Dear Friends,

Welcome to the first report originating from the newly established Amyloidosis Center at Boston University School of Medicine, and our affiliated hospital, Boston Medical Center! I welcome you on behalf of our researchers, clinicians, and staff. The purpose of this expanded newsletter is to thank all of you for your support and acknowledge our major donors, and to update you on some of the highlights of the last year. It has been an exciting year in so many ways, with important transitions and events for our Center and for amyloidosis research at the Boston University Medical Campus.

A little over a year ago, we participated in the XIIIth International Symposium on Amyloidosis in Groningen, the Netherlands. Much has happened in the field since then: the summary of research discoveries on the following pages will update you on some of the highlights.

This year, we were designated as a Center of Excellence by Dean Karen Antman and Boston University President Robert Brown. Our amyloidosis research program has been in existence since 1960, when Dr. Alan Cohen first identified the fibrillar structure of amyloid deposits in tissues. At that time no one knew what proteins were in amyloid deposits, or why they occurred. A few years later, Dr. Cohen was joined by a young physician scientist, Dr. Martha Skinner, who went on to lead our program, turning it into a multidisciplinary research program that was a model for other centers around the world. Dr. Skinner brought together clinicians and scientists, all focused on increasing our understanding of the causes of amyloidosis and developing a cure, and she established a clinical program based at our affiliated hospital, Boston Medical Center. Dr. Skinner’s contributions have been recognized by the amyloidosis research community with her election as President of the International Society of Amyloidosis. Many of us owe our involvement in amyloidosis research to Dr. Skinner’s leadership and mentoring, and many of you owe your hope and your health to her years of dedication to finding better treatments for patients suffering from amyloidosis. You will enjoy reading her reminiscences on page 5, on the occasion of her appointment as Professor Emerita at Boston University.

Throughout our program’s history we have been lucky to have the participation of a dedicated group of clinicians and scientists, some of whom have gone on to start or to join programs at other medical centers around the world. Particular credit goes to those who worked on the first stem cell transplants, Drs. Ray Comenzo, Evan Vosburgh, and Daniel Wright. Dr. Vaishali Sanchorawala, who now directs the stem cell transplant program, took care of the first patients, as a fellow. Dr. Karen Quillen now runs the blood stem cell collection and banking program. Kathy Finn RN, NP has directed the transplant and clinical trials program staff since the beginning. Dr. Rodney Falk (now at Harvard Vanguard and Brigham & Women’s Hospital) was overseeing the management of cardiac disease, and Dr. Laura Dember (now at the University of Pennsylvania) was leading the management of kidney disease. Many other specialists now participate in our clinical program, including Drs. Mark Sloan (hematology), Frederick Ruberg, Hans Meier-Ewert, and Flora Sam (cardiology), Lauren Stern and Andrea Havasi (renal), Robert Lowe and Hannah Miller (GI), Janice Wiesman (neurology), Caryn Libbey, Rosemary O’Connell, and Shayna Sarosiek (internal medicine), and others; the clinical program is directed by Dr. John Berk (pulmonary, hereditary and localized amyloidosis). This year, our diagnostic laboratory, directed by Dr. Lawreen Connors, will be re-accredited by the College of American Pathologists.

We are all devoted to improving diagnosis and treatment of amyloidosis. We have a great responsibility to our patients, their friends and families, our donors, and our colleagues, to educate doctors and patients about the disease, to steadily improve amyloidosis diagnosis, and to develop new therapies. Inside this report, you will learn about recent breakthroughs in research and about our trainees; contributions of some of the special supporters of our program; and stories from some of our patients. I want to particularly acknowledge the contributions of John and Eliot Stewart, and Ann and Terry Peel. They have worked with us for many years to secure critical funding and support for amyloidosis research. John is greatly missed.

David C. Seldin, M.D., Ph.D.
Amyloidosis Center Director
About 80% of the patients we see have systemic AL (amyloid light chain) amyloidosis, and consequently much of our laboratory and clinical research is devoted to understanding this disease and finding better treatments. However, amyloidosis due to inheritance of mutations in genes such as transthyretin (TTR) or age-related deposits of TTR in “senile systemic amyloidosis” (SSA) has not been neglected, and in fact some of the biggest breakthroughs this past year have been in SSA, so I would like to start with an update on that.

