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BIOFEEDBACK

THE FISCHELL DEPARTMENT *of* BIOENGINEERING
A. JAMES CLARK SCHOOL *of* ENGINEERING

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A NEWSLETTER FOR ALUMNI AND FRIENDS OF THE FISCHELL DEPARTMENT OF BIOENGINEERING AT THE A. JAMES CLARK SCHOOL OF ENGINEERING, UNIVERSITY OF MARYLAND, COLLEGE PARK.

IN THIS ISSUE:

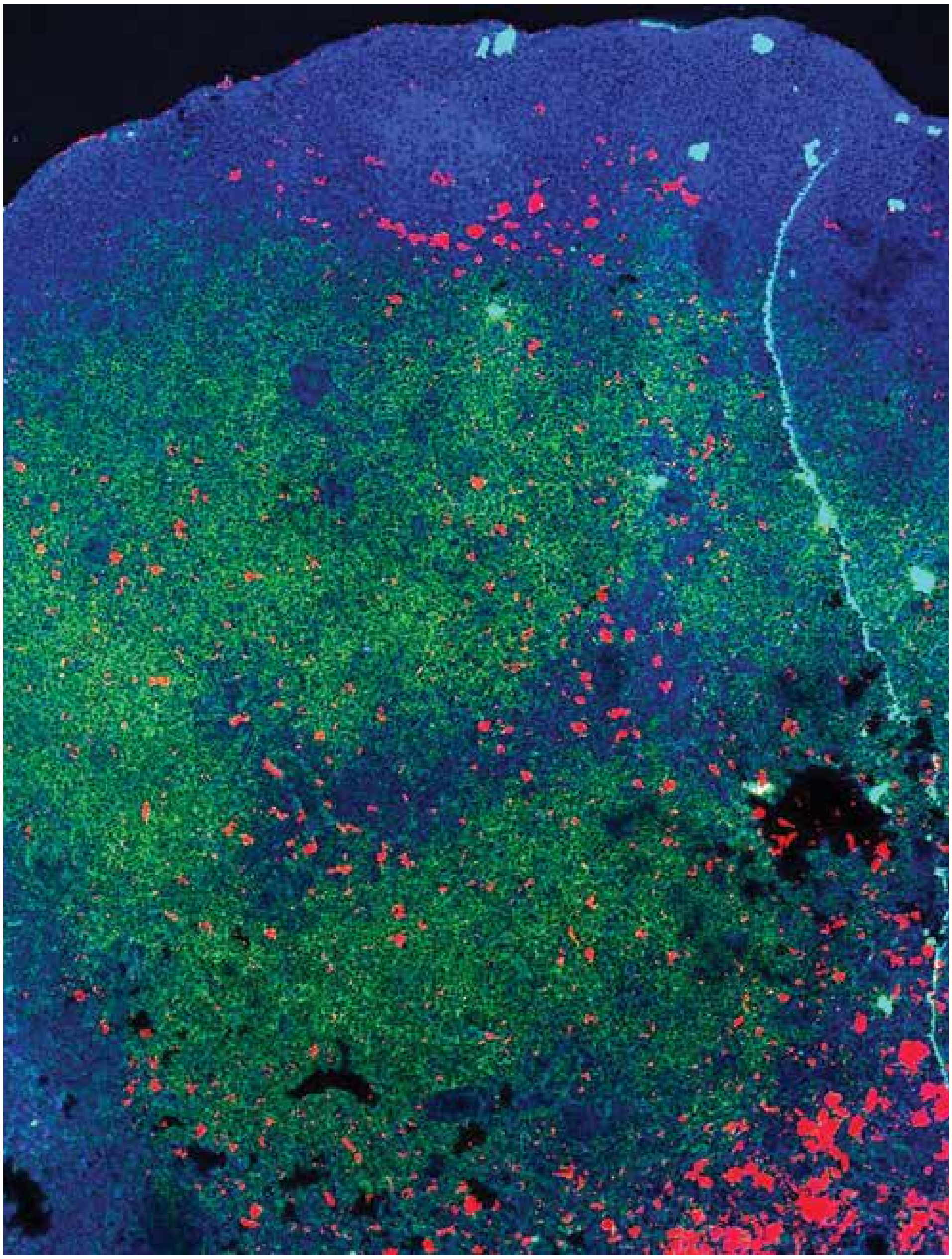
Arming the Immune System to Fight Cancer

Researchers Are Developing Cancer Vaccine Technology to Inject Directly into the Lymph Nodes to Help Fight Pediatric Cancer

Fischell Researcher Helps Arm the Immune System to Fight Cancer

In 2004, a form of cancer known as neuroblastoma claimed the life of Alexandra (Alex) Scott, a little girl