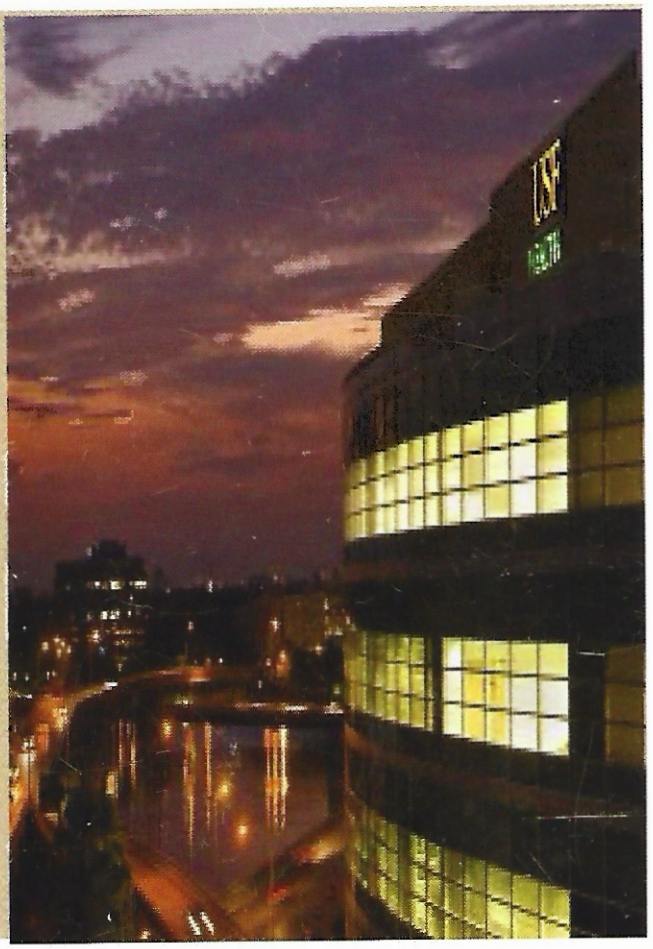
UNIVERSITY OF SOUTH FLORIDA

Division of Allergy and Immunology
Department of Internal Medicine
Joy McCann Culverhouse Airway Disease Research Center and The James A. Haley V.A. Medical Center
Tampa, Florida



2007-2008 Annual Report

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USF HEALTH

UNIVERSITY OF SOUTH FLORIDA

University of South Florida College of Medicine, Department of Internal Medicine, Division of Allergy and Immunology Annual Report 2007-2008

The late Samuel C. Bukantz, M.D., founded the University of South Florida College of Medicine, Department of Internal Medicine, Division of Allergy and Immunology in 1972. Richard F. Lockey, M.D. succeeded Dr. Bukantz in 1983 and is the current Director of the Division. Mrs. Joy McCann Culverhouse endowed the Division in 1997 and The Joy McCann Culverhouse Airway Disease Research Center was dedicated in February 1998. In 1998, Mabel and Ellsworth Simmons endowed the Division with a grant for education and research. The goals of the Division are: first, to provide care to patients with allergic and immunologic diseases at the University of South Florida College of Medicine, Tampa General Hospital, James A. Haley V.A. Medical Center, All Children's Hospital, and H. Lee Moffitt Cancer Center; second, to train students, residents, and fellows in the subspecialty of allergy and immunology; and third, to conduct basic and clinical research in allergy, asthma, and immunology.

Individuals interested in collaborating with members of the Medicine Division may contact Richard F. Lockey, M.D. or any faculty member at (813) 972-7631 (e-mail: rlockey@health.usf.edu). John W. Sleasman, M.D. or any other faculty member in the Pediatric Division may be contacted at 727-553-3533 or Jsleasma@health.usf.edu.

This years annual report is dedicated To the late Jewell and Samuel C. Bukantz, M.D.

Samuel Charles Bukantz, MD, Professor Emeritus and founding Director of the University of South Florida Division of Allergy and Clinical Immunology, Department of Internal Medicine, passed away on Sunday evening, Oct. 19, 2008. He was 97. His loving wife of 67 years, Jewell Bukantz, passed away earlier in the year on August 7. She was 93.

Dr. Bukantz, whose distinguished career in academic medicine spanned more than 60 years, helped build USF's fledgling allergy division into one of the largest, most well-respected in the world. One of Dr. Bukantz's significant accomplishments was during his residency at Mount Sinai Hospital in New York City (1934-1938) when he met with Mayor Fiorello LaGuardia and succeeded in creating the first salary for interns in the United States, $15 a month. More importantly, he met and wooed his late wife, Jewell Williams (Bukantz), a student nurse at Mt. Sinai School of Nursing. They were married in 1941. Other highlights of his career included an allergy fellowship in 1946 at Washington University Medical School in St. Louis, and Medical and Research Director of the Children's Asthma Research Institute in Denver (1958-1963). In 1967, he became Associate Professor of Medicine at NYU and began private practice in allergy in the faculty practice offices. Dr. Bukantz joined the USF College of Medicine in 1972 as the first director of the Division of Allergy and Clinical Immunology in the Department of Internal Medicine and Chief of the Section of Allergy at James A. Haley Veterans' Hospital. He was among the handful of senior faculty who took night call at the newly opened Haley VA Hospital before the internal medicine residency program was filled. His wife Jewell, a nurse, assisted him at the USF Clinics and helped trained some of the earliest USF fellows in the specialty. She often talked about how she taught the young fellows to do skin tests. Jewell Bukantz was a remarkable woman with enormous energy and resilience. Her passion was growing orchids and sharing their beauty with others.