### Familial Amyloidosis

Familial amyloidosis is most commonly due to inheritance of a mutant form of the serum protein transthyretin (TTR). Though he didn’t know it at the time, this was the form of familial amyloidic polyneuropathy first identified by Dr. Andrade in 1952 in Portugal, where some rare breakthroughs. Dr. Jeffery Kelly at the Scripps Institute in La Jolla, California, reported in 1999 that molecules that bind and stabilize TTR in the blood can prevent amyloidosis in the test tube. Two drugs identified in that work (diflunisal and tafamidis) were tested in clinical trials in patients with ATTR. The tafamidis study showed promising results, leading to approval in Europe; even more promising, our collaborators Dr. Ronglih Liao at Brigham and Women’s Hospital and Dr. Jordan Shin at Massachusetts General Hospital have sequentially to control disease activity in our patients. Dr. Vaishali Sanchowala is the principal investigator of these studies. At the same time, we are learning more and more about the mechanisms of disease, and these studies will pave the way for more targeted and less toxic therapies. Basic research breakthroughs in the last year include development of animal models of disease, using mice and small laboratory fish called zebrafish. These are complementary model systems to test drugs in humans, and so much of our basic physiology is similar. With “transgenic” mice that produce human AL amyloid deposits in their stomachs, we can test the efficacy of oral anti-amyloid medications. Even more promising, our collaborators Dr. Ronglih Liao at Brigham and Women’s Hospital and Dr. Jordan Shin at Massachusetts General Hospital have respectively shown that the zebrafish develop cardiac problems in the presence of human amyloidogenic light chain proteins or messenger RNA. For the first time, we now have model systems in which to test therapies targeting the cardiomyopathy associated with AL amyloidosis.

Thus, the last year has brought dramatic progress in amyloidosis research. None of this work would have been possible without the support of federal agencies, foundations, and in particular many individuals who have generously supported these studies. We are grateful to those who have participated in clinical research studies in the hopes of helping themselves and others with these diseases. Their tremendous dedication and unselfishness cannot be overvalued.

### AL (Light Chain) Amyloidosis

For AL, survival has been steadily improving for the past 15 years, as we have learned how to apply stem cell transplantation effectively and safely for patients. Ongoing clinical trials are devoted to optimizing responses to high-dose combination therapies. Nonetheless, many patients still present with advanced disease that makes this treatment risky, and not everyone responds to it. Luckily, the menu of drugs or treatments of patients with AL amyloidosis is steadily expanding. Treatments developed for patients with the bone marrow cancer multiple myeloma have the potential to work for patients with AL amyloidosis, since both diseases are caused by bone marrow plasma cells. With research support from companies such as Takeda/Millennium and Celgene and others, we are studying promising new drugs, and learning how to use them sequentially to control disease activity in our patients. Dr. Vaishali Sanchowala is the principal investigator of these studies. At the same time, we are learning more and more about the mechanisms of disease, and these studies will pave the way for more targeted and less toxic therapies. Basic research breakthroughs in the last year include development of animal models of disease, using mice and small laboratory fish called zebrafish. These are complementary model systems to test drugs in humans, and so much of our basic physiology is similar. With “transgenic” mice that produce human AL amyloid deposits in their stomachs, we can test the efficacy of oral anti-amyloid medications. Even more promising, our collaborators Dr. Ronglih Liao at Brigham and Women’s Hospital and Dr. Jordan Shin at Massachusetts General Hospital have respectively shown that the zebrafish develop cardiac problems in the presence of human amyloidogenic light chain proteins or messenger RNA. For the first time, we now have model systems in which to test therapies targeting the cardiomyopathy associated with AL amyloidosis.

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### Senile Systemic Amyloidosis

The protein TTR is also the troublesome for patients with age- related or so-called senile systemic amyloidosis (SSA), a cause of cardiac disease in older patients. In this age-related form of amyloidosis, the TTR gene is not mutated, and the disease is not hereditary. Dr. Lawrence Connors’ work studying the natural history of this disease, which is being recognized more and more by cardiologists in our aging population, has demonstrated that this disease, occurring predominantly in men, is not as benign as was previously appreciated. Accumulating data on exercise capacity and cognition in this population will help us understand who needs treatment, and we are optimistic that drugs such as diflunisal and tafamidis will also be useful for these patients. SSA may turn out to be the most common form of amyloid heart disease in the U.S.

