without even knowing exactly what they are allergic to. Often, they treat their undiagnosed allergies with over-the-counter (OTC) and prescription drugs that only mask the symptoms. Due to their low efficacy, many patients resort to combining OTC and prescription medications for treatment. In fact, a recent survey reported that many adults with allergic rhinitis take two to four medications simultaneously to control their allergic rhinitis symptoms.^{lxxix} When parents were surveyed about which medications their children used for allergy symptom relief, more than half (54 percent) reported the use of an OTC medicine, whereas slightly fewer (48 percent) reported use of prescription medications.^{lxx lxxi lxxii lxxiii}

Numerous studies have examined the potential economic benefit of asthma and allergic rhinitis treatment with SCIT, demonstrating significant savings to patients, government agencies and insurance companies. A 2011 study conducted in Florida found cost savings associated with SCIT for Medicaid enrollees diagnosed with allergic rhinitis. The data was collected from 1997-2008 from claims of Medicaid enrolled adults and children. Significant differences in total median healthcare costs were evident as early as three months after SCIT initiation and increased throughout the 18 month analysis. Over that time period, the study showed that immunotherapy treatment generated a per-patient healthcare cost savings of 41 percent (\$7,286) for adults, and 33 percent (\$5,921) for children.^{lxxiv lxxv lxxvi}

With asthma and allergic rhinitis driving direct and indirect health-related costs for patients and payers, aggressive intervention should be encouraged.^{lxxvii lxxviii lxxix lxxx lxxxi} The benefits of immunotherapy as a preventive treatment mitigating asthma and new allergy sensitizations are evident not only while immunotherapy is performed, but for several years after its interruption.^{lxxxii}

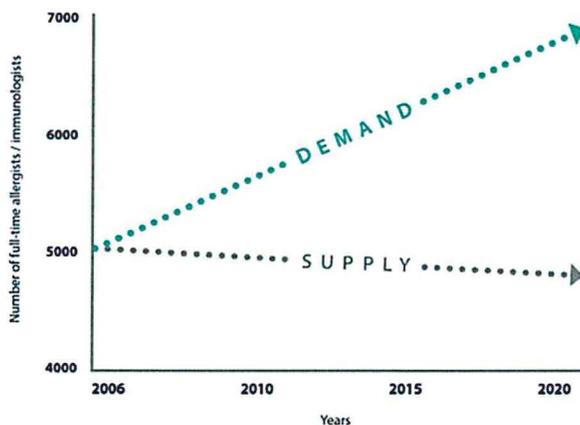


In summary, SCIT typically produces the following results:

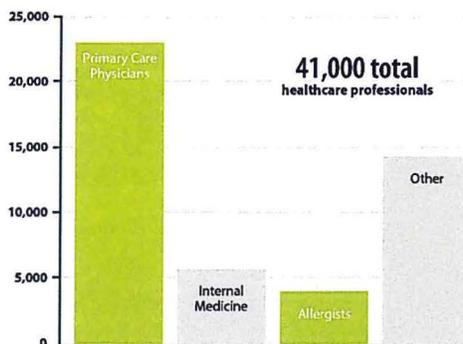
- Significant clinical improvement
- Decrease in the use of OTC and prescribed antihistamines and nasal steroids
- Diminished severity of allergic asthma
- Less frequent use of asthma medications
- Diminished severity of the other comorbidities

Advancing SCIT Delivery Models

Until now, the only real relief for allergies and allergic asthma has remained primarily in the hands of allergists who administer SCIT. This already small community of less than 5,000 physicians ^{lxxxiii} is expected to decline by 6.8 percent by 2020, while demand for allergy-related services is projected to increase by 35 percent by the same year. ^{lxxxiv} This forecast only scratches the surface of the true demand for allergy and asthma care, as only a portion of the approximately 60 million Americans suffering from allergic rhinitis are aware of their condition and seek specialty care. While nearly four in five people know allergies are serious, only one in five are seen by a specialist. ^{lxxxv}

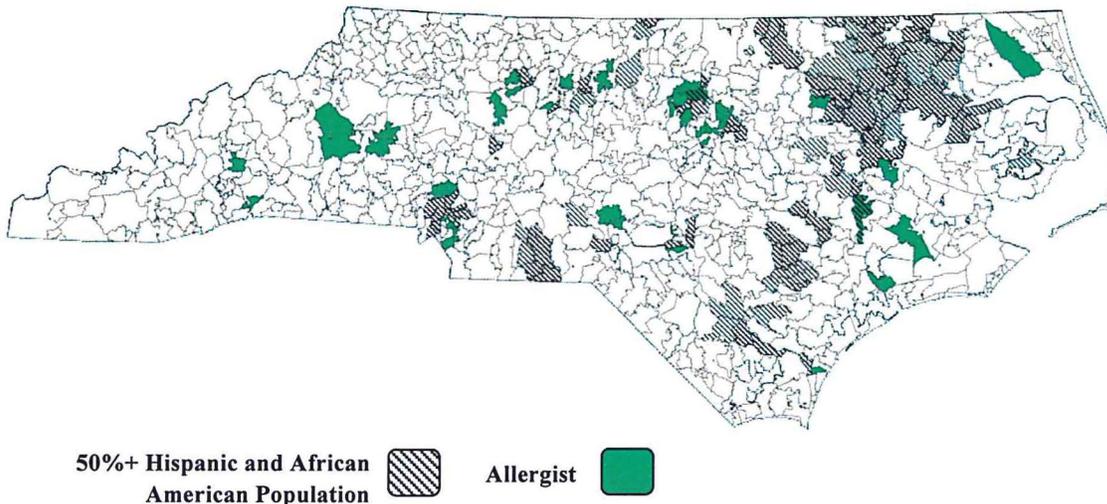


While seasonal and perennial allergic rhinitis create unnecessary medical costs, harm quality of life and impact work force and school productivity, it has been shown that not nearly enough practicing specialists exist to treat the number of patients in need. In addition, allergists primarily work in large metropolitan areas, leaving suburban and rural patients without access to care. In fact, according to Centers for Medicare and Medicaid Services (CMS), only 50 percent of patients receiving SCIT are currently being treated by an allergist, due largely to the lack of supply. The balance is being treated by Ear, Nose and Throat (ENT) and Primary Care Physicians. In data assessed in 2012 from across the United States, there were 41,000 healthcare professionals involved in immunotherapy, 23,000 of those professionals were primary care physicians.^{lxxxvi}



The map of North Carolina illustrates the typical distribution of where an allergist is located in relation to the minority population. As previously mentioned, the CDC recently reported that African Americans and Hispanics manifest the highest asthma prevalence (11.2 percent and 16.1 percent respectively) in contrast to that of Caucasians (7.7 percent) and Asian Americans (5.2 percent). Today, 11.2 percent of individuals living below the poverty line have asthma. The map

clearly shows that access to allergy care is being restricted to those populations who are being hit hardest by allergic rhinitis, asthma and other allergic diseases.

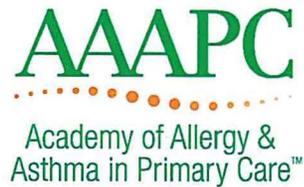


In a recent survey conducted by Harris Interactive of 2,087 adults who have allergies, two-thirds responded that they would rather see a primary care physician for their allergies than an allergist. Also reported, nine in 10 would try a treatment that would stop allergic reactions and not just treat the symptoms and the same number of respondents agreed that if there was a way to safely and effectively treat the cause of their allergies (not just mask symptoms) at home, they would try it. ^{lxxxvii}

Academy of Allergy and Asthma in Primary Care

To support the physician community, the Academy of Allergy and Asthma in Primary Care (AAAPC), non-profit professional association, was formed. The mission of this member-based association is to foster the ability of physicians to provide high quality, patient-accessible diagnostic and therapeutic allergy and asthma care. AAAPC is a voice for thousands of physicians and patients using allergy and asthma diagnostic and therapeutic services to raise awareness of the link between allergy care and asthma prevention, particularly in pediatric and family practice populations.

While the Patient Protection and Affordable Care Act (PPACA) is putting renewed focus on primary care, it is important to better arm primary care physicians (PCPs) with the tools and



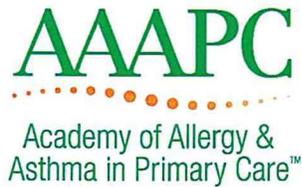
skills needed to meet the challenges of chronic conditions and to make a real impact on improving patient care. Additionally, with family physicians often serving as the “first line of defense” in the treatment of many chronic conditions, the ability to provide more specialized treatment also translates to increased access to these services for a greater number of patients.

Primary Care: Innovations in Delivery Models for Treating Allergic Rhinitis and Asthma

As demand for specialty services in the primary care setting grows, support is needed from all agencies in the Federal government to empower primary care physicians to address care needs that specialists may be unable to fully meet. Importantly, CMS permits primary care physicians to be reimbursed for providing SCIT and additional recent studies^{lxxxviii} have demonstrated the ability of primary care physicians to diagnose and assess individuals with allergic rhinitis.

While allergen SCIT is a treatment used by both allergists and primary care physicians, key differences exist in how each physician group administers the treatment. Typically, only a low-risk population of allergic patients receive SCIT from a primary care physician. This patient population is specifically identified as those with mild to moderate seasonal and perennial allergies. Any patient who has a severe allergic case, is referred to an allergist for care, a specialist best trained and equipped to manage patients with the most serious asthma and allergic conditions and reactions. High risk patients include those with food allergies, venom, and severe or uncontrolled asthma, rather than sensitivity to seasonal and perennial allergies. By segmenting the patient population in this way, patients are able to access the provider and care that is best suited for their quality of life.

Most Primary Care Protocols minimize the potential occurrence of adverse reactions (such as anaphylactic shock) by utilizing a slow build-up phase, emphasizing patient education and compliance. The protocol is different than what one would expect to see in an allergist’s practice. While this build-up is slower than what an allergist would offer, the antigen load over the course of one year is similar, and is ideal for low risk patients. Both models focus on delivering efficacious dosing in a safe manner. The PCP model differs by providing smaller injection volumes more frequently, over a longer buildup phase, typically using 280-300 units in the course of one year of treatment. Through a slower buildup process, PCPs have been able to significantly lower what is commonly known as the “Systemic Reaction Rate,” a grading system defined by the World Allergy Organization.^{lxxxix} According the Practice Parameters, authored by Linda Cox, MD, et al, the frequency between injections is empiric but might be as short as one day without any increase in the occurrence of systematic reactions.^{xc} As specialists, allergists have specific training in administering SCIT in stronger amounts over a shorter period of time, typically in the 120-180 units a year range. This treatment method is best suited for patients with the most serious allergy conditions.



A Proven Safety Track Record

The practice of offering SCIT self-administration is commonly used by the allergist community. Significant numbers of both allergists and otolaryngic allergists prescribe self-administered outpatient SCIT for the treatment of seasonal allergies. According to a national American Academy of Otolaryngic Allergy (AAOA) Morbidity and Mortality Survey, up to 30 percent of otolaryngic allergists prescribe home-based SCIT. The survey authors concluded that home-based SCIT is a safe treatment option in low risk patients. Similarly, a recent survey of American Academy of Allergy, Asthma, and Immunology (AAAAI) members demonstrated that a portion of allergists allow patients to receive SCIT at home.^{xcv}

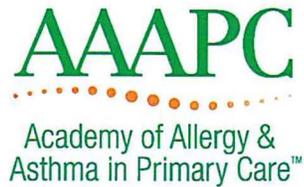
Multiple studies have demonstrated that self-administered SCIT is safe when key protocols are followed. A large prospective study by the Tufts University Department of Otolaryngology and Uppsala University Department of Immunology recorded approximately 635,600 patient encounters and 1,144,000 allergy injections. Sixty percent of injections were given at home. The study demonstrated that home-based SCIT was found to be safe and it had significantly (26-fold) fewer major reactions than office-based immunotherapy.^{xcvi} Another key study by an allergist, Dr. Warren V. Filley reported that more than 2.1 million home SCIT injections produced no mortalities.^{xcvii}

In a study of 24,892 patients published in the *Annals of Allergy, Asthma & Immunology* showed allergy testing performed by allergists resulted in systemic reactions in 0.4 percent of cases.^{xcviii} In contrast, systemic reactions only occurred in 0.02 percent of the patients undergoing allergy testing by physicians utilizing a common Primary Care protocol. Thus, there is a 20-fold greater chance of a systemic reaction if allergy testing is performed by an allergist, in comparison to a physician utilizing the common PCP testing protocol. In addition, the systemic reaction rates in the study were well below published rates of four to seven percent reported by board certified allergists. The study reaction rate is 0.18 percent per patient on home-based immunotherapy and 0.003 percent per injection. By contrast, studies published by board certified allergists report a systemic reaction rate of four to seven percent per patient and a 0.2 percent systemic reaction rate per injection for patients receiving immunotherapy.

Despite the differences in the number of units in both of these models, the primary care protocol (300 unit protocol) will most often cost less than the allergist protocol (120 to 180 units). While this may seem counterintuitive, the cost stems from the actual delivery of the injections themselves. Currently, insurance carriers and patients pay for multiple visits, and the associate shot fees, to the allergist's office to receive SCIT, as opposed to most Primary Care protocols, which leverage self-administration, limiting the number of office visits to only when the dosage level is increased.

