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**Leading medical research fuels cutting-edge patient care**
The past year has been one of profound and positive change for our department. Since coming on board as chair of the Department of Medicine (which is part of UHealth—the University of Miami Health System, South Florida’s only university health system) in May 2007, the department has witnessed great progress and undergone much change as we continue on our quest to become one of the best departments of medicine in the nation.

We have added many new recruits to our impressive list of faculty, which has grown from approximately 260 members to more than 316, including eight new division chiefs and nearly 60 faculty, with an additional 100 potential recruitments underway.

One of the ways we are reinvigorating the department is by developing an even stronger leadership team. Efforts in this area have been very successful, due to pivotal recruitments in the following areas:
Chair’s Report

**Cardiovascular**—Joshua M. Hare, M.D., is the chief of the Cardiovascular Division (UHeart) and director of the Interdisciplinary Stem Cell Institute. He is leading the world’s first stem cell trial that will eventually lead to the treatment of patients with heart failure using a non-surgical treatment that repairs the heart muscle itself.

**Endocrinology**—Antonio C. Bianco, M.D., Ph.D., from Harvard Medical School, has come on board as division chief of the Division of Endocrinology. He is an extremely talented investigator in thyroid disease. Among his initiatives will be substantial recruitment in the areas of type 2 diabetes and metabolic bone disease. Both of these areas are ripe for collaborative growth and expansion on our campus.

**Gastroenterology**—Maria T. Abreu, M.D., the division’s enthusiastic new chief, has doubled the size of the division with multiple recruitments underway. Prior to coming on board, Dr. Abreu was the director of the Inflammatory Bowel Disease (IBD) Center and an associate professor of medicine in the Division of Gastroenterology at Mount Sinai School of Medicine in New York.

**Hematology and Oncology**—Mark D. Pegram, M.D., an internationally renowned cancer expert who was a co-investigator on the landmark research that led to the development of Herceptin, the first FDA-approved targeted therapy for use in early-stage HER-2 positive breast cancer, recently joined the Division of Hematology-Oncology. He will continue to develop novel therapeutics as well as antibody and chemotherapy combinations therapies for breast cancer.

**Krishna Komanduri, M.D.** from the University of Texas M.D. Anderson Cancer Center, also joined the department as the director of the division’s burgeoning Stem Cell Transplant Program. He replaces Mark Goodman, M.D., assistant professor of medicine, who acted as the interim director of the program. Dr. Komanduri will help to develop a nationally prominent program in bone marrow transplantation, which will integrate novel science as well as expand clinical indications and activity in stem cell research.

**Hepatology**—Paul Martin, M.D., from Mount Sinai School of Medicine in New York City, has assumed the helm of the Division of Hepatology and is aggressively recruiting faculty with interests in transplantation and hepatocellular carcinoma (primary cancer of the liver).

**Hospital Medicine**—Amir Jaffer, M.D., from the Cleveland Clinic Lerner College of Medicine and with significant assistance from Joshua D. Lenchus, D.O., R.Ph., and Efren C. Manjarrez, M.D., has rapidly established a robust Division of Hospital Medicine providing superb hospitalist services at the new University of Miami Hospital.

**Nephrology**—Jochen Reiser, M.D., Ph.D., from Harvard Medical School, already has recruited Drs. Mundel, Wolf, Faul, and Gupta and has many other exciting recruitments underway. Dr. Reiser’s clinical interests lie in the areas of chronic kidney diseases, proteinuria syndromes, and end-stage renal disease.
I am very pleased that **Mauro Moscucci, M.D.**, former professor of medicine at the University of Michigan, is vice chair of our Department for Clinical Affairs. Mauro brings great skills in the organization of complex clinical research enterprises. He also will direct the Humana program.

I would like to thank three other departmental leaders who have made enormous contributions to the department. **Sheri Keitz, M.D., Ph.D.**, has been a major force in reviving the department's activities at the Veterans Administration (VA). Teaching programs and clinical care are set to improve dramatically under her leadership. **Robert W. Hoffman, D.O.**, has made substantial progress in helping develop departmental research initiatives. He has begun a monthly departmental research seminar series, developed a credible inventory of departmental research space, including occupancy and grant support, and he is playing a critical role in space reallocation. Finally, **Steve Symes, M.D.**, along with his team, has done a fantastic job with our house staff by improving teaching, morale, Accreditation Council for Graduate Medical Education (ACGME) compliance, and our performance in the match.

In addition to our overall increase in clinical and non-clinical faculty, there has been an increase in National Institutes of Health (NIH) funding from $6.7 million in FY 2006 to $17.7 in FY 2007. Although some of these components represent funding to the Genetics Institute currently ‘housed’ in the Department of Medicine, we have experienced significant expansion in our research activities, and growth next year will be even more robust.

We do face some challenges. With such fast-paced growth, the department must address critical space needs. Since clinical, office, and research space are all at a premium here in South Florida, we have begun to aggressively reallocate some departmental space while we continue to consider new space opportunities. We hope to have more news on this front very soon.

Lastly, I want to thank our entire faculty and staff for their extraordinary efforts and continued support during this past year and beyond. I believe the department is poised for greatness and your continued dedication will undoubtedly translate into major successes not only for each of you personally, but for our department as a whole. I look forward to working closely with you in the months and years to come.

Marc E. Lippman, M.D.
Kathleen & Stanley Glaser Professor and
Chair of the University of Miami
Miller School of Medicine
Department of Medicine
Dr. Marc Lippman’s arrival and subsequent efforts in developing a first-rate academic department of medicine has required substantial administrative support. The management infrastructure has grown in size and expertise, assuring that adequate support is available.

During the fiscal year 2008, more than 94 potential faculty members were recruited. As a result, 55 new faculty members were signed on to the department, many of them physician-scientists. The administrative team has worked tirelessly assuring that both pre- and post-award activity designed to support researchers is available to every scientist. In addition, many of the new faculty have required laboratory space. Defining such locations and then renovating these laboratories has been demanding yet satisfying work.

The finance section of the department was active due to the implementation of two new programs developed by Dr. Lippman. First, each faculty member in the department now has an individual profile that describes that person’s effort. Administrative and research responsibilities are quantified based on funding. Clinical effort is defined as a combination of half-day clinic services as well as inpatient ward and consultation service attending.

The faculty profile system has served as a base for the new clinical incentive program. Bonuses are paid based on the relative value unit (RVU), a factor used in pricing of medical services generated. Benchmarks are based on national standards for individual specialties. Individual benchmarks are prorated based on the percent of clinical effort. RVUs that are higher than the 60th percentile for a given specialty are paid a bonus based on a specified dollar value per RVU. A total of 28 percent of the faculty earned an incentive payment. The future goal is that 100 percent of faculty are producing at a level that warrants payment.

There are numerous positive things about this program. First, faculty are able to see a direct result of their clinical work. The program is easy to understand and is fair and equitable. Since payments are based on RVUs generated, not on clinical dollars collected, it makes little difference to individual faculty what type of insurance their patients have.

An office of business development was created in an effort to foster a productive relationship with the private medical community in the region and to oversee practice expansion. This unique entity is charged with identifying and bringing forward clinical expansion opportunities off-campus that will help drive the expected rapid growth of the health system.

During the next year the administrative group has several defined goals. First and foremost it must assure the management infrastructure provides the highest level of support available so that faculty can see patients, conduct research, and teach trainees. Major areas of focus include improving billing operations, improving patient access and patient satisfaction survey results, and defining a more timely and accurate budgeting process. The group plans to develop an administrative bonus system, which will reward individuals for meeting defined goals. We believe it will be important to develop an employee recognition program designed to acknowledge exemplary performance.
The Office of Research in the Department of Medicine promotes and facilitates ethical clinical, translational, and basic research of the highest scientific caliber.

Established in 2007, the Office of Research helps investigators and the Department of Medicine community in meeting the varied administrative and regulatory requirements of the University of Miami Miller School of Medicine. The office is a shared resource for the department and serves as an information warehouse, a training resource, as well as a consultative unit. The office is responsible for developing a culture of regulatory compliance through training, education, grant review, and other monitoring processes.

The newly constructed Miller School of Medicine’s 15-story Clinical Research Building, which opened in late 2006, accommodates researchers from a wide range of disciplines who are now located throughout the medical campus. It’s also home to the Miller School’s Clinical and Translational Science Awards (CTSA) initiative.
During the past year, the office has had many significant accomplishments. We launched the first Department of Medicine Office of Research website; developed a new research database, which helps the department keep the most up-to-date research information on each faculty member and division’s efforts; reviewed and approved over 350 proposal submissions from within the department and from external departments as well; reviewed and approved all sponsored-related transactions; assisted all new investigators with the transfer of their grants; trained new investigators and staff on the submission and management of research projects; and launched a monthly departmental research seminar series with overwhelming positive feedback.

Currently, the Department of Medicine has over 350 funded ongoing research projects with more than $36 million in extramural funding; this includes research in the Clinical Research Building, the Diabetes Research Institute, Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine, the University of Miami Hospital, as well as many other sites. This research has often been made possible or greatly enhanced by philanthropic gifts, including endowed chairs.

As federal funding for research (such as that provided by the National Institutes of Health) has declined in terms of real dollars during the past eight years, philanthropic support has taken on increasing importance. Very often research funded though gifts, or other endowments that support the research in the early phases of development and discovery, are essential to enable such projects to evolve into major research trials or studies that can then successfully compete to obtain extramural federal or corporate funding. Such generous private-public partnerships have allowed the University of Miami to grow to international stature in medical research.
The Department of Medicine continues to lead the University of Miami Miller School of Medicine in medical student education. Our faculty is responsible for approximately 30 percent of all the teaching during the entire four-year curriculum and receives over $1.2 million in direct support from the school for these efforts—more than any other department.

Medical student education is a key component of the department’s mission.
The top levels of the administration are populated by Department of Medicine faculty, including Mark O’Connell, M.D., senior associate dean for medical education and the recipient of the Bernard J. Fogel, M.D., Endowed Chair in Medical Education, Robert Hernandez, M.D., senior associate dean for medical student administration, and Alex Mechaber, M.D., associate dean for undergraduate medical education. After many years of dedicated service to help bring diversity to the Miller School of Medicine, Astrid Mack, Ph.D., associate dean for minority affairs, retired this year. In addition, department faculty members direct many of the courses, clerkships, longitudinal themes, and other educational programs. Some of the highlights are listed below.

**Years One and Two: The Basic Sciences and the Organ System Modules**

After receiving a foundation of traditional basic sciences during the first six months, the remainder of the first two years is taught in organ system modules, where organ system-specific basic sciences and clinical aspects of health and disease are taught together. This “new” curriculum is no longer new, and these modules, many of which are directed by department faculty, now are all well-run courses, showcasing innovation in medical education.

For example, during the Renal Module, Warren Kupin, M.D., arranges a tour of a dialysis facility for students while a select few get to observe a kidney transplant. Maureen Lowery, M.D., successfully coordinates the interdisciplinary approach used during the Cardiovascular Module, bringing together pathology, physiology, pediatrics, and genetics. She also works with the Gordon Center for Research in Medical Education and uses simulation to teach the relationship between physical exam findings and pathophysiology. Many of the modules are moving to small group teaching, known to be a more effective method of learning. This past year, Rheumatology (Elaine Tozman, M.D.) and Infectious Diseases (Gio Baracco, M.D.) were taught primarily through small group case-based learning, complemented by traditional lectures. Our students’ performance on the USMLE Step 1 exam is above the national average and has been improving on a yearly basis.

**Doctoring Course/Longitudinal Themes**

Department of Medicine faculty also direct several of the longitudinal themes that span either the first two years in the Doctoring Courses or throughout the entire four-year curriculum. The Clinical Skills Theme (Alex Mechaber, M.D.) exposes the students early in their first year to patients via community preceptors and faculty mentors. Students consistently perform well during their end-of-year competency exams, which mimic the USMLE Step 2 Clinical Skills Exam. Our students have a remarkably high pass rate. The Population Health Theme (Erin Marcus, M.D.) teaches about public health, screening and prevention, and health literacy. Dr. Marcus, working with Thomas Hooton, M.D., also has just started a four-year Medical Student Women’s Health Pathway. A small select group of students interested in Women’s Health receive intensive mentorship, attend monthly seminars, and present research findings at the Institute of Women’s Health Annual Research Day. The Geriatric Theme and Clerkships (Michael Mintzer, M.D.) offer a well-structured four-year curriculum, much of which is competency-based. They have expanded a great deal utilizing computer-based and web-based learning.
Years Three and Four: The Clinical Years

The third year Internal Medicine Clerkship (Paul Mendez, M.D.) continues to be highly regarded by the students for both the residents’ and faculty’s enthusiasm for teaching. This year, rotations have expanded to the Sylvester Comprehensive Cancer Center and to the sub-specialty ward teams at Jackson Memorial Hospital. The fourth year Ward Medicine Sub-Internship (Mark Gelbard, M.D.) continues to be the best preparation for internship the school has to offer.

Miller School at FAU

The faculty at our Miller School of Medicine at Florida Atlantic University’s regional campus has been very busy implementing a new curriculum. This new curriculum, now in its second year, focuses more on the chronic illness and continuity care model. Plans are for these students to stay in Palm Beach (and not travel to Miami) for their clinical third and fourth years. The students have a longitudinal continuity patient panel they will follow throughout their four years. The program is administered by Daniel Lichtstein, M.D., and Stephanie Wragg, Ph.D., with the assistance of many other department faculty.

Match

In contrast to the national trend, Internal Medicine continues being one of the most popular career choices among Miller School of Medicine graduates. Twenty-four percent of the graduating seniors matched into internal medicine or medicine/pediatrics residency programs this year. We continued a trend of sending students to excellent programs across the nation, and as in past years, a nice-size cadre of students will stay in Miami. This year, four of the 12 staying for categorical internal medicine spots are Alpha Omega Alpha (AOA) students. AOA is the honor society for medical students, residents, and faculty.

Student Awards

The Eric Reiss Outstanding Student in Medicine Award was awarded to Jonathan Colasanti, M.D., for the best performance during the Internal Medicine clerkship. Kathleen “Molly” McShane, M.D., was the recipient of the American College of Physicians Award, which is given to the student who best exemplifies the principles, skills, and spirit an internist. The Department of Medicine Professionalism Award was awarded to Rosario “Russ” Colombo, M.D. All of these seniors graduated in May (Class of 2008).

Faculty Awards

The department and several of its faculty received several coveted school-wide teaching awards this year. The Cardiovascular Module was voted as the most outstanding pre-clinical course and the internal medicine clerkship was selected as the most outstanding clinical clerkship. Kudos to Maureen Lowery, M.D., and Paul Mendez, M.D., respectively, as well as all the other faculty and residents who teach in these courses. Joe Esterson, M.D., was awarded the B. K. Simon Award for best teacher and mentor by the graduating senior class for the second year in a row. Three of the four George Paff Teaching Awards, voted on by each class, went to Drs. Esterson, Don Temple, and Alex Mechaber. As a reflection of his many years of dedication to the school, Mark O’Connell, M.D., received the University Faculty Senate’s prized annual Outstanding Teaching Award. Earlier in the year, he was also endowed the Bernard J. Fogel Chair in Medical Education.