### In Their Own Words

Samuel Finkielstein

Eighteen years ago I did not come to Boston to visit our three sons and their families who lived there, I came looking for medical help. It was a very distressing situation. I was not so optimistic that doctors in Colombia could not make a diagnosis. I remember a very honest professor of a well- respected medical school, telling me “I have no idea what you have.” After about one month of testing, another physician reached a conclusion: “The bad news is that you have amyloidosis; and the good news is that the best place for the treatment is here in Boston at the Boston University Medical Center.” Of course I understood what it meant to have a terminal disease, and did not keep it a secret from my family. I started treatment at the Amyloidosis Center, under the guidance and inspiration of Dr. Martha Skinner, I found that the people that work there created an environment of excellence in care that provided a patient with support and most important, hope. I found, that it was possible for me to absorb that spirit, and extend it to my family. When caregivers and family work in unison the patient gets the power and support that is vital to survive. I feel lucky to be alive all these years and enjoy the company of my wife, the maturity of our children and the growth of our grandchildren.

At the end of the day, the secret is that as long as we are alive we try daily to do the best we can to improve the life of those around us, and to pass that feeling on to our family and friends.

Dr. Michael Greene, PhD graduate, and Dr. Lawreen Connors his mentor, on the occasion of receiving his degree.

Charlotte Traub

October 3, 1995 is the day I found out I had inherited the dreaded familial amyloidosis gene. I was 36 years old, a wife and mother of two sons, ages 3 and 9. I had witnessed the devastating effects of the disease on members of my family and had watched my dad die at age 46 from complications caused by the disease. My husband broke the news to me, and we both were considered what the future held for me and for our family. Over the course of the next few days and weeks, we clung hard to each other and to our faith in God. People all over the world were praying for me, and I felt encouraged and ready to face the challenge of this disease.

I called Boston Medical Center to set up an evaluation. Dr. Martha Skinner called me on the phone, I affirmed my fears, and offered HOPE! My first trip to Boston was in November of that same year, and we were met by a wonderful, caring staff. We got there not knowing what to expect, and left knowing I was among the best doctors in the world. My only huge disappointment was that I didn’t meet Dr. Skinner on that first visit!

“The dedication and hard work of the people involved in this program are like no other, and after 17 annual visits and evaluations, we are privileged to call them ‘family!’ Thank you, Dr. Skinner, for all your hard work on behalf of those of us with amyloidosis. Our prayers continue for all of you there.

Fast forward to today. I am still showing no clinical evidence of the disease. I am on an active liver transplant list so that if the time comes, I will be ready. I thank God for the research program at Boston Medical Center and for all the doctors through the years who have contributed. We have referred many people to the program and have personally seen the good results in their lives. Clinical trials continue and bring great hope. I am confident that one day soon, I will be able to tell my sons that even if they have the gene, they will NOT need a liver transplant. The dedication and hard work of the people involved in this program are like no other. After 17 annual visits and evaluations, we are privileged to call them “family!” Thank you, Dr. Skinner, for all your hard work on behalf of those of us with amyloidosis. Our prayers continue for all of you there.

I wish to underscore the fact that the progress of the "dreaded amyloidosis disease" is due to the hard work and dedication of the people involved in the program at Boston University Medical Center.

The dedication and hard work of the people involved in this program are like no other, and after 17 annual visits and evaluations, we are privileged to call them “family!” Thank you, Dr. Skinner, for all your hard work on behalf of those of us with amyloidosis. Our prayers continue for all of you there.
I have worked in the Amyloid Program almost from its beginning. By chance I became part of the new Amyloid Program at Boston University School of Medicine when I became a rheumatology fellow more than 40 years ago. The Program was started in 1960 by Dr. Alan Cohen; he just had made the discovery that amyloid deposits in biopsy tissues had a fibril structure. If the deposits had structure, he felt they could be isolated and analyzed biochemically. When I joined the Rheumatology Section of the Department of Medicine in the late 1960s, isolation and biochemical analysis of amyloid fibrils became my research project. At that time, really nothing was known about amyloidosis or amyloid diseases except that they were often rapidly fatal. The amyloid proteins had to be identified so that the disease processes could be understood, and tests developed to make the diagnosis. We worked diligently. Other groups did too. And discoveries were shared at periodic international meetings.