The in-office method used mostly by allergists ends up costing the patient more in shot co-pays alone than the actual immunotherapy. In fact, patient cost is often cited as a key reason why patients suspend SCIT (rendering the treatment ineffective). In a blind study, the insurance payer costs associated with SCIT delivery from allergists and PCP's utilizing a 300 unit self-administration protocol was reviewed. The total shot and medication costs were reported following the protocols of the American Academy of Allergy, Asthma, and Immunology (AAAAI) practice parameters, a sampling of allergists and primary care physicians. The costs were driven by both the actual costs of IT, office visits and shot fees. The 300 unit model used by PCP's does not include shot fees, resulting in the lowest cost to insurance payers of only \$3,090. While allergists and AAAAI practice parameters costs to the insurance payers was \$3,867 and \$4,809 respectively due to the numerous office visits and shot fees. This study shows that the PCP protocols are ultimately saving payers on healthcare costs associated with SCIT.



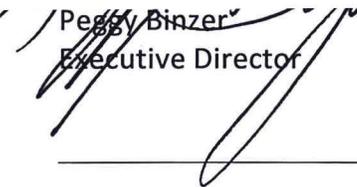


Conclusion

The burden of allergies and asthma today, both in terms of cost as well as impact on vulnerable patient populations, is heavy and continuing to grow. Increasing access to high quality care for allergic asthma, as well as allergic rhinitis, is critical. Limiting SCIT to in office treatment is not consistent with the standard of care and results in limiting access to care, increasing health care costs and contributing to health disparities.

I welcome the opportunity to discuss this further with you. Please contact me at 703.581.9285.

Sincerely,


Peggy Binzer
Executive Director

ⁱ Request for Information: Topics to be Considered for Systematic Reviews and a Possible Update to Clinical Practice Guidelines for the Management of Asthma. Notice Number: NOT-HL-14-203

ⁱⁱ Schaffer FM, Whelchel L, Soliz H, Crimmins T, Ebeling M, Hulseley T, & Garner L. (2012) The Safety of Home Immunotherapy Utilizing the United Allergy Services Immunotherapy Protocol. *Annals of Allergy, Asthma, and Immunology* 109:A121.

ⁱⁱⁱ *Allergy facts and figures*. (n.d.). Retrieved from <http://www.aafa.org/display.cfm?id=9&sub=30>

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^{vi} Hankin C.S., Cox, L., Bronstone A. The Health Economics of Allergen Immunotherapy. *Immunol Allergy Clin North Amer.* 31(2):325-41,2011.

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^{xi} Meltzer E.O., Blaiss M.S., Derebery M.J., et al. Burden of allergic rhinitis: results from the Pediatric Allergies in America survey. *J Allergy Clin Immunol* 124. (Suppl 3): S43-S70, 2009.

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NATURE OF THE CASE

1. This case concerns a conspiracy and agreement among the three national allergist trade associations and certain of their officers and board members to restrict competition in the market for allergy testing and allergen immunotherapy for seasonal and perennial allergies. The three trade associations, AAAAI, ACAAI, and JCAAI, responded to pleas from their members to engage in a “turf war” to address the “encroachment” in the market by primary care physicians and UAS. In response, and it keeping with the “turf war” motif, these three independent associations of competitors agreed to form “RADAR,” a joint venture of those organizations to recruit local allergists from every state, regional, and local allergist society in the nation to fight back against these competitors, and to provide a message board called “Basecamp” for those representatives to coordinate their anticompetitive activities.

2. Defendants, including not only these trade associations, but the leaders listed in this complaint and some RADAR members, actively engaged in their self-described “turf war” by contacting insurance companies, managed care organization health plans, and other third-party payors to convince them not to do business with or reimburse the allergy testing and allergen immunotherapy services of primary care physicians and UAS. Defendants engaged in this conduct despite, and in spite of governmental organizations such as the Centers for Medicare and Medicaid Services and the Texas Medical Board, which otherwise pay for and authorize the services of these competitors. The purpose of Defendants’ contacts with private third-party payors and encouragement of other members to engage in this behavior is to accomplish their anticompetitive objectives through persuasion, enticement, or coercion, and were economically motivated to protect Defendants’ turf.

3. The result has been a threatened and actual restriction on competition in the market for allergy testing and allergen immunotherapy to the ultimate detriments of consumers. By

attempting to take away competitors' means to compete, namely reimbursement by third-party payors, Defendants have aimed to essentially deprive the market of a lower cost alternative and deprive patients of the ability to choose which businesses and physicians may provide allergy testing and allergen immunotherapy. Defendants' intended result is to protect their own profits and ensure that patients continue to pay their inflated prices, despite the need for additional supply in the market. Because such anticompetitive conduct aimed at private parties is not protected activity, but forbidden by the Sherman Act, the Texas Free Enterprise and Antitrust Act, and Texas common law, the Court should put an end to this turf war and restore and protect competition.

JURISDICTION, VENUE AND INTERSTATE COMMERCE

4. This action is brought under Section 1 of the Sherman Act, 15 U.S.C. § 1, the Texas Free Enterprise and Antitrust Act, Tex. Bus. & Comm. Code § 15.05, and the common law of torts for civil conspiracy and tortious interference with both current contracts and prospective business relations.

5. This Court has subject matter jurisdiction over Plaintiffs' claims pursuant to 28 U.S.C. §§ 1331 and 1337, 15 U.S.C. §§ 15 and 26, and 28 U.S.C. § 1367(a).

6. The Court may exercise personal jurisdiction over Defendants Gross, Mansfield, Weldon, Dallas Allergy and Asthma Center, P.A., and Lyndon E. Mansfield M.D., P.A., a professional association, because they are located in Texas and have continuous and systematic business contacts with Texas that are substantial, and because this action arises out of and is related to those purposeful contacts with Texas.

7. The Court may exercise personal jurisdiction over Defendants JCAAI, AAAAI, and ACAAI because they regularly conduct business in Texas, including with Texas-based physicians to whom they market and communicate directly through phone calls, writings, and over the

internet, including via their respective websites. Additionally, they have purposefully directed specific actions at Texas, including phone calls, emails, letters, and publications. This action arises from and specifically relates to those purposeful contacts with the State of Texas.

8. The Court may exercise personal jurisdiction over all Defendants, including Defendants Dr. Aaronson, Dr. Sublett, and PSF, PLLC because they expressly aimed tortious conduct at the State of Texas knowing that the brunt of their intended injury would be felt by residents of Texas, and particularly by UAS, a San Antonio, Texas-based company. Defendants have expressly engaged in such tortious conduct individually by committing antitrust violations, as well as interfering with contracts and prospective business relationships in Texas with the intent to harm residents of Texas. They have done so through communications directed to persons and entities located in Texas, with the aim of gaining extensive benefit, advantage, business, and profit from these contacts with Texas.

9. For example, on February 8, 2011, Dr. Aaronson and Dr. Sublett helped issue a letter to Regional, State, and Local Allergy Society Leaders announcing the formation of the Regional Advocacy Discussion and Response (“RADAR”) initiative aimed at addressing the encroachment of non-allergists. *See* Exhibit E-4 to Plaintiffs’ Motion for Preliminary Injunction and Temporary Restraining Order (Motion for Preliminary Injunction”), Dkt. No. 12-25. The letter, which was signed by Dr. Sublett, sought to recruit local representatives from every corner of the country, including Texas, to assist in carrying out RADAR’s mission, the true intentions of which were to restrict access to the market for allergy testing and allergen immunotherapy. An AAAAI published report on “Ongoing Activities Relevant to the [RADAR] Initiative,” admits that one of the means by which RADAR attempted to address the perceived encroachment by non-allergists, was to engage in “[o]ngoing communication with insurance companies” to represent the specialty “in discussions about appropriateness of care.” *See* Exhibit G to Plaintiffs’ Motion for

Preliminary Injunction at 3, Dkt. No. 12-35. Those discussions have resulted in the refusal of insurance companies to reimburse claims submitted by primary care physicians residing in Texas who are supported by UAS. The encouragement of such actions by local representatives from every state in the country clearly demonstrates a nationwide pattern of anticompetitive conduct which has resulted in direct harm to entities located in Texas, including UAS and the practices of the Texas primary care physicians whom it supports.

10. Further, Dr. Sublett sent an email dated May 5, 2011 to the President of the Texas Allergy, Asthma & Immunology Society (“TAAIS”), Dr. Stuart Abramson, who was located in Texas, approving and authorizing the creation and distribution of anticompetitive letters aimed at primary care physicians, insurance companies, and managed care organizations throughout Texas. *See* Exhibit P to Plaintiffs’ Motion for Preliminary Injunction and Temporary Restraining Order, Dkt. No. 12-46. The communication indicates that both Dr. Aaronson, JCAAI’s acting Executive Director, and Dr. Gross, the organization’s Executive Vice President, were also personally involved in approving these communications. Despite acting in their capacity as officers of JCAAI, Defendants’ actions also benefitted themselves individually as physicians and their businesses engaged in the market for allergy testing and allergen immunotherapy, and thus were undertaken in more than any pure associational capacity. The fiduciary-shield defense protects against liability for officers of organizations just by being officers, but does not protect the individual Defendants from liability for their own tortious conduct, especially not from antitrust liability. The letters that Drs. Aaronson, Gross, and Sublett approved on behalf of JCAAI, were intended to injure UAS, as well as the Texas primary care physicians that it supports. As the referenced communication from TAAIS seeking approval for the letters asserts, they were revised to alter the “tone that was felt to be too targeted to a company and therefore could be construed as a restraint of trade statement.” *Id.* at 2. However, regardless of the revisions, the intended target

of the harm sought to be inflicted remains the same. Communications among the TAAIS leadership confirm that UAS was the intended target of the letters which Drs. Aaronson, Gross, and Sublett approved as described below. *See* Exhibit T to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-50 ("Because of "restraint of trade" issues, we cannot more directly attack [UAS], but the above approaches [including the draft letters] are within our legal rights."). The clear purpose of the Defendants' tortious conduct both with Texas and with others outside of Texas as described below was to injure UAS and prevent competition from the physicians whom it supports. The benefit of those actions was meant to accrue to board-certified allergists' businesses, such as PSF, PLLC, which belongs to Dr. Sublett.

11. Dr. Sublett and Dr. Aaronson jointly participated in multiple JCAAI newsletters discussed below, which Dr. Sublett signed, and which were distributed to JCAAI members in Texas and support the basis for the claims in this Complaint. The October 5, 2011 issue of JCAAI Newsletter entitled "More on Remote Practice," which was sent under Dr. Sublett's signature and originally drafted by Dr. Aaronson, mentions efforts to address the remote practice of allergy and specifically mentions "one such scheme featured in . . . a "Business Builder" article in *Medical Economics*." Dr. Sublett testified under oath that the company featured in the referenced article was UAS. *See* Exhibit A (September 7, 2012 Deposition Testimony of Dr. James Sublett, M.D. at 143:14-15). The newsletter, addressed to JCAAI's nationwide membership, including members in Texas, goes on to "recommend[] against engaging with any company that promotes [the remote practice of allergy]." Dr. Sublett also participated in RADAR, including its online message board "Basecamp," in which Dr. Sublett specifically sought information concerning UAS to target that company. Dr. Sublett and Dr. Aaronson also participated in the AAAAI Annual Meeting and the JCAAI meeting from February 22-26, 2013 in

San Antonio, Texas, at which both participated in discussions concerning the ongoing activities of RADAR and Defendants as described in this Complaint.

12. Defendants could reasonably expect to be held accountable by a Texas court for the anticompetitive injuries suffered in Texas that were the intended result of their conspiracy. As such, the Court's exercise of personal jurisdiction over Defendants would not violate traditional notions of fair play and substantial justice.

13. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendants inhabit or transact business in this District and a substantial part of the events or omissions giving rise to these claims occurred in this District, including, but not limited to, the conspirators' attempts to organize a group boycott using insurance companies, managed care organizations, and physicians located in this district to harm UAS, which is also located in this District. In addition, venue is proper in this District pursuant to 15 U.S.C. § 22 because JCAAI, ACAAI, and AAAAI each transact business in the District, such as accrediting members of their organizations in the District and providing support services to those members in the District.

14. Defendants' conduct, including their attempts to organize a group boycott against non-allergist physicians and their businesses and support staff, including AAAPC members and UAS, and their tortious interference with AAAPC members and UAS's contracts and prospective business relations all cross state lines. Defendants' activities that are the subject of this Complaint are within the flow of, and substantially have affected, interstate commerce.

PARTIES

Plaintiffs

15. AAAPC is a 503(C)(6) non-profit organization of over 250 member physicians with its principal place of business in Washington, the District of Columbia. The AAAPC is an organization that fosters the ability of physicians to provide high quality, patient accessible

diagnostic and therapeutic allergy and asthma care. Part of AAAPC's purpose is to represent the interests of over 2,000 primary care physicians that provide allergy and asthma care to their patients, including the ability to practice in the market for allergy testing and allergen immunotherapy in Texas and nationwide. AAAPC's claims are limited to injunctive relief, it has standing to bring these claims on behalf of its members to protect their interests, as those members would have standing to sue individually, but are not necessary parties to this suit. AAAPC has appeared through undersigned counsel in this cause.

16. United Biologics, LLC d/b/a United Allergy Services is a Delaware limited liability company with its principal place of business in San Antonio, Bexar County, Texas, in the Western District of Texas. UAS participates in the market for allergy testing and allergen immunotherapy through providing support services for physicians practicing allergy testing and allergen immunotherapy in Texas and nationwide. As a result, UAS and the primary care and other physicians UAS supports, compete directly with the businesses of board-certified allergists, including Defendants Dallas Allergy and Asthma Center, P.A.; PSF, PLLC; and Lyndon Mansfield M.D., P.A. As a direct target of Defendants' activities to eliminate it from the market for allergy testing and allergen immunotherapy, and thus reduce competition in that market, UAS has standing to seek treble damages and injunctive relief under the Clayton Act in addition to standing for its other claims. UAS has appeared through undersigned counsel in this cause.