When Dr. Bukantz stepped down from clinical activities in 1983, he was succeeded by his protege Richard Lockey, MD. In June 2004, Dr. Bukantz retired following a distinguished career in academic medicine spanning more than 60 years. He remained active in the Division until the year before his death. Dr. Bukantz was an extraordinary academician, clinician and researcher. He was completely dedicated to the specialty and his sensitivity and compassion for mankind touched the lives of everyone he encountered.

Dr. and Mrs. Bukantz were dearly loved and will be truly missed. Their tenderness and passion for life profoundly affected the lives of their family, friends and colleagues. They are survived by two daughters, Dorothy Bukantz and Jessica Blueberry and one granddaughter, Emily

In loving memory of Jewell and Samuel C. Bukantz, M.D.

USF HEALTH

UNIVERSITY OF SOUTH FLORIDA

DIVISION OF ALLERGY AND IMMUNOLOGY
FACULTY AND STAFF

Core Faculty

Richard F. Lockey, M.D., University Distinguished Health Professor, Professor of Medicine, Pediatrics, and Public Health; Division Director; Joy McCann Culverhouse Chair of Allergy and Immunology

Roger W. Fox, M.D., Professor of Medicine, Pediatrics and Public Health

Dennis K. Ledford, M.D., Professor of Medicine and Pediatrics

Shyam S. Mohapatra, Ph.D., Professor of Medicine, Molecular Medicine, and Pediatrics; Director of Basic Research, Joy McCann Culverhouse Airway Disease Research Center; Director, University of South Florida Health Signature Program in Allergy, Immunology and Infectious Diseases; Mabel & Ellsworth Simmons Professor of Medicine

Mark C. Glaum, M.D., Ph.D., Assistant Professor of Medicine and Pediatrics

Homero San-Juan-Vergara, MD, PhD, Assistant Professor of Medicine

Prasanna Kumar Jena, Ph.D., Research Instructor, Joy McCann Culverhouse Airway Disease Research Center

Arun Kumar, Ph.D., Research Instructor, Joy McCann Culverhouse Airway Disease Research Center

Weidong Zhang, M.D., Ph.D., Research Instructor, Joy McCann Culverhouse Airway Disease Research Center

Weidong Xu, Ph.D., Research Instructor, Joy McCann Culverhouse Airway Disease Research Center

Joint Faculty

John W. Sleasman, M.D., Professor of Pediatrics and Medicine; Robert A. Good Professor of Immunology; Chief, Division of Allergy and Immunology, Department of Pediatrics, University of South Florida, All Children's Hospital

Gary W. Litman, Ph.D., University Distinguished Health Professor, Andrew and Ann Hines Chair in Pediatrics, Professor of Pediatrics and Medicine

Stuart M. Brooks, M.D., Professor of Public Health and Medicine

Noorbibi Day, Ph.D., Professor of Pediatrics and Medicine

Sandra G. Gompf, M.D., Associate Professor of Medicine

My Lien Dao, Ph.D., Associate Professor of Biology and Medicine

Mitchel J. Seleznick, M.D., Associate Professor of Medicine

Morna Dorsey, M.D., M.M.Sc., Assistant Professor of Pediatrics and Training Program Director, Pediatric Division

Robert Nickeson, Jr., M.D., Assistant Professor of Pediatrics and Medicine

Nathan Tang, M.D., Clinical Assistant Professor of Pediatrics and Medicine

Michael Nieder, M.D., Affiliate Associate Professor of Pediatrics and Medicine; Director, Blood and Marrow Transplant Program, All Children's Hospital

Mandel R. Sher, M.D., Affiliate Professor of Pediatrics and Medicine

Clinical Faculty

Robert E. Windom, M.D., Clinical Professor of Medicine

Monroe J. King, D.O., Clinical Associate Professor of Medicine and Pediatrics

G. Edward Stewart II, M.D., Clinical Associate Professor of Medicine

Hugh H. Windom, M.D., Clinical Associate Professor of Medicine

Rosa Codina, PH.D., Clinical Assistant Professor of Medicine

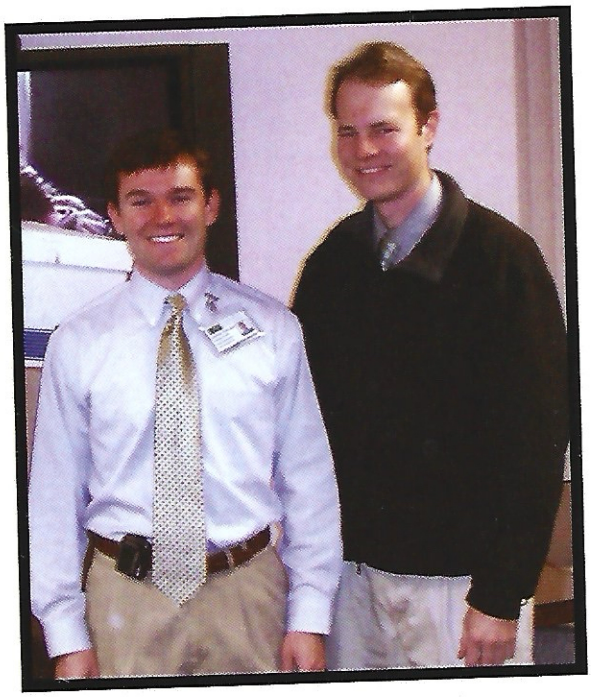
Mary L. Jelks, M.D., Clinical Assistant Professor of Medicine

Brett E. Stanaland, M.D., Clinical Assistant Professor of Medicine

Fellows -in-Training

Andrew Bagg, M.D., 2008 Graduate
Ronald Purcell, M.D., 2008 Graduate
Byol Shin, D.O., 2008 Graduate

Joshua Phillips, M.D., 2nd year chief fellow
Mathew Varghese, M.D., 2nd year fellow
Dennis Kim, M.D., 1st year fellow
Efren Rael, M.D., 1st year fellow



Joshua Phillips, M.D. and Andrew Bagg, M.D.