Due to the talents, efforts, dedication, and leadership of many faculty in the Department of Medicine, our medical students continue to receive an outstanding education. Our medical students clearly appreciate the department’s efforts and, as such, we owe them a debt of gratitude for making our medical school’s undergraduate medical education programs such a success.
The Internal Medicine Training Program at Jackson Memorial Medical Center, selects 38 highly competitive medical graduates—many from the University of Miami—from over 3,000 applicants each year to train in the specialty of Internal Medicine. Full-time faculty (numbering more than 400) with the University of Miami Miller School of Medicine’s Department of Medicine, serve as role models, clinician teachers, and research mentors.

Our program successfully prepares residents for future careers in general and subspecialty medicine. The patient population we serve includes those from all walks of life and socio-economic status within Miami-Dade County, neighboring counties, and the Southeastern United States. We also serve as a respected referral center for patients from Latin America, the Caribbean, and the rest of the world.
The diverse patient population seen at our three principal institutions—Jackson Memorial Hospital, the Miami Veterans Affairs Medical Center, and the University of Miami Hospital and Clinics, all part of the UHealth network—provide house staff with a challenging wealth of unique clinical encounters and opportunities.

Examples of “best practices” within our training program include programs on resident scholarly activity, as well as patient safety and procedures. Within the newly created specialty residency training track in Hospital Medicine, Joshua Lenchus, D.O., R.Ph., F.A.C.P., has created a formalized instructional curriculum, which specifically focuses on achieving competency, safety and expertise in invasive bedside procedures, specified by the American Board of Internal Medicine. Under this new training concept, invasive bedside procedures are taught by a multi-disciplinary team of attending physicians from the Miller School faculty. Each procedure is packaged as an individual module, complete with 12 components, and an innovative checklist helps appraise the resident’s baseline technical proficiency. Informed consent, self-assessment, and patient safety, are key elements of the training process.

The Resident Scholarly Activity Program (RSAP), spearheaded by Leonardo Tamariz, M.D., M.P.H., is a three-phase curriculum aimed to improve the quality of the research projects pursued by the residents and increase the number of projects submitted for publication in peer-reviewed journals. The first phase of the curriculum starts in the first year of training with a series of lectures to facilitate identifying mentors, preparing an IRB proposal, and improving epidemiological and biostatistical knowledge. The second phase of the curriculum continues with research-in-progress meetings in the second year to assure research milestones and the quality of each project. The third phase is a formal presentation of the research methods and findings during the third year of residency.

UHealth is a comprehensive network of six hospitals, two dozen outpatient facilities, 1,200 doctors, and more than 8,000 associates. As the region’s only university health system, UHealth is a vital component of the South Florida community.
Program Overview
Our goal is to train residents to be skilled internists and to have the ability to be expert self-learners as they progress into our everchanging health system. Our vision is to mentor the future leaders in academic medicine. To this end, we have established and emphasized a clear foundation of core internal medicine clinical experiences and curricular content in the form of lectures/case-based discussions, simulation, and web-based training. We fully endorse and emphasize the competencies as described by the Accreditation Council for Graduate Medical Education (ACGME), which include patient care, medical knowledge, professionalism, systems-based practice, practice-based learning and improvement, and interpersonal and communication skills.

Core Curriculum
The foundation of the Internal Medicine Training Program takes place through a wide range of learning methods. A key component is experiential learning, where every resident rotates through a variety of inpatient and outpatient venues. These include General Medicine wards, subspecialty wards (such as Hematology, Oncology, Cardiovascular Medicine, and Nephrology) ICUs (medical and cardiac), Emergency Room, Research, Ambulatory, and Geriatrics rotation.

Regularly scheduled didactics include the Emergencies in Medicine lecture series, Morning Report, Core Curriculum Noon Conferences, Grand Rounds, Resident Update and Feedback Session, Journal Club, which includes the Cardiovascular Disease Forum, Board Review, Hospitalist Grand Rounds, Evidence Based
Veterans Affairs

It has been the best kept secret until now. The Veterans Administration (VA) has been nationally recognized by a variety of publications, including The New York Times, The Washington Post, and Business Week for providing “the best care anywhere.” As VA staff, it’s nice to see our hard work receive national recognition.

The VA has become the standard-bearer for quality in American health care; we’ve made headlines in customer satisfaction and patient safety. The VA’s electronic health record system has earned Harvard University’s prestigious “Innovations in American Government” award and the Miami VA Healthcare System has won the Sterling Award for “Best in the VA System.”

Recognizing

Medicine (EBM) Lecture Series, Resident Scholarly Activities Program, and Jay Weiss Grand Rounds. Intermittent special conferences include workshops on teaching residents how to teach, tips on fellowship application, and career preparation.

Traditional experiential and didactics training methods are supplemented by web-based educational programs, simulation training, and innovative one-on-one faculty interaction. A classic example is our recently instituted Patient Safety and Procedure Service, in which each second year resident undergoes simulation training and then is directly supervised for every procedure at the bedside with a faculty member.

Every resident also pursues an individualized scholarly project. Projects can range from review articles or chapters in textbooks to retrospective studies, clinical trials, and bench research. Each resident is assigned a core faculty advisor, one of the five program directors, who will assess their progress toward competence, review evaluations, and identify target areas for improvement. The core faculty advisor also focuses residents toward career-oriented personalized training by referral to specialized mentors and early exploration of various career pathways.

Dr. Mendez leads a group of graduate and undergraduate students during rounds at Jackson Memorial Hospital (JMH).
The Cardiovascular Division brings together many of the world’s leading experts in cardiovascular medicine and research. Under the leadership of Joshua M. Hare, M.D., F.A.C.C., F.A.H.A., division chief and director of the Interdisciplinary Stem Cell Institute, and Alan W. Heldman, M.D., F.S.C.A.I., interventional cardiologist and professor, the division’s expert cardiologists provide patients with the highest quality of care by performing a full range of cardiovascular procedures using the latest technology in state-of-the-art facilities. Advanced technology and cutting-edge treatments are offered at all of the practice locations and use a caring, thoughtful, patient-centered approach.

University of Miami Health System cardiologists (UHeart) see patients at the University of Miami Hospital (UMH), at other University of Miami locations, and at Jackson Memorial Hospital (JMH). The team performs groundbreaking procedures in the areas of electrophysiology (including atrial fibrillation ablation), complex and investigational procedures in interventional cardiology (including percutaneous aortic valve replacement), the most advanced treatment options for congestive heart failure and cardiomyopathy (including heart transplantation), and leads research in the use of bone marrow derived stem cells to repair heart muscle in patients who have suffered a myocardial infarction.

Joshua Michael Hare, M.D., F.A.C.C., F.A.H.A.
Division Chief/Louis Lemberg Professor
Director, Interdisciplinary Stem Cell Institute

Gervasio Antonio Lamas, M.D., F.A.C.C., F.A.H.A.
Associate Chief and Professor

Ray E. Hershberger, M.D.
Chief, Miami Veterans Affairs Medical Center and Professor

Pat Caralis, M.D., J.D., associate program director, Internal Medicine Residency Program, and associate chief for education, received the University’s Provost’s Award for Teaching Excellence this year.

The hard work continued this year, with some of our VA-funded researchers receiving recognition and making major contributions to national knowledge.

Hermes Florez, M.D., in the Divisions of Endocrinology and Gerontology, received the first UM K12 award, supported by the Dean’s office, which provides four years of research support for scientific career development.

The Nephrology section has been prolific: Ivonne Schulman, M.D., Edgar Jaimes, M.D., and Leopoldo Raji, M.D., section chief, presented innovative research on Insulin Resistance in Salt-Sensitive Hypertension: Role of NFkB Activation by Angiotensin II at the XVIIth Scientific Meeting of the Inter-American Society of Hypertension. Dr. Schulman was awarded an honor as “Young Research Investigator” for her presentation by the Miami VA.

Gordon Dickinson, M.D., chief of the Division of Infectious Diseases and VA Section Chief, co-hosted the XIII International Course on Infectious Diseases in Buenos Aires, Argentina, and the XIV Comprehensive Meeting on AIDS in Cali, Colombia.

Robert Hoffman, D.O., chief of the Division of Rheumatology and Immunology and VA Section Chief, has been continuously funded by the National Institutes of Health (NIH) and the VA since beginning his career. His work has led to the hypothesis that systemic lupus erythematosus, or lupus (SLE), is a T-cell-dependent, antigen-driven immune process. His current research seeks to dissect the molecular mechanism behind selective loss of self-tolerance in these diseases.
A Revolution in Cardiac Medicine

Imagine the ability to treat patients with heart failure using a procedure that repairs the heart muscle itself. Stem cell researchers in the Cardiovascular Division at the University of Miami Miller School of Medicine are one step closer to achieving that goal. Recent approval from the Food and Drug Administration (FDA) is allowing them to conduct a stem cell therapy research study using a needle-tipped catheter system to inject adult bone marrow-derived stem cells directly into the heart.

Adult stem cells derived from bone marrow are injected into the heart and tested as a potential therapy to promote cardiac muscle repair after myocardial infarction.
If this novel approach proves successful, tens of thousands of patients could benefit. This trial adds to the ongoing NIH-funded work being conducted within the Cardiovascular Division to develop stem cell therapy. The division’s unique environment fosters excellence both in basic scientific work and in clinical investigation. Meanwhile, active basic programs studying heart-derived cardiac stem cells may soon also lead to clinical investigation as a treatment for heart attack and heart failure.

BioCardia, a California-based biotechnology company, developed the minimally invasive percutaneous catheter system for the safe delivery of cells to the heart through a helical, or spiral-shaped, needle. Joshua M. Hare, M.D., F.A.C.C., F.A.H.A., division chief and director of the Interdisciplinary Stem Cell Institute at the Miller School, will lead the world’s first stem cell trial of this type. Alan W. Heldman, M.D., F.S.C.A.I., an interventional cardiologist and professor in the Cardiovascular Division, has been using the BioCardia Helical Injection Catheter to inject stem cells into the heart in preclinical stud-

A handful of groundbreaking cardiac stem cell trials being conducted by the Cardiovascular Division offer great lifesaving promise for people with heart disease.

Advancing stem cell research is translating into better patient care.
For those elderly patients who suffer from aortic stenosis—a potentially life-threatening narrowing of the valve that restricts blood flow—a revolutionary, minimally invasive heart procedure may prove to be a viable new option for them. The new procedure is a percutaneous catheter-based aortic valve replacement, and it is currently being investigated in an FDA-regulated clinical trial, available at a handful of select facilities across the nation. The University of Miami is the only facility in Florida offering this investigational option.

William O’Neill, M.D., F.A.C.C., and Alan W. Heldman, M.D., F.S.C.A.I., implanted the new heart valve in the first two patients at the University of Miami Hospital in April 2008. Just days after undergoing the valve replacement procedure, patients experienced dramatic relief of symptoms, such as shortness of breath and fatigue.

Predicting the Outcome for Heart Failure Patients

Bettina Heidecker, M.D., a postdoctoral fellow in the Cardiovascular Division, recently won the highly prestigious Samuel A. Levine Young Clinical Investigator Award. The national award, recognizing innovative research and promoting careers in clinical cardiovascular investigation, honored Dr. Heidecker’s discovery of a groundbreaking new way to predict the outcome for heart failure patients. Dr. Hare and three other scientists from Johns Hopkins University and Brigham and Women’s Hospital worked with Dr. Heidecker on the study of an expression profiling test that was able to predict the risk of deterioration in patients with new onset heart failure.

A Minimally Invasive Alternative to Open-Heart Surgery?

For those elderly patients who suffer from aortic stenosis—a potentially life-threatening narrowing of the valve that restricts blood flow—a revolutionary, minimally invasive heart procedure may prove to be a viable new option for them. The new procedure is a percutaneous catheter-based aortic valve replacement, and it is currently being investigated in an FDA-regulated clinical trial, available at a handful of select facilities across the nation. The University of Miami is the only facility in Florida offering this investigational option.

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Advanced Cardiac Electrophysiology

Under the direction of Vivek Y. Reddy, M.D., cardiologists at the University of Miami are developing highly sophisticated ways of performing intricate procedures to cure arrhythmias such as atrial fibrillation and ventricular tachycardia. Dr. Reddy and his team are world leaders in applying imaging techniques and new ablation technologies to enhance the accuracy and effectiveness of ablation procedures.
Most patients with heart disease are treated with broad-spectrum drugs such as beta blockers (which target more than one area of the body), often causing unwanted side effects. Many cardiac medications used today were developed decades ago and work by blocking certain receptors at the cell’s surface. Researchers in the Cardiovascular Division, including Michael S. Kapiloff, M.D., Ph.D., a cell and molecular biologist, are taking science a step further by examining the signaling processes that occur deeper inside the cell. By closely examining the individual molecules responsible for cell behaviors, they hope to identify intracellular targets (rather than cell-surface receptors) for novel heart failure medications. One such protein, mAKAP, is found on the cardiac myocyte’s nuclear membrane and is critical in the heart’s response to stress.

Dr. Kapiloff’s team also has been performing screens for novel scaffolding proteins that bind specifically to calcineurin Aβ, a phosphatase isoform required for cardiac hypertrophy. The identification of new regulatory molecules that are involved in the development of cardiac hypertrophy and/or heart failure may lead to potential therapeutic targets for these common cardiac syndromes.
The **Division of Clinical Pharmacology** offers a top-quality research service, a network of university-based collaborating research scientists, and stringent quality assurance that conform with FDA regulatory requirements. The division has the technology to conduct a wide variety of clinical trials and can provide the required scientific and pharmacokinetic support in conducting clinical research studies.

The division also conducts original research in the areas of hypertension and renal disease, pharmacokinetics in diabetes mellitus, the effect on renal potassium excretory function of various antihypertensive drugs, platelet aggregation, and the clinical pharmacology of antibiotics, anti-hypertensives, central nervous system drugs, and cardiovascular agents.

**Combating Severe High Blood Pressure**

It is often called the “silent killer” because individuals with the condition typically have no recognizable symptoms until it’s too late. That’s because if left uncontrolled, high blood pressure can lead to stroke, heart attack, heart failure, and even kidney failure. Still, very little is known about how blood pressure damages the artery or how blood pressure gets so high in the first place.

**Prevalence of High Blood Pressure in Americans**

Behavioral Risk Factor Surveillance System, 20 states, 2005

![Graph showing the prevalence of high blood pressure in Americans by age group](image)
Richard M. Preston, M.D., and his team are examining the mechanisms of severe high blood pressure (systolics greater than 180), which afflicts about one to two million Americans. What they’ve found is that the platelets in those with severe hypertension are activated to a higher extent than in normal patients or patients with mild hypertension.

There also seems to be an important link between platelet activation, thrombosis, and vascular injury, since platelets seem to be partly responsible for the vascular damage often found in these individuals. This research should help shed light as to why some people develop severe hypertension so that better weapons can be created to prevent it.

Since hypertension is a risk factor for cardiovascular disease, effectively lowering blood pressure while also treating the symptoms of menopause would be a welcome therapy for these women.

Novel Hormone Replacement Therapy for Post-Menopausal Women

The division also has an ongoing funded pilot study investigating the effect of a novel compound known as drospirenone-estradiol (a drug Dr. Preston has been studying since 1999) as a preferred hormone replacement therapy for post-menopausal women who are also pre-hypertensive—women with blood pressure in the 130-140 over 85-89 range. For many women going through menopause, especially those in this “gray zone” of hypertension, blood pressure can continue to increase over time, especially with the consumption of salty foods.