Defendants

17. The American Academy of Allergy, Asthma & Immunology is a Wisconsin non-profit organization of physicians with its principal place of business at 555 East Wells Street, Suite 1100, Milwaukee, WI 53202-3823 and has appeared through counsel in this cause.

18. The American College of Allergy, Asthma & Immunology is a Minnesota non-profit organization of physicians with its principal place of business at 85 West Algonquin Road, Suite 550, Arlington Heights, IL 60005 and has appeared through counsel in this cause.

19. Dallas Allergy and Asthma Center, P.A. is a Texas professional association owned and operated by Dr. Gary Gross with its principal place of business at 5499 Glen Lakes Dr., Ste. 100, Dallas, TX 75231 and has appeared through counsel in this cause.

20. PSF, PLLC d/b/a Family Allergy & Asthma LLC is a Kentucky limited liability company owned and operated by Dr. James Sublett, with its principal place of business at 9800 Shelbyville Road, Ste. 220, Louisville, KY 40223. It can be served through its registered agent, Ivan J. Schell, 500 W. Jefferson Street, Ste. 2400, Louisville, KY 40202.

21. The Joint Council of Allergy, Asthma & Immunology is an Illinois non-profit organization of physicians with its principal place of business at 50 N. Brockway St., Suite 304, Palatine, IL 60067 and has appeared through counsel in this cause.

22. Lyndon E. Mansfield M.D., P.A., a professional association, is a Texas company owned and operated by Dr. Lyndon Mansfield, with its principal place of business at 2121 Wyoming Ave., El Paso, TX 79903 and has appeared through counsel in this cause.

23. Dr. Donald W. Aaronson is an individual residing in the state of Illinois and is the Executive Director of JCAAI, and has specially appeared through counsel in this cause.

24. Dr. Gary Gross is an individual residing in the state of Texas, is the Executive Vice President of JCAAI, and the owner of Dallas Allergy & Asthma Center, P.A., and has appeared through counsel in this cause.

25. Dr. Lyndon Mansfield is an individual residing in the state of Texas, is a member of the Board of Directors of JCAAI, and is the owner of Lyndon Mansfield, M.D., P.A., and has appeared through counsel in this cause.

26. Dr. James Sublett is an individual residing in the state of Kentucky and is the Immediate Past President and a member of the Board of Directors of JCAAI, the Vice President of ACAAI, the owner and founder of PSF, PLLC d/b/a Family Allergy & Asthma LLC, and has specially appeared through counsel in this cause.

27. Dr. David Weldon is an individual residing in the state of Texas and is a member of the board of regents of ACAAI and has appeared through counsel in this cause.

28. Defendants' acts detailed herein were authorized, ordered, and/or done by them or their organizations, businesses, officers, agents, employees, and/or representatives, while actively engaged in the management of their business and affairs.

BACKGROUND

29. Defendants Drs. Aaronson, Gross, Mansfield, Sublett, and Weldon are licensed physicians in their respective states and are in the business of providing allergy care to patients in their area and the places where their practices do business. Defendants operate their businesses either individually, or through professional associations or limited liability companies, which not only provide physician services for allergy care, but also provide support services necessary to provide the allergy care, including Defendants Dallas Allergy and Asthma Center, P.A.; PSF, PLLC; and Lyndon Mansfield, M.D., P.A. Drs. Aaronson, Gross, Mansfield, Sublett, and Weldon are also members of some or all of the three national trade organizations composed of

board-certified allergists, AAAAI, ACAAI, and JCAAI, and act on behalf of those organizations as either officers or board members.

30. The individual defendants market themselves within their sub-specialty as “board-certified allergists,” which is a certification a physician obtains from the American Board of Allergy and Immunology (“ABAI”), a private organization established in 1971. The ABAI only qualifies physicians who are already board-certified in either pediatrics or internal medicine, and who participate in a three-year fellowship in an ABAI training program. Currently there are less than 3,000 board-certified allergists practicing nationwide. The number of fellowships and board-certified allergists is shrinking.

31. Despite not being certified by ABAI, many physicians have historically treated patients for allergy-related symptoms, especially in treating aero-allergies and mold allergies, otherwise known as seasonal and perennial allergies. These physicians, who include board-certified pediatricians, board-certified family physicians, board-certified otolaryngologists (“ENTs”), and other specialists and primary care physicians, have practiced allergy care long before the creation of ABAI. As explained below, however, there is an important distinction between treating allergy-related symptoms and treating the underlying cause of allergies, the latter of which can only be accomplished through allergy testing and allergen immunotherapy.

32. While the number of physicians who receive ABAI accreditation is shrinking, board-certified allergists and their businesses are still the dominant players in the market for allergy testing and allergen immunotherapy. Almost every practicing board-certified allergist is in the business of allergy testing and allergen immunotherapy. Collectively, board-certified allergists as a group participate in more allergy testing and allergen immunotherapy than any other player in the market.

33. Board-certified allergists have the power to influence the market through their trade organizations. As the national organizations of board-certified allergists, AAAAI, ACAAI, and JCAAI, both individually and jointly are dominant players in the market for allergy testing and allergen immunotherapy. AAAAI, ACAAI, and JCAAI, which collectively represent virtually every board-certified allergist in the United States, publish and control the most respected medical journals related to allergy care, and distribute influential allergy practice guidelines that, if misunderstood or misused, can change the shape of the marketplace for allergy-related services.

34. The most common method of treating seasonal allergies includes the use of over-the-counter and prescription medications, such as nasal steroids and anti-histamines, which combat the symptoms of allergic rhinitis. It is estimated that currently 50-60 million Americans are affected by allergic rhinitis, which is one of the fastest growing health care epidemics in the United States.

35. Despite the temporary usefulness of over-the-counter and prescription allergy medications, these medications do nothing to desensitize or cure the patient, i.e., they fail to address the underlying cause of allergic rhinitis for seasonal and perennial allergies, instead masking the patient's condition by treating the symptoms. The only known potential cure or actual treatment of allergic rhinitis for seasonal and perennial allergies is allergen immunotherapy, a process of introducing allergens incrementally into the patient's system to desensitize the patient to such allergens. Most physicians who provide care through allergen immunotherapy do so by first testing the patient for allergies through use of a skin prick test.

THE MARKET FOR ALLERGY TESTING AND ALLERGEN IMMUNOTHERAPY

36. To compete in the market for allergy testing and allergen immunotherapy for seasonal and perennial allergies, firms rely on physicians licensed in that particular state to practice medicine, technicians for which there is no licensing process in most states, and other

employees. The firms must also purchase all necessary equipment to compete, including skin prick test kits, antigens, vials, needles, and other materials necessary to perform allergy testing and mixing of allergen immunotherapy. The firms must also be paid for the services performed, either by the patient directly, or by a “third-party payor” (“TPP”), such as a commercial insurance company, a managed care health plan, Medicare, or Medicaid. Approximately 98% of the services for allergy testing and allergen immunotherapy are paid for at least in part by third-party payors, and those services are billed to those third-party payors under agreements or regulations that require submissions in accordance with the Current Procedural Terminology (“CPT”) code set maintained by the American Medical Association.

37. During the testing of a patient, the physician performs a physical examination of the patient, and based on that examination and the patient’s medical history, may recommend to the patient a skin prick test. If the patient consents, the skin prick test is typically applied by a technician to the patient’s skin at the direction of the physician. The skin reacts to the allergic materials contained on the test, and the technician usually measures and records the size of the reaction, and the physician reviews the results. If a firm bills a third-party payor for a skin prick test, the firm does so under CPT Code 95004.

38. If the physician determines that a patient is allergic to an allergen, the physician may recommend allergen immunotherapy to the patient. Should the physician deem it appropriate to place the patient on allergen immunotherapy and the patient consents to the treatment, the allergen immunotherapy is typically mixed by the technician under the physician’s supervision. The allergen immunotherapy is composed of antigens that are mixed with a diluent. The mixture is then diluted into serial dilution vials for administration to the patient starting with the lowest concentration and progressing to the highest concentration, called a “maintenance

dose.” If a firm bills a third-party payor for the mixing of allergen immunotherapy, the firm does so under CPT Code 95165.

39. The most common form of administration of allergen immunotherapy in the United States is through the use of subcutaneous shots, otherwise known as “SCIT” or “allergy shots.” If a firm bills a third-party payor for the administration of SCIT or allergy shots, the firm does so under CPT Code 95115 for a single injection or 95117 for two or more injections if those injections are administered in the office by a technician. Many physicians in their own professional judgment allow some of their patients to self-administer allergy shots outside of the office, particularly those patients who demonstrate a low risk of side effects and who would benefit from the increased rate of compliance that is associated with self-administered allergy shots. Historically and today, a majority of physicians who prescribe allergen immunotherapy for their patients recommend patient self-administration in appropriate cases. Self-administration is a safe and effective method for certain patients and is also less expensive, because the patient and their insurer are not billed for shot administrations that the patient self-administers.

40. In 1996, AAAAI, ACAAI, and JCAAI collectively formed a “Joint Task Force” to act as authors and editors of “Practice Parameters,” otherwise known as recommendations to their members. The first “Practice Parameters for Allergen Immunotherapy,” published in 1996, recommended that board-certified allergists should no longer permit self-administration of allergy shots by patients, except in “exceptional cases in which allergen immunotherapy cannot be administered in a medical facility.” Instead, the Practice Parameters recommended that allergy shots should be administered by the physician’s technician in the physician’s office. The Practice Parameters were the collective response of AAAAI, ACAAI, and JCAAI to the then-common practice of permitting self-administration of allergy shots by many board-certified allergists as well as non-board-certified allergists, including ENTs, board-certified family physicians, board-

certified pediatricians, and other primary care physicians. The Joint Task Force recognized at the time that the trend towards patient self-administration would threaten the business of board-certified allergists, who most benefit from the high margins charged to patients and insurance companies for injections administered in the office, often between \$20 and \$30 per injection. Nevertheless, the “Practice Parameters” were only “recommendations” and explicitly stated that they did not intend to supplant the judgment of individual physicians. Despite the recommendation contained in the Practice Parameters, including some board-certified allergists and a majority of ENTs and primary care physicians in individual cases, most physicians permit self-administration of allergen immunotherapy for the appropriate patients,.

INCREASE IN COMPETITION IN THE RELEVANT MARKET

41. While the number of people who suffer from allergic rhinitis has grown along with the need for allergen immunotherapy, the number of board-certified allergists has declined. It is estimated that only 2-6% of the patients who would benefit from allergen immunotherapy actually receive this therapy. *See* Exhibit Z to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-57 at 15. Most specialists, including board-certified allergists, are typically located in large urban or wealthy suburban areas. This shortage has left rural and poor urban areas largely without access to allergy testing and allergen immunotherapy. In addition to location, cost is an issue as well. The high cost of these treatments also decreases the ability of poor and rural patients to receive the necessary treatments, as does the requirement by most board-certified allergists that patients travel to and pay for shot administration in the office.

42. In 2009, Plaintiff United Biologics, LLC was formed and began doing business in San Antonio, Texas under the name “United Allergy Labs” or “UAL.” UAL’s business model represented a response to the shortage of physicians who practiced allergy testing and allergen immunotherapy despite the growing need for those services. While some board-certified family

physicians, board-certified pediatricians, and other primary care physicians practiced allergy testing and allergen immunotherapy, most did not based on the large economic barrier to entry into the market. Notably, purchasing and stocking the necessary allergy testing equipment and antigens for immunotherapy, as well as training and maintaining technicians to assist in administering tests and mixing immunotherapy, is an expense that usually prevents most primary care physicians from providing allergy testing and allergen immunotherapy. UAS helps physicians and their businesses overcome this economic barrier by contracting with those businesses to assist those business's entry into the market. Since 2009, UAS has assisted more than 2,000 providers of allergy testing and allergen immunotherapy across 29 states to enter the market for allergy testing and allergen immunotherapy.

43. As part of the contractual relationship between UAS and physicians, practice groups, and hospitals, UAS is responsible for all of the non-physician services necessary to compete in the market for allergy testing and allergen immunotherapy, including the equipment, allergy testing kits, antigens for immunotherapy mixing, and other materials that UAS purchases from the established suppliers in the industry. UAS trains and provides technicians to assist physicians in the medical practice of allergy testing and allergen immunotherapy. Those technicians are located by UAS, and are required to meet more rigorous standards than the technicians typically relied on by the businesses of board-certified allergists, including engaging and passing a program concerning allergy testing and allergen immunotherapy administered by the University of the Incarnate Word School of Nursing. Physicians rely on the services of UAS employed technicians to personally provide allergy care to the patients that the physician determines may benefit from this treatment. This includes the physician supervising the provision of and reading the allergy test, consulting the patient on the potential for allergen immunotherapy in response to positive

test, and supervising the mixing of antigens for treatment through allergy shots for patients who are amenable and have consented to treatment.

44. Together, primary care physicians and UAS have provided a less expensive and more widely available alternative for consumers than the businesses of board-certified allergists in the market for allergy testing and allergen immunotherapy. The entry of at least 2,000 additional primary care physicians in the United States market for allergy testing and allergen immunotherapy since 2009 has begun to address the 94-98% of allergy patients who could benefit from allergen immunotherapy but currently go untreated. Those patients primary care physicians who have entered the market offer a lower-cost option to patients, are more conveniently located to the patients, and have shorter wait times for an appointment and shorter wait times in the office. Those patients who have been permitted to self-administer their allergy shots have also benefitted in reduced cost by not being charged as often for shot administration, or from incurring the expense of taking off work or school to travel to a medical facility for shot administration.