Left, Byol Shin, M.D.

Roger Fox, M.D. and Andrew Bagg, M.D.

Research Staff Members

Gary B. Hellermann, Ph.D.

Sandhya Boyapalle, Ph.D.

Xiaoyuan (Sonya) Kong, M.D.

Guoqing Liu, Ph.D.

Jia-Wang Wang, Ph.D.

Students and Visiting Research Scholars

Yvonne Davis, B.Sc.

Shawna Shirley, B.Sc.

Alison Jones, M.S., R.N.

Xiaoqin Wang, B.Sc.

Sang-Joon Park, M.D.

Administrative Personnel

Administrative Assistant to the Division Director
Michelle Grandstaff-Singleton, LPN, Clinical Research Administrator and Administrative Assistant to the Division Director

Administrative Personnel for the Division and The James A. Haley V.A. Medical Center
Peggy Hales, Program Assistant
Becci Carter, Administrative Secretary
Geeta Gehi, Administrative Secretary

Administrative Personnel-USF Joy McCann Culverhouse Airway Disease Research Laboratory
Stephanie Medley, Administrative Secretary

Clinical Research Unit Personnel
Michelle Grandstaff-Singleton, LPN, Clinical Research Administrator
Michelle Hernandez, B.A., Clinical Research Coordinator
Shirley McCullough, B.S., Clinical Research Coordinator
Sarah Lewis, BFA, Regulatory Coordinator

Administrative Personnel- All Children's Hospital
Amy Kramer, Training Program Assistant

BASIC RESEARCH PROJECTS

A. Inflammatory Lung Disease

1. The atrial natriuretic peptide (ANP) signaling pathway in pathogenesis of lung disease.

1a. Inhibiting ANP signaling through its receptor, NPRA reduces lung inflammation in an experimental asthma model.

The human body has many systems that do double or even triple duty. Kidneys filter impurities from the blood, but also regulate the blood volume and levels of sodium and potassium. The heart pumps the blood, but also makes hormones that regulate blood pressure. One of these heart hormones, ANP, plays an important role in regulating inflammation in the lungs. It activates several different kinds of cells by attaching to a receptor called NPRA on the cell surface. Isatin is a small molecule drug that interferes with ANP signaling. Using an asthmatic mouse model, we have found that isatin inhibition of ANP signaling through NPRA reduces the inflammation in the lungs and allows the mice to breathe better. A derivative of the ANP prohormone, NP73-102, decreases the level of NPRA on the cell surface and inhibits ANP signaling. This year we have continued investigating the mechanism of NPRA action and developed new nanoparticle formulations to reduce inflammation and disease. The anti-inflammatory peptide, NP73-102, has proven to be a strong candidate for DNA-based therapy aimed at inflammation, cancer and virus infection. We are still working out how it acts but now have a clearer idea of the other proteins, such as Hsp-90, that it interacts with and this gives us a handle on understanding the mechanism.

1b. Other N-terminal natriuretic peptides are biologically active.

NP73-102 is not the only peptide derived from the ANP prohormone with anti-inflammatory properties. Vessel dilator (VD), which is located in the same part of the hormone as NP73-102, also prevents the lung damage in mice from an allergic asthma attack. VD's mechanism of action is unknown, but we are actively studying it. These therapeutic peptides have a great advantage over conventional drugs. They can be targeted to specific cells by using nanoparticle carriers and produced on location from DNA plasmids encoding the peptides. This increases their pharmacological effectiveness and reduces side effects

1c. Mutations in the ANP pathway are associated with asthma.

As mentioned before, ANP is a hormone that wears several hats. It was first discovered as the hormone responsible for maintaining sodium-potassium balance in the body and the volume of fluid in the blood that has a critical effect on blood pressure. Our lab and others, however, have been studying its role in the immune system and have discovered that ANP signaling through its receptor NPRA has a major effect on inflammation in asthma, cancer and other diseases. As in all diseases, there is a genetic component along with the effects of environment, and we have been studying ANP to determine if mutations in the gene affect its activity. Such changes are known to affect the activity of ANP in regulating blood pressure and cardiovascular disease, but few studies have been done to look at the inflammatory aspects of ANP-NPRA signaling. Our results will be published soon and will show that single base changes in the ANP gene can have significant effects on its activity. This knowledge enables us to design better drugs and DNA-based therapeutics to modify the inflammatory activity of ANP to protect people from diseases such as asthma and allergy.

