A Message from the Director

With the close of our 2020 fiscal year in July, the Mary H. Weiser Food Allergy Center (MHWFAC) has celebrated an important milestone: The completion of our first five years and the fulfillment of significant goals that were established at the launch of the center in the spring of 2015.

Like you, we are weathering unprecedented disruptions in 2020, but, thankfully, our talented researchers have been able to continue their scientific work at U-M and in concert with other food allergy experts around the globe. As you will read, the MHWFAC and U-M Food Allergy Clinic faculty were involved in the pivotal Phase Three trial of Palforzia, the first-ever oral therapy for peanut allergy, which was approved by the U.S. Food and Drug Administration in January.

Another highlight for our team was to be awarded in June a Discovery Center of Distinction designation by the leading food allergy advocacy group FARE (Food Allergy Research & Education), through a rigorous competitive review. This designation will connect us with an elite network of more than 40 other top food allergy research hubs. The U-M Food Allergy Clinic also was named a Clinical Research Center of Distinction.

Looking ahead with optimism, we have rescheduled our “Mechanisms and Treatment of Food Allergy” scientific symposium for June 2021, and hope to welcome an international array of researchers and other key opinion leaders to Ann Arbor. Longer term, our strategic plan for the center’s next five years includes a renewed focus on translational research and more interdisciplinary collaborations within U-M and beyond.

This is an unprecedented time in food allergy – including discovery, translational science and the development of therapeutic options for our patients. We are energized and focused, and we thank you for your continued interest in and support of our work.

Sincerely,
James R. Baker, Jr., MD
Director
Mary H. Weiser Food Allergy Center
MHWFAC Strategic Planning
Our mission at the inception of the center was to:

• Perform cutting-edge research in the pathogenesis and treatment of food allergy
• Become a national center for information and public policy surrounding food allergy
• Establish the Michigan Medicine Food Allergy Clinic as a preeminent source of food allergy medical care in the country.

We have made huge strides toward these goals, often in advance of target dates, including the hiring of world-class research faculty, establishing collaborations with clinical faculty on human trials, and the raising of significant endowment funds that allow the center to be self-sustaining.

After securing a large anonymous gift, we established the Michigan Food Allergy Research Accelerator (M-FARA) Program, which supports one-year pilot grants as well as an annual international symposium.

Our championing of public policy initiatives, community outreach and holistic approach to patient care -- including the funding of a social worker role to support families at the clinic – round out the MHWFAC’s endeavors.
Looking Ahead- The Next Five Years

We will continue this successful trajectory by continuing to nurture scientific discovery at our laboratories, and by cultivating new opportunities through:

• Focusing on translational research development
• Broadening our discovery science plan by leveraging our expertise and partnerships
• Maintaining clinical excellence
• Continuing to build awareness of the center throughout the scientific and medical communities, among advocacy organizations, regulatory bodies, pharmaceutical companies, donors, U of M colleagues and supporters, and the general public
Guiding the MHWFAC is the latest facet in Dr. Baker’s long career as a physician, educator and leader. From his clinical expertise as an allergist to roles in industry, academic research, advocacy work and more, his expertise is invaluable to the center and to numerous other organizations.

In addition to directing the MHWFAC through its first five years and into the future, attracting best-and-brightest faculty to our labs, Dr. Baker has worked with Aimmune Therapeutics to obtain FDA approval for its first-ever therapy for patients with severe peanut allergy: Palforziza. His testimony at FDA hearings in September 2019 helped pave the way for the drug’s approval in January. Dr. Baker recently initiated a new research program to develop an in vitro assay using a mast cell line, to substitute for the double blinded food challenge in the diagnosis of food allergy. This assay, which requires only a patient blood sample, is safer and easier than a food challenge, and could be standardized for use at any clinical site – a remarkable changes for patients and their health care providers.

Over the past year, Dr. Baker also has created a public policy initiative and obtained competitive funding for a project that will study billions of health care records to bolster epidemiological knowledge of peanut allergy and the demographics of patients. Two graduate students are working on the study, which already has generated two manuscripts.