45. Third-party payors, especially commercial carriers, have also benefitted from this lower cost option of competitors. Lower reimbursement rates for primary care physicians as compared to specialists result in a significantly lower cost for allergy testing as billed under CPT Code 95004, the mixing of allergen immunotherapy as billed under CPT Code 95165, and a substantial reduction or elimination of costs billed for shot administration under CPT Codes 95115 and 95117. Additionally, the system as a whole has benefitted from the increased utilization of allergen immunotherapy, which studies have shown reduces the overall costs to patients and third-party payors in terms of expenses for medication, office visits, and hospital visits for more chronic conditions that develop when the patient goes untreated by allergen immunotherapy.

46. Nevertheless, when board-certified allergists began discovering that primary care physicians in their local communities were practicing allergy testing and allergen immunotherapy (particularly in combination with UAS) instead of referring those patients to the businesses of board-certified allergists, many became upset at the entry of additional competitors. These allergists, which included members of JCAAI, AAAAI and ACAAI, as well as state trade organizations such as TAAIS, began to complain to the leaders of those organizations about this increase in competition.

MEDICAL BOARD COMPLAINTS

47. Defendants' first line of attack against the competition for allergy testing and allergen immunotherapy was to attack the non-allergist physicians directly. To this end, Defendants conspired to file or cause others to file false medical board complaints against primary care physicians who work with companies like UAS, and then to influence the medical board's consideration of those complaints unjustly. The first of the complaints were filed by Dr. Michael Vaughn, an ACAAI member and a board-certified allergist in private practice in San Antonio, Texas. Dr. Vaughn discovered that these once referring family physicians were now competitors because UAS was providing those physicians with the necessary support services to provide patients with allergy testing and allergen immunotherapy. Dr. Vaughn filed the complaints with the Texas Medical Board ("TMB") in the summer and fall of 2010, alleging that certain physicians practicing in San Antonio, Texas were practicing allergy testing and allergen immunotherapy outside of their scope of practice, without proper training, and were inappropriately permitting patients to self-administer the allergy shots. After filing the complaints, Dr. Vaughn attended the November 16, 2010 Annual Meeting of ACAAI and on that date made a presentation to the ACAAI Board regarding the entry of additional competitors in the San Antonio market for allergy testing and allergen immunotherapy. Dr. Vaughn reported this

information to the ACAAI Board, which agreed to write a letter to the TMB discouraging the practice of physicians relying on allergy services companies like UAS to provide allergy testing and allergen immunotherapy. Following this presentation, the ACAAI Board agreed by consensus to send a letter of appreciation to Dr. Vaughn for his presentation.

48. After learning of Dr. Vaughn's complaints, Defendants encouraged all board-certified allergists to complain to the TMB if they discovered any primary care physicians practicing allergy testing and allergen immunotherapy with the assistance of UAS. In a December 2010 Texas Allergy, Asthma & Immunology Society ("TAAIS") newsletter, Dr. Weldon openly solicited board-certified allergists in Texas to report physicians who partner with companies like UAS to the TMB. That newsletter was a collaborative effort by the leadership of TAAIS and board members of ACAAI and JCAAI, including Dr. Weldon and Dr. Mansfield, respectively. The complaints to the TMB about primary care physicians practicing allergy testing and allergen immunotherapy included claims that those physicians were not qualified to provide such care, were providing substandard care by relying on support services from UAS, and were permitting patients to self-administer their allergy shots, which Defendants term "home immunotherapy."

49. In addition to encouraging complaints to the TMB, Defendants also attempted to influence the TMB's consideration of those complaints. On March 31, 2011, the ACAAI board sent a letter to the TMB regarding "specific practices of allergy by non-allergists." This letter was approved by the ACAAI Board during the March 23, 2011 ACAAI Executive Committee meeting. The TMB letter cited extensively from "Allergen immunotherapy: A practice parameter third update," misleadingly referring to this joint publication by JCAAI, ACAAI, and AAAAI as the "standard of care" despite disclaimers in that publication and the fact that there is no nationally accepted standard of care for allergen immunotherapy. Due in part to the Defendants' conspiracy, the joint publications of JCAAI, ACAAI, and AAAAI continued to discourage patient

self-administration of allergen immunotherapy, which Defendants had identified as a threat to their business model.

50. In addition to outside attempts to influence the complaints, certain Defendants, specifically Dr. Gross, Dr. Mansfield, and Dr. Weldon, attempted to use their positions as volunteer “expert reviewers” for the TMB to improperly influence the TMB’s consideration of the complaints. Despite being made aware of the complaints by Dr. Vaughn and other colleagues and encouraging the filing of additional complaints, Dr. Gross, Dr. Mansfield, and Dr. Weldon failed to disclose this information and their conflict of interest to the TMB, a violation of their agreements with TMB and Texas State Law.

51. Despite Defendants’ attempts to influence TMB, the TMB dismissed complaints against primary care physicians practicing allergy testing and allergen immunotherapy. The TMB’s rulings specifically found that primary care physicians may practice allergy testing and allergen immunotherapy under Texas Medical Practices Act. The rulings also found that the physician’s decisions to permit their patients to self-administer allergy shots does not violate the standard of care. After receiving these negative rulings, Defendants worked with other board-certified allergists in Texas in an attempt to alter future TMB decisions by volunteering as expert reviewers, included Defendants Dr. Gross, Dr. Mansfield, and Dr. Weldon, as well as their colleagues Dr. William McKenna, Dr. Wesley Stafford, and Dr. Theodore Freeman. Defendants and/or their co-conspirators also attempted to influence a TMB board member, Dr. Hari Reddy, also a JCAAI, ACAAI, and AAAAI member. Despite the actions of Defendants, the TMB never agreed with Defendants’ recommendation that primary care physicians are not qualified to practice allergy testing and allergen immunotherapy or that self-administration of allergy shots is a violation of the standard of care.

52. Defendants' complaints and actions directed at the TMB are not the basis of the claims in this Complaint, but help explain Defendants' motivation to turn to illegal activity to accomplish the result they were unable to obtain through TMB complaints. As Dr. Weldon explained in an email to the leaders of TAAIS about losing the fight at the TMB level: "We need to survive our specialty. We need to capture the attention of our non-allergist colleagues. We need to get managed care to understand the differences provided by a ABAI BC allergist. If we don't, then we are dinosaurs waiting for the inevitable. Judging from the most recent response by the TMB in favor of the family practitioner who was practicing allergy, I would say we are fading fast." See Exhibit Y to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-55 at 2.

CONSPIRACY TO RESTRICT COMPETITION IN THE MARKET FOR ALLERGY TESTING AND ALLERGEN IMMUNOTHERAPY

53. The evidence already in the record attached to Plaintiffs' Motion for Preliminary Injunction demonstrates the illegal activities that form the basis of this Complaint, specifically an agreement among the Defendants to restrain trade and restrict competition in the market for allergy testing and allergen immunotherapy and to tortious interfere with AAAPC members and UAS's contracts and prospective business relations. The timeline attached hereto as Exhibit B tracks the timing of the agreement and when each of the parties joined the conspiracy.

54. The agreement to restrict competition in the practice of allergy testing and allergen immunotherapy began after Defendants learned of UAS and the entry of primary care physicians into the market in Texas. Defendants and other board-certified allergists in the nationwide market commonly referred to these competitors, specifically primary care physicians who practice with the support of UAS, as the "remote practice of allergy," or "remote allergy." The term was originally adopted by board-certified allergists and their trade associations in reference to allergen immunotherapy that was remotely provided to competitor physicians by off-site mixing labs, but came to include the practice of primary care physicians who rely on a UAS technician to assist in

allergy testing and allergen immunotherapy. *See* Exhibit E-13 to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-29.

55. To respond to this rise in competition, in 2009, ACAAI created its "Marketing the Allergist Campaign" as part of an initiative to ensure that allergy specialists did not lose market share to new entrants. Dr. Mansfield represented to the Board of Directors and Committee Chairs of TAAIS on May 1, 2009 that ACAAI's newly minted Marketing the Allergist Campaign was making a "strong effort" to respond to increasing frustrations "with losing business to other specialists." *See* Exhibit B-3 to Plaintiffs' Motion for Preliminary Injunction, Dkt. No. 12-3.

56. By 2010, the conspiracy grew into a concerted effort to remove the economic incentive of their competitors to provide allergy testing and shots by attempting to cut off the main source of funding to these competitors, namely insurance companies and managed care health plans, otherwise known as third party payors. Without reimbursements from third party payors, the board-certified allergists' competitors would be unable to compete in the market for allergy testing and allergen immunotherapy. Leaders of TAAIS, including Dr. Mansfield and Dr. Weldon agreed that the organization should contact physicians and third-party payors in an effort to convince them not to do business with UAS. To that end, those board-certified allergists began drafting letters that would be disseminated on behalf of TAAIS to all physicians and third-party payors in Texas denouncing the practices of these competitors. *See e.g.* Exhibit J to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-38.

57. In the midst of drafting these letters, Defendants began contacting insurance companies directly. Original attempts began with phone calls to individual insurance companies following Defendants' agreement that they should convince insurance companies not to pay or to restrict reimbursement to their non-allergist competitors. In coordination with Dr. Mansfield and Dr. McKenna, and in accordance with Defendants' agreement, Dr. Victor Estrada, a then TAAIS

Board Member and board-certified allergist in private practice in San Antonio, Texas spoke with a representative of Humana of Texas (“Humana”), a conversation he documented in an email to Dr. Mansfield and Dr. McKenna on June 5, 2010. *See* Exhibit J to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-38. According to Dr. Estrada, Humana was engaged in “red-flagging claims with certain codes coming in by primary care offices and are considering their options, such as, denying payment, considering charges as out of network, and even asking for their money back on previously paid claims.” *Id.* at 2. Dr. Estrada expressed the hope that this would occur with all of the major carriers and “maybe some changes coming.” *Id.* Dr. McKenna remarked on the “great news,” and the three doctors continued to discuss a letter to insurance companies that would encourage them not to pay competitors who are not board-certified allergists. *Id.* at 1.

58. In September, 2010, Dr. Weldon engaged in a 45 minute conversation with an official at Blue Cross/Blue Shield of Texas (“BCBS Texas”), in which he told her to “suspect and to watch for abuse by primary care physicians” who practice “remote allergy” and that “she needed to have her organization look into” only allowing board-certified allergists to test and prescribe allergen immunotherapy. Dr. Weldon documented this conversation in an email to his fellow TAAIS board member and allergist colleague, Dr. William McKenna. *See* Exhibit K to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-39. In Dr. Weldon’s email, he explained that: “If it all pans out, we may be in for what we wanted... [I]f something GOOD comes of this, then perhaps all of this prescribing over the internet (remote practice) and inappropriate billing (and thus, making it economically unfeasible for competitors) will subside and we will again be able to look at ourselves as ‘The Allergist’ and not have to share that title with some nitwit technician in an ENT practice.” *Id.* at 2 (emphasis added).

59. On September 25, 2010, the TAAIS Executive Director, Connie Mawer, circulated an Agenda and Reports for a September 28, 2010 conference call among the TAAIS Board Members and Committee Chairs, including their consideration of letters to be drafted and sent to insurance companies and primary care physicians throughout the State of Texas about their competitors. *See Exhibit D-11 to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-16.* On September 26, 2010, Dr. Weldon responded in an email to the TAAIS Board and Committee Chairs regarding the need for letters to the market stating: "This is a turf war folks, like it or not, and it looks like we need to take a stand right now for our profession or else return to practicing primary care medicine (with a side of allergy, perhaps)." *Id.* at 2.

60. The TAAIS Board, including Dr. Weldon, met on September 28, 2010 and according to the meeting minutes, "discussed a draft letter to PCPs [primary care physicians] developed by a small Ad Hoc Committee which informs [them] of 'allergy companies' popping up in Texas and marketing allergy skin testing and immunotherapy to [primary care] practices. This letter is currently under legal review." *See Exhibit D-12 to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-17.* The Board also agreed to send voting delegates to the ACAAI November 2010 Annual Meeting in Phoenix, Arizona to present the letter concerning primary care physicians and "Texas scope of practice issues." Dr. McKenna also suggested "that the first draft letter could be revised to also be sent to third party payors." *Id.*

AAAAI, ACAAI, AND JCAAI JOIN THE CONSPIRACY

61. On September 30, 2010, Dr. Weldon forwarded a draft of the TAAIS letter to primary care physicians via email to certain officers and members of the board of directors of AAAAI, ACAAI, and JCAAI, including Dr. Aaronson. *See Exhibit D-9 to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-14.* Starting off his email, Dr. Weldon stated "Welcome to our world in Texas – this is what I've been beating my chest about for the past few years and for

which we have been unable to counter. Call them charlatans or whatever — unlike the monsters under our beds of our youth, they DO exist.” *Id.* Dr. Weldon’s email expressed a desire to expand efforts in furtherance of their conspiracy and attempt to convince managed care organizations to stop paying, refuse to credential or accredit, or reduce reimbursement for their non-board-certified allergist competitors who are supported by UAS. He called for the leadership of the three national organizations “to partner with managed care to deter [the competition].” *Id.* The intentions behind his call to action were clear. He continued, “If we stop the economic incentive by showing that we ‘do it better’, then we may get the upper hand in this mess. Yet if we bury our minds in the academia of interleukins and hope that the competition will just ‘go away,’ then we will find ourselves out of a job.” *Id.*

62. On November 12, 2010, the TAAIS delegates to the ACAAI Annual Meeting raised their concerns over the encroachment by non-board-certified allergists into the market for allergy testing and allergen immunotherapy to the ACAAI Board of Regents. A presentation was given “about the difficulties in San Antonio with the practice of allergy by non-allergists.” *See* Exhibit C-3 to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-6. The presentation, which is attached to the minutes of the ACAAI House of Delegates meeting specifically identifies UAS, then doing business as “United Allergy Labs (UAL)” which Dr. Vaughn stated “provides the PCP [primary care physician] with one of their ‘trained’ allergy testing technicians that work out of the PCP’s [primary care physician’s] office (but is a UAL employee).” *Id.* at 3. Following the presentation, “[a] motion was made and passed to refer this problem to the Board of Regents for action. The JCAAI is already aware of the issue and has given advice to the Texas Allergy Society.” *Id.* at 1.