2. Use of stem cells for reducing inflammation in an experimental asthma model.

The testing of adult stem cells for cell therapy in a variety of human diseases is a rapidly growing area of research. Human bone marrow transplants have been used to cure disease for decades, and bone marrow is an excellent source of adult stem cells. To correlate with other experiments, we use stem cells obtained from the bone marrow of mice. Stem cells from healthy mice are grown in culture dishes and then injected into asthmatic mice. The stem cells migrate to the lungs of the asthmatic mice and help to reduce the inflammation and breathing problems that are associated with this disease. The lymphocytes in the asthmatic lung have cytokine profiles that are known as Th2-type. In mice given intravenous injections of stem cells, the Th2 cells switch to the healthy Th1 type. This new therapy has not been tested on humans, but it has a great potential for treating a variety of inflammatory diseases from asthma to lung cancer.

3. The role of microRNAs in the genesis of asthma.

MicroRNAs (miRNAs) are small molecules, 18 to 25 bases, that have a large effect on gene expression. It is estimated that from 30 to 50% of human genes are regulated by miRNA, and one miRNA can control as many as 200 genes. Mutations in the DNA that codes for miRNAs may contribute to many human diseases such as cancer, asthma, allergy and chronic infections. We have developed a microarray detection system for miRNAs that allows us to obtain a profile of the types and amounts of a large number of miRNAs. Correlation of miRNA expression with inflammation, allergy, and asthma in the mouse model is underway. We are also creating transgenic mouse models that overexpress or are deficient in these miRNAs in order to study their function.

4. Isolation and characterization of a new human mast cell line (USF-1) as a model for use in inflammatory disease research.

A stable human mast cell line derived from human cord blood stem cells has been established. Compared to the standard NIH mast cell lines, HMC-1 and LAD-2, this line shows greater stability with respect to the markers FcR1 and CD117, grows faster and requires a much simpler growth medium, hence it is significantly less expensive to use. USF-1 is not a tumor cell line like the other cell lines, so retains all of its natural physiological functions. Currently we are incorporating the SV-40 large T gene into USF-1 to immortalize it. One interesting preliminary result has to do with the plant compound, resveratrol, which is the active anti-inflammatory principle in grape skins and red wine. Resveratrol has been tested on the new human mast cell line, USF-1, and was found to increase an anti-inflammatory protein, SirT-1, and inhibit mast cell degranulation and release of histamine

B. Biology of Host-Virus Interactions: DNA-based antiviral therapeutics.

1. Respiratory syncytial virus (RSV) subverts the innate antiviral immune response.

Respiratory syncytial virus is a significant killer of infants and has been associated with pneumonia in the elderly. Vaccination against this virus is largely unsuccessful because RSV is able to inhibit the immune system's antiviral surveillance program. The first protein made by the virus after it infects a cell is called NS1. This protein inhibits interferon which is an antiviral compound critical for the body to mount an effective antiviral defense. Great progress has been made in understanding how NS1 does this and how to counteract the viral subversion of the immune system. These research findings may be extremely beneficial in preventing death and severe illness in babies and young children.

The mitochondria of the cells are targets of the NS-1 protein. Mitochondria are primarily known as the producers of ATP, the cell's energy supply, but they also are involved in antiviral defense. Two mitochondrial proteins, MAVS (mitochondrial antiviral signaling gene) and the adaptor protein, RIG-I, have to get together to trigger expression of antiviral genes and it is here that RSV's tactical weapon, NS-1, acts. Using a combination of *in vitro* and *in vivo* experiments, showed that NS-1 blocks interaction of MAVS with Rig-I thereby short-circuiting the antiviral system and prolonging survival of the virus. By targeting NS-1, we hope to stop RSV infections before they start.

2. Respiratory syncytial virus NS-1 protein is localized to the nucleus.

The activity of the RSV protein NS-1 is quite complex. RSV infects lung cells and makes copies of itself, eventually resulting in damage to the lung that can be lethal. The NS-1 protein blocks the antiviral interferon response of the cells allowing the virus to grow. How does NS-1 do this? As described above, one way is by interfering with the interaction of mitochondrial proteins, but NS-1 does other things. Data show that NS-1 localizes to the cell's nucleus but in doing so, it blocks the entry of a protein called STAT-1 that is necessary for expression of antiviral genes. NS-1 binds preferentially to *importin-α5*, a nuclear transport protein, and keeps it from binding to STAT-1. Hence, STAT-1 is prevented from entering the nucleus and cannot switch on the antiviral program. Antiviral therapeutics that target NS-1 should be effective in restoring a good immune response.

C. Nanomedicine

1. Microfluidic-microelectronic devices for rapid detection of biomarkers for lung disease.

A microfluidic device using a gold nanowire detector for rapid and sensitive measurement of an inflammatory marker called 8-isoprostane has been developed. The ability to measure this compound in a doctor's office would be highly useful in determining the severity of an asthmatic attack and in testing the effects of combinations of anti-asthmatic drugs. The device was also modified to see if nitric oxide, another indicator of inflammation associated with asthma, could be detected and this was done successfully. Very low levels of these compounds can be measured in the exhaled breath of a patient.

The detector principle can be applied to the detection of many different molecules and also to various pathogens such as paramyxovirus and HIV. Military use of these devices under field or battle conditions would have a great advantage, for example, to screen blood donors for pathogens such as HIV and hepatitis. Such device does not yet exist.

2. Development of implantable polymer scaffolds for proliferation of adult human stem cells.

The therapeutic use of adult stem cells will be a major force in medicine in the next decade. There are natural sources of these cells but increased use will quickly outstrip the supply unless methods are found to increase their proliferation under artificial conditions that mimic the body. We have engineered and constructed a spin-coater device that is able to create an artificial scaffold for the growth of stem cells. The material from which the scaffold is generated can be modified chemically in a variety of ways to aid the growth and stability of cells that are attached to the scaffold. Different scaffolds and modifications will be tested to determine which ones give the best growth and maintenance of 'stemness' of the cells. Ultimately the scaffolds will be implanted into test animals to see how well they can function *in vivo*.

3. Use of Sertoli cells for targeted delivery of plasmid DNA to lung.

Sertoli cells are found in the testes where they are responsible for nurturing spermatogonial cells and maintaining the proper environment for sperm production. If Sertoli cells are carefully separated from the testes tissue of immature mice, they can be obtained as a relatively pure population with very special properties. We injected Sertoli cells into mice and found that the cells preferentially appeared in the lung where they remained for some time. This characteristic homing to the lungs makes Sertoli cells a potential candidate for delivery of DNA therapeutics (plasmids) to the lung for treatment of asthma and other lung diseases. Sertoli cells can be loaded with nanoparticles containing an anti-inflammatory compound such as curcumin. When

D. Plant Extracts and Allergic Diseases

1. Curcumin alters dendritic cell activity and reduces inflammation.

Plant extracts and other natural compounds offer a huge area for discovery of novel anti-inflammatory agents. A study of the activity of curcumin, an ingredient in curry powder, was completed this year with extremely interesting findings. Curcumin from the turmeric plant has been used for years as a alternative medicinal compound in the treatment of a wide variety of inflammatory diseases. We discovered a link between the anti-inflammatory properties of curcumin and the innate immune system. Dendritic cells are the cells of the immune system that look for pathogens, cancer cells and foreign substances and 'present' them to the T lymphocytes which then mount an immune response. Results showed that incubation of dendritic cells with curcumin caused them to undergo changes that reduce their inflammatory activity. While this may sound contrary to what was just said about the importance of dendritic cells watching out for attacks on the body, they sometimes go overboard and cause more damage through excessive inflammatory response as in asthma. It is this over-reaction that curcumin is inhibiting.

2. Other plant extracts for reducing inflammation.

The lab collaborates with a number of labs around the world. India is a country with a long history of using botanicals in medicine and we are working with a pharmacology professor in India who studies the mechanism of these drugs and how to improve their activity while reducing side effects. We will continue our investigation of complementary medicine to identify possibe compounds of importance in medicine.

E. Inhibitor of tumor cell proliferation

1. NP73-102 inhibits tumor cell proliferation in cell cultures and in animals.

Evidence for the anticancer activity of NP73-102 continues to mount. The combination of a plasmid that produces the peptide with nanoparticles made of the natural polymer chitosan produces a powerful anticancer agent that can be delivered by a variety of routes. We have given it to mice as nose drops and by injection, and even as a cream applied to the skin. All of these methods provided significant protection against breast cancer, lung cancer, melanoma, prostate and other tumors. As a further advancement of the study we are testing NP73-102 against ovarian cancer in rhesus macaques. The results from this study should be in by the end of 2008.

CLINICAL RESEARCH PROJECTS

1. Repeated nasal challenge in skin prick-puncture negative, intradermal positive dust mite allergic rhinitis patients

Skin prick-puncture testing is a specific test to determine whether or not an individual is allergic. The primary goal of this study is to evaluate the clinical usefulness of intradermal skin testing when prick-puncture tests are negative. Intradermal skin testing is more sensitive but less specific than prick-puncture testing. There is little evidence-based data to support the clinical relevance of a negative prick-puncture test with a positive intradermal test result. This study's hypothesis is that subjects who have a clinical history of perennial rhinitis symptoms associated with dust exposure or not associated with other perennial allergens, will have a positive challenge with *Dermatophagoides pteronyssinus* when they have a positive interdermal test and a negative prick-puncture test. Subjects who are prick-puncture negative and intradermal skin test positive to *Dermatophagoides pteronyssinus* will be challenged with nasal sprays containing either placebo or *Dermatophagoides pteronyssinus* extract solutions three times daily each for two weeks to determine whether such challenges cause allergic symptoms

2. Pollen and Mold Counts and Immunochemical Quantification of Outdoor Allergens

Particles, other than pollen, which transport aeroallergens, have been described. The Division, which houses the Pollen and Mold Counting Station for Tampa, has two collectors adapted to collect both pollen and pollen aeroallergens. The collectors are located on the roof of the James A. Haley V.A. Medical Center Research Building. Pollen counts are performed twice weekly, disseminated to local media once weekly, and to the Internet twice weekly. Dr. Mary Jelks reads and interprets the slides.