Patient referrals to our Program started in 1972. At first there were 6 or 8 patients per year, and gradually the numbers increased. This year more than 500 patients will visit the Amyloid Clinic; and because of research advancements many will participate in clinical trials. We now know that the most common type of amyloidosis is AL and it is a bone marrow abnormality. We have discovered inherited gene mutations cause many different familial types. With the improved technology of today, new types are still being discovered. As I look back our research progress was very slow; technology was so old fashioned compared to today. It took days to identify one amino acid (building block) in the chain of an amyloid protein. Dr. Karl Schmid, a very brilliant biochemist at the Medical School who advised me on protein sequencing, spent his whole working life determining the amino acid sequence of one protein which today could be sequenced in hours or days. Analysis of DNA sequence was just beginning in the 1970s and similarly was an arduous process. By the 1980s we had identified many amyloid proteins; we were beginning to identify gene mutations, and we could fairly accurately diagnose amyloid type. Rationales for treatment were being discussed. Our first clinical trial using oral chemotherapy for AL amyloidosis began in 1987. The results prompted our trial of high-dose chemotherapy and autologous stem cell transplantation in 1994. And the first liver transplant in the United States for the most common type of familial amyloidosis was performed in 1992 in collaboration with Dr. David Lewis at the Lahey Clinic.

For me it was rewarding to have a job that was making new knowledge, and to realize that the discoveries were making a difference in people’s lives. Our research team continues to feel the excitement of discovery. Lawrene Connors, the director of our laboratory along with David Seldin and our dedicated scientists, Elena Klimtchuk, Tatiana Prokaeva, Brian Spencer, Halli Cui, Gloria Chan, Jennifer Ward and our students Michael Greene, Clarissa Koch, and Jacquelyn Sikora are discovering new complexities that emerge as each new bit of knowledge is found. Fortunately, with today’s technology they can work at a faster pace. One reason for the faster pace has been top notch equipment in the Gerry Laboratory. We are very grateful to Terry and Ann Peel for the equipment they helped us obtain through HRSA grants. And we thank them for the work they have done to bring the need for amyloid research to the United States Congress and to the National Institutes of Health.

As I retire from day-to-day work this year, I realize the most rewarding part of my work has been the privilege of seeing the extraordinary courage of people who fought a rare disease with a bravery you can’t imagine. I know all of my clinical colleagues, Vaishali Sanchorawala, David Seldin, John Berk, Janice Wiesman, Rick Ruberg, Hans Meier-Ewert, Lauren Stern, Andrea Havasi, Caryn Libbey, Rosemary O’Connell, Mark Sloan, and Carl O’Hara feel honored by this privilege too.

I have been fortunate to spend my working life in a job that exceeded all my expectations. One cannot put a value on the thrill of research discovery in the laboratory or the realization that our work was helping people. It has been my good fortune to work with a team of people who give so generously of their time and energy to research and to the care of very ill patients.

I am pleased that David Seldin has succeeded me in directing the Center. With our new Center status, he will competently and brilliantly guide future direction. For my future, I have been awarded Professor Emerita status. I will be continuing to work on special projects with the dedicated team of scientists in our new Amyloidosis Center.

The Stewart Pin

John Stewart was a man of many talents. For 14 years John’s incisive thinking, creativity, and gentle way helped guide our program’s growth to become a Center of Excellence.

During the course of our relationship we learned of another talent. John was a pilot. Not just any pilot who simply enjoyed flying or traveling to a destination unencumbered by ground traffic. He was an Angel Flight volunteer who, when called, would carry a patient across country for urgent medical care.

And, there was yet another talent. We didn’t learn of it until the 2012 dinner that honored John and his wife Eliot. John designed jewelry! During the reception I noticed John’s daughter and Eliot were wearing identical pins, a crossed pick and shovel of gold. When asked, Eliot told us that John had them made to honor what he called his “pick and shovel team’. Those who rolled up their sleeves, picked up the tools, and pitched in to help. Why a pick and shovel? Maybe they date back to John’s early education and training as an engineer, or perhaps even further to his ancestors working the earth in Scotland.