And as the COVID-19 crisis began, Dr. Baker was able to ensure that MHWFAC’s research and advocacy programs continued to function during this difficult time. Additionally, he successfully obtained commercial grants to support COVID-19 research related to diagnostics for viral infection and immunity to the virus.
Dr. Gupta’s research into the various outcomes of early introduction of peanut in the prevention of peanut allergy has been integral in advancing our knowledge and had led to two high-quality peer-reviewed publications.

One aspect of this advancement is an assessment of primary care physicians knowledge about the guidelines for early introduction of peanut showed inadequate knowledge. Based on this study, her team is currently running a pilot to increase compliance of primary care physicians with early introduction, by alerting them to high risk babies through the electronic health record. The pilot aims to increase compliance, and effect a reduction in the incidence of peanut allergy.

Dr. Gupta’s interest does not only lie in the pure clinical arena of providing care to patients. She and psychologist Catherine Peterson have conducted a literature review in which they have looked at the psychological and neurodevelopmental aspects of Food Protein Induced Enterocolitis Syndrome (FPIES). The researchers found a paucity of data and identified a need to conduct more studies in this area, so interventions can be employed to improve quality of life of patients with FPIES.

Dr. Gupta also is conducting a study to improve the diagnostics of peanut allergy by studying correlation of peanut component testing and oral food challenge outcomes. The abstract was accepted for publication at the 2020 annual AAAAI meeting.
Dr. Hogan has more than 20 years of experience in basic immunology research, concentrating in development of animal model systems to study underlying immunological processes that predispose and exacerbate allergic reactions. Since being recruited to MHWFAC 3 years ago, Dr. Hogan has made immense progress. Over the past fiscal year he has been awarded several new grants from the National Institutes of Health to study food allergy responses at the molecular and cellular level in various organ systems, including the digestive system.

During the period covered by this report, Dr. Hogan also published 12 new papers in peer-reviewed scientific journals and served as a featured speaker at numerous conferences in the United States and internationally. He has been appointed as Vice-Co Chair for the 2022 Gordon Research Conference in Food Allergy.
Dr. Huffnagle’s research interests for the past two decades include the interaction between opportunistic fungal pathogens, the fungal/bacterial microbiome, and the immune system during respiratory disease and in the development of allergic responses. He co-leads a multi-laboratory research group whose focus is on the immunology, pathobiology and microbiology of mucosal surfaces with interests and expertise encompassing an array of interdisciplinary approaches, including applying high-throughput sequencing and gene expression technologies to biological processes and disease.

Since joining with MHWFAC 5 years ago, Dr. Huffnagle has been part of many efforts to enrich the food allergic field including our current Southeast Michigan Food Allergy Collaborative with Henry Ford Health System and completing the second year of an undergraduate course about food allergies. Over the past year he has served as visiting professor at the University of Alabama-Birmingham, the National Heart, Lung & Blood Institute and the Broad Institute for Genomics, Massachusetts Institute of Technology. Dr. Huffnagle also delivered presentations at several international conferences.
Dr. Kim has been a researcher for almost 30 years and when he was recruited to MHWFAC 4 years ago, he jumped feet first into establishing his laboratory and work towards enhancing our center. His dedication has resulted in a grant from the National Institutes of Health to study the role of retinoic acid and its receptor in regulating immune cells among his many other accomplishments.

In collaboration with scientists at Purdue University and University of Arizona, the Kim lab established and characterized a new animal model of food allergy. This model will be useful for research on food allergy and development of therapeutics; the Kim lab is currently studying the gene expression profile of this model during food challenge.

Dr. Kim and colleagues also discovered that a specialized immune cell population — NKT cells — is regulated by vitamin A. NKT cells regulate various immune responses including food allergy immune responses.