3. Effect of Supplemental Oral Curcumin in Patients with Atopic Asthma

Curcumin, a naturally occurring polyphenolic molecule derived from the root of the *Curcuma longa* plant, has been shown in animal models to have intracellular molecular targets such as transcription factors AP-1 and NF-βκ. It prevents the secretion of both pro-inflammatory (TNF-α, IL-6) and anti-inflammatory (IL-10) cytokines. Cucrumin given in vitro to *Dermatophagoides farinae* stimulated lymphocyte cell cultures demonstrated a decreased production of IL-2, IL-4, IL-5, and GM-CSF. The propose of this pilot study is to evaluate the effect of oral supplementation of curcumin on patients with persistent atopic asthma in a randomized, double-blinded, placebo-controlled fashion. Patients who demonstrate allergic

4. Measurement of natriuretic hormone peptides in exacerbation of asthma

Evidence exists that atrial natriuretic peptide is a regulator of smooth muscle airway tone. In animal models, atrial natriuretic peptide is a potent bronchodilator. Natriuretic hormone peptides include atrial natriuretic peptide, vessel dilator peptide, kalliuretic peptide, long natriuretic peptide and brain natriuretic peptide. For these reasons, we wish to measure atrial natriuretic peptide and 4 other natriuretic hormone peptides (vessel dilator peptide, kalliuretic peptide, long natriuretic peptide and brain natriuretic peptide) encoded by the same gene and derived from the same pro-hormone. We hypothesize that there is a statistically significant decrease of natriuretic hormone peptides in subjects with asthma exacerbation compared to levels following treatment of an exacerbation of asthma. Measurement of natriuretic hormone peptides in a patient suffering an asthma exacerbation may be useful to the clinician. If our hypothesis is correct, and natriuretic hormone peptides are decreased, such information may be valuable to evaluate patients with an exacerbation of asthma. Although asthma presents with shortness of breath, coughing and wheezing, other conditions can also present similarly (congestive heart failure, myocardial infarctions, vocal cord dysfunction, interstitial lung diseases). Studying the relationship of natriuretic hormone peptides during exacerbations may help to better understand the physiology and pathogenesis of asthma.

5. Procalcitonin as a diagnostic aid in the diagnosis of acute bacterial sinusitis

The purpose of this pilot study is to determine if clinical bacterial sinusitis is associated with elevated procalcitonin. Sinus infection is one of the most commonly diagnosed diseases in the United States, affecting nearly 16% of the population annually. Although viral upper respiratory infection is relatively straightforward in terms of diagnosis and management, the diagnosis of acute bacterial sinusitis is difficult and is often incorrectly made, resulting in a high rate of inappropriate use of antibiotic therapy for viral infections. Current recommendations advise that acute bacterial sinusitis should be suspected when upper respiratory infection symptoms last greater than 10-14 days. Procalcitonin is a 116 amino acid peptide that is a precursor of calcitonin. Although confined mainly to the thyroid C-cells in health, procalcitonin can be induced in multiple cells lines in inflammatory conditions and is elevated in bacterial infections. Procalcitonin levels have been shown to be elevated in bacterial but not in viral infections. We hypothesis that elevated procalcitonin levels predicts the presence of bacterial sinusitis in patients presenting with sinus complaints.

6. Systemic Reactions to Allergen Immunotherapy

The goal of the study is to identify the risk of systemic reactions, predisposing factors, and the response to epinephrine given when the first sign of a systemic reaction or anaphylaxis occurs. Allergen immunotherapy is a commonly used therapy for atopic diseases, predominantly allergic rhinitis. It has proved to be effective in reducing the symptoms of allergic rhinitis and asthma. Despite its clinical benefit, there is risk of systemic reactions associated with this procedure. Several studies have evaluated the risk retrospectively, but many limited the definition of systemic reaction. It is suspected that the systemic reaction rate to allergen immunotherapy with aeroallergens is higher than previously reported. This study is a retrospective review of patients with systemic reactions to allergen immunotherapy over a 1-year period. The reactions of patients who report any systemic symptoms (rhinitis, shortness of breath, wheezing, rash, chest tightness, headache, dizziness, light-headedness, abdominal pain, or difficulty swallowing) are recorded at the time of the reaction. Subsequently, charts are reviewed to identify patients at greater risk for a systemic reaction

7. Efficacy of Using Oxymetazoline Hydrochloride Combined with Nasal Glucocorticosteroid to Treat Perennial Allergic and Nonallergic Rhinitis in Subjects with Persistent Nasal Congestion.

This study hypothesizes that treatment with oxymetazoline, in addition to a nasal glucocorticosteroid for fourteen days, will decrease the nasal congestion persisting in subjects with allergic or nonallergic rhinitis despite maximum recommended dosages of a nasal glucocorticosteroid. It is also hypothesized that nasal glucocorticosteroid therapy will prevent the development of rhinitis medicamentosa secondary to therapy with oxymetazoline. The primary endpoint will be the change in Average Daily Nasal Congestion Scores from baseline to the end of treatment with oxymetazoline. The secondary endpoint will compare quality of life scores at the baseline visit to visits on day 7, day 14, and day 28. Since the study began, 33 subjects have been screened and 26 subjects have been randomized. Subject recruitment is still in progress.

8. Does Addition of a Topical Antibiotic to Treat Chronic Rhinosinusitis Improve Efficacy?

Chronic rhinosinusitis is a pervasive and costly disease. Estimates reveal that the costs of treating over 20 million Americans suffering from this diagnosis exceeds $4.3 billion per year. Primary therapy consists of oral antibiotics and nasal steroid sprays with some studies advocating nasal irrigation. Intravenous antibiotics and surgery were used for severe or recalcitrant cases. Several studies have investigated the use of topical antibiotics in rhinosinusitis, but no prospective, blinded, controlled study has been done. The purpose of this prospective, randomized, double blinded, placebo controlled clinical study is to establish whether the addition of a topical antibiotic to a conventional regimen of oral antibiotics and topical nasal steroids results in a significant improvement in radiographic findings and quality of life when compared to oral antibiotics, nasal steroids, and saline placebo irrigation.

9. Role of the Natriuretic Peptide Cascade in the Genesis and Control of Asthma

The purpose of this research study is to determine indicators in the blood that may reveal a trend towards asthma and provide information on the risk of later development of allergy and asthma. Brain natriuretic peptide (BNP) and atrial natriuretic peptide (ANP) in the blood are being studied. ANP plays a role in how the lungs work and in development of the immune system and in the immune system's response to microbesand allergens. The amount of IgE in the blood will be measured, and the DNA sequence will be analyzed for specific changes that may influence a person's susceptibility to asthma. Two groups of children/adolescents will be studied: an experimental group consisting of persons who have a physician diagnosis of allergic disease and a control group with no diagnosis of allergic disease.

PHARMACEUTICAL SPONSORED STUDIES

Studies funded by pharmaceutical companies are conducted at the Division's Clinical Research Unit (CRU). Funds from these studies support the Division's research and clinical training program. Seven studies were completed in 2007, nine in 2008 and eleven additional studies will continue into 2008. To date, the CRU has agreements for seven new studies in 2009.

The CRU is a member of the American Lung Association's Asthma Clinical Research Center network, one of 20 centers throughout the United States. The American Lung Association Clinical Research Center completed two studies in 2007, and one study is still in progress. The American Lung Association has several protocols pending approval.

Pharmaceutical Sponsors

Alcon Laboratories
Almirall Pharmaceuticals
Altana/Byk Gulden
AstraZeneca Pharmaceuticals
Dyax Corporation
Genentech Inc.
GlaxoSmithKline
Merck and Co., Inc.
MedImmune
Novartis Pharmaceuticals
Pharming Inc.
Sanofi-Aventis Pharmaceuticals
Schering-Plough Corporation
Sepracor Inc.
Skye Pharma

USF HEALTH

Making Life Better

Basic and Clinical Research Support

Endowments

The Joy McCann Culverhouse Endowment

The Mabel and Ellsworth Simmons Endowment

Extramural Funding

American Lung Association of Florida
- Asthma Clinical Research Center Award

Florida Biomedical Research

National Institute of Health, National Heart, Lung, and Blood Institute

Pfizer Visiting Professor Grant

Veteran Affairs Merit Review Award

Veterans Affairs Career Scientist Award

Florida Hi Tech Cooridor Grant

Biotechnology Company

A USF associated "spin-out" biotech company was formed under the direction of Shyam Mohapatra, Ph.D., 2004 - present. http://www.transgenex.com

Division's On-Line Journal

Shyam Mohapatra, Ph.D., Gary Hellerman Ph.D., and staff established an on-line journal, *Genetic Vaccines and Therapy* in 2004 - present. http://www.gvt-journal.com

PUBLICATIONS

BOOKS

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Faculty and Staff Awards: 2008

Roger W. Fox, M.D., *"The Best Doctors in America" Guide 2007- 2008*

Mark C. Glaum, M.D., Signature Interdisciplinary Program in Allergy, Immunology and Infectious Disease Synergy Pilot Award ($20,000) Signature Program In Allergy, Immunology, and Infectious Diseases, USF, 2007

Mark C. Glaum, M.D., Selected as one of *"Best Doctors in America" Guide 2007-2008*

Dennis K. Ledford, M.D., Listed *in the "Best Doctors in America" Guide 2007-2008*

Richard F. Lockey, M.D., Award of Distinction - Distinguished University Health Professor, University of South Florida College of Medicine, August 7, 2007

Richard F. Lockey, M.D., Recipient, 2008 AAAAI Distinguished Clinician Award, American Academy of Allergy Asthma and Immunology, March 17, 2008.

Richard F. Lockey, M.D., Tenured, University of South Florida College of Medicine, August 7, 2007.

Richard F. Lockey, M.D., Recipient, Distinguished Alumni Award, J. P. McCaskey High School, Lancaster, PA., May, 2007

Richard F. Lockey, M.D., Member appreciation award, Education and Research Trust (ERT) Resource Development Committee, 2003 – 2007.

Richard F. Lockey, M.D., Manchester Who's Who Among Executives and Professionals, "Honors Edition", 2006/2007.

Richard F. Lockey, M.D., Listed *in the "Best Doctors in America" Guide 2007-2008*

Shyam S. Mohapatra, Ph.D., Tenured, University of South Florida College of Medicine, August 7, 2007

Shyam S. Mohapatra, Ph.D., Excellence in Innovation Award, University of South Florida, November 7, 2008

Shyam S. Mohapatra, Ph.D., "International Business Person of the Year" Award by the Indo-US Chamber of Commerce of Tampa Bay, Tampa, 2008

Shyam S. Mohapatra, Ph.D., Senior VA Career Scientist Award 2008

Shyam S. Mohapatra, Ph.D., Finalist, Health Care Hero's Award, Tampa Bay Business Journal on Health Care Innovation and Research. 2007.

Shyam S. Mohapatra, Ph.D., A Career Scientist Award, 2007.

Shyam S. Mohapatra, Ph.D., "International Business Person of the Year" Award by the Indo-US Chamber of Commerce of Tampa Bay, Tampa, 2008

Shyam S. Mohapatra, Ph.D., Senior VA Career Scientist Award 2008

Shyam S. Mohapatra, Ph.D., Finalist, Health Care Hero's Award, Tampa Bay Business Journal on Health Care Innovation and Research. 2007.

J. W. Wang, First Place Allergy Presentation Award, SIPAIID 2nd Annual Symposium 2008.

J. W. Wang, Outstanding poster award, USF Research Day 2008.

Joshua Phillips, M.D., Recognized in *America's Top Pediatricians 2008*

Joshua Phillips, M.D First Place-Poster Presentation, FAAIS Annual Meeting 2008

Joshua Phillips, M.D Recognized in *America's Top Physicians* 2007-2008

Joshua Phillips, M.D Recognized in Marquis' *Who's Who in America* 2006-2008

VISITING PROFESSOR EDUCATIONAL PROGRAM 2007-2008

Wayne Anderson, Ph.D.; Head, Applied Genetics, Respiratory GlaxoSmithKline, Research Triangle Park, North Carolina; "The Double Helix: Changing the Pardigm of Personalized Medicine"; September 17, 2008.

Eugene R. Bleecker, M.D.; Co-Director, Center for Human Genomics Section Head, Pulmonary, Critical Care, Allergy & Immunologic Diseases, Wake Forest University School of Medicine , Winston-Salem, North Carolina 27157; "Pharmacogenetics and Personalized Medicine in Asthma"; August 06, 2008

Markus W. Ollert, M.D.; Professor of Molecular Dermatology & Immunology, Director of Clinical Research Division in Molecular & Clinical Allergotoxicology Vice-Chairman, Dept of Dermatology & Allergy Munich, University of Technology Munich, Germany; "Immunotherapy for Insect Venom Anaphylaxis: from Extracts to Molecules"; May 1, 2008.

Gene L. Colice, M.D.; Professor of Medicine, The George Washington University School of Medicine, Director, Pulmonary, Critical Care & Respiratory Services Washington Hospital Center, Washington, D.C.; "Inflammation in Small Airways" January 31, 2008.

Jennifer M. Puck, M.D.; Professor of Immunology, Department of Pediatrics and Institute for Human Genetics, University of California, San Francisco Medical School, San Francisco, California; "Advances in Genetics of Primary Immune Disorders"; October 10, 2007

Juan C. Celedon, MD, Dr.PH,; Associate Professor of Medicine, Channing Laboratory & Division of Pulmonary/Critical Care Medicine Brigham and Women's Hospital, Harvard Medical School Boston, Massachusetts "Asthma in Hispanics"; July 17, 2007.

Jenny Ting, PhD; University of North Carolina, Alumni Distinguished Professor of Microbioloigy – Immunology Program Leader Lineberger Comprehensive Cancer Center; " CATERPILLER, Plexin and Semaphorin: New gene families in innate and adaptive immunity" ; March 19, 2007.

Stephen Peters, MD,; Professor of Medicine and Pediatrics, Associate Director, Center of Human Genomic, Wake Forest University Health Sciences Winston-Salem, NC; ":From Concept to Practice: The Pharmacology of Asthma"; April 10 & 11, 2007.

Todor Popov, MD, PhD; Associate Professor Clinical Centre of Allergology, Medical UniversitySofia, Bulgaria**;** " Mucoadhesive Approach for Drug Delivery"; February 21, 2007.

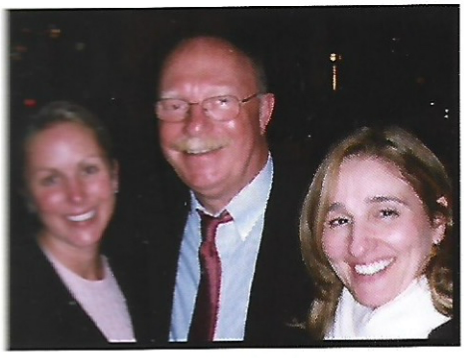
Steven D. Douglas, MD, Section Chief for Immunology, The Children's Hospital of Philadelphia; "Selected Insights into HIV/AIDS: Immunology/Pathogenesis: Gender, Stress-Depression, and Adolescents"; February 20, 2007

Robert Wise, M.D.; Johns Hopkins Asthma & Allergy Ctr., Div of Pulmonary & Crit Care Medicine, Baltimore, Maryland; "Bronchial -Obstructive Lung Disease" and " Asthma vs. COPD" ;January 23, 24, 2007.

Burton Zweiman, M.D. , University of Pennsylvania School of Medicine, Emeritus Professor of Medicine, Philadelphia, PA; "The Possible Relationship of Chronic Urticaria to Systemic Disease" ;January 5, 2007.

Newman L. Stephens, M.D., FRCP (London), Professor of Physiology, University of Manitoba, Winnipeg, Canada; " Prolifercation (focus on non-muscle myosin light chain kinase) Differentiation (regulation by TGFb1) in smooth muscle"; December 4, 2008.

2007 Alumni Society Annual Dinner



UNIVERSITY OF SOUTH FLORIDA

USF HEALTH

The Joy McCann Culverhouse Airway Research Center Faculty and Staff

From top row, left to right:
(Top) Arun Kumar, Hongyu Zheng, Murali Kanakanalli
(2nd row) Leigh Nattkemper, Guoqing Liu, Xiaoqin Wang, Weidong Zhang
(3rd row) Mahasweta Das, Xiaoyuan Kong, Brittany Caddick, Subhra Mohapatra
(4th row) Sandhya Boyapalle, Jia-Wang Wang, Juli Garay, Wilson Xu, Yvonne Davis
(5th row) Gary Hellermann, Shyam Mohapatra, Shawna Shirley, Stephanie Medley, Prasanna Jena (kneeling) Liotta Dowdy

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