John Stewart had many talents!

John W. Carpenter
Development Counselor

I learned from Dr. Skinner that there was hope—and she had examples to prove it.”

Thank you from all the Wellbringts to Dr. Skinner, Dr. Seldin and their world-class highly professional and competent staffs for keeping me around an extra 13 years. Family life and grandchildren, in particular, are a treat.
STATEMENT ON AMYLOIDOSIS
BY
ANN D. PEEL
PRIVATE CITIZEN, BETHESDA, MARYLAND

THE SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES COMMITTEE ON APPROPRIATIONS U.S. HOUSE OF REPRESENTATIVES
MARCH 15, 2013

Mr. Chairman,

Amyloidosis is an often misdiagnosed, often fatal disease. I ask that you include language in the Committee’s report for fiscal year 2014 urging the National Institutes of Health and other health agencies to fund research for amyloidosis and to increase awareness of the disease.

In previous testimony before this Committee, I described my efforts to combat the life-threatening disease primary amyloidosis. I have obtained treatment for amyloidosis and want to use my experience to help others.

Amyloidosis can literally kill people before they even know that they have the disease. It often leads to heart, kidney, liver and other organ failure. Left untreated, there is an average survival of 15 months from the time of diagnosis.

I’m happy to report that, since I began appearing before this Subcommittee several years ago, progress has been made in research and treatment for various types of amyloidosis. However, only limited research is currently being funded. Much, much more needs to be done.

Thousands of people die because they were diagnosed too late to obtain effective treatment. Thousands of others die never knowing they had amyloidosis. The small number of those with amyloidosis who are able to obtain treatment face challenges that can include high dose chemotherapy and stem cell replacement or organ transplantation.

Amyloidosis is vastly under-diagnosed. This is especially the case in the African-American community.

AMYLOIDOSIS

Amyloidosis occurs when cells malfunction and produce proteins that deposit in organs, such as the heart, kidney and liver. These misfolded proteins clog the organs until they no longer are able to function—sometimes at a very rapid pace.

In addition to primary amyloidosis, a blood or bone marrow disorder, there are also cases of inherited or familial amyloidosis and secondary or reactive amyloidosis. All three types of amyloidosis, left undiagnosed or untreated, are fatal.

There is no explanation for how or why amyloidosis develops and there is no known reliable cure.

AMYLOIDOSIS TREATMENT

Boston University School of Medicine and other centers for amyloidosis treatment have found that high dose intravenous chemotherapy followed by stem cell replacement, or rescue, is an effective treatment in selected patients with primary amyloidosis. Abnormal bone marrow cells are killed through high dose chemotherapy and the patient’s own extracted blood stem cells are replaced in order to improve the recovery process.

I am part of a clinical trial and have gone through this procedure twice.

The high dose chemotherapy and stem cell rescue and other new drugs have increased the remission rate and long term survival dramatically. However, more research needs to be done to provide less risky forms of treatment.

RESEARCH, DIAGNOSIS AND TREATMENT

Researchers are moving forward with limited funding to develop targeted treatments that will specifically attack the amyloid proteins. Additional funding for research and equipment is needed to accomplish this task. Only through more research is there hope of further increasing the survival rate and finding treatments to help more patients.

Timely diagnosis is also of great concern. Although I was diagnosed at a very early stage of the disease, many people are diagnosed after the point that they are physically able to undertake treatment.

Early treatment is the key to success. More needs to be done in this area to alert health professionals to identify this disease.

CURRENT INITIATIVES

Through the leadership of this Committee and the further involvement of the U. S. Government, a number of positive developments have occurred.

• The National Institutes of Health has substantially increased its interest in amyloidosis. The NIH, particularly the Office of Rare Diseases, participates in meetings and symposiums and works closely with organizations doing research and outreach on amyloidosis.

• There has been increased basic and clinical research at the Boston University Amyloid Treatment and Research Program: a model for the disease is under development; factors that cause protein misfolding are being identified; and new clinical trials are underway.

• Increased Federal funding for research, equipment and treatment has been another important element. This is essential to speed the pace of discovery for basic research.