The lab also published an article in the June issue of *Scientific Reports* on the beneficial role of dietary fiber metabolites in regulation of inflammatory responses. The findings provide scientific basis for the use of such metabolites, their precursors (prebiotics) or microbes (probiotics) in suppressing various inflammatory conditions.
Dr. Lukacs has been with the center since the beginning: 6 years ago. Under his co-leadership with Dr. Baker and 27 years of experience, the center has thrived. Currently, he is leading a new project that will examine the impact of maternal factors during pregnancy, along with early-life environmental exposures and the development of the infant’s microbiome that influence allergic responses, especially the induction of food allergy.

MHW faculty Gary Huffnagle, PhD and Catherine Ptaschinski, PhD, will add basic science expertise. This multi-center inner-city birth cohort study is funded by a National Institutes of Health Program Project Grant. Partners at Detroit’s Henry Ford Health System will lead clinical research and epidemiology expertise, while investigators at the University of California San Francisco will be examining the mother and infant microbiome.
Dr. O’Konek has been a researcher for 12 years and joined the center 5 years ago. In that time, she and her team have worked on the development of vaccines to food allergy. They have previously published that just three doses of an intranasal food allergy vaccine suppresses established food allergy in mice.

In late 2019, they published a follow-up study in the journal, Allergy in which demonstrated that the protection from allergic reaction conferred by the vaccine persisted for at least 16 weeks after the final dose. Work continues, encouraged by these results, as they suggest this vaccine induces long-term suppression of allergic immune responses.
Dr. Ptaschinski has been at the University of Michigan for eleven years and in MHWFAC for the past 5. During that time, she has grown as a researcher and is now currently studying the role of a molecule called stem cell factor in the contribution to allergic disease. She and her team currently have a manuscript under revision looking at this molecule in eosinophilic esophagitis, and an undergraduate student in the lab delivered an oral presentation on this work at a conference in November.

The team also has been studying this molecule in anaphylactic food allergy, which was presented at the Society for Leukocyte Biology annual meeting in Boston in November.

Dr. Ptaschinski also was the recipient of a 2019 M-FARA Pilot Grant to study the role of the epithelial barrier in food allergy. Preliminary results from this project were presented at the Gordon Conference on Food Allergy in Ventura, CA in January.
In June, the MHWFAC was named a **Discovery Center of Distinction** by FARE, the leading food allergy research, advocacy and education organization, when it launched a new version of the FARE Clinical Network. The network was established in 2015 to link top food allergy centers nationwide for collaboration on the development of new therapies.

In addition, Michigan Medicine’s Food Allergy Clinic was named a **Clinical Research Center of Distinction**. Several clinic faculty members are affiliated with the MHWFAC.

The strength of this partnership contributed to the MHWFAC’s success in receiving the Discovery Center of Distinction designation, said Nicholas Lukacs, PhD, scientific director of the MHWFAC. Detroit’s Henry Ford Health System, which collaborates with the MHWFAC, also received the Clinical Research Center of Distinction designation.

“We are particularly pleased to be a part of the FARE network given our focus in basic and translational research at the MHWFAC and Henry Ford,” said Dr. Lukacs. “Our combined clinical and basic research expertise in the Southeast Michigan Food Allergy Consortium will put us in the top 10 leading centers in FARE’s network.”

FARE’s announcement brings the number of research hubs and clinics in its nationwide network to 44. To date, the network sites have participated in more than 45 clinical trials in food allergy including those that led to the development and market release the first ever FDA-approved treatment for peanut allergy in January 2020.

Discovery Centers of Distinction and Clinical Research Centers of Distinction also will participate in multi-center clinical trials and will help to train the next generation of investigators in food allergy.
Investigators at the MHWFAC and the Epidemiology and Allergy Divisions at Detroit’s Henry Ford Health System (HFHS) have teamed up to establish the Southeast Michigan Food Allergy Collaborative (SMFAC) to coordinate research and clinical trials related to food allergy.

SMFAC scientists will leverage strengths from both institutions to investigate the development and mechanisms that lead to food allergy.