Since hypertension is a risk factor for cardiovascular disease, effectively lowering blood pressure while also treating the symptoms of menopause (such as the unpleasant hot flashes typically associated with it) would be a welcome therapy for these women.

What Dr. Preston’s team has found is that this particular compound packs a powerful, potentially life-saving punch. The estrogen estradiol helps reduce the number and severity of hot flashes, while the progestin drospirenone not only protects the uterus from cancer, it has also been found to lower blood pressure as well as any hypertensive drug. These findings, especially the compound’s ability to effectively lower blood pressure, could pave the way for its use as a beneficial hormone replacement therapy for many post-menopausal women with pre-hypertension. Patients should beware of the potential hazards of hormone replacement therapy, which include cardiovascular disease, blood clots, and heightened cancer risk.
People with severe kidney disease and chronic renal failure may benefit from additional studies that Dr. Preston and his colleagues currently are conducting. Here’s what they know: As kidney disease progresses, most individuals will begin to have problems processing the potassium in their bodies, which can lead to high levels of potassium in the blood, a condition known as hyperkalemia. At its worst, hyperkalemia can cause rhythm problems in the heart, that if severe enough, can lead to cardiac arrest.

Several clinical trials over the last decade have examined many of the drugs on the market that help slow the progression of kidney disease, concluding that these medications also work for congestive heart failure and other forms of cardiac disease. The problem is that these drugs also promote the retention of potassium by the kidneys, which can pose dangerous health risks to some patients. To better identify those individuals with chronic renal failure who could safely benefit from such drugs (without predisposing them to the development of hyperkalemia), this team of investigators is testing two different generic drugs to identify those patients who could benefit from the drug’s long-lasting benefits without developing a potassium retention problem.
Located in the heart of the medical center, members of the Division of Emergency Medicine provide emergency care at the Jackson Memorial Hospital Emergency Care Center (JMH ECC), a high-volume, high-acuity emergency department that offers a full range of patient services. Their clinical education role is conducted at the JMH ECC and at the Miller School’s Gordon Center for Medical Education, where division faculty members ensure that physicians-in-training, medical students, and EMS paramedics receive top-notch academic preparation.

Emergency medicine clinicians represent a team of specialists that provide direct patient care for emergencies that range from acute, life-threatening cardiac emergencies to all types of acute medical conditions and injuries, treating emergency patients of all ages. In their role as educators, faculty members provide one-on-one training with hands-on experience in the emergency department, which serves as a rich educational environment for resident physicians and medical students. A wide variety of classroom education is also provided, including lectures, conferences, procedural skills labs, and simulation training. Our faculty members also conduct cutting-edge clinical research with focused expertise in a variety of areas such as toxicology, pediatric emergency medicine, out-of-hospital emergency care, and emergency cardiac care.

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Division Chief /Professor

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Armando Clift, M.D.
Richard Couce, M.D.
Winifred Fili, M.D.
Carmen Teresa Garcia, M.D.
Marc Grossman, M.D., F.A.C.E.P.
Mitchell Grubman, M.D.
Yoram Gutfreund, M.D.
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Craig Smith, M.D.
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Linda Robinson, M.D., F.A.C.E.P.

Assistant Professor
Ivette Motola, M.D., F.A.C.E.P.
Certian heart attack patients in Miami-Dade County can breathe easier these days, thanks to the landmark, countywide “STEMI Alert” project that was implemented in 2007 by local Fire Departments in conjunction with the Cardiac Division and the Division of Emergency Medicine at the Miller School of Medicine, which is part of UHealth. Called ST-segment elevation myocardial infarction, or “STEMI,” and caused by a completely blocked artery, patients suffering from this type of heart attack are now whisked through the Emergency Department to the Catheterization Lab (“Cath Lab”) much sooner for artery-opening interventions, resulting in reduced damage to the heart and better chances for survival.
As part of the UHealth network of hospitals, Jackson Memorial Hospital and University of Miami Hospital are two of the major STEMI centers for the system, providing outstanding coordination of care between prehospital paramedics, emergency department, and cath lab personnel, including many physicians in the Divisions of Emergency Medicine and Cardiology. All six fire rescue departments in Miami-Dade County joined together in 2007 to form one of the first countywide STEMI networks in the United States. Under the coordination of Miami-Dade County Fire Rescue and its Emergency Medical Services Medical Director Donald Rosenberg, M.D., professor of cardiology at the Miller School of Medicine, the project sets performance goals and tracks critical data on all STEMI patients. Under the direction of the City of Miami EMS Medical Director Kathleen Schrank, M.D., division chief and professor of emergency medicine, a similar but much smaller program has been in place since 1996. All fire rescue paramedics are now trained to diagnosis acute STEMI heart attacks right in the home so that care can begin immediately, with early alerts to the EDs and interventional cardiologists. Most of that training is done through the Miller School’s Gordon Center for Research in Medical Education.

**Rapid Heart Attack Care**

The division has been a leader in providing patients with prompt treatment for heart attacks. Dr. Schrank, began a pre-hospital program for rapid heart attack care in 1989 by placing 12 lead EKGs onto rescue trucks for early diagnosis. Since 1996, the program also coordinated fire rescue care with transport to specific hospitals that could provide immediate thrombolysis through the use of “clot-buster” drugs. As acute heart attack care moved toward immediate cath lab intervention with emergency angioplasty, she then narrowed the city network criteria for hospitals in 2003 to assure patients were transported to those facilities that could properly perform this procedure.

**Physician Education in Emergency Medicine**

During the first month of medical school, Miller School of Medicine students participate in an “Emergency Responder Course” as part of their doctoring program. Division faculty provide rapid-fire sessions on how to safely approach emergency situations at home or out on the street, and what to do for basic care with minimal resources until fire rescue arrives.

For juniors and seniors, division faculty provide a full clinical clerkship in emergency medicine, where students learn rapid, focused care for patients presenting with the whole spectrum of illnesses and injuries, as well as where underlying causes and diagnoses are not yet known. Simulation lab training is an integral part of this clerkship—an outstanding learning experience for all future physicians.

**Surviving Sudden Cardiac Death**

- Practice preventive measures (eat healthy, exercise, don’t smoke; treat hypertension, diabetes, and high cholesterol)
- Call 911 as early as possible for unconsciousness but also for symptoms of a heart attack or stroke
- Start CPR (learn chest compressions and perform them until fire rescue arrives)
- Rapid AED use (use an Automatic External Defibrillator if one is nearby—it will tell you exactly what to do)
- Fire Rescue (911) will add state-of-the-art resuscitation treatment and transport the victim to the nearest resuscitation center
Survival from Sudden Cardiac Death: Induced Hypothermia

When a healthy 82-year-old woman suffered cardiac arrest (asystole) at home, it took rescuers 45 minutes to re-establish her heartbeat. In the past, her chance of neurologic recovery after such a prolonged cardiac arrest was extremely poor. Now new research has revealed that cooling the victim’s body temperature soon after the pulse is restored can help patients recover fully. That was indeed the case here, where the patient was cooled and then airlifted for emergency angioplasty. Two weeks later she walked out of the hospital fully functional.

Lowering the body temperature to 33°C (92°F) for about 24 hours allows the brain cells to enter into a very low metabolic state, thus protecting them from any damage. Armed with this knowledge, the Division of Emergency Medicine is coordinating a multidisciplinary program across various divisions at Miller School of Medicine, as well as fire rescue and multiple local hospitals, to have this protocol available countywide.

Physicians and nurses from the Emergency Medicine, Neurology, Neurosurgery, Critical Care Medicine, and Cardiovascular have teamed up to establish the Induced Hypothermia Program at Jackson Memorial Hospital (Jackson), which offers this treatment to cardiac arrest survivors around the clock. Jackson was the first Emergency Department in the county to offer induced hypothermia care, beginning in early 2007. As of October 2008, University of Miami Hospital and five other hospitals also began this treatment, and City of Miami Fire Rescue is beginning the cooling process in the rescue trucks.

Multidisciplinary research being conducted in the Miller School of Medicine continues to develop this tool for treating other emergencies. Cooling the body, it seems, also may help victims of traumatic brain and spinal cord injuries, massive strokes, and massive heart attacks.

From left to right, Dr. Schrank with Lieutenant Michael Mesa, Firefighter Jose L. Gonzalez, and Firefighter Damian Beitra from City of Miami Fire Rescue, arriving at the JMH Emergency Care Center.
Diseases of the thyroid gland, bone, and metabolic control including thyroid nodules, osteoporosis, obesity, and diabetes affect tens of millions of Americans and many more worldwide. The Division of Endocrinology, Diabetes, and Metabolism is undergoing integrated research efforts to better understand the fundamental function of these glands and tissues, as well as the disease mechanisms that lead to dysfunction and potentially death. For years, the division has provided quality patient care and hosted a highly sought post-doctoral fellowship training program in endocrinology. Division faculty also lead groundbreaking research in the areas of type 1 diabetes and lipid metabolism, much of it conducted, at or in association with, the Diabetes Research Institute (DRI) of the University of Miami. Antonio Bianco, M.D., Ph.D., the division’s new chief, is an internationally recognized physician-scientist who is working to broaden the research focus of the division to include thyroid disorders, bone metabolic disease, and metabolic syndrome.

Antonio Bianco, M.D., Ph.D.
Division Chief and Professor

Professors
Rodolfo Alejandro, M.D.
Ronald Goldberg, M.D.
Silvina Levis-Dusseau, M.D.
Jennifer Marks, M.D.
Daniel Mintz, M.D.
Jay Skyler, M.D.
Jay Sosenko, M.D.

Emeritus Professor
Lawrence Fishman, M.D.

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Angel Alejandro, M.D.
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Maria Del Pilar Solano, M.D.

Research Professors
Luca Inverardi, M.D.
Ricardo Pastori, Ph.D.

Research Associate Professor
Alberto Pugliese, M.D.

Research Assistant Professor
Armando Mendez, Ph.D.

For Type 1 Diabetes, an autoimmune disease where the body’s own immune system destroys the pancreatic beta cells responsible for making insulin, which regulates blood glucose, much of the research being conducted focuses on ways for patients to successfully achieve insulin independence.

Currently, there is a critical shortage of healthy insulin-producing cells when compared to the number of diabetic patients who could potentially benefit from them. Researchers, including Luca Inverardi, M.D., are looking at developing new complementary sources of transplantable insulin-producing tissue by exploring the use of a variety of cell types such as embryonic stem cells, adult stem cells, cord blood, amniotic fluid, liver cells, among others, to identify optimal alternative sources of insulin-producing cells.
Improving Islet Cell Survival

Rodolfo Alejandro, M.D., and his team, are using FDA-approved compounds approved for other indications (such as type 2 diabetes) and applying them to islet transplantation with promising results. Preliminary results show that when a supplemental infusion of islets is given to patients months to years after the first transplant, in conjunction with a drug called Exenatide (the first of a new class of medications used for the treatment of type 2 diabetes) islets are protected from dying so that this supplemental infusion allows the patient to become insulin independent. The DRI, in conjunction with the National Institutes of Health (NIH), is part of a multi-center trial that will be launched soon to test how to use this hormone to improve islet cell survival and allow patients to obtain insulin independence with fewer islets than currently needed.

Researchers also are looking at the use of compounds that may improve immunosuppression in diabetic patients, improve their glucose sensitivity, and even favor proliferation of the beta cells that are transplanted. Much of the research being conducted by Luca Inverardi, M.D., and his team, focuses on developing ways to make biological replacement of insulin-producing tissue more viable in patients. His research team conducts a broad range of basic research in the areas of transplant immunology, tolerance induction, and cytoprotection, as well as immunogenetic studies to prevent diabetes.

Combating Diabetes through Lifestyle Interventions

Ronald B. Goldberg, M.D., is examining the pathophysiology, diagnosis, and management of dyslipidemia (the excess of lipids, especially cholesterol, in the blood), glucose intolerance, and their vascular complications. He is the principal investigator of the University of Miami’s center of the Diabetes Prevention Program (DPP) Outcomes Study, a national program that is demonstrating that lifestyle interventions with such insulin-sensitizing drugs as metformin and thiazolidinedione troglitazone help reduce the development of type 2 diabetes in patients with impaired glucose tolerance. In addition, lifestyle changes improved cardiovascular risk factors and decreased the prevalence of the metabolic syndrome. Dr. Goldberg also has been funded to study the importance of novel biomarkers in the development of diabetes and its complications. At the same time, working in DPP, Hermes Florez, M.D., Ph.D., is assessing the functional decline associated with aging in metformin-treated patients and in patients undergoing lifestyle intervention.

Since 2000, researchers have demonstrated that patients with longstanding diabetes could achieve insulin independence following infusions of insulin-producing islet cells, which are extracted from the pancreas of donors and transplanted into a patient’s liver. Known as the Edmonton protocol (named for the islet transplantation group at the University of Alberta in Edmonton, Canada, where the protocol was first created in the late 1990s), the technique was later successfully repeated at several centers worldwide (including the University of Miami), representing a tremendous leap forward in the global effort to cure the disease. Long-term results have revealed impressive success rates for islet cell transplantation. However, over time, the transplanted islets in these patients have lost some of their function, requiring most patients to resume low doses of insulin. Investigators, therefore, continue to research ways to improve islet cell transplantation.
Understand Thyroid Hormone

New Ways to Control Thyroid Hormone Action

Antonio Bianco, M.D., Ph.D., studies the mechanisms underlying thyroid hormone action, specifically the metabolism of the thyroid hormone. The thyroid gland secretes an inactive hormone, thyroxine (T4), which must be metabolized to T3 to become active. This process is known as deiodination and takes place in tissues throughout the body. Deiodination also can inactivate thyroid hormone, stopping thyroid hormone action. Thus, thyroid secretion depends on the balance between these activating and inactivating reactions, which are mediated by enzymes known as deiodinases. Dr. Bianco’s goal is to better understand the deiodinases and to develop methods that will modify (increase/decrease) thyroid hormone action in specific tissues. This approach can be used to increase metabolism and applied to other important areas such as embryonic development and disease states.

Thyroid Hormone Signaling and Metabolism

Many attempts have been made to use thyroid hormones as therapeutic agents for obesity and hyperlipidemia. However, this strategy has serious side effects, including atrial fibrillation and accelerated bone loss with osteopenia and osteoporosis. Discoveries in Dr. Bianco’s laboratory have revealed that deiodinases can direct the actions of thyroid hormone and accelerate metabolism in specific tissues. This mechanism, which was identified in small rodents through the use of bile acids in their diet, provides “protection” against obesity and insulin without affecting other tissues. Subsequently, Dr. Bianco’s team has found that small molecules present in different food sources, such as flavonols, can activate this metabolic pathway and increase energy expenditure.

Thyroid Hormone Action in Illness

It is well known that thyroid hormone is critical for embryonic development. Embryos have a way of controlling thyroid hormone action according to the tissue/organ and to the gestational age. Pioneer studies performed in Dr. Bianco’s laboratory have found that critical master genes that regulate development, such as the Hedgehog family of genes, act by affecting the activity of the deiodinases. This discovery has led to the identification of a similar mechanism in skin cells (keratinocytes), offering a potential therapeutic approach to basal cell carcinoma and other neo-plasias that develop in response to the Hedgehog family of genes. Studies in Dr. Bianco’s laboratory, in collaboration with Dr. Stephen Huang from Harvard Medical School, demonstrated that the sick heart inactivates thyroid hormone by changing its pattern of deiodinase expression. These results may lead to new strategies to treat ischemic heart disease, as well as brain ischemic disease.