63. The referenced advice of JCAAI to the Texas Allergy Society occurred at the November 2010 Annual Meeting, where Dr. Aaronson relayed to Dr. Weldon concerns of

JCAAI's outside counsel about the TAAIS letter to primary care physicians, including that it was too targeted at a particular company. *See* Exhibit E-5 to Plaintiffs' Preliminary Injunction Motion [Dkt. No. 12-26] at 3.

64. A week later, on November 19, 2010 Dr. Weldon sent an email to the Board of Directors of TAAIS to give them a report on the ACAAI House of Delegates Meeting. *See* Exhibit D-10 to Plaintiffs' Preliminary Injunction Motion, Dkt. 12-15. Dr. Weldon explained that he asked the ACAAI "to delay any recommendations until we have had the opportunity to ponder a definite plan of action." *Id.* Dr. Weldon expressed his opinion that the ACAAI "should bring back revisions of the position statements, especially regarding 'Remote Practice of Allergy.'" *Id.* Dr. Weldon explained the reasoning behind doing so: "*Taking it one step further, if PCPs who practice allergy are not reimbursed because of questionable practices, and their patients are then having to absorb the costs of SLIT or watered-down SCIT given at home, then more than likely their allergy practices will fade.*" *Id.* (emphasis added). To accomplish this assault on the payment of competitors, Dr. Weldon explained that allergists could use the joint standards of AAAAI, ACAAI, and JCAAI to "educate manage care organizations of this threat and of the current (and near future) practice parameters of immunotherapy and diagnostic allergy testing. If managed care believes that a 'standard of care' equates with current practice parameters, we may have a foothold in order to launch our cause." *Id.* at 1-2. Dr. Weldon also revealed that he "talked with Lynn Mansfield at the meeting and he does not want 'the letter issue dropped – he still feels it is a worthwhile effort to be pursued.'" *Id.* at 2. Dr. Weldon also suggested that the board-certified allergist organizations should encourage their membership to "flood journals with articles regarding safety issues and reports of adverse reactions." *Id.* Revealing the economic motivation for these actions, Dr. Weldon explained that "for those of us in private practice, we have a lot to lose if we do not take a stand and 'protect our turf'" *Id.* Dr. Weldon concluded his

email by suggesting that the issues he raised were ones “that I feel we need to consider seriously and then dialogue over e-mails instead of taking up telephone time during quarterly board meetings.” *Id.*

65. On November 19, 2010, Dr. Abramson, the then President of TAAIS, responded to Dr. Weldon’s email by replying to him and the entire TAAIS Board stating “David, you are welcome to do whatever you like as an individual, as are others in TAAIS,” with the rest of the sentence redacted by TAAIS as referencing their legal opinion. *See* Exhibit D-13 to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-18 at 3. By that time, TAAIS had received its legal review back from Jeff Henry, a lawyer in private practice in Austin, Texas, regarding the proposed letters to primary care physicians. Mr. Henry’s “legal opinion” was to “‘not send’ due to liability and anti-trust [sic] issues.” *See* Exhibit L to Plaintiffs’ Preliminary Injunction Motion [Dkt. No. 12-40] at 1. Dr. Abramson went on to reject Dr. Weldon’s request for a written record of their plan, stating “I feel strongly that we should have these discussions on conference calls, not e-mails.” *Id.*

ACAAI AND TAAIS AGREE TO WRITE LETTERS TO THIRD PARTY PAYORS

66. On the morning of November 22, 2010, Dr. Weldon responded directly to just Dr. Abramson’s email to him about the letter issue stating “If you wish to handle this specifically by phone conferences, then that is how we will handle it. However, I am currently on the Board of Regents for the ACAAI and I request that you please also consider our opinions on this matter.” *See* Exhibit O to Plaintiffs’ Preliminary Injunction Motion [Dkt. No. 12-45] at 1. That same day, Dr. Abramson responded to Dr. Weldon’s email accepting Dr. Weldon’s request, stating “We want to be on the same page with the ACAAI Board of Regents as well.” *Id.* The email prompted Dr. Weldon to respond back, “It’s too bad we can’t find a lawyer that will have the same opinion as we do – the other ‘allergists’ do.” *Id.*

67. On November 23, 2010, Dr. McKenna, the past-president of TAAIS, responded to all of the TAAIS Board of Directors concerning his disappointment “that our grand effort, to communicate to PCPs about the dastardly allergy marketing company techniques, is of course dead in the water.” *See* Exhibit D-13 to Plaintiffs’ Preliminary Injunction Motion [Dkt. 12-18] at 6. Dr. McKenna then proposed to the TAAIS Board “two actions.” First, TAAIS would send “a communication to TAAIS membership of our attempted effort and result of due diligence,” including the legal opinion of its private lawyer and the advice of JCAAI’s lawyer Dr. Aaronson passed on to Dr. Weldon. *Id.* “Second, as was our intent at the outset, the next effort was to inform TPPs of the same issue and this still should be done.” Dr. McKenna acknowledged that “some of you have expressed this also,” and pledged to work with those Board members, namely “David Weldon, Lyndon [Mansfield], Victor [Estrada] and any others toward this next step.” *Id.*

**AAAAI, ACAAI, AND JCAAI AGREE TO FORM “RADAR” FOR PURPOSES OF
RESTRICTING COMPETITION**

68. While the letters in Texas were still under discussion, the conspiracy continued to grow on the national stage. Following the TAAIS delegation’s plea to the ACAAI House of Delegates about the entry into the market for allergy testing and allergen immunotherapy by primary care physicians relying on allergy services companies including UAS, all of the national allergy organizations responded. Specifically, as a result of that meeting, the leadership of AAAAI, ACAAI, and JCAAI agreed to a concerted effort and joint agreement to fight back against these new competitors. The organizations jointly agreed to form “RADAR,” or the “Regional Advocacy Discussion and Response” initiative, a joint task force aimed at addressing the encroachment of competitors on their turf of allergy testing and allergen immunotherapy. The purpose of this initiative was to recruit and train select local allergists in advocacy and other

skills, such as persuading, enticing, or coercing third-party payors, so that the national associations could coordinate their efforts to restrict access to the market from the top down.

69. The forming of RADAR was a result of the meeting of the leadership of the AAAAI RSLAAIS Assembly and the ACAAI House of Delegates at the ACAAI Annual Meeting, where those leaders “reviewed a plan to develop a more robust infrastructure to assist state/local AAI [allergy, asthma, and immunology] societies in addressing local issues.” *See* Exhibit E-4 to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-25. Subsequent to that meeting, “[i]n December 2009, the AAAAI Federation of Regional, State and Local AAI Societies (RSLAAIS) Assembly held a series of conference calls with state and local AAI society leaders to identify issues of concern to practicing allergists. Several common concerns were expressed by allergists around the country. Those included:.... Encroachment- Non-allergy providers representing themselves as trained A/I specialists... [and] Changing healthcare environment- Tactics to position A/I specialists in the evolving healthcare model.” *Id.*

70. As a result of those conference calls with allergists around the country, in or around late December or early January 2011, three members of the AAAAI Board, Dr. Daniel Steinberg, Dr. Jim Tracy, and Dr. Sharon Marks, met with the ACAAI House of Delegates. The AAAAI Board members’ report from the meeting with ACAAI was documented in a January 5, 2011 email from the AAAAI President, Dr. Mark Ballow, to the three AAAAI representatives, copying the rest of the AAAAI Board. *See* Exhibit H to Plaintiffs’ Preliminary Injunction Motion [Dkt. No. 12-36]. Dr. Ballow stated “Thank you for sharing the outcome of the recent joint meeting between yourselves and the ACAAI House of Delegates. As you know, we have made a concerted effort to collaborate with the College [ACAAI] and this is another good example of the possibilities for strengthening our relationship. We greatly appreciate the work that has gone into the Regional Advocacy Discussion and Response (RADAR) initiative.” *Id.* at 1. Attached to the

email was a document titled “AAAAI Ongoing Activities Relevant to the Regional Advocacy Discussion and Response (RADAR) Initiative January 2011.” *Id.* at 3-5. Among the activities detailed was “Fiscal Realities, Ongoing efforts through national organizations” and “Ongoing communications with insurance companies about appropriate reimbursement for specialty care.” *Id.* at 4. Other activities included addressing “Encroachment by non-allergists” explaining “Ongoing communication with insurance companies allows the specialty to be represented in discussions about appropriateness of care.” *Id.* at 5. AAAAI’s Winter Meeting took place a few days later on January 9, 2011 in Chicago, in which these topics were discussed. *Id.* at 1.

71. As a result of all of these meetings of the national and state allergy organizations, on February 8, 2011, AAAAI, ACAAI, and JCAAI issued a letter to Regional, State, and Local Allergy Society Leaders throughout the country seeking to recruit local representatives to carry out RADAR’s mission. *See* Exhibit E-4 to Plaintiffs’ Preliminary Injunction Motion, Dkt., No. 12-25. The letter was drafted on the joint letterhead of all three national associations, and executed by their joint leadership, including Dr. Sublett, as acting President of JCAAI. Among the issues to be addressed by the RADAR initiative were the two issues where these organizations agreed to contact insurance companies, specifically: “Encroachment- Non-allergy providers representing themselves as trained A/I specialists” and “Changing healthcare environment- Tactics to position A/I specialists in the evolving healthcare model.” *Id.* The letter requested that each regional, state, and local society identify two individuals to serve as points of contact “to be trained to serve as conduits accessible by all three national organizations to channel information on issues impacting A/I patients and the physicians who serve them.” *Id.*

TAAIS JOINS RADAR AND TAKES ANTICOMPETITIVE ACTION

72. On February 12, 2011, Dr. Weldon sent an email to the TAAIS leadership calling for their involvement in the national RADAR initiative. *See* Exhibit Y to Plaintiffs’ Motion for

Preliminary Injunction, Dkt. No. 12-55. He wrote that “the initiative [was] going to demand the concerted attention of all organizations,” in order to address “the survival of [their] specialty.” *Id.* at 2. In a particularly impassioned plea, he stated that “it is OUR field that stands to disappear if we do not step up to the plate for it.” *Id.* at 4. The President of TAAIS, Dr. Abramson, thanked Dr. Weldon for his “thoughtful comments,” and promised to follow up “regarding planned actions, including . . . efforts with RADAR.” *Id.* at 1.

73. In line with its pledge to be on the same page as the ACAAI Board and in participation with RADAR, the TAAIS leadership resumed their letter writing campaign and rewrote the letters to primary care physicians to be more “informational” in nature. *See* Exhibit L to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-40. The minutes of the February 22, 2011 Executive Committee Conference Call indicate that such revisions were specifically made to address the earlier legal opinion advising TAAIS “not to send” due to “liability and anti-trust [sic] issues.” *Id.* However, no attempt was made to change the letters to third-party payors to conform to the legal opinions TAAIS had previously received. The letters to third-party payors that existed at the time were blunt, encouraging them to review and deny competitor physicians’ claims for reimbursement, and referring to those physicians’ reliance on UAS for support services as the “remote practice” of allergy, which was represented to be “at best of poor quality and at worst... fraudulent.” *See* Exhibit R to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-48. The letters also suggested that insurance companies should “control” the practice of allergy testing and allergen immunotherapy by non-allergists by “economic means,” and offered that board-certified allergists should be relied on to review the claims of non-allergists, in an attempt for Defendants to gain control over the payment and prices of allergy testing and allergen immunotherapy. *Id.*

DEFENDANTS INTIMIDATE ALLERGISTS ASSOCIATED WITH UAS

74. By this time, Defendants had already begun to resort to persuade, coerce, and intimidate to carry out their conspiracy to orchestrate a group boycott of UAS's services by board-certified allergists. For example, through their breach of confidence at the TMB, Defendant Dr. Weldon and his co-conspirators learned that Dr. Allen Kaplan, who is a former AAAAI president, was listed as a UAS Advisory Board member. On March 19, 2011, Dr. Weldon questioned Dr. Kaplan about his relationship with UAS. After discussing a course of action with Dr. Weldon, Dr. McKenna wrote to Dr. Kaplan in an email dated March 24, 2011. In that email, Dr. McKenna falsely claimed that he was investigating a claim of malpractice against UAS on behalf of the TMB. Dr. McKenna also mentioned his substantial credentials within the allergy community, referenced his awareness that Dr. Kaplan was listed as an advisor for UAS, and asked Dr. Kaplan if he could comment about a complaint made to the TMB. All this was in an attempt to intimidate Dr. Kaplan and to cause him to terminate his advisory relationship with UAS or risk being ostracized from the allergist community. After the email discussion between Dr. Kaplan and Dr. McKenna, as well as a verbal discussion between Dr. Kaplan and Dr. Weldon, Dr. Kaplan terminated his agreement with UAS. Updates about the investigation into Dr. Kaplan's cooperation with UAS made their way up the chain in the national allergist associations, eventually reaching the Executive Medical Director of ACAAI, Dr. Bob Lanier. Subsequently, allergists have continued to pressure their colleagues to avoid forming relationships with UAS.