The partnership arose from previous studies that brought together experts from both institutions to examine the development of allergies early in life, and the long-term consequences due to environmental and nutritional influences. MHWFAC has access to the large food allergy patient population at Michigan Medicine, and the University of Michigan’s outstanding research laboratories. Henry Ford Health System, meanwhile, has established numerous patient cohorts that allow researchers to examine the development of food allergy starting at birth, as well as the influence of mothers during gestation.

Members of the consortium have been funded by National Institute of Allergy and Infectious Diseases (NIAID) to examine the development of allergies in a new 3000-patient birth cohort established by HFHS. The study will assess not only the development of food allergies early in life, but the continued responses throughout the patients’ childhood.
Federal regulators in January approved the first-ever peanut allergy treatment in a development called "a defining moment for the peanut allergy community." Palforzia, a desensitization treatment intended for children and teens from age 4-17, was approved at the end of January by the U.S. Food and Drug Administration. It was developed by Aimmune Therapeutics, Inc. of Brisbane, California.

"Finally, we can offer patients an alternative to the difficult task of absolutely avoiding all peanut," said MHWFAC Director Baker, who serves as a consultant to Aimmune. He testified in favor of Palforzia during the FDA evaluation.

Patients and doctors at U-M, including clinicians who partner with the MHWFAC, participated in clinical trials that led to the drug’s approval. Subjects taking the oral medication built up tolerance over a 28-week period. After that, they take a maintenance dose indefinitely; it’s too soon to tell if patients eventually will be able to stop taking Palforzia yet maintain the protection from severe allergic reactions.

The U-M allergy clinic may begin offering the treatment to patients as soon as the fall of 2020.
Fulfilling a key metric from its five-year plan, the MHWFAC invited food allergy scientists, industry representatives and regulators to its inaugural symposium, “Mechanisms and Treatment of Food Allergy,” originally scheduled for June 2020. An array of eminent speakers agreed to present at the conference, and registration from scientists worldwide was robust.

Postponed until June 2021 following COVID-related safety concerns, the symposium was replaced by a series of bi-weekly online seminars featuring MHWFAC researchers. The live, interactive series was well-attended by a broad group of researchers and has provided an interactive meeting place for scientists with common interests, pending the return of in-person symposia.
Pilot Grants

Three University of Michigan researchers received pilot grants from the MHWFAC’s Michigan Food Allergy Research Accelerator Program (M-FARA) in July 2019.

The one-year, $50,000 grants are funded by the M-FARA endowment established by an anonymous donor. This gift aims to establish a program designed to transform how individuals understand the fundamental mechanisms that are driving an increase in food allergy rates in both children and young adults. Additionally, the program seeks to develop innovative strategies to diagnose and treat food allergies.

Current recipients and their projects are:

- **Taeko Noah, Ph.D.** – Research Investigator, MHWFAC
  “Tuft cells as a driver of reactivity to food allergens”

- **Catherine Ptaschinski, Ph.D.** – Assistant Research Professor, Department of Pathology
  “Role of the intestinal epithelial barrier on the development of Food Allergy”

- **Chase Schuler, M.D.** – Assistant Clinical Professor, Allergy Division, Department of Internal Medicine
  “Investigating biomarkers and mechanisms of food anaphylaxis”
MHWFAC faculty in March hosted fellow researchers from four centers to share discovery and research through lectures and a poster session during the 2020 Mucosal Immunology Symposium.

The Society for Mucosal Immunology – Michigan Local Chapter event, organized in part by MHWFAC Research Assistant Professor Catherine Ptaschinski, PhD, and Research Investigator Taeko Noah, PhD, brought together researchers from the University of Michigan, Michigan State University, Wayne State University, and the University of Toledo for discussion of current topics in immunology at mucosal surfaces.

MHWFAC Scientific Director Nicholas Lukacs, PhD, delivered the keynote address at U-M's Palmer Commons.
Outreach
As one of a handful of clinics nationwide to include a behavioral specialist on its staff, the U-M clinic is at the forefront of this holistic approach to food allergy management.

Kim Menzel, LMSW, ACSW, is a full-time, integral member of the Michigan Medicine Food Allergy Clinic care team, thanks to a grant via the MHWFAC. She meets with all patients and their families to manage anxiety, identify gaps in food allergy knowledge, and develop coping strategies.

As a complement to Ms. Menzel’s work, and thanks to a grant from a generous supporter, the Michigan Medicine Food Allergy Clinic is able to offer a free download of a guide to managing anxiety from the publication Allergic Living to up to 1,000 patients. This 90-page special edition includes expert advice, human-interest features and practical tips for every household coping with food allergy.
To extend psycho-social support beyond the clinic, the MHWFAC is sponsoring a new "Conversations with a Food Allergy Counselor" monthly webinar series, to help families be careful – but not fearful – in managing food allergy.

During the free, live sessions, Kim Menzel, LMSW, ACSW, and special guests take audience questions and discuss topics such as food allergy-related anxiety, managing a new diagnosis of food allergy or FPIES, navigating treatment, transitions to school and university, and coping strategies to reduce the everyday stress of both caregivers and individuals with food allergy.

Recordings are posted on the MHWFAC YouTube channel, and a companion blog featuring more coping and skills-building tips will launch in early FY21.
A new public health initiative, supported by the MHWFAC, is analyzing billions of health insurance records to elucidate trends in the incidence of food allergy – from age and gender to geographic distribution.

To date, the understanding of food allergy prevalence and trends has been limited by available data. Most of the nationally representative data come from self/parental reports, which are known to provide overestimates. Alternative data sources are small and subject to selection bias. These problems have prevented recognition of food allergy as a public health problem, limited resources available for accommodations for patients and stymied efforts for treatments.

The study, “Understanding the Epidemiology of Food Allergy in the US,” will be conducted in conjunction with the University of Michigan’s Gerald R. Ford School of Public Policy and the U-M School of Public Health.

“As clinicians and researchers, we are excited at the opportunity to perform this analysis,” said MHWFAC Director Baker. “More information about ongoing trends in who develops food allergy will, we hope, improve the allocation of public resources toward treatment and research.”

This project will contribute to the literature on the epidemiology of food allergy by analyzing a unique database of 24 billion privately billed healthcare procedures that covers over 15 million individuals since 2007. Access to these proprietary data will be gained through a partnership with the national, independent nonprofit, FAIR Health.

The research is funded via MCubed, a U-M program that stimulates innovative research and scholarship by distributing real-time seed funding to multi-unit, faculty-led teams.
Communications

As the MHWFAC gathers momentum in discovery, outreach and interdisciplinary collaborations, additional communications resources have been developed. Led by a veteran advisor familiar with the global food allergy arena and an experienced communications director, recent efforts include:

• An updated, newsier website, UofMFoodAllergy.org
• Quarterly electronic newsletters
• Curated list-servs for scientists, supporters, patients and the general public
• Social media outreach via Twitter @UMFoodAllergy, Instagram and YouTube
• Press releases and additional media cultivation

• Event publicity
• Outreach to food allergy influencers and bloggers
• Consistent branding and marketing efforts for webinars and symposia
• Enhanced communication with major donors
• Upcoming “Giving BlueDay” digital fundraising campaigns
@UMFoodAllergy

- Established Twitter account February 2019; 402 impressions
- Grown to 280 quality followers including clinicians, advocates, families
- Frequently amplified by influential social media accounts
- June 2020: 9,379 impression
Support Food Allergy Research

Together, we can make a difference for patients with food allergy.

To learn more about our faculty, our research and giving opportunities, contact MHWFAC Development Officer Allyson Mlynarek at (734) 763-7080 or adoan@med.umich.edu

Photo credits:
Melissa Scola: Nature photography, Researchpalooza, various headshots
Camren Clouthier: Immunology Symposium
U-M Communications: Headshots, Laboratory Photography