Improving the Management of Insulin-Requiring Diabetes

The Kosow Diabetes Treatment Center, under the direction of Luigi Meneghini, M.D., M.B.A., and Luz Marina Prieto, M.D., have been investigating methods for optimizing insulin management in type 1 diabetes and insulin-deficient type 2 diabetes. These clinical research trials focus on the development and implementation of effective insulin-adjustment algorithms for both the hospital and outpatient settings. Cutting-edge insulin delivery and glucose monitoring technologies are also under investigation, including, but not limited to, continuous glucose monitoring-enhanced insulin pump systems, inhaled insulin deliveries, and new insulin analogs. Clinical research also explores better ways of improving diabetes-related patient education.
Preventing Cardiovascular Disease in Patients with Type 2 Diabetes

Cardiovascular Disease (CVD) is the leading cause of death in individuals with diabetes. While good glycemic control has long been accepted as critical in the prevention of the small blood vessel complications of diabetes (blindness, kidney failure, and nerve damage leading to lower extremity amputations), it has been less clear what role glucose control per se plays in the prevention of large vessel disease, or CVD, particularly in type 2 diabetes. Division researcher Carlos Abraira, M.D., was the national co-chair of a recent study that followed 1,800 individuals with type 2 diabetes for six years, which evaluated whether strict glucose control was better than standard control on the subsequent development of CVD. The results showed that the group who had very strict control of blood glucose had no better outcome than those on standard treatment, and in fact had three times the rates of hypoglycemia. The rates of CVD events in both groups, however, were lower than expected, probably due to the meticulous control of other CVD risk factors, including blood pressure, blood lipids, and smoking cessation. Jennifer B. Marks, M.D., was the principal investigator of the Miami site for the study, which followed about 100 patients. Hermes Florez, M.D., Ph.D., a co-investigator for the Miami site, recently received the VA 2008 Best Overall Young Research Investigator Award.

Improving Knowledge on Type 1 Diabetes

Sponsored by the NIH, Type 1 TrialNet (TrialNet) is helping to improve the medical community’s knowledge of type 1 diabetes. This large consortium of clinical centers and physicians is dedicated to the prevention and intervention of type 1 diabetes and conducts studies to identify people at risk for developing diabetes, find ways to circumvent the development of the disease, as well as to slow disease progression. Jay S. Skyler, M.D., is the program’s study chairman. Heading the Miami Clinical Center of TrialNet is Jennifer B. Marks, M.D. Current studies focus on the immune and metabolic profile of people at risk for developing type 1 diabetes. A prevention trial to test immuno-suppressive drugs that may preserve B-cell function in people with new onset diabetes also is underway. Dr. Skyler continues to investigate the clinical aspects of diabetes, specifically improving the care of type 1 diabetes.

With an emphasis on the causes, prevention, and cure of type 1 diabetes, Alberto Pugliese, M.D., focuses his research on the analysis of genetic and immunological factors that leads to, or protects against, the development of type 1 diabetes. One of his areas of clinical investigation assesses prevention and intervention strategies in patients at increased risk of type 1 diabetes as well as those newly diagnosed. He also is monitoring the recurrence of autoimmunity in transplanted patients and β-cell regeneration in the context of autoimmune diabetes.

Ricardo Pastori, Ph.D., has used his expertise in molecular biology to develop key technologies that assist the DRI’s efforts to cure diabetes through islet cell transplantation. He also is experienced in the design and manufacturing of protein transduction domains (PTD), an innovative method to induce protein expression that can potentially be adopted to the expression of genes. He currently is developing PTDs that can be used to transducer proteins into islets.

Armando J. Mendez, Ph.D., focuses primarily on understanding pathways and mechanisms of intracellular and extracellular lipid metabolism and transport related to the development of atherosclerosis and to lipid and lipoprotein abnormalities that occur as a consequence of diabetes.
The Division of Gastroenterology provides quality patient care, conducts cutting-edge clinical research in disorders of the gastrointestinal tract, and educates physicians in the diagnosis, management, and treatment of patients with gastrointestinal disorders. Faculty members in the division have a wide range of special research interests, including esophageal disorders, inflammatory bowel disease, gastrointestinal cancer, disorders of the pancreas, and diagnostic and therapeutic gastrointestinal endoscopy. The division's nationally and internationally recognized faculty also serve as attending physicians in the Gastroenterology Residency Training Program at Jackson Memorial Hospital (including many affiliated hospitals such as the University of Miami Hospital, the University of Miami Hospital and Clinics, Sylvester Comprehensive Cancer Center, Miami Veterans Affairs Medical Center, and Mount Sinai Medical Center) by educating physicians seeking a career in this specialty.

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Marcelo Larsen, M.D.
Javier Parra, M.D.
Afonso Ribeiro, M.D.
Daniel Sussman, M.D.
Hendrikus Vanderveldt, M.D.

An estimated one million people in the United States have inflammatory bowel disease (IBD)—a set of conditions where the intestinal tract becomes inflamed, ulcerated, and painful—but the actual number of those affected is likely to be much higher than that.

What was once considered a disease that afflicted individuals of European descent, IBD has become more indiscriminate, striking minority populations, such as Latinos, in growing numbers; Maria T. Abreu, M.D., division
The division’s research is working to find out why IBD is increasingly striking minority populations, such as Hispanics.

CHIEF AND PROFESSOR OF MEDICINE, IS VERY CLOSE TO FINDING OUT WHY.

At the basic science level, Dr. Abreu studies how bacteria are recognized by the gut. Researchers in her laboratory have discovered the importance of bacterial signaling in aiding the gut to repair itself. However, when there is constant damage, as in ulcerative colitis, a disease of the large intestine or colon, the individual can become predisposed to cancer.
Dr. Abreu is also interested in the genetics of IBD and how different genetic mutations affect the manifestation of the disease. For example, the genes that have been linked to Crohn’s disease also are involved in the innate immune response—how bacteria are recognized by the body immediately and then fought off. Such information may soon have tremendous implications for treatment. It’s believed that future genetic blood tests will help determine which patients are more likely to develop Crohn’s disease and which type of therapy would be most beneficial to administer. The division plans to conduct clinical trials to test the effect of different types of immune interventions on IBD and determine which patients are most likely to benefit from therapy.

Genetically speaking, one of the interesting questions Dr. Abreu hopes to answer is whether the genes that cause IBD in Hispanics are the same ones that cause the disease in the European population. If, in fact, the genes are found to be similar, Dr. Abreu believes she may be able to use the information gained from studying the mutations that cause IBD in Europeans to find the best way to approach the disease in Latinos.

Pinpointing Tumors with Greater Accuracy

Afonso C. Ribeiro, M.D., uses novel endoscopic techniques, such as endoscopic ultrasound, for the diagnosis and staging of gastrointestinal malignancies. The technology allows physician-scientists to target an area as small as five to seven millimeters (about the size of a pea) around the pancreas.

Dr. Ribeiro also uses photodynamic therapy (PDT) to treat carcinomas and Barrett’s esophagus, a condition that develops in some people with chronic gastroesophageal reflux disease (GERD) or inflammation of the esophagus. While endoscopic ultrasound and PDT aren’t new, its effectiveness and accessibility have improved dramatically over the last decade. PDT is a relatively simple procedure that involves photosensitive chemicals and a specially designed and targeted light source. Dr. Ribeiro uses PDT to treat very small esophageal cancers with the goal of eliminating the entire tumor or precancerous area. He also is testing its use in treating cancer of the bile duct (the tubes that connect the liver and gall bladder to the small intestine), which only a handful of medical centers in the United States are doing. Although not FDA-approved yet, this technology has shown promise in ablating these tumors while also effectively opening up the biliary tree so that patients don’t get
jaundice. It is usually performed as a form of palliation in patients who are not candidates for surgery.

Dr. Ribeiro and his colleagues also are performing other forms of endoscopic therapy, such as endoscopic mucosal resection (EMR) and radiofrequency ablation. EMR is considered an endoscopic alternative to surgical resection; it involves the local resection of small polyp-like tumors in the esophagus by using a small cap and wire loop at the end of the endoscope. This technique allows a deeper resection and analysis of the tumor staging. Radiofrequency ablation of Barrett’s esophagus involves positioning a balloon that delivers radiofrequency to the entire esophagus circumference, effectively ablating the precancerous tissue. Other techniques, such as the “freezing” of tumors in the esophagus using liquid nitrogen, are also being researched and will offer yet another treatment option for patients with gastrointestinal cancers.

Dr. Ribeiro and his colleagues are using endoscopic ultrasound and gold fiducial markers to pinpoint (mark) tumors so that radiation oncologists can effectively target these hard-to-reach tumors in the chest, abdomen, or pelvis. This technique is applied to tumors situated within the reach of the endoscope adjacent to the gut, such as pancreatic and prostate cancer.

### Screening for Colon Cancer: The Role Culture Plays

The division also performs hundreds of screening colonoscopies in indigent patients, generally of Hispanic origin, a population that would otherwise go unscreened for colon cancer. Data shows that Hispanics in the United States get screened for the disease less often when compared to other populations in the United States. Researchers such as David Kerman, M.D., are studying ethnic and cultural differences that make people more or less likely to undergo a colonoscopy. During a study that was meant to identify what types of polyps Hispanic patients develop, Dr. Kerman discovered that Hispanic women receive a colonoscopy five times more often than Hispanic men. This simple observation is leading to a careful study to determine why this occurs, and more importantly, how to get Hispanic men to have screening colonoscopies. Once more information is obtained, the division will likely implement grassroots programs in the community to instill the importance of such screenings in this population.
An Ounce of Prevention is Worth a Pound of Cure

The United States spends more per capita on health than any other country in the world, and that rate of spending is only increasing, states the Centers for Disease Control and Prevention (CDC). Part of the reason healthcare costs are soaring may be that only 55 percent of recommended preventive care is administered to patients and just 52 percent of the recommended screenings are performed, according to the June 2003 issue of the New England Journal of Medicine.

In the existing model, a typical primary care practice can care for as many as 4,000 patients; this means a physician will often see as many as six to eight patients an hour. In such an environment, doctors don’t have adequate time to listen to patients’ concerns, let alone provide a more proactive approach to their healthcare.
The division’s private practices focus on accessing all necessary resources to promote patients’ long-term health by working together with patients to prevent and/or delay the onset of serious illnesses and avoiding long-term health complications.

Investigating a Weighty Issue

As the problem of obesity continues to contribute to so many medical problems, physician-scientists in the division are searching for new and different methods of evaluating patients as well as helping them with weight management.

Judi Woolger, M.D., is investigating novel methods of helping people to do just that. One exciting tool under investigation is the use of personalized diet recommendations based on immunological blood testing. With this type of testing, patients receive their own list of dietary recommendations based on their blood test results. Physician-scientists from the division hope this can provide patients with very specific instructions on what foods they can and cannot eat in an effort to help them lose weight.

Preliminary information also has shown that this type of diet modification may assist people with other complaints, such as headaches, abdominal bloating, or pain, not to mention helping to control blood sugar levels. Dr. Woolger’s research into the topic also will help determine how effective these markers are and how much they will impact researchers’ efforts to help people lose weight.
Knowing full well the existing model of care was not benefitting physicians or their patients, the Division of General Internal Medicine, through its collaboration with MDVIP, the national leader in personalized care, has adopted a revolutionary health care approach for patients at its Key Biscayne Clinic.

Under the direction of Robert R. Kemper Jr., M.D., Ph.D., who has been heading the practice since 2005, and Albert Garcia-Romeu, M.D., the clinic has become a “boutique” or preventive care practice by offering personalized, high-quality care to a low volume of patients (the number of patients is capped at 600) who have round-the-clock access to their doctor.

The concept is simple: Patients pay an annual fee of $1,500 that covers all preventive medical services, the cornerstone of which is a comprehensive annual physical, including an extensive review of systems, a broad range of blood work, spirometry, an EKG, as well as vision and hearing testing. Since all patients are encouraged to complete a physical every year, doctors can pinpoint a potential health concern early on before it escalates into a major health problem. And with a more manageable patient base, the physician gets to know every patient in his/her practice and therefore will have a better sense when something is wrong—whether physical or emotional—with the person in the future.

This mode of care provides improved care at three levels. Patients receive same-day or next-day appointments, 24-hour telephone and e-mail access to their physician, phone calls that are returned promptly, long office visits with their physicians (75-90 minutes are scheduled for the annual physical visit and a minimum of 30 minutes is allotted for follow-up visits), as well as physician coordination of specialty care referrals. Patients also have wellness and healthy lifestyle planning, access to home visits should they become incapacitated, and online access to the MDVIP and Duke University’s educational and medical sites, in addition to the clinic’s exclusive services over the year.
The Division of Gerontology and Geriatric Medicine is dedicated to the improvement of health, independence, and quality of life of older persons and focuses on reducing the burden of dependent persons through interdisciplinary learning and discovery. Divisional training and research activities are based in interdisciplinary care models established and maintained by the faculty.

Golden Age
Growing old gracefully is as much an art as it is science. Just ask Bernard A. Roos, M.D., a biochemist, endocrinologist, and geriatrician who heads the Division of Gerontology and Geriatric Medicine at the Miller School of Medicine. Dr. Roos has dedicated his professional career to the study of aging, specifically focusing on finding a preemptive and preventative approach to chronic diseases—such as osteoporosis, cancer, diabetes, and Alzheimer’s—that afflict many individuals as they grow older.
In addition to exercise and nutrition, which are at the heart of the division’s approach to aging, researchers are testing novel forms of communication to recognize and manage chronic health problems in the elderly early on.

Based on the innovative technology-integrated care-coordination program created nine years ago known as T-Care, the division’s team of geriatricians and scientists, working in concert with the Miami Veterans Healthcare System (VA), the University of Miami’s College of Engineering, and prominent industry partners such as IBM and Humana, are making major strides in the care of vulnerable and frail persons by integrating computer-linked monitoring and communication systems with sophisticated voice recognition-based technology and data-mining approaches.

The T-Care program provides interdisciplinary care by having a nurse or social worker call to monitor the patient’s health each day by asking simple, health-related questions. The demonstration pilot program saved the VA millions of dollars because patients with potential health problems (such as pneumonia) were detected much earlier, before their health had deteriorated further.

After discovering that 70 percent of the nurses’ time was spent calling people, Dr. Roos and his College of Engineering colleague Herman S. Cheung, Ph.D., patented the next generation of this technology. Known as GeriSCOPE, this state-of-the-art interactive voice recognition-based technology approach automates the day-to-day evaluation of older persons with chronic diseases by having the system call the patient and then provide status notification to the patient’s care manager and family.

Patients are encouraged to exercise to reap the long-term health benefits.

The division is conducting major laboratory and translational research focusing on the metabolism and regulation of the aging skeleton and the treatment and prevention of osteoporosis and osteoarthritis to improve the quality of life of individuals with age-related bone and joint damage. In partnership with the VA-based center of excellence in geriatrics, the GRECC, studies into the complex biology of bone and joint development, maintenance, and repair have paved the way to fascinating discoveries involving adult bone marrow mesenchymal stem cells (BM-MSCs). These unspecified progenitor cells located in the bone marrow hold the potential to differentiate into various mature cell types and then regenerate a wide range of tissues (including vascular, glandular, and neural) damaged by aging or trauma.

The division recently negotiated a $2 million, multi-year research contract with Stemyx to translate MIAMI cells into improved medical therapy across a range of degenerative chronic diseases.

MIAMI cells can differentiate into mesodermal (osteoblastic, chondrocytic, adipocytic), endodermal (hepatocytic, pancreatic), and ectodermal (neuronal, glial) lineages. The ability to differentiate into these lineages appears to be independent of the age of the donor.

The key to these advances resides in what the division’s researchers have dubbed the MIAMI cells—pluripotent marrow-isolated adult multilineage inducible cells. MIAMI cells are a unique purified adult stem cell preparation that provides a standardized cellular therapy approach to bolster internal tissue repair and prevent progression and disability for persons with common chronic illnesses. This biological research involves a patented method of isolation and in vitro differentiation of a unique subpopulation of stromal cells from human bone marrow. Division researchers are testing the hypothesis that purified subpopulations of stem cells are more effective and predictable in their therapeutic effects than just general stem cells extracted from the bone marrow to be later used for repair of tissues, including bone, cartilage, fat, brain, muscle, and blood vessels. Dr. Roos believes that routine use of such novel biotherapies in humans will occur within ten years.
Predicting Patient Outcomes

Although diffuse large B-cell lymphoma (DLBCL), the most common type of non-Hodgkin’s lymphoma is curable in some patients, survival is unpredictable and depends upon cell type, and on how far the disease has progressed (the stage of the disease) at the time of diagnosis. The disease’s lack of predictability has prompted researchers in the Division of Hematology-Oncology and Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine (both part of the UHealth system) to study ways to better predict patient outcomes through analysis of gene expression, a new and vital tool in the battle against this disease.
The National Cancer Institute estimates there will be an estimated **66,120 new cases of non-Hodgkin lymphoma** diagnosed in the United States in 2008.

Izidore Lossos, M.D., has identified six novel genes that essentially act as key prognostic factors for large cell lymphoma. Dr. Lossos and his research team recently cloned and characterized a novel human gene, HGAL (human germinal center-associated lymphoma), which predicts outcomes in patients with diffuse large B-cell lymphoma (DLBCL) as well as Hodgkin's disease. Using the six-gene model, Lossos and his colleagues have launched a multi-center study where DLBCL patients’ prognostic factors are carefully being analyzed as they undergo treatment with Rituximab (an intravenous drug that is used to treat rheumatoid arthritis and B-cell non-Hodgkin's lymphoma), added to standard chemotherapy. Dissecting the function of HGAL could ultimately lead to a better understanding of patients’ overall survival and the development of more effective therapies for patients.

Dr. Lossos is also the sole recipient of the prestigious 2007 Celgene Young Investigator Award for Achievements in Clinical Hematology Research, a national award given to a single outstanding young faculty investigator on a nationally competitive basis.

A Promising New Protocol

Dr. Lossos recently designed an innovative and promising new protocol for mantle cell lymphoma, an uncommon form of lymphoma that accounts for about five percent of non-Hodgkin’s lymphoma in the United States. Although the results of the protocol still are considered preliminary, the initial trial results have proven very promising. The trial uses eight medications (standard chemotherapy typically uses a combination of four to five drugs), which are given at a high dose and at a "dose-dense" condensed schedule. Although the results still are preliminary, a large percentage of patients who have completed the therapy are in complete remission.
Researchers Granted Translational Research Award

Joseph D. Rosenblatt, M.D., and Seung-Uon Shin, Ph.D., recently were awarded a three-year Leukemia and Lymphoma Society Award. The goal of this Translational Research Award Program is to encourage and provide early-stage support for clinical research in leukemia, lymphoma, and myeloma, which is intended to develop innovative approaches to treatment, diagnosis, and prevention. Drs. Shin and Rosenblatt are working on developing a novel fusion antibody, which will increase the potency and biological activity of Rituximab, widely used in the treatment of non-Hodgkin's lymphoma, by linking lymphoma-targeting sequences in an antibody to a unique immune-activating protein called NKG2D-ligand.

The Viral Oncology Program at Sylvester Comprehensive Cancer Center—which has a particular focus on AIDS-related lymphomas—is one of the nation’s preeminent viral oncology programs, thanks, in part, to the efforts of William Harrington Jr., M.D. By examining oncogenic viruses—viruses that induce development of certain forms of cancer—Dr. Harrington’s team is studying the use of antiviral agents in viral-induced malignancies. Recently, Dr. Harrington has expanded his ongoing efforts in Brazil, where several new therapeutic and diagnostic NIH-funded clinical research projects are underway. His research has provided key insights into the pathogenesis of HTLV1, Epstein Barr Virus (EBV), and HIV-related lymphomas that have been translated into new therapies. His laboratory collaborates closely with the laboratory of Glen N. Barber, Ph.D., associate director for basic science and the Eugenia J. Dodson Chair in Cancer Research at Sylvester Comprehensive Cancer Center, and an expert in interferon biology and signal transduction. Interferon signal transduction is the mechanism by which interferons (proteins produced by cells) help regulate the body’s immune system and aid in the fight against viruses and certain forms of cancer. His work is particularly relevant to cancers in immunodeficient patients.

With the backing of two National Cancer Institute (NCI) research awards, Dr. Harrington and division colleagues, including Juan Carlos Ramos, M.D., are developing novel therapies for Epstein Barr virus-related lymphoma (Epstein Barr virus is an infection that in some cases can cause non-Hodgkin's lymphoma) and conducting new research projects that are targeting Burkitt lymphoma, one of the most common pediatric lymphomas in the developing world.

With the backing of two NCI research awards, division researchers are developing novel therapies for Epstein Barr virus-related lymphoma.
Predicting the Best Treatment for Patients

Dr. Ramos is one of only five researchers in the nation to receive a Damon Runyon Clinical Investigator Award, which will support his groundbreaking work on the role of an oncogenic protein in adult T-cell leukemia/lymphoma (ATLL). ATLL is caused by the human T-cell leukemia virus (HTLV-1) and is endemic in southern Japan, certain regions of Brazil, and western Africa. Ramos’ work is helping to predict which patients will respond to interferon-based therapy so that ATLL patients selectively receive the most effective treatment soon after diagnosis.

Improving Patients’ Access to New Cancer Treatments

Aimed at speeding promising therapies from the lab to the patient, division researchers Caio Max S. Rocha Lima, M.D., and Jaime Merchán, M.D., M.M.Sc., direct a successful Phase I drug development program. (Phase I trials are the first human tests of an experimental therapy. Designed to determine a drug’s safe dosage and safety, they often provide new leads that allow for the development of promising new anti-cancer drugs.) Dr. Rocha Lima also acts as the co-leader of both the Colorectal Cancer and Pancreatic, Liver, and Related Cancers Site Disease Groups. The program is the only academic Phase I testing center dedicated to drug development for cancer patients in South Florida. Its creation in late 2005 has markedly improved patients’ access to new cancer treatment approaches.

The center currently has 19 active Phase I clinical trials in progress that are testing a variety of novel agents and combinations. Ongoing and planned trials include the use of oncolytic viruses, which are viruses that kill tumors, agents that target angiogenesis (angiogenesis is the growth of the new blood vessels, which is necessary for cancerous tumors to continue growing and spreading), as well as novel agents that target tumor metabolism.
Putting the Breaks on Breast Cancer

With the rate of breast cancer mortality in Florida among the highest in the nation, it comes as no surprise that breast cancer has been a top priority for the Miller School for some time. Joyce M. Slingerland, M.D., Ph.D., F.R.C.P.(C), was recruited in 2002 to head research efforts in breast cancer and to lead the Braman Breast Cancer Institute at Sylvester Comprehensive Cancer Center, a multidisciplinary translational research institute devoted to advancing research in cancer prevention, diagnosis, and treatment for breast cancer. Dr. Slingerland is a recognized authority on cell cycle regulation in relation to breast cancer, with particular emphasis on the p27 cell cycle regulator. She has a major laboratory effort and has continued to recruit key individuals to increase expertise in the areas of molecular pathology, epidemiology, and clinical trials in breast cancer.

Noted physician-scientist Stefan Glück, M.D., Ph.D., F.R.C.P. (C), heads the multidisciplinary clinical efforts within the institute. Dr. Glück has played a major role in the division’s outreach efforts and has helped to increase the quality and number of clinical trials conducted at the institute, improving therapeutic options for breast cancer patients throughout the region.

Mark D. Pegram, M.D., who recently joined the faculty from the University of California at Los Angeles (UCLA), is an internationally renowned expert who was a co-investigator on the landmark research and clinical trials that led to the development of Herceptin, the first FDA-approved targeted therapy for use in HER-2 positive breast cancers. His current research focuses on understanding the molecular pathways by which the HER-2 receptor regulates breast cancer cell growth. Dr. Pegram is interested in finding new ways to manipulate this pathway and in the development of new drugs to block HER-2 signaling. He will play a major role in the further clinical development of translational breast cancer research at the University.

Marc E. Lippman, M.D., who joined as chair of the Department of Medicine in 2007, is also making major contributions in breast cancer. A pioneer in studying the role of estrogen in breast cancer, he developed the first system that allowed for extensive testing for receptors for estrogen at the molecular level. Dr. Lippman currently is working on biological markers that will predict which breast tumors will respond to hormone therapy. He also acts as a senior advisor to W. Jarrard Goodwin, M.D., F.A.C.S., Sylvester’s Director, and has accelerated recruitment efforts to the University.
The Division of Hepatology/Center for Liver Diseases has earned a world-renowned reputation for state-of-the-art clinical care and research and is an international leader in education, research, and care of patients with diseases of the liver and biliary tract. Fellows from more than 26 foreign countries have studied with the division’s faculty.

The division collaborates closely with the Miller School of Medicine’s Departments of Surgery and Radiology (part of UHealth—the University of Miami Health System) in the treatment of patients. Over the last ten years, the team has treated more than 1,000 liver transplant patients. Our physicians also are an integral part of the liver transplant program at the Miller School of Medicine.

The Hepatology Diagnostic Laboratory is located at the Rosenstiel Medical Science Building with outpatient facilities located at the University of Miami Hospital and Clinics. Pre- and post-transplant clinics are located at the Highland Park Building, and inpatient and outpatient facilities are housed at Jackson Memorial Hospital and the Miami Veterans Affairs Medical Center. Additionally, there is a 15-bed liver unit at the new University of Miami Hospital.

An estimated five million people in the United States are infected with the hepatitis C virus, a major cause of liver disease that can lead to chronic hepatitis, scarring with progression to cirrhosis of the liver, liver cancer, and even death. Of those, approximately 12.5 percent (400,000) have been treated for the disease, yet less than half (150,000) achieve a sustained virological response.

Paul Martin, M.D., F.A.C.P.
Division Chief/Professor

Center for Liver Diseases Director/Professor

Lennox J. Jeffers, M.D., F.A.C.P.
Assistant Chief/Professor

Professors
Christopher B. O’Brien, M.D.

Assistant Professor
Leopoldo Arosemena, M.D.
Flavia Mendes, M.D.

Instructor
Ravi Ghanta, M.D.
To make matters worse, another 600,000 people have been diagnosed but not treated for the virus (mainly due to the significant side effects of current treatment options), while another four million have yet to be diagnosed because of limited screening programs.

Although these statistics may seem grim, the treatment for hepatitis C actually has advanced significantly since the Division of Hepatology at the University of Miami Miller School of Medicine (part of UHealth) conducted its first study in 1988. At that time, the drug interferon (part of a family of naturally occurring proteins produced by cells of the immune system, which help to fight off the virus) was administered alone for six months. Patients on the drug, however, suffered many side effects, including flu-like symptoms, depression, and anxiety, with only a fraction of patients responding to treatment. By 1989, a diagnostic test for the hepatitis C virus (HCV) was developed and the duration of the interferon therapy was extended to one year. Still, only approximately nine percent of patients cleared the virus. Today, the overall cure rate with current therapy is 55 percent. Furthermore, the division is heavily involved in many studies involving the exciting new direct antivirals for hepatitis C.

The Role Ethnicity Plays in Treatment

There also is increasing concern that one’s ethnicity may affect a patient’s ability to respond to antiviral therapy for hepatitis. Lennox J. Jeffers, M.D., F.A.C.P., and Paul Martin, M.D., have been involved in an ongoing multicenter study in Latino patients, which seems to indicate these patients may be less responsive to interferon than non-Hispanic whites. (Similar data exist for African Americans.) Armed with such information, these researchers hope to confirm Latino patients are less likely to respond to what is currently available to treat HCV treatment so that there may be further impetus to study new drugs in this and other important populations.

In the coming years, studies of such drugs will help to considerably expand the treatment options available to manage hepatitis C, especially for those patients who have failed to respond to prior interferon therapy.
One of the major complications of any form of cirrhosis is development of variceal bleeding due to portal hypertension (an increase in the pressure within the portal vein—the vein that carries blood from the digestive organs to the liver—caused by a blockage in the blood flow throughout the liver). This back pressure around the liver in turn causes these blood vessels to rupture. Lennox J. Jeffers, M.D., F.A.C.P., who has received multi-year funding from the Blacher Family Foundation for his ongoing research in the field, has had longstanding interest in management of this often lethal complication of liver disease. A paper he authored in the *Journal of Hepatology* found that transjugular intrahepatic portosystemic shunt or TIPS (a radiological procedure where a small, tubular metal device or stent is placed in the middle of the liver to improve blood flow to and from the organ) is as effective as a surgical shunt in preventing varices or rebleeding.

Flavia Mendes, M.D., in an encouraging study published in *Hepatology*, reported data suggesting that the mortality rate from the major form of liver disease affecting the bile ducts in adults, namely primary biliary cirrhosis and primary sclerosing cholangitis, may be diminishing, perhaps reflecting the widespread use of ursodeoxycholic acid for these disorders (recently approved by the FDA) as well as increased access to liver transplant for patients with more advanced disease. Another study describing the consequences of abnormal liver function tests in patients with inflammatory bowel disease (Crohn’s disease and ulcerative colitis) found these abnormalities may identify a group of patients with a poorer prognosis.

### Fatty Liver Disease: A Growing Epidemic

Non-alcoholic fatty liver disease (excess fat in the liver) now is reaching epidemic proportions in the United States due to the increasing incidence of obesity in the U.S. population. One study underway in the division is evaluating Hispanic patients to determine whether the pattern of routine liver tests can predict if the patient is at risk for developing fatty liver disease. These tests seem to be a better predictor of the occurrence of the disease than the presence of diabetes. Many diabetes patients have fatty liver, a major predictor for the disease in other ethnic groups.
Although there is no cure for hepatitis B, you can successfully suppress the virus so that it’s undetectable in patients.

Managing Chronic Hepatitis B

The division is conducting a number of studies addressing the management of chronic hepatitis B. In a recent review, Dr. Schiff stressed the importance of prophylactic anti-viral therapy for patients with clinically non-apparent chronic hepatitis B who are undergoing chemotherapy. In such patients the virus can reactivate and result in a fatal flare of hepatitis B infection. Dr. Schiff now recommends oncologists screen for surface antigen and core antibody before administering cancer chemotherapy to avoid reactivation of the virus in these patients.

Figures A and B show the contrast between a smooth surface liver in a patient with relatively mild liver disease (A) and a patient with cirrhosis (B).
Developing Alternative Treatment Strategies for HCV

Since early 2000, researchers in the division have been studying an ever-widening array of novel antiviral agents—such as protease inhibitors and polymerase inhibitors—which are being used in conjunction with pegylated-interferon to effectively treat HCV.

Division researchers have been investigating the use of direct antivirals (also known as “small molecules”) to treat HCV, (e.g. protease and polymerase inhibitors currently used to suppress HIV). Protease inhibitors such as boceprevir and telaprevir actually attack the HCV virus directly (interferon has an indirect response on the immune system) to successfully rid patients of the virus. Although they will ultimately replace interferon, they will initially be used in conjunction with interferon and ribavirin for treatment of HCV. In addition, when used in combination with other drugs, these new antivirals are showing much promise in not only eliminating HCV, but also preventing the development of drug-resistant strains of the virus.

Eugene R. Schiff, M.D., recently presented a study on the use of the protease inhibitor boceprevir at the European Association for the Study of Liver Disease’s Annual Meeting in Milan, Italy. The Phase II, dose-finding study was used in people who failed a combination treatment using pegylated interferon and ribavirin. More importantly, the results of this study led to proper dose requirements for boceprevir, which was used in a later study in the division. Boceprevir, and several similar drugs, are in various stages of development and will become part of HCV treatment strategies. Although they will probably not replace interferon, they will work in conjunction with interferon to treat HCV.

Christopher O’Brien, M.D., co-authored a paper on the use of taribavirin as an alternative to ribavirin in the treatment of HCV. One of the major limiting factors in the management of HCV with the currently available therapy is the development of hematological side effects. Taribavirin appears to produce less anemia than ribavirin, which is a major component of current regimens. This study raises the possibility of successfully treating more patients with hepatitis C without the dose-limiting complications of anemia.
The rapidly expanding Division of Hospital Medicine, which has 19 faculty members, provides clinical care in multiple locations across the University of Miami medical campus, including inpatient care for cancer patients at the University of Miami Miller School of Medicine where procedures, such as bone marrow and lumbar punctures, also are performed. The division also provides inpatient care to patients at the new University of Miami Hospital (UMH) and works closely with internal medicine residents at Jackson Memorial Hospital to provide both an inpatient teaching service, as well as an internal medicine consultative service for surgical patients.

In addition, the division has started a special track focused on Hospital Medicine for second- and third-year residents interested in this field. They are taught about patient safety, quality improvement, transitions of care, palliative care, and risk management through hands-on seminars, journal clubs, patient safety conference, and a required quality improvement project.

The division also plays a key role in educating medical students. At UMHS, fourth-year students from the University of Miami are working under the supervision of hospitalists to complete their medicine sub-internships. The third year students rotate with the hospitalists at both JMH and Sylvester.

Katya Dimas, M.D.
Jenny Drice, M.D.
Ali Garcia, M.D.
Tatwig Guirguis, M.D.
Angelica Jimenez, M.D.
Venkat Kalidindi, M.D.
Joshua Lenchus, D.O., R.Ph., F.A.C.P.
Lisa Victoria Luly-Rivera, M.D.
Tariq Mahmood, M.D.
Kostiya Peki, M.D.
Alex Rico, M.D.
Cynthia Rivera, M.D.
Shahryar Saba, M.D.
Andres Arredondo Soto, M.D.
Jessica Zuleta, M.D.

The division’s vision

A New Trend in Medicine: Hospital Medicine

With malpractice and healthcare costs rising and patient safety a growing concern, it’s not surprising that hospital medicine—the care of hospitalized patients—is the fastest growing specialty in the United States. It’s estimated that in the next five years there will be close to 30,000 hospitalists in the United States alone. To keep up with this growing trend, the Miller School of Medicine (part of UHealth) recently created the Division of Hospital Medicine, with the vision of not only enhancing the quality of care and patient outcomes but also educating students and residents about the core competencies of this medical specialty. The division strives to ensure the utmost satisfaction of patients, providers, and referring doctors.
Hospitalists are predominantly physicians certified in internal medicine who specialize in the care of hospitalized patients.

Finding Safer Anticoagulants for Patients

Anticoagulants or blood thinners are used to treat patients with clotting disorders but they themselves are a leading cause of morbidity and mortality in hospitals today. What’s more, venous thromboembolism or VTE (which occurs when a blood clot forms inside a vein) is the third leading cause of cardiovascular death after myocardial infarction and stroke and a common admitting diagnosis to the hospitalist service. It often occurs in hospitalized patients. It’s not surprising, then, that much of the division’s research is currently evaluating new anticoagulants for both the treatment and prevention of this disease.

Amir K. Jaffer, M.D., is involved in several clinical trials looking at many of the new anticoagulants for both treatment and prevention of VTE. Specifically, he is studying new oral anticoagulants that would ultimately replace some of the older agents (such as warfarin) and some injectable medications (such as heparin) that are used often in hospitals today. He is also a steering committee member of the first, randomized clinical trial (set to start in fall/winter 2008) that will study how patients already on warfarin therapy—specifically those who have a common type of arrhythmia known as atrial fibrillation—should be managed at the time of their surgery. This first-of-its kind, $25 million randomized clinical trial, called “BRIDGE,” is being supported by the National Institutes of Health and is being performed in conjunction with Duke Clinical Research Institute. Both JMH and UMH will serve as sites for this trial.
The division is collaborating with residency program directors to build a specialty residency training track in hospital medicine to help residents become better prepared for this burgeoning field. In addition, members of the division are involved with quality improvement projects at all three hospitals.

Joshua D. Lenchus, D.O., R.Ph., F.A.C.P., has been instrumental in creating a formalized instructional curriculum, specifically focusing on invasive bedside procedures, which were identified by the American Board of Internal Medicine for resident understanding and competence. Such procedures include extracting fluid from the lungs or abdominal cavity, conducting a spinal tap, and placing IV lines, or temporary dialysis catheters, in a patient.

Dr. Lenchus, along with former intern Laura K. Erben, M.D., created the standardized course, which has led to a much safer way to teach residents. This new model is in direct contrast to the traditional apprenticeship model—known by the adage “see one, do one, teach one”—considered an outdated model of instruction for such procedures.

Under this new training concept invasive bedside procedures are taught by a multi-disciplinary, volunteer team of attending physicians from the Miller School of Medicine faculty. Each procedure is packaged as an individual module, complete with 12 components, and an innovative checklist helps appraise the resident’s baseline technical proficiency. Once the resident has completed the training, he/she then becomes part of a volunteer medical “procedure” team that can then be called by other services in the hospital to perform such procedures.

Since July 2007, the division has trained 30-40 residents who have performed more than 400 procedures. Dr. Lenchus is currently conducting research and hopes to show that this innovative curriculum and hands-on training lead to fewer complications and improved patient safety. He plans to export the course throughout the Miller School’s hospitals and beyond to achieve a standard method of procedural instruction.
Statistics reveal that an estimated 30 percent of people with HIV don’t receive adequate medical care. Some miss their appointments due to lack of reliable transportation or pending family obligations, while others never access the care they need in the first place. Regardless of the reason, this lack of medical attention is making many with HIV even sicker, with an ever-growing number requiring hospitalization.
It’s estimated that **15-18 percent** of HIV-positive individuals in the U.S. who are not yet on treatment have transmitted resistance; however, preliminary evidence suggests that the true figure may be higher.

Division of Infectious Diseases

It’s not surprising, then, that enhancing access to medical care for persons with HIV has been an important area of study for the Division of Infectious Diseases for quite some time. Through recent funding from the Centers for Disease Control (CDC), Allan E. Rodriguez, M.D., is researching better ways to improve the medical care HIV-positive patients receive by helping them access—and continue to receive—proper medical care.

This CDC-funded research project, currently in the planning phase, will implement grassroots communications strategies, such as the distribution of brochures in clinics, to remind patients and medical providers of the importance of ongoing medical care for HIV-positive patients. The University of Miami Miller School of Medicine’s Special Immunology Clinic at Jackson Memorial Hospital is one of five clinics in the United States collaborating with the CDC to monitor the access to care of this particular patient population. The project’s ultimate goal is to identify those patients who have problems staying in medical care and to help them receive proper medical care.

Connecting hospitalized HIV-positive Haitian-Americans into medical care is another population Dr. Rodriguez is studying. Due to various cultural, language, and system barriers, HIV-positive Haitians are not accessing the medical care they need. Studies have shown that when HIV-positive Haitians become hospitalized, they are much sicker than their black American counterparts. Dr. Rodriguez recently completed a trial to see if behavioral case management intervention will help get this group back into care. If he finds these interventions do work, Rodriguez hopes to implement them into daily practice, making them a part of the standard of care.
A Shifting **Focus** in HIV Care

Fifteen years ago, caring for HIV-positive patients meant taking care of individuals who typically were very sick and dying. Medical professionals were trained to treat the opportunistic infections and malignancies that would arise in this patient population. The care of HIV-positive patients has shifted dramatically in the last decade. Since medical advances now allow HIV patients to lead longer, more productive lives, physicians are now focusing their attention on patient adherence, adverse effects of treatment, and the emergence of antiretroviral resistance.

The study of antiretroviral resistance and the management of patients failing therapy because of resistance is a major focus of the clinician scientists at our center. For example, **Rafael Campo, M.D.**, has been awarded a grant from the National Institutes of Health/National Institute of Allergy and Infectious Diseases (NIH-NIAID) to study the growing number of patients who are infected with forms of HIV that are resistant to antiretroviral therapy. The two-year grant, which is a collaborative effort with Charles B. Hicks, M.D., at Duke University Medical Center, will enroll 120 patients during this two-year project.

When antiretroviral therapy fails and resistance emerges, patient non-adherence is frequently blamed for the failure. However, it is possible that a resistant virus may be transmitted to patients who have never been on treatment and that the presence of this resistant virus may be ultimately responsible for treatment failure.

Dr. Campo believes the current resistance testing methodologies are insensitive because resistant minority variants of HIV exist at a percentage (or frequency) that is low enough to escape detection. This study, therefore, attempts to use a currently available technique in a novel way to detect the true extent of resistant minority variants, as well as to assess whether patients who do have this type of resistance are more likely to fail therapy than those who do not. The ultimate goal of the research is to identify a mechanism for detecting resistance to medication before it leads to treatment failure.

Other investigators in the division are studying how best to manage persons co-infected with hepatitis C virus, the management of tuberculosis among persons with HIV infection, detection of human papilloma virus in HIV-infected persons, and newer therapies for treatment of HIV infection. There also are projects investigating how best to diagnose and treat serious fungal infections, especially among persons who have undergone organ transplantation or who are receiving treatment of malignant disease.
The E.M. Papper Laboratory of Clinical Immunology in the Division of Laboratories offers expert assessments of immune function to the medical community. The laboratory serves as a clinical reference laboratory for physicians as well as a research core facility. The laboratory, directed by Mary Ann Fletcher, Ph.D., and Nancy Klimas, M.D., serves as the core laboratory resource for University of Miami research into chronic fatigue syndrome and related fatiguing illnesses. It also offers clinical and research assays to many University of Miami clinical and basic science researchers, as well as to hospitals and pharmaceutical companies.

Mary Ann Fletcher, Ph.D.
Division Chief/Professor

Nancy G. Klimas, M.D.
Professor

For the estimated four million Americans with CHRONIC FATIGUE SYNDROME (CFS)—a debilitating disease characterized by severe, incapacitating fatigue that doesn’t improve with rest and can actually worsen with physical or mental activity—just getting through the day can be a challenge. Among these estimates are veterans with Gulf War Illness (GWI) who report symptoms identical to CFS. That’s because individuals with CFS and GWI not only experience severe fatigue, they often complain of muscle and body aches, have difficulty concentrating, and therefore perform poorly on the job.
After more than two decades of research into this baffling and complex disorder, Mary Ann Fletcher, Ph.D., and Nancy Klimas, M.D., co-directors of the Emanuel M. Papper Laboratory of Clinical Immunology in the Division of Laboratories at the Miller School of Medicine, are shedding light on the biological and physiological mechanisms of this complex disorder to develop effective treatments for patients.

Current efforts are looking at better ways of characterizing this elusive disease. Scientists point to several key areas: infectious agents such as viruses, problems with hormone regulation in the body’s endocrine system, disturbances in the autonomic regulation of blood pressure and pulse, and immunologic dysfunction.

As many as 80 percent of CFS sufferers go undiagnosed, since many other illnesses share the same symptoms of the disorder.

The division’s ongoing research into CFS and GWI has led to many pivotal discoveries. One important finding made by Drs. Fletcher and Klimas is that natural killer cell (NKC) function, an essential part of innate immunity and one of the body’s major defenses against viruses, is a common immune abnormality in all three syndromes. Lower NKC function decreases the body’s ability to fight new viral infection; it’s also pivotal in keeping old virus infections at bay (in a latent form).

One goal for researchers in the division is to define objective markers, which are proteins that can be detected in the blood and used to determine whether an individual is at risk for developing a disease. Currently, a CFS diagnosis is made solely on clinically grounds, since no markers associated with the disease have been found. Identifying such markers will enable clinicians to effectively diagnose CFS, follow the progress of the disease, and monitor the effects of therapeutic approaches. CFS is an umbrella term, covering several subgroups. Drs. Klimas and Fletcher believe they will identify biochemical and immunologic markers for CFS that will be used to diagnose the illness, help put the patient in the right subgroup, and predict recovery or relapse.
The “Good Day/Bad Study” also seeks to find biomarkers that can be used to predict partial relapse and/or partial recovery in CFS patients. Drs. Fletcher and Klimas, along with their team, will examine 150 patients over a five-year period by drawing their blood on “good” days (when individuals feel relatively healthy and active) as well as on “bad” days (when patients cannot get out of bed due to severe fatigue) and compare it to that of healthy individuals.

A pilot study originally funded by the CFIDS Association of America (CFIDS stands for chronic fatigue and immune dysfunction syndrome), which was then spun into an NIH grant, is helping researchers study the role of two specific biomarkers in the development of CFS—neuropeptide Y (NPY) and dipeptidyl-peptidase (CD26). These peptides, formed from amino acids, regulate many physiological and disease processes in the cardiorespiratory, immune, nervous, and endocrine systems. NPY is an important neurotransmitter produced by sympathetic nerve endings in response to stress and is elevated in CFS. Meanwhile, low CD26 will produce elevated levels of the peptide, resulting in immune dysfunction, and ultimately, the symptoms of CFS. Dr. Klimas presented the findings of this research to the Academy of Behavioral Medicine Research in June 2008.

The Gulf War Illness Research Study is a large genomics study that is analyzing the role of gene expression patterns in the symptoms of Gulf War Illness compared to CFS.

The Gulf War Illness Research Study, being conducted in conjunction with the Centers for Disease Control (CDC) and funded by the Veteran’s Administration and the Department of Defense, is a large genomics study that is analyzing the role of gene expression patterns in the symptoms of Gulf War Illness compared to CFS. By using a technique called gene expression by microarray, researchers are examining patients’ gene expression before, during, and after exercise. It’s hoped that those genes that are expressed can be singled out, allowing researchers to know what proteins those genes code for so that they can then identify biomarkers for the disease.

Dr. Fletcher using flow cytometry, a technique that sorts and examines microscopic particles.
The Division of Nephrology and Hypertension is being reshaped into a highly translational renal medicine program that incorporates basic science, clinical research, drug discovery, and excellence in patient care, thanks to Jochen Reiser, M.D., Ph.D., the new chief of the division and his team of distinguished faculty.

Under the leadership of Arif Asif, M.D., an internationally recognized authority and founder of interventional nephrology and the director of the division’s Interventional Nephrology Program, the division performs all kinds of renovascular procedures and is frequently visited by other divisions from around the nation for consultation.

The division also has several in- and outpatient dialysis units that serve as treatment centers for patients with acute and chronic renal failure. David Roth, M.D., the clinical director of the division, ensures patients of the division receive world-class nephrology care at the University of Miami Hospital, Jackson Memorial Hospital, and the Miami Veterans Administration Medical Center (Miami VA).

Podocytes (in yellow) are the key component of the glomerular filtration barrier.

Diseases of the kidney are among the most prevalent of internal medicine disorders, affecting children and adults alike. The number of people with a leakage of plasma proteins into the urine (known as proteinuria), for example, is estimated at close to 500 million worldwide. According to the National Institutes of Health (NIH), studies show that the level and type of proteinuria (whether the urinary proteins are albumin only or include other proteins) strongly determine the extent of damage and whether you are at risk for developing progressive kidney failure.
Although a vast amount of novel information about the cell types and mechanisms guiding renal filtration in healthy patients and those with disease now exists, only very little has translated into a refined treatment of proteinuria syndromes. Yet the risk of death due to cardiovascular disease (such as heart failure or stroke due to damaged blood vessels often associated with the disease) and progressive renal injury associated with urinary protein loss are still dangerously imminent.

In fact, in countries with underserved health care, effectively treating proteinuria would be a cost-effective way to halt the need for renal replacement therapies (such as dialysis) and kidney transplantation, thus saving many lives, even for those who are underprivileged.

The Division of Nephrology and Hypertension is undertaking many efforts to develop cell-specific renal therapies. Several findings from division researchers have led to the identification of various tools, pathways, and compounds that are required to create the first renal cell-specific, anti-proteinuric drug.

Clinical Research Sheds Light on Chronic Kidney Disease

Despite significant advances in the detection and treatment of cardiovascular disease, patients with chronic kidney disease (CKD) remain at markedly increased risk of dying from cardiovascular causes when compared to age-matched individuals without kidney disease. Although traditional risk factors such as hypertension, obesity, and diabetes contribute to this disparity, these risk factors alone do not adequately explain the higher risk of cardiovascular mortality among patients with CKD. As a result, non-traditional risk factors, such as disorders of mineral metabolism, have gained attention as potentially novel therapeutic targets for improving outcomes in patients with CKD.

Myles Wolf, M.D., M.M.Sc., and his team have been actively involved in examining the increasingly critical role of disordered mineral metabolism in contributing to cardiovascular morbidity and mortality across the spectrum of chronic kidney disease.

Using a variety of approaches that include large, population-based epidemiological studies, as well as detailed human physiological experiments, Dr. Wolf and his colleagues have focused on the association between abnormal phosphorus metabolism and cardiovascular disease in patients with kidney failure. Their work has uncovered novel associations between a recently discovered hormone, fibroblast growth factor 23 (FGF-23), and adverse outcomes in patients with kidney disease. FGF-23 is a critical homeostatic hormone involved in the regulation of phosphorus and vitamin D metabolism.

While elevated concentrations of FGF-23 were initially demonstrated to be the cause of rare syndromes characterized by urinary phosphorus wasting and bone disease, no studies had linked FGF-23 with hard outcomes such as mortality in larger populations. In a study that was published in the New England Journal of Medicine, Dr. Wolf and his team were the first group to demonstrate that FGF-23 is strongly associated with mortality in a diverse cohort of patients initiating hemodialysis. Importantly, they showed that this association was independent of known risk factors for mortality on hemodialysis, including contemporaneous phosphate concentrations, suggesting a potential direct link between FGF-23 and mortality in kidney disease.

These researchers subsequently have discovered important new links between FGF-23 and left ventricular hypertrophy (the thickening of the myocardium (muscle) of the left ventricle of the heart), a common and important risk factor for cardiovascular mortality in patients with CKD.

Dr. Wolf and his team also conduct detailed physiological studies aimed at deciphering the mechanisms by which FGF-23 regulates phosphate and vitamin D metabolism in humans. Their focus is to better characterize these pathways, with the ultimate goal of discovering new potential treatments that may ameliorate the notably increased risk of cardiovascular disease in millions of patients with kidney disease.
Understanding Kidney Disease

The kidney filtration barrier is located in the glomerulus of the kidney. Each kidney has approximately one million of these filtration units. Podocytes are a central component inside a glomerulus, and with the use of their structure, they ensure proper kidney filtration.

In a variety of kidney diseases podocytes are damaged, which results in a structural reorganization of these cells that leads to a leaky filtration barrier. The consequence is the loss of blood proteins into the urine. All together, these events will often cause further kidney damage. Proteinuria also can potentially lead to end-stage renal failure.

In the past decade, blockade of the renin-angiotensin system has led to significant improvement in slowing this disease, which has resulted in partial protection. However, until now no curative treatment is available. Using cell-culture models of podocytes and molecular-biochemical methods as well as animal models, researchers from the division have identified that common forms of podocyte failure resulting in proteinuria are caused by an enzyme called cytoplasmic cathepsin L that cleaves important regulatory proteins of the podocyte, which in turn leads to their malfunction and urinary protein loss. Blocking the detrimental action of this enzyme or protection of targets from enzymatic destruction stabilize podocyte function and reduce proteinuria in animals.

Researchers know that this enzyme also is present in diseased human kidneys and, as a result, are currently working on the development of specific inhibitory compounds that are the promising drugs of the future.

Basic Science Nephrology Will Lead to Novel Renal-Protective Drugs
Another feature of failing podocytes is their change in the dynamic movements of their cellular processes. In a recent study in *Nature Medicine*, division researchers describe the identification of a pathway that leads to this increased motility. Blockade of this pathway by a small molecule called cyclo-RGDfV inhibits podocyte motility during disease and restores urinary protein loss. The division also has evidence that this disease mechanism operates in humans as well. Scientific advancements of division members have led to the establishment of the Miami Institute of Renal Medicine that houses its own drug discovery center—The Peggy and Harold Katz Family Drug Discovery Center. The institute is directed by Peter Mundel, M.D., a renowned researcher in glomerular biology with more than 120 original publications. In a recent landmark paper, he describes for the first time how a commonly used drug, namely cyclosporine A, executes its protective function on podocyte cells in the kidney. This study allows the creation of novel, more effective drugs that omit many of the serious side effects of cyclosporine.

Improving Kidney Outcomes in Minority Populations
The clinical research program also has an ongoing commitment to improving kidney disease outcomes among racial and ethnic minorities.

The program, in fact, is participating as a key site in the African-American Study of Kidney Disease and Hypertension (AASK) trial, a multi-center, NIH-funded study of risk factors for the prevention and treatment of kidney disease progression among African Americans, under the direction of Gabriel Contreras, M.D. Dr. Contreras also is engaged in a number of studies examining novel treatments for glomerulonephritis in racially and ethnically diverse populations.
The Division of Pulmonary and Critical Care combines state-of-the-art clinical care and basic science and translational research to serve patients with respiratory and critical illnesses. The division’s research initiative emphasizes the development of better approaches to the prevention, care, and treatment of lung disease and critical illnesses.

Nationally and internationally recognized experts make up the division’s team of faculty. They have experience in managing the entire spectrum of lung disease and critical care, with special interests in asthma and chronic obstructive pulmonary disease (COPD), lung cancer, cystic fibrosis, tuberculosis and non-tuberculosis mycobacteria, lung transplantation, pulmonary hypertension, and the study and treatment of septic shock and acute lung injury.

Matthias A. Salathe, M.D.
Division Chief/Professor

Professors
Horst J. Baier, M.D., J.D.
Robert M. Jackson, M.D.
Daniel Kett, M.D.
Michael Light, M.D.
Arthur A. Pitchenik, M.D.
Roland M.H. Schein, M.D.
Joseph Weintraub Family Foundation Chair

Research Professor Emeritus
Philip L. Whitney, Ph.D.

Associate Professors
Gregory Conner, Ph.D.
Elio Donna, M.D.
Debra Fertel, M.D.
Rosanna Forteza, M.D.
Marilyn K. Glassberg, M.D.
Andrew A. Quartin, M.D.

Assistant Professors
Alexandre R. Abreu, M.D.
Jaime F. Avecillas, M.D.
Michael A. Campos, M.D.
Cameron Dezfulian, M.D.
Marina Casalino Matsuda, Ph.D.
Eliana S. Mendes, M.D.
Andreas Schmid, M.D.
Shirin Shafazand, M.D., M.S.

Giving Patients a Fighting Chance

Once considered a children’s disease since those afflicted rarely lived to reach adulthood, today people with cystic fibrosis (CF)—an inherited chronic disease that affects the lungs and digestive system—can live well into their 30s and 40s, thanks to advances in research, medical treatment, and expanding nutritional support. As a result, many CF patients are entering adulthood and finding few physicians who are properly trained to care for their disease.

In response, the University of Miami’s Adult

Symptoms of Cystic Fibrosis

People with CF can have a variety of symptoms, including:
- Salty-tasting skin
- Persistent coughing, at times with sputum (phlegm)
- Frequent lung infections
- Wheezing or shortness of breath
- Poor growth/weight gain in spite of a good appetite
- Frequent greasy, bulky stools or difficulty in bowel movements

Source: Cystic Fibrosis Foundation
If You Build It, They Will Come

Under the direction of Matthias A. Salathe, M.D., and Michael Light, M.D., the Adult CF center provides comprehensive clinical care and conducts clinical and basic science research as well. Adult CF patients suffer from lung disease, as well as other complications and disorders such as diabetes, gastrointestinal problems, and osteoporosis. The role of the Adult CF Center is to provide comprehensive outpatient care to individuals with CF as well as inpatient care should patients require hospitalization due to severe lung infection or in the most dire of cases, lung transplantation.

Cystic Fibrosis Center in the Division of Pulmonary and Critical Care has undergone a significant expansion, doubling the number of referrals to the center in the last three years alone. This has been accomplished thanks, in part, to funding from the Cystic Fibrosis Foundation (CFF), which recently incorporated the University of Miami’s CF Center into the transitional expansion of the Therapeutic Development Network to test new promising medications in patients suffering from the disease.

In patients with Cystic Fibrosis, a defective gene and its protein cause the body to make thick and sticky mucus that eventually clogs the lungs and leads to life-threatening lung infections. This mucus also obstructs the pancreas and stops natural enzymes from helping the body break down and absorb food.

Source: Cystic Fibrosis Foundation
Although the gene associated with CF was discovered in 1989, prompting many to think a cure was close at hand, there is still no cure for CF. Basic research studies conducted by Gregory E. Conner, Ph.D., and Matthias A. Salathe, M.D., have identified a defect in CF epithelial cells, resulting in a malfunctioning innate defense response against bacterial infection. This defect may contribute to CF patients being more susceptible to bacterial lung infections.

In collaboration with the Department of Cell Biology and Anatomy, researchers in the division have identified a peroxidase anti-infection system, which is produced by cells of the tracheal and bronchial mucosa (the moist, inner lining of certain organs of the body such as the lungs; glands in the mucosa produce mucus).

Known as the lactoperoxidase system (a common system that works in many areas of the body, including the mouth, eyes, breast glands, and lungs), it uses hydrogen peroxide to oxidize thiocyanate, a simple anion found in the blood and airway secretions. Normal bronchial epithelial cells concentrate thiocyanate in airway secretions at least ten times over the level found in blood. Thiocyanate is used by the peroxidase enzyme in the airways, which converts the thiocyanate into a substance that is effective in fighting bacteria, fungi, and viruses. What division researchers have found is that thiocyanate cannot be transported across the airway cells with the CF mutation so its levels in CF airways are predicted to be extremely low. This causes the antibacterial system to break down so that it cannot mount its usual defense against bacteria. Armed with such information, researchers hope to find ways to “fix” this defect so that the airway cells in CF can work properly, allowing the body’s innate defense response to successfully fight off infections when needed.

Airway epithelial cells in cultures are followed over time (day 15 and 20 after plating) by staining them for markers of differentiation (cilia in red).
Antibiotics that Target the Lungs

As part of the efforts of the Cystic Fibrosis Foundation’s therapeutic development network, a number of clinical research projects in the division are currently examining new therapies for CF patients, such as aerosolized antibiotics that specifically target the lungs. These new treatments deliver relatively high doses of antibiotics directly to the lungs to fight the infectious causes of lung disease in CF patients, such as pseudomonas infections. By stopping the vicious cycle of such respiratory infections—which often result in progressive loss of lung function and shortened life expectancy—patients’ quality of life would improve dramatically.

A Breath of Fresh Air

inhaled corticosteroids, the most effective drugs on the market today to control asthma, offer more benefits to asthma patients than originally believed. That is what Gabor Horvath, M.D., Ph.D., Adam Wanner, M.D., and the division’s research team have discovered while conducting pivotal basic science research related to asthma. Not only do inhaled corticosteroids help to suppress asthma-associated airway inflammation, their studies show that these drugs improve bronchodilation as well. In a series of in vitro experiments, Drs. Horvath, Salathe, Conner, and Wanner reported a new immediate form of interaction between corticosteroids and beta-2-agonists that suggest the need for further study on the benefits of this combined inhalation therapy. This is what they’ve found: While steroids have been known to help reduce airway inflammation, they also help to constrict bronchial vessels so that patients have less edema in the airways. Steroids also help to make inhaled beta-2-agonists (such as albuterol) more available to airway smooth muscle, providing asthmatics with two beneficial effects in controlling asthma.

Dr. Light administers a special breathing test to a patient.
A New Treatment for Vascular Disease in Smokers?

Eliana S. Mendes, M.D., and Adam Wanner, M.D., found that endothelial dysfunction, a condition of blunted vasodilation (widening of blood vessels resulting from relaxation of the muscular wall of the vessels) that is associated with cigarette smoking and cardiovascular disease, is also present in the airways of healthy smokers and patients with chronic obstructive pulmonary disease (COPD). The investigators treated subjects with an inhaled corticosteroid for three weeks. After the treatment, normal endothelial function was restored in these subjects; three weeks after stopping the treatment, endothelial dysfunction recurred. It is not known if the treatment with inhaled corticosteroids also restores endothelial function outside the lung, such as the coronary and cerebral arteries; however, this is the first time that a pharmacologic intervention has been shown to improve vascular function in cigarette smokers. The research team is about to start a similar study in smokers in whom brachial arterial function will be assessed to determine if inhaled corticosteroids also have a beneficial effect on extrapulmonary systemic vascular function.

Interventional Bronchoscopy

The division also is one of just a handful of medical centers in the region to use newer bronchoscopic techniques. In addition to providing physicians with pulmonary assessments of complications associated with cancer treatment, Elio Donna, M.D., uses autofluorescent bronchoscopy to diagnose early lung cancer in patients at high risk. An endobronchial ultrasound bronchoscopy incorporates an ultrasound probe for real time guidance of transbronchial needle aspiration of enlarged lymph nodes that may be affected by cancer. Electromagnetic navigation bronchoscopy incorporates GPS-like technology to guide biopsies of small peripheral pulmonary nodules. Interventional bronchoscopy techniques, such as electrocautery, cryocoagulation, intrabronchial radiotherapy or brachytherapy (placing a radioactive material inside the body), photodynamic therapy, and intrabronchial stents, are used to manage malignant airway obstruction in cancer patients. These diagnostic techniques are often done in collaboration with faculty from the Departments of Otolaryngology, Thoracic Surgery, and Radiation Oncology and provide state-of-the-art diagnosis and treatment of cancer in the respiratory tract.
The Division of Rheumatology and Immunology is one of the nation’s leading research and education centers for rheumatic diseases in the country and provides patients with comprehensive care in the subspecialty of rheumatology. Over 5,000 patients are seen annually in a variety of settings, including clinics, inpatient consultation, emergency room, and rehabilitation areas. The division’s mission is to provide the highest level of patient care, to train physicians in the care of patients with arthritis and the rheumatic diseases, and to advance the knowledge of arthritis and rheumatic diseases through research.

An estimated 60 million Americans are afflicted by an autoimmune disease, where the body’s own immune system mistakenly attacks itself, which then leads to myriad health problems, and in some severe cases, even death. Systemic lupus erythematosus or lupus (SLE), and mixed connective tissue disease (MCTD) are among the more severe rheumatic autoimmune diseases and still require lifelong treatment.

Although SLE and MCTD can afflict men and women of any age, they most commonly strike women in their late teens and early twenties.
According to the Centers for Disease Control, an estimated 46.4 million (21.6 percent) of adults have self-reported, doctor-diagnosed arthritis.

Although not life-threatening, the disease can significantly limit a person's mobility and function. Dr. Carlos Lozada, a nationally renowned educator and researcher in osteoarthritis and the inflammatory arthritides, such as rheumatoid arthritis, has participated in multiple clinical trials in osteoarthritis including the use of non-steroidal anti-inflammatory drugs (NSAIDs) and intra-articular therapies and in the use of disease-modifying drugs in rheumatoid arthritis. One of his current projects is based upon many years of basic research in model systems and patients by scientists at the Miller School, including Herman Cheung, Ph.D., and Dr. Hoffman.

While there have been some advances in the overall management of the SLE and MCTD, no new drugs have been approved for the treatment of lupus in over 25 years.

To tackle this problem, division researchers, such as Robert W. Hoffman, D.O., also the division's chief, are examining pathogenesis (the origination of the disease) to better understand the mechanism behind what is known as loss of tolerance. Normally, individuals are tolerant of their own self-antigens. In some cases, though, this tolerance can be broken, prompting the immune system to start attacking itself, which is what occurs in autoimmune diseases. Researchers, therefore, are examining the steps that occur in this process to better understand how and why the immune system becomes dysfunctional in the first place and develop new forms of therapy.
Autoimmune diseases may be more common and more severe in African Americans and Hispanic patients. The division currently cares for a group of more than 500 patients with SLE and MCTD to determine why certain groups are afflicted by these diseases.

Eric L. Greidinger, M.D., has made major contributions to lupus research. He was among the first to make the seminal observation that structural changes in antigens (specifically in MCTD) seem to be important in the autoimmune process. (In autoimmune diseases, different antigens are targeted by the immune system, which are unique to specific tissues. For example, in rheumatoid arthritis, the antigens that are present in the joints seem to be particularly targeted.) More importantly, Dr. Greidinger has identified that autoantigens could activate immune cells via the innate immune receptor Toll-like Receptor (TLR) 3. Toll-like Receptors now are widely recognized as playing a central role in autoimmunity.

Marcos Maldonado, M.D., has enrolled patients in ongoing clinical trials in MCTD to find better therapies to treat the disease, while Elaine Tozman, M.D., and Carlos Lozada, M.D., are actively involved with the study of SLE and MCTD. Dr. Lozada has performed a number of clinical trials on osteoarthritis and rheumatoid arthritis and currently is designing new clinical research studies (see box at left.) Dr. Tozman has made major contributions in the treatment of lupus nephritis and is particularly focused on studying lupus in men.
On December 31, 2007, the University of Miami ended its Momentum Campaign, which propelled the University of Miami into a new era as one of the nation’s leading research universities. During the Momentum Campaign, the Department of Medicine raised more than $53 million in gifts and pledges over the 7.5 year period.

Although this annual report only reflects this past fiscal year, a significant number of donors successfully partnered with the Department of Medicine during the Momentum Campaign to help us advance innovative research and provide the highest level of clinical management and educational programs.

As we transition into one of the nation’s top research universities, continued financial resources are needed in our pursuit of excel-
lence. Therefore, we invite you to utilize the enclosed envelope and make a generous donation to any of the areas featured here in the Department of Medicine’s annual report. This is just the beginning. We need you to help us achieve even greater accomplishments.

As the Chairman of the Department of Medicine stated, there has been significant progress over the past year. We want to thank the donors for believing in our vision. Without their strong support, the department would not have had the capability to intensively recruit the doctors and provide them with the freedom to explore and advance their research and clinical interests.

We have asked a few donors to share their motivations for and thoughts about giving back to our Department.
The honor roll of donors includes gifts and pledge payments made from June 1, 2007, through May 31, 2008.

**HONOR ROLL**

### $1,000,000 or more
- Flight Attendant Medical Research Institute
- The Peggy and Harold Katz Family

### $500,000 to $999,999
- Leukemia and Lymphoma Society
- Wallace H. Coulter Foundation

### $250,000 to $499,999
- American Heart Association/Texas
- Breast Cancer Research Foundation
- Mr. and Mrs. Terry R. Taylor
- Damon Runyon Cancer Research Fund

### $100,000 to $249,999
- American Federation for Aging Research (AFAR)
- American Lung Association/South Carolina
- Association of American Medical Colleges (AAMC)
- Avon Foundation

### $50,000 to $99,999
- American Heart Association
- Cenegenics, Inc.
- CFIDS Association of America
- The Dana Foundation
- Donald W. Reynolds Foundation
- Schering Corporation
- Robert & Gertrude Barnett Foundation
- Mrs. Leila Applebaum
- Cordis Corporation
- Mr. and Mrs. Juan C. Escotet
- Mr. and Mrs. Raul J. Valdes-Fauli
- Woman’s Cancer Association of the University of Miami

### $25,000 to $49,999
- Anthony R. Abraham Foundation, Inc.
- Aileen S. Andrew Foundation
- Alpha One Foundation
- American College of Rheumatology
- Audrey Love Charitable Foundation
- Caja Madrid Foundation
- Community Foundation of Broward
- Genzyme Corporation
- Gilead Sciences
- The Jay Bon Salle Foundation
- Omnicare Clinical Research, Inc.
- Roche Laboratories
- Mr. Robert Rubinstein*
- St. Jude Medical, Inc.
- Valeant Pharmaceutical

### $10,000 to $24,999
- Abbott Laboratories
- Mr. Franco Abraham
- American Lung Association/Florida
- Anonymous
- Applebaum Foundation, Inc.
- Mr. and Mrs. Jose Tarajano
- Benaroya Research Institute at Virginia Mason

*Deceased*
One Breath Closer to a Cure

Every breath is a victory for Marc Buoniconti. The 41-year-old spent nearly a year on a ventilator after sustaining a spinal cord injury that left him paralyzed from the shoulders down. Eventually, he learned to breathe on his own again, but the circumstances left their mark.

“I never forgot what it was like not to be able to breathe and the complications that arise from being on a respirator,” Buoniconti recalls.

His painful rehabilitation only inspired him to help others overcome respiratory ailments and limited mobility. In 1985, Buoniconti co-founded the Miami Project to Cure Paralysis. Today, he is president of the research center. He also became actively involved with the Miller School’s Division of Pulmonary and Critical Care and its International Bronchitis Center, for which he recently raised $50,000 through the Coral Gables Wine and Food Festival.

“When I had an opportunity to help, I talked to Adam Wanner, M.D. [former chief of the Division of Pulmonary and Critical Care and currently a professor of medicine in the division] about some of the needs in his department. I wholeheartedly agreed to lend my name, and I really got involved with the American Lung Association [ALA],” he says.

He started by getting involved with the ALA through the Las Olas Wine and Food Festival in 1999 and also helped launch the International Bronchitis Center at the University of Miami. Now he’s been working with the Coral Gables Wine and Food Festival to support the International Bronchitis Center in the Division of Pulmonary and Critical Care.

The son of All-Pro and Hall of Fame linebacker and former Miami Dolphin Nick Buoniconti, Marc Buoniconti was on a similar athletic path until 1985 in South Carolina, where he played football for the Citadel. During a game against East Tennessee State, the 19-year-old received the injury that changed his life forever. He was treated at the Miller School of Medicine.

“Just remembering those experiences and the people who took care of me and were able to wean me off of the respirator is something I have never forgotten,” says Buoniconti.

When he was well enough he transferred to the University of Miami and graduated with a degree in psychology. In 1992, his family created the Buoniconti Fund to Cure Paralysis, the national fundraising arm of the Miami Project to Cure Paralysis.

As a natural carryover from his prior work, Buoniconti became active with the Division of Pulmonary and Critical Care. His original goal there was to establish a fund for a basic science and clinical team of the world’s best pulmonary scientists to find more effective treatments and an ultimate cure for chronic bronchitis. Since 1998, Buoniconti has helped raise $500,000 for the division, which is funding research related to the lungs and airway diseases.

“I am very fortunate to have the opportunity to volunteer and give my time to help other causes, and the more I do, the more involved I become, the more addicted I have become to helping other people,” adds Buoniconti. “And there is nothing more important than giving back and making a difference in the lives of others; I am just so fortunate to be able to do that.”
The Value of Doctor-Patient Relationships

Peggy and Harold Katz’ $5 million gift to the Division of Nephrology at the University of Miami Leonard M. Miller School of Medicine is a testament to the value of the doctor-patient relationship.

Suffering from polycystic kidney disease (PKD), in 2000 Peggy Katz, then a full-time resident of Philadelphia, sought treatment miles away from home with David Roth, M.D., in the Division of Nephrology, later undergoing a kidney transplant in 2003 with George W. Burke, M.D., in the Division of Transplantation at the Miller School of Medicine.

Though she and her husband had been active philanthropists for years, the care Mrs. Katz received from the doctors and staff at the Miller School of Medicine inspired them to give back even more.

“Without the relationship I had with these doctors, I would’ve just been giving nameless to something. It’s nice when you know the people you are entrusting with large sums of money. You have that confidence that the money is going to be put to good use,” says Mrs. Katz.

The recent $5 million gift will establish an endowed chair in the Division of Nephrology dedicated to cutting-edge kidney disease research, continued support for the Physician-Scientist Fund, as well as support to establish a new drug discovery center known as The Peggy and Harold Katz Family Drug Discovery Center.

PKD is a progressive, genetic disorder of the kidneys and characterized by the presence of multiple cysts in both organs. The disease also can cause damage to the liver, pancreas, and sometimes even the heart and brain.

“Dr. Roth and Dr. Burke were incredible. They gave a tremendous amount of support to my family; it was the place to be. And it wasn’t just them; this wonderful support translated down to the teams that they had in place… I was just thankful I was there,” says Katz.

Mrs. Katz and her husband, who is chairman of the board for H. Katz Capital Group and owner of L.A. Weight Loss Franchise, had been dividing their time between Florida and Pennsylvania. Upon learning of the diagnosis, they began looking for a nephrologist in Miami, knowing they would be spending even more time in South Florida. Katz’s doctors in Philadelphia and the board of the Polycystic Kidney Foundation on which she served all highly recommended Dr. Roth.

At the time, Dr. Roth was the chief of the Division of Nephrology. In 2003, he was the first to be named the William Way Anderson Chair in Nephrology. In this capacity, he supports research studies that aim to improve treatments for conditions related to kidney failure, such as hypertension, vascular disease, and diabetes. Dr. Roth also can be credited with introducing the Katzes to the university.

“I became aware of the University of Miami through Dr. Roth…,” recalls Mrs. Katz. “As a result of that relationship and future open discussions about philanthropic support, we gave our first $1.25 million gift to the University of Miami in 2003, which went to help junior faculty establish research programs and secure peer-reviewed funding. That’s really how both my husband and I (through our family foundation) got involved and began to give to the University of Miami.”

It’s now clear there is no better endorsement for supporting medical research than personal experience. “It makes us feel good about what we are doing…,” she adds, “because we know we can be impacting someone else’s life.”
“It makes us feel good about what we are doing... because we know we can be impacting someone else’s life.” Peggy Katz

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Getting Back to the Business of Life

Raul J. Valdes-Fauli is a busy man. The lawyer and former four-term mayor of Coral Gables regularly travels throughout Latin America and is active in numerous professional, trade, and civic groups.

In June 2006 he was diagnosed with liver cancer, putting a halt to his demanding schedule. But doctors at the University of Miami Leonard M. Miller School of Medicine’s Center for Liver Diseases quickly returned him to the business of life.

“They were very effective. By effective, I mean compassionate and efficient. They gave me a course of treatment to eliminate my cancer and also put me on a list for a transplant, which I received within four months. After the transplant I was in the hospital for four days and within a month I was back at work,” says Valdes-Fauli.

Liver cancer is on the rise, with the number of cases in the United States roughly doubling in the past 20 years. About 16,000 Americans die of liver cancer each year, and some estimates put the number of people at risk for the disease in the U.S. at four million.

Once Valdes-Fauli learned of his illness, Eugene R. Schiff, M.D., the director for the Center for Liver Diseases, referred him to Lynn G. Feun, M.D., a professor in the Department of Medicine and co-group leader of the Melanoma Clinical Oncology Research program at the University of Miami Sylvester Comprehensive Cancer Center.

Because his cancer indicators (alpha-fetoprotein, or AFP) were so high, Valdes-Fauli was not an immediate candidate for a liver transplant.

Dr. Feun placed him on a drug called Avastin. The drug is a therapeutic antibody designed to inhibit Vascular Endothelial Growth Factor (VEGF), a protein that plays an important role in tumor angiogenesis and maintenance of existing tumor vessels. By binding to VEGF, Avastin is designed to interfere with the blood supply to tumors, a process that is critical to tumor growth and metastasis.

By November, the drug had lowered Valdes-Fauli’s AFP count from 12,000 to approximately three, at which point he became eligible for a liver transplant. He received his new liver in February 2007 from Andreas G. Tzakis, M.D., Ph.D., professor of surgery, chief of the Division of the Liver/Gastro-Intestinal Transplant Program, and director of the Miami Transplant Institute.

Since his successful liver cancer treatment, Valdes-Fauli intends to continue his support of the Miller School by committing to raise $1 million for the division’s Center for Liver Diseases. Over the past year, he has already helped raise $150,000 and will continue to raise additional funds for the school through the Valdes-Fauli Family Research Fund, which he established with his family.

“The gift will go towards research, specifically to fund the investigative work of Dr. Schiff and the Center for Liver Diseases,” Valdes-Fauli says.

He adds: “I’m very supportive of the University of Miami, the Miller School, and UM/Sylvester... In addition to the treatment, all of the doctors who cared for me—Dr. Schiff, Dr. Feun, and Dr. Tzakis—not only did an expert job, but they also are wonderful people, which makes it even more gratifying to support their efforts as well as the school. They are wonderful and very compassionate people.”

After his ordeal, it seems his greater concern today is the toll time inevitably takes on the body. And he is thankful for it.

“When I wake up in the morning something usually hurts, but it’s usually a finger or a toe, which has more to do with my age than my liver. Imagine, I underwent a full liver transplant and I was in the hospital for just a few days... it was just miraculous, and I am eternally grateful to all the University and all of the doctors who treated me,” Valdes-Fauli concludes.
Advancing innovative research through the help of philanthropic support

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