NATIONAL ORGANIZATIONS ENCOURAGE AND PARTICIPATE IN TAAIS'S ANTICOMPETITIVE CONDUCT

75. During this time, JCAAI's leaders also privately encouraged TAAIS in its letter writing campaign, but publicly maintained the opposite. In the March 16, 2011 JCAAI News You Can Use Newsletter, which was drafted by Dr. Aaronson and executed and sent under the

signature of Dr. Sublett to JCAAI members across the nation, including Texas, JCAAI members were informed that “JCAAI’s legal advisors [had] repeatedly warned . . . against actions which might be considered *restraint of trade* – such as writing letters to the primary care physicians or commercial companies (especially on local allergy society stationery) condemning such unscientific behavior.” *See* Exhibit C-5 to Plaintiffs’ Preliminary Injunction Motion at 2, Dkt. No. 12-7 (emphasis in original).

76. Nevertheless, in an April 4, 2011 email to the leaders of the Greater Houston Allergy and Immunology Society (GHAIS), Dr. Abramson, the then President of TAAIS, explained that “TAAIS has been aware of the ‘scope of practice’ issues surrounding various laboratories, including Smart Allergy and United Allergy Labs for more than several months.” *See* Exhibit N to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-42 at 1. As Dr. Abramson continued, “We have drafted 2 letters—one for PCP’s and one for 3rd party payers.” Further explaining, Dr. Abramson stated “The Joint Council (JCAAI) is aware of our work in this area—there are significant medicolegal issues involved” referencing the JCAAI’s prior newsletter. Dr. Abramson also revealed that “[a]t the AAAAI meeting, Bob Lanier, Executive Director for the ACAAI, complemented me on TAAIS efforts.” As a result of this encouragement from the national organizations, Dr. Abramson explained “So, TAAIS has been a leader nationally in this effort, and we will continue to press forward with this effort.”

77. In line with the private and secret encouragement of TAAIS, JCAAI approved the TAAIS letters. On or about May 4, 2011, then TAAIS President Dr. Abramson emailed Dr. Sublett to seek JCAAI’s comments on TAAIS’s letters to primary care physicians and third-party payors. *See* Exhibit P to Plaintiffs’ Motion for Preliminary Injunction [Dkt. 12-46] at 2. As Dr. Abramson explained in his email to Dr. Sublett, “As you are aware, there are several laboratory entities that are encroaching on the practice of allergy by advertising their services to physicians

as a way of replacing referrals to allergists.” *Id.* In reference to the prior JCAAI opinion Dr. Aaronson relayed to Dr. Weldon in November 2010, Dr. Abramson stated “Our initial letters had a tone that was felt to be too targeted to a company and therefore could be construed as a restraint of trade statement.” *Id.* In response, Dr. Sublett relayed to Dr. Abramson the email and edits of Rebecca Burke, outside counsel for JCAAI. *Id.* at 1. Dr. Sublett then stated “I hope this helps. Good luck on your endeavors.” *Id.* As a result of that communication, Dr. Abramson emailed the TAAIS Executive Committee reporting on the “Good news” and suggesting that the letters were ready to go out.

78. Despite having quietly approved the TAAIS letters to primary care physicians and insurance companies, JCAAI leadership attempted to cover up their involvement by publicly representing to its members in a June 8, 2011 newsletter drafted by Dr. Aaronson and Dr. Sublett that JCAAI had recommended that the letters “be withdrawn because [they] could raise antitrust issues.” *See* Exhibit E-10 to Plaintiffs’ Motion for Preliminary Injunction at 1-2, Dkt. No. 12-27. The public newsletter, signed by Dr. Sublett and distribute to JCAAI members, including members in Texas, was met with confusion by TAAIS Board Members, who understood JCAAI to have approved the letters. On June 9, 2011 Dr. Robert Mamlok expressed this confusion to TAAIS Executive Director, Connie Mawer, who recalled in an email to Dr. Mamlok and Dr. Abramson that the letter referenced “was approved by the JCAAI.” *See* Exhibit E-11 to Plaintiffs’ Motion for Preliminary Injunction at 1-2, Dkt. No. 12-28.

79. By this time, ACAAI leadership had also given their seal of approval on the TAAIS letters. *See* Exhibit N-Part 1 to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-42. AAAAI also received and reviewed the letters on August 10, 2011 just before they were to be released to the public. The letters were discussed in connection with an AAAAI Executive Board

Agenda item, item X or 10, specifically relating to UAS. *See* Exhibit No. Q to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-47.

80. At that time, the letters were set to go out to executives and representatives of insurance companies and third-party payors in Texas, including representatives of Aetna, BCBS Texas, Cigna, Texas Medicaid & Healthcare Partnership (TMHP), Trailblazers Health Enterprises, UniCare, United Healthcare, and Valley Baptist Health Plans. *See* Exhibit S to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-49 at 8. To avoid revealing the true target of the letters and thus antitrust scrutiny, Defendants and TAAIS planned to follow up the letters with phone calls identifying UAS as the subject of the letters. *See* Exhibit T to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-50. The purpose of the phone calls instead of identifying UAS in writing was "Because of 'restraint of trade issues'" Defendants "cannot more directly attack UAL." *Id.* Dr. Abramson employed this same strategy previously suggested by Defendants JCAAI, Dr. Aaronson, and Dr. Sublett, sending the letters to Tom Banning, the Executive Director of the Texas Academy of Family Physicians on August 9, 2011, and following up that communication orally representing in a phone conversation that the letters pertained to physicians relying on the services of companies like UAS.

STATE COURT INJUNCTION AGAINST TAAIS ACTION

81. On August 11, 2011, after discovering that the letters had been sent to Mr. Banning, UAS filed suit and obtained a Temporary Restraining Order ("TRO") against further publication of the letters to insurance companies. *See* Exhibit U to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-51. On June 11, 2012, an agreed temporary injunction was entered to replace the TRO, and that temporary injunction stayed in place until an Agreed Permanent Injunction was issued as part of a settlement on February 1, 2013. *See* Exhibits V and W to Plaintiffs' Preliminary Injunction Motion, Dkt. Nos. 12-52 and 12-53. The Injunction prohibits TAAIS and

the individual defendants, who included various TAAIS board members and board members of the national allergist associations, from participating in or encouraging efforts to convince insurance companies or physicians not to do business with or pay the defendants' competitors. For a period of time Defendants suspended some of their anticompetitive conduct, but later resumed that conduct on a national level.

DEFENDANTS RESUME CONTACTING THIRD PARTY PAYORS

82. Despite the existence of temporary and permanent injunctions against their co-conspirators, Defendants ultimately intensified their efforts to orchestrate and carry out a group boycott against UAS and primary care physicians, including AAAPC members. The same day that Dr. Sublett and JCAAI approved the TAAIS letters, members of RADAR began participating in discussions on an online message board called "Basecamp." *See* Exhibit C-7 to Plaintiffs' Preliminary Injunction Motion, Dkt. No. 12-8. These discussions, which began on May 5, 2001 and continued through at least July 18, 2011, included coordination among these board-certified allergists, who are normally competitors, in approaching insurance companies and convincing them not to pay or to limit payment to competitors who are not board-certified allergists. The message board specifically mentions UAS by name and contains further calls to action by Dr. Weldon. In a post he drafted on May 10, 2011, he writes "What we need is not rhetoric and 'ya-ya' but rather an aggressive attack on public senses without 'mentioning names.'" *Id.* at 6. Despite a RADAR member's admission that he was "acutely aware of how easily such a discussion might . . . run afoul of various anti-trust [sic] laws," the group pressed on, continuing to believe that the "AAAAI and ACAAI must join together to make this happen or [they would] continue to lose ground." *Id.* at 8-9. As part of their effort to convince insurance companies and managed care organizations to stop doing business with or paying their competitors, Defendants, including some of the leaders of JCAAI, ACAAI, and AAAAI, implemented an idea previously

suggested by Dr. Weldon and began to suggest to third-party payors that the publications of these organizations define the standard of care for the practice of allergy testing and allergen immunotherapy. Up until this point, those organizations and allergists as a whole declined to suggest their publications defined the “standard of care,” namely because of legal concerns over the potential effect on many of their own members who did not follow the recommendations of those publications, such as the recommendation against permitting patients to self-administer allergy shots. *See* Exhibit D-5 to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-12 at 2; Exhibit D-7 to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-13 at 1.

83. To that end, Defendants Dr. Sublett and Dr. Aaronson authored a JCAAI “New News You Can Use” newsletter that was sent to all JCAAI Members on October 5, 2011 addressing at length the “remote practice of allergy” (“RPA”) moving into JCAAI member communities. *See* Exhibit E-13 to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-29. Dr. Sublett and Dr. Aaronson specifically targeted what they termed “the new version of RPA” which was “the imbedding of a ‘certified allergy technician’ in a primary care physician’s office, where they perform skin testing to inhalants and then begin allergen immunotherapy and treatments.” *Id.* at 1. The business practices to which Defendants JCAAI, Dr. Aaronson, and Dr. Sublett referred were those of UAS, which was featured in a “Business Builder” article in *Medical Economics* as pointed out in the newsletter. The newsletter documented what JCAAI had done to respond to this threat, including “the appointment of a task force on the RPA to develop proactive approaches and strategies,” “monitoring the activity of these companies from the stand-point of the legality of their activities, especially related to billing,” and “working with the College & the Academy on marketing strategies and other responses.” *Id.* The newsletter then stated to all JCAAI members that “We believe one approach you can take is to educate primary care physicians AND local carriers about the standard of care.” *Id.* The newsletter directed that

members should rely on a 75 slide set directed at primary care physicians and insurance carriers jointly created by AAAAI and ACAAI. Members were encouraged to present these talks in their neighborhood being careful to keep their presentation “general in nature” and “not [to] mention any particular company.” *Id.* at 2. Revealing the motivation to hurt UAS and primary care physicians economically, the newsletter stated that “This type of communication – brought to the carriers – could be very helpful, since they do not want to pay for ineffective treatments.” *Id.* The newsletter then noted the ongoing lawsuit by UAS against the TAAIS and noted that as of yet, “This particular suit does not contain any anti-trust [sic] allegations.” The newsletter then stated that “JCAAI recommends against engaging with any company that promotes RPA.” *Id.*

HARM TO COMPETITION FROM DEFENDANTS’ CONDUCT

84. As a result of the coordinated action and collaboration of members of RADAR and the encouragement of JCAAI, members of all three national organizations, AAAAI, ACAAI, and JCAAI began to contact physicians and insurance carriers in their communities about the business practices of primary care physicians and UAS in their participation in the market for allergy testing and allergen immunotherapy. These members, acting on behalf of Defendants, contacted insurance companies and managed care health plans through representatives of those organizations, including fraud investigators, provider relation representatives, and medical directors.

85. Among other things, Defendants and these members attempted to persuade, entice, or coerce these representatives of third-party payors through use of materials distributed by AAAAI, ACAAI, and JCAAI, falsely suggesting that those organizations defined the standard of care for allergy testing and allergen immunotherapy and that primary care physicians were not adequately trained or qualified to perform allergy testing and allergen immunotherapy. These same actors also stated that primary care physicians’ reliance on the services of UAS was inappropriate, that

primary care physicians were engaged in billing fraud and “pass through billing,” that the practice of “home immunotherapy” was “investigational” and should not be reimbursed. If a third-party payors expressed reluctance to stop doing business with primary care physicians or UAS, Defendants and AAAAI, ACAAI, and JCAAI members suggested that those payors should reduce the amount paid to competitors for the mixing of immunotherapy under CPT Code 95165, but not reduce payment for shot administration in a board-certified allergists’ office under CPT Codes 95115 and 95117. The goal of these suggested price changes was to disproportionately reduce payment to Defendants’ competitors, who rely more on reimbursement of the mixing of immunotherapy under CPT Code 95165 and less on the reimbursement of shot administration under CPT Codes 95115 and CPT Codes 95117.

86. Some of the contacts with third-party payors were performed by Defendants themselves and other officers and directors of AAAAI, ACAAI, and JCAAI. For example, Dr. Allen Meadows, former ACAAI Speaker of the House of Delegates, reported to Dr. Weldon on October 9, 2011 that as instructed, he had been in contact with local insurance carriers regarding the remote practice of allergy. *See* Exhibit D-17 to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-20.

87. Although not all members heeded AAAAI, ACAAI, and JCAAI’s encouragement, either directly or through RADAR, to contact insurance companies, some did with differing degrees of success. Angry at the lawsuit against their colleagues, Defendants continued contacting insurance companies, including fraud investigators, provider representatives, medical directors, and advisory board members over the phone and in person, rather than through letters, in furtherance of their preexisting agreement. One such insurance company contacted was BC/BS Texas in or around June 2011, which had previously been contacted by Dr. Weldon. Following this contact, BC/BS Texas fraud investigators audited the medical records of numerous primary

care physicians in Texas, including Dr. Bernice Gonzalez in San Antonio, Texas, and denied claims to many primary care physicians.

88. Around the same time, JCAAI contacted Aetna claiming that primary care physicians and UAS were overbilling them for allergen immunotherapy and that Aetna should reduce the amount of units paid for allergen immunotherapy under CPT Code 95165. As a result of that contact, Aetna decided to reduce the amount it would permit to be billed to CPT Code 95165 to 90 units annually from 300 previously, a policy that also negatively impacted board-certified allergists. Following complaints, JCAAI's representatives, including Dr. Aaronson and Dr. Gross met with representatives of Aetna on July 25 and October 26, 2012, including an Aetna Senior Medical Director, Dr. Chris Jagmin, to propose raising the amount of units back to 120, to which Aetna agreed to do for the first year of allergen immunotherapy. Subsequent to those two conversations, Dr. Gross engaged in a follow-up meeting with Dr. Jagmin in which he complained about Aetna's decision to continue to pay primary care physicians working with UAS, acting in the interests of himself, JCAAI, and Dallas Allergy & Asthma Center, P.A.