REQUEST FOR FISCAL YEAR 2014

Mr. Chairman, I ask that the Committee take the following actions to help address this deadly disease:

• First, include language in your report identifying amyloidosis as an important concern and encouraging more research to find a cure.

• Second, continue to encourage the Centers for Disease Control and the National Institutes of Health to educate the American public and medical profession on the need to diagnose this disease at an early stage.

The United States Congress and the Executive branch working together are essential to finding a cure for and alerting people to this terrible disease. Help me turn what has been my own life-threatening experience into hope for others.

Thank you for your consideration.

This spring, Ann and Terry Peal again took it upon themselves to offer testimony to the Subcommittee on Labor, Health and Human Services, and Education and Related Agencies of the U. S. House of Representatives Committee on Appropriations. They first did this in 2005, soon after Ann was diagnosed and successfully treated for amyloidosis at Boston Medical Center, and have requested this opportunity annually.

The House Appropriations Committee sets priorities for the federal budget. Each year, they invite members of the public to testify about budget priorities. The Subcommittee on Labor, Health and Human Services, and Education and Related Agencies determines funding and priorities at the National Institutes of Health, the major federal source of funding for biomedical research. Amyloidosis had never been a priority area. Following Terry and Ann’s testimony in 2005, the NIH convened its first Symposium on Amyloidosis in June 2006, to identify priority areas for research. This led to funding through NIH and also through the Health Resources and Services Administration (HRSA) for Boston University, Boston Medical Center, the Mayo Clinic, and other institutions. Many of the breakthroughs that we have made in research were made possible through this support.

Terry and Ann help the Amyloidosis Center in many ways. Terry is a member of Dean Antman’s Advisory Board, they both attended a dinner in honor of Board Member and Amyloidosis Center advisor John Stewart, and Eliot Stewart, and they co-sponsored a recent informational event at Sandi Stewart and Michael Abram’s house in Washington D.C., that was attended by area patients, family, and friends of the program, including U.S. Senator Robert Casey. We are so lucky to have so many supporters and advocates for amyloidosis research, who are helping us to improve the lives of our patients and families.

Ann Peel (right) and her daughter, Amanda Crowley (center) speak with Karen Antman, MD (left), Provost of the Boston University Medical Campus and Dean of Boston University School of Medicine. This dinner took place back in October 2012 in honor of the late Dean’s Advisory Board member John Stewart and Eliot Stewart.
Amyloidosis Center Photos

Dr. Lawreen Connors, Lab Director (right), with some of the Gerry Laboratory team

Drs. John Burk, Center Clinical Director and Rick Ruberg, Cardiologist

Drs. Saulius Girnius and Vaishali Sanchorawala, Hematologists

Ms. Janis Johnson, Center Coordinator

Ms. Elizabeth Pelletier, Patient Coordinator

Ms. Samantha Pappin, Research Coordinator

Dr. Elena Klimchuk, Biophysicist

Dr. Lawreen Cannon, Gerry Laboratory Director

Clarissa Koch, PhD student
AMYLOIDOSIS CENTER DONOR LIST 2011-2012

The Amyloidosis Center at Boston University School of Medicine is pleased to recognize the generosity of its many donors whose support has assisted us in enhancing and continuing our progress in discovering a cure for amyloidosis. We thank our donors for their ongoing participation and commitment. This donor list recognizes individuals who have made gifts totaling $250 or more to the Amyloidosis Center.

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- David S. Levine Golf Tournament
- Friends of Mary Milani
- Howard Weitzman Amyloidosis Research Benefit
- Narragansett Wings Motorcycle Club
- Sharpminds Music Academy
- University of New Hampshire A Capella Groups

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Bequests: Estate of Helen Burr
The Amyloidosis Center gratefully accepts financial support for our research and clinical programs from patients, family, and friends.

For information on bequests and other planned giving options contact us at the address listed above or by phone. Donations can be made through our website or by mail.

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Website: www.bu.edu/amyloid

Amyloidosis Center Photos

John Carpenter, Development Counsel (left), with Samuel Finkielsztein

Drs. Hans Meier-Ewert, Cardiologist and David Seldin

Dr. Carl O’Hara, Pathologist

Dr. David Seldin (right) with Dr. Tatiana Prokoeva and Brian Spencer in the Gerry Laboratory