89. Around the same time, Dr. Sublett's business partner, Dr. Stephen J. Pollard, acting on behalf of Dr. Sublett, PSF, PLLC, and JCAAI, also approached and met with medical directors and representatives of Anthem Blue Cross/Blue Shield of Kentucky. *See* Exhibit F to Plaintiffs' Preliminary Injunction Motion at ¶ 8, Dkt. No. 12-30. Similar to Dr. Gross's meeting with Aetna, Dr. Pollard attempted to persuade Anthem Blue Cross/Blue Shield of Kentucky representatives that they should not pay or do business with primary care physicians or UAS for allergy testing and allergen immunotherapy.

90. More recently, representatives of AAAAI, ACAAI, and JCAAI have met with managed health plans in Texas in an effort to convince them not to do business with primary care physicians or UAS in the market for allergy testing and allergen immunotherapy. Nothing

prevents primary care physicians from providing allergy treatment and immunotherapy to their patients. A specialist certification is not required by the standard of care in Texas nor any other state in which Plaintiffs operate. Centers for Medicare and Medicaid Services pays for allergy testing and allergen immunotherapy for primary care physicians, as do Medicaid plans administered by each individual state. Yet, Defendants suggest that primary care physicians are incapable of providing allergy testing and allergen immunotherapy to their patients and are determined to shut primary care physicians and businesses like UAS out of the market. At Dr. Weldon's suggestion, these Defendants targeted managed care health plans because those plans are incentivized to deny claims. Specifically, managed health plans are paid annual on a per capita basis from the state health and human services commission, which requires them to pay all covered claims under federal and state Medicare and Medicaid regulations. If managed care organizations could reason that claims for services did not meet the standard of care, then that health plan could plausibly deny the claims and pocket the difference.

91. Defendants have had recent success targeting these organizations. For example, on or about February, 2013, an ACAAI representative contacted Superior HealthPlan ("Superior"), a Texas managed care organization. The representative supplied Superior's Chief Medical Officer, Dr. David Harmon, an "opinion" or position statement ACAAI stating that organization forbids "home immunotherapy" and thus Superior should not do business with nor reimburse the practices of primary care physicians who rely on UAS, who permit self-administration of allergy shots. Following this contact, Dr. Harmon contacted various primary care physicians who had billed Superior for allergy testing and allergen immunotherapy and stated Superior would no longer pay them for allergy testing and allergen immunotherapy based on the position of ACAAI. Subsequently, Superior began denying all claims submitted by the businesses of primary care physicians for allergy testing and allergen immunotherapy for more than 18 primary care

providers doing business with UAS, some of whom are AAAPC members. In all more than 200 claims have been denied, totaling more than \$500,000 in lost revenue to those providers and UAS from Superior alone.

92. On August 1, 2013, Drs. Aaronson, Casale, Cox, Honsinger, and Webster, which includes the current Presidents of all three national allergist associations, JCAAI, AAAAI, and ACAAI, as well as the Executive Director and Executive Vice President of JCAAI, wrote another position statement entitled “Location Matters.” *See* Exhibit X to Plaintiffs’ Preliminary Injunction Motion, Dkt. No. 12-54. “Location Matters,” raises unfounded fears about the safety of self-administration of allergen immunotherapy, citing an increase in the risk of death. “Location Matters” is written in such a way as to conflate the standard of care with the non-binding practice parameters created by the allergist associations. While the publication of Location Matters or other journals is not in itself illegal, the use of these journals by board-certified allergists to claim privately to managed care organizations that they should not pay claims that do not meet these standards is anticompetitive.

93. The very next day after Location Matters was published, on August 2, 2013, Superior announced a “credentialing policy” set to take effect on October 1, 2013 which limits reimbursements to physicians with the equivalent of a two-year specialist program, functionally precluding primary care physicians from receiving reimbursement for allergy testing and allergen immunotherapy. *See* Exhibit F at ¶ 9 and F-2 to Plaintiffs’ Motion for Preliminary Injunction, Dkt. Nos. 12-30 and 12-32.

94. Around the same time Superior began denying claims, El Paso First Health Plan (“El Paso First”), another managed care organization that covers Texas Medicaid patients in El Paso, also began calling primary care physicians. Specifically, the Chief Medical Officer of El Paso First called those physicians in an effort to coerce those physicians to no longer engage in allergy

testing and allergen immunotherapy based on the positions of ACAAI. El Paso First had previously been contacted by Dr. Mansfield regarding claims data for allergy testing and allergen immunotherapy and Dr. Mansfield, a director of JCAAI and ACAAI, is believed to be the contact with El Paso First. As a result of those communications, numerous primary care physicians stopped engaging in allergy testing and allergen immunotherapy for El Paso First patients, and some were denied claims for previous services.

95. Also around the same time period, Parkland Community Health Plan (“Parkland”), a third-party payor for managed care services based in Dallas, Texas, was contacted by a representative of JCAAI, Dr. Gross. Dr. Gross and his business Dallas Allergy and Asthma Center represent the main competitor to the physicians in Parkland’s network in Dallas who received these letters. Following that communication, on October 1, 2013, Parkland’s medical director, Dr. Barry Lachman, wrote a letter to at least four primary care physicians announcing Parkland’s new policy of not reimbursing services provided by primary care physicians or any physician in association with companies like UAS. *See* Ex. F-3 to Plaintiffs’ Motion for Preliminary Injunction, Dkt. No. 12-33. In it, Dr. Lachman equated the standard of care with AAAAI practice parameters, just as Defendants intended in crafting their position statements. The primary reason given for Parkland’s refusal to reimburse these physicians is that “AAAI [sic] states that physicians should have specialized training before providing these services.” *Id.* The Parkland letter then explicitly attacks permitting certain patients to self-administer allergy shots using the same arguments and referencing the same articles that Defendants presented in “Location Matters.” The letter concludes by threatening to exclude primary care physicians who continue to provide allergy care from the Parkland network, especially those in contract with UAS. *See* Exhibit F at ¶ 10 and F-3 to Plaintiffs’ Motion for Preliminary Injunction, Dkt. Nos. 12-30 and 12-33. As a result of these letters, Dr. Osehotue Okojie and at least three other primary

care physicians ceased participation in the market for allergy testing and allergen immunotherapy for patients associated with Parkland HealthPlan. *See* Ex. C (Declaration of Osehotue Okojie, M.D.).

96. Following the recent success with managed care organizations, Defendants began making headway with commercial carriers as well. In line with an earlier proposal by a member of RADAR, members of AAAAI began contacting “the Blues,” otherwise known as the Blue Cross/Blue Shield of each state. *See* Exhibit C-7 to Plaintiffs’ Motion for Preliminary Injunction, Dkt. No. 12-8 at 1. As the RADAR post on Basecamp explained, if the Blues in one state restrict primary care physicians from allergy testing or allergen immunotherapy, “it would be great information to disseminate to others so that we can approach our local blues and try to change policy as well.” *Id.*

97. On December 10, 2013 following meetings with a board-certified allergist and AAAAI representatives, Blue Cross/Blue Shield of North Carolina announced a change in its policy effective February 11, 2014, stating “Immunotherapy self-administered in the home setting is considered investigational.” This statement mirrors statements made to other third-party payors by AAAAI representatives and could be interpreted to purportedly deny reimbursement to physicians that permit patients to self-inject allergy shots. *See* Exhibit F at ¶ 11 and F-4 to Plaintiffs’ Motion for Preliminary Injunction, Dkt. Nos. 12-30 and 12-34.

98. More recently, representatives of AAAAI, ACAAI, or JCAAI have approached other Blues to attempt to convince them to restrict the market for allergy testing and allergen immunotherapy by refusing to pay primary care physicians and those doing business with UAS. For example, Blue Cross/Blue Shield of Florida reported having considering changes to their policy following contacts with allergist. *See* Exhibit F to Plaintiffs’ Preliminary Injunction

Motion at ¶ 12, Dkt. 12-30. Blue Cross/Blue Shield of Kansas more recently has been denying claims for any primary care physician in contract with UAS. *Id.*

99. The level of activity has risen more recently, especially since this lawsuit was originally filed on January 13, 2014. For example, on January 22, 2014, Parkland demanded repayment of reimbursements which had previously been issued to primary care physicians. *See* Exhibit F to Plaintiffs' Preliminary Injunction Motion at ¶ 12, Dkt. 12-30. In the past few weeks, Coventry of Kansas has suggested that after consultations with allergists, it may change its policies regarding reimbursement of primary care physicians or any physician that relies on the services of UAS. *Id.* Similarly, during this time frame, physicians have called Plaintiffs to express concerns that other commercial carriers and health plans may no longer reimburse allergy testing and allergen immunotherapy performed by primary care physicians, including El Paso First, with some third-party payors threatening to seek their money back. *Id.* As recently as March 2014, Plaintiffs have learned that Humana has demanded repayment of claims previously approved for services provided by primary care physicians in Kentucky, the market dominated by Defendants Dr. Sublett and his business, PSF, PLLC. Commercial carriers such as the Blues and others are prone to coercion, persuasion or enticement because Defendant purport to represent violations of the standard of care, increased costs, and other claims, all of which are false.

PLAINTIFFS HAVE BEEN DAMAGED BY THE DEFENDANTS' ACTIONS

100. Plaintiffs have been damaged by actions taken Defendants and their co-conspirators to boycott AAAPC members and UAS. The direct result of Defendants actions and the encouragement of AAAAI, ACAAI, JCAAI, and RADAR members to persuade, entice, and coerce insurance companies on behalf of those organizations has caused insurance companies and managed care organizations like Superior, Parkland, Humana, Blue Cross/Blue Shield of North Carolina, and Blue Cross/Blue Shield of Kansas to avoid or stop reimbursing primary care

physicians altogether; and managed care organizations including Texas Children's Health Plan and Community Health Choice to avoid certifying or approving primary care physicians for reimbursement; and other insurance companies like Aetna and Blue Cross/Blue Shield of Texas to change and reduce the amounts they are willing to pay primary care physicians in accordance with price fixing advocated by Defendants.

101. As a direct result of Defendants' actions, AAAPC members and UAS have lost revenue and corresponding profits that they would have generated but for the actions of Defendants. AAAPC members and UAS have been forced to expend substantial resources to ensure that those they do business with do not terminate existing agreements and have also experienced difficulty in entering into business relationships with others because of the Defendants' anticompetitive public relations campaign.

102. UAS has been damaged by questions and resistance from its existing physician and practice group partners as well as from prospective business partners, insurance companies, and consumers. The result has been most noticeable in terms of lost revenue and corresponding lost profit for services that would have otherwise been provided to physicians. The lost revenue and profit is determined both by a decrease in services to existing contractual relationships with physicians, as well as loss of expected revenue and profit from new contracts that did not materialize.

103. UAS has also been damaged by a direct boycott on the part of board-certified allergists and their trade organizations, including AAAAI, ACAAI, and JCAAI. While UAS supports primary care physicians who compete with the allergists, there is no reason that an allergist could not employ UAS as well or at least assist and advise UAS. In addition to the interference with Dr. Kaplan's contract to advise UAS, Defendants have also dissuaded or attacked board-certified allergists that could do business with UAS.

104. UAS and AAAPC members have experienced damages in terms of out-of-pocket expenses, lost profit, and loss in value of their business. Plaintiffs anticipate that UAS and AAAPC members have experienced additional damages, but such damages are difficult to determine at this time because Plaintiffs' investigation into the extent of the damage they have suffered at the hands of Defendants is ongoing. Also much of the additional damage that UAS and AAAPC members have suffered is not easily calculable, such as damage to their goodwill and to the patient-physician relationship.

COUNT ONE

SHERMAN ACT § 1 VIOLATION AGAINST ALL DEFENDANTS

105. Plaintiffs incorporate by reference paragraphs 1 through 104 as if fully alleged herein.

106. At all times relevant to the Complaint, Defendants and others have combined and conspired to eliminate competition in the market for allergy testing and allergen immunotherapy for seasonal and perennial allergies, in Texas and nationwide. Defendants actions include restricting participation in the market for all physician and non-physician services provided by non-board certified allergist physicians and their staff or contracting partners, including AAAPC members and UAS. In furtherance of their conspiracy, Defendants have agreed to engage in a coordinated campaign to restrict competition by discouraging physicians who are not board-certified allergists from the practice of allergy testing and allergen immunotherapy, by targeting the physicians themselves, and by targeting their businesses and contractual relations, including their use of UAS to become competitors to board-certified allergists and their businesses. In furtherance of their conspiracies and illegal agreements, Defendants have engaged in and encouraged contact with physicians, insurance companies, managed care organizations, and other third parties in an attempt to persuade, entice, or coerce them not to do business with Defendants'

competitors, AAAPC members and UAS, or to fix prices to competitively disadvantage these competitors to discourage competition in the market. This group boycott and price fixing campaign has been at least partially successful and is the direct and foreseeable result of Defendants agreements to contact third party payors, form RADAR, solicit members to join RADAR, to directly contact third-party payors, and to encourage AAAAI, ACAAI, and JCAAI members to contact third party payors on those associations' behalf.

107. The Defendants' actions are a *per se* violation of the Sherman Act. The Defendants represent board-certified allergists and all three national allergy trade associations, a dominant group of horizontal competitors with substantial market power in the market for allergy testing and allergen immunotherapy. Defendants have engaged in joint collaborative action to destroy their legitimate competition by orchestrating a group boycott and encouraging price fixing in an attempt to deny competitors access to customers and markets that are necessary to compete. Namely, the Defendants have interfered with primary care physicians' relationships with insurance companies, managed care organizations, and other third-party payors and thereby their ability to receive reimbursement for the allergy care they provide. The Defendants have also discouraged primary care physicians from working with UAS, without whose services many of them will not be able to overcome the barriers to entering the allergy services market. By discouraging primary care physicians from working with UAS and persuading, enticing, or coercing third-party payors to deny or decrease reimbursements to those who do, the Defendants have similarly denied UAS elements access to markets that are necessary for it to compete. There are no plausible arguments that these anticompetitive effects are outweighed by any countervailing procompetitive benefits, so the Defendants should not escape a *per se* designation.

108. Strictly in the alternative, the Defendants' anticompetitive actions justify an antitrust action under the rule of reason analysis. The agreements that Defendants have entered,

maintained, renewed and enforced with one another have had the purpose and effect of eliminating competition for the provision of allergy testing and allergen immunotherapy, especially in areas where third-party payors have begun to refuse or limit reimbursements to AAAPC members and physicians who are supported and assisted by UAS. Adequate reimbursements from third-party payors are essential for primary care physicians and UAS to effectively compete with board-certified allergists in the relevant market. As the result of Defendants' conduct, some consumers have been deprived of the competition offered by AAAPC members, UAS-supported physicians, and other primary care physicians in all relevant geographic markets in Texas and other states, leaving patients to choose between paying more for allergy treatment or going without. Defendants actions and statements demonstrate that they are not exercising only altruistic concerns, but are motivated by the benefits of a restriction in competition, including protecting their turf and their profits. Defendants actions are also not mere advocacy of the services of board-certified allergists, but are directed at eliminating competitors and thus restricting competition, to the ultimate harm of patient choice.

109. As a direct and proximate result of Defendants' past and continuing violations of Section 1 of the Sherman Act, Plaintiffs have suffered injury and damages in an amount to be proved at trial.

110. UAS also seeks money damages from Defendants jointly and severally for these violations. These actual damages should be trebled under Section 4 of the Clayton Act, 15 U.S.C. § 15.

111. Plaintiffs also seek injunctive relief. The violations set forth above are continuing and will continue unless injunctive relief is granted.

COUNT TWO

**TEXAS FREE ENTERPRISE AND ANTITRUST ACT VIOLATION
AGAINST ALL DEFENDANTS**

112. Plaintiffs incorporate by reference paragraphs 1 through 111 as if fully alleged herein.

113. At all times relevant to the Complaint, Defendants and others have combined and conspired to eliminate competition in the market for allergy testing and allergen immunotherapy in Texas for seasonal and perennial allergies. Defendants actions include restricting participating in the market for all physician and non-physician services provided by non-board certified allergist physicians and their staff or contracting partners, including members of AAAPC and physicians supported by UAS. In furtherance of their conspiracy, Defendants have agreed to engage in a coordinated campaign to restrict competition by discouraging physicians who are not board-certified allergists from the practice of allergy testing and allergen immunotherapy, by targeting the physicians themselves, and by targeting their businesses and contractual relations, including their use of UAS to become competitors to board-certified allergists and their businesses. In furtherance of their conspiracies and illegal agreements, Defendants have engaged in and encouraged contact with physicians, insurance companies, managed care organizations, and third party payors in an attempt to convince those persons and entities to refuse to do business with or pay for the services performed by AAAPC members and UAS, or to reduce payment for those services disproportionately to payment for services performed by Defendants and other businesses of board-certified allergists. This group boycott and price fixing campaign has been at least partially successful and is the direct and foreseeable result of Defendants agreements to contact third party payors, form and solicit members to RADAR, and to encourage AAAAI, ACAAI, and JCAAI members to contact third party payors on those associations' behalf.

114. The result of that illegal *per se* boycott and price fixing has been to eliminate or restrict AAAPC members' and UAS's ability to market and provide their services in Texas. For example, as explained above, certain Texas insurance companies and managed care organizations have either stopped reimbursements for allergy care by physicians who are supported and assisted by UAS or restricted or interrupted those reimbursements. As a result, UAS, Texas primary care physicians, Texas based members of AAAPC, and Texas allergy patients are all being denied the benefits of fair competition.

115. The Defendants' actions are a *per se* violation of the Texas Free Enterprise and Antitrust Act ("TFEAA"). The Defendants represent board-certified allergists, a dominant market group of horizontal competitors. They have engaged in joint collaborative action to destroy their legitimate competition by encouraging a group boycott and fixing prices in an attempt to deny their competitors access to customers and markets that are necessary to compete. Namely, the Defendants have interfered with primary care physicians' relationships with insurance companies, managed care organizations, and other third-party payors and thereby their ability to receive reimbursement for the allergy care they provide. The Defendants have also discouraged primary care physicians from working with UAS, without whose services many of them will not be able to overcome the barriers to entering the allergy services market. By discouraging primary care physicians from working with UAS and decreasing reimbursements to those who do, the Defendants have similarly denied UAS access to markets that are necessary for it to compete. There are no plausible arguments that these anticompetitive effects are outweighed by any countervailing procompetitive benefits, so the Defendants should not escape a *per se* designation.

116. Strictly in the alternative, the Defendants' anticompetitive actions justify an antitrust action under the rule of reason analysis. The agreements that Defendants have entered, maintained, renewed and enforced with one another have had the purpose and effect of

eliminating competition for the provision of allergy testing and allergen immunotherapy and the associated support services, especially in areas where third-party payors have begun to refuse or limit reimbursements to AAAPC members and physicians who partner with UAS. As the result of Defendants' conduct, consumers have been deprived of the competition offered by AAAPC members, UAS-supported physicians, and other primary care physicians, leaving patients to choose between paying more for allergy treatment or going without.

117. As a direct and proximate result of Defendants' past and continuing violations of the TFEAA, Plaintiffs have suffered injury and damages in an amount to be proved at trial.

118. UAS seeks money damages from Defendants jointly and severally for these violations. Defendants' violations were willful and flagrant. UAS's actual damages should therefore be trebled under Section 15.21 of the TFEAA.

119. Plaintiffs also seek injunctive relief. The violations set forth above are continuing and will continue unless injunctive relief is granted.

120. As required by Section 15.21(c) of the TFEAA, a copy of this Complaint shall be mailed to the Attorney General of Texas.

COUNT THREE

TORTIOUS INTERFERENCE WITH EXISTING CONTRACTS AND BUSINESS RELATIONS AGAINST ALL DEFENDANTS

121. Plaintiffs incorporate by reference paragraphs 1 through 120 as if fully alleged herein.

122. In addition, or in the alternative, Defendants' conduct described herein constitutes tortious interference with the existing agreements between AAAPC members and insurance companies, managed care organizations, practice groups, and patients, as well as existing agreements between UAS and its many physicians and practice groups. Defendants' conduct,

which was neither justified nor privileged, was intended to cause insurance companies, managed care organizations, practice groups, and patients to cease their agreements or doing business with primary care physicians, including AAAPC members, as well as to cause physicians and practice groups to cease or reduce their engagement under agreements with UAS. Defendants' conduct constitutes willful and intentional acts of interference with those agreements. Such conduct caused injury to AAAPC members and UAS by, among other things, reducing business under these agreements causing a reduction in revenue and corresponding profits generated from these agreements and making it more difficult for AAAPC members and UAS to conduct their operations and business and by causing them to expend considerable resources in order to ensure that agreements and business arrangements are not terminated as a result of Defendants' actions.

COUNT FOUR

**TORTIOUS INTERFERENCE WITH PROSPECTIVE BUSINESS RELATIONS
AGAINST ALL DEFENDANTS**

123. Plaintiffs incorporate by reference paragraphs 1 through 122 as if fully alleged herein.

124. In addition, or in the alternative, Defendants' conduct described herein constitutes tortious interference with AAAPC members' and UAS's prospective business relations. There was a reasonable probability that, absent Defendants' actions, AAAPC members would have entered into additional business relationships with insurance companies, managed care organizations, practice groups, and patients, and that UAS would have entered into additional business relationships with third parties, including other physicians and practice groups. Defendants intentionally interfered with these relationships by attempting to prevent payment to AAAPC members and other physicians who are not board-certified allergists who are assisted and supported by UAS, as well as to prevent physicians and practice groups from entering into

business with UAS. Defendants' conduct was independently tortious or unlawful for the reasons described herein, including for violating and encouraging and participating others in violating the Sherman Act, the TFEAA, the Texas State Court Injunction, making false, fraudulent, defamatory, and disparaging statements regarding AAAPC members and UAS and their businesses, and participating in a breach of statutory and contractual duty of confidentiality owed to the Texas Medical Board. Defendants' interference proximately caused injury to AAAPC members and UAS by, among other things, reducing revenue and corresponding profits from these business relationships and making it more difficult to conduct operations and causing AAAPC members and UAS to expend considerable resources in order to further their business.

COUNT FIVE

CIVIL CONSPIRACY AGAINST ALL DEFENDANTS

125. Plaintiffs incorporate by reference paragraphs 1 through 124 as if fully alleged herein.

126. In addition, or in the alternative, Defendants' conduct described herein constitutes a civil conspiracy to violate the Sherman Act and the Texas Free Enterprise and Antitrust Act, as well as to tortiously interfere with Plaintiffs' current contracts and prospective business relations. Defendants and others have combined and conspired to eliminate competition for the provision of allergy testing and allergen immunotherapy and the associated support services in the form of physicians who are not board-certified allergists, including AAAPC members and those supported by UAS. In furtherance of their conspiracy, Defendants and others have agreed to engage in a coordinated campaign to restrict competition by discouraging physicians who are not board-certified allergists from the practice of allergy testing and allergen immunotherapy by targeting the physicians themselves and by targeting their businesses, including their use of UAS to become competitors with board-certified allergists and their businesses. In furtherance of their

conspiracies and illegal agreements, Defendants and their other co-conspirators have engaged in and encouraged contact with physicians, insurance companies, managed care organizations, and third party payors in Texas and elsewhere in an attempt to convince those persons and entities to engage in a group boycott of the services of AAAPC members and UAS and to fix prices for these services to discourage competition. Defendants and their other co-conspirators have also taken actions to interfere with Plaintiffs' current contracts and prospective business relationships. As a direct result of the overt acts taken in furtherance of Defendants' conspiracy, Plaintiffs have suffered considerable injury to their businesses and their ability to compete in the marketplace. Defendants are all jointly and severally liable for the actions taken in furtherance of their conspiracy.

APPLICATION FOR PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

127. Plaintiffs incorporate by reference paragraphs 1 through 126 as if fully alleged herein.

128. The actionable conduct of Defendants over the past few years has recently threatened and is starting to cause imminent and irreparable harm to AAAPC members and UAS. Starting around October 2013, the number of third party payors who report being contacted increased dramatically and at the urging of Defendants and their co-conspirators, actions to stop doing business with or reimburse these competitors started to grow. More recently, since the original filing of this Complaint, additional third party payors have expressed the same concerns raised by Defendants, threatening to remove primary care physicians and UAS from the market entirely.

129. To preserve the status quo until trial in this cause, Plaintiffs hereby request the Court to preliminarily enjoin and restrain Defendants, and their agents, servants, employees and all persons acting under, and in concert with, or for them, through both a temporary restraining

order and a preliminary injunction, from: (i) engaging in contacts or discussions with insurance companies, managed care organizations, or other third-party payors concerning who should perform allergy testing or allergen immunotherapy or whether or how much those organizations should reimburse for those services, (ii) contacting, discussing, or disseminating materials to third-party payors, physicians, or others in the industry regarding the business practices or services of primary care physicians or UAS; or (iii) taking action or encouraging others to take action restrained above or otherwise to harm AAAPC members' or UAS's businesses.

130. Upon judgment in this cause, Plaintiffs further request the Court to enter a judgment permanently enjoining and restraining Defendants, and their agents, servants, employees and all persons acting under, and in concert with, or for them, from: (i) engaging in contacts or discussions with insurance companies, managed care organizations, or other third-party payors concerning who should perform allergy testing or allergen immunotherapy or whether or how much those organizations should reimburse for those services, (ii) contacting, discussing, or disseminating materials to third-party payors, physicians, or others in the industry regarding the business practices or services of primary care physicians or UAS; or (iii) taking action or encouraging others to take action restrained above or otherwise to harm AAAPC members' or UAS's businesses.

ATTORNEYS' FEES

131. Plaintiffs incorporate by reference paragraphs 1 through 130 as if fully alleged herein.

132. 15 USCA § 15 and TFEAA § 15.21 both provide for the recovery of attorney fees and costs of suit in private enforcement actions under the antitrust laws. Plaintiffs therefore seek recovery of their attorneys' fees on this statutory basis as a remedy for the costs they have incurred as a result of Defendants' conduct.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury pursuant to FED. R. CIV. P. 38(b) of all issues triable of right by jury.

PRAYER FOR RELIEF

Therefore, Plaintiffs demand judgment as follows:

- a. Adjudge and declare that Defendants have engaged in unlawful conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.
- b. Adjudge and declare that Defendants have engaged in unlawful conduct in violation of Section 15.05(a) of the TFEAA, Tex. Bus & Comm. Code § 15.05(a).
- c. Preliminarily and permanently enjoin Defendants from violating Section 1 of the Sherman Act, 15 U.S.C. § 1 and Section 15.05(a) of the TFEAA, Tex. Bus & Comm. Code § 15.05(a).
- d. Adjudge and declare that Defendants unlawfully interfered with Plaintiffs' existing contracts and business relations.
- e. Adjudge and declare that Defendants unlawfully interfered with Plaintiffs' prospective business relationships.
- f. Adjudge and declare that Defendants unlawfully engaged in a civil conspiracy.
- g. Against all Defendants, jointly and severally, award UAS damages in an amount to be proved at trial, to be trebled with interest.
- h. Against all Defendants, jointly and severally, award Plaintiffs their attorney's fees and costs of this suit; and
- i. Award such other further relief as the Court deems just and proper.

DATED: April 7, 2014.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2014, I electronically submitted a true and correct copy of the above with the clerk of court for the U.S. District Court, Western District of Texas, using the electronic case file system of the Court. I hereby certify that I have served all counsel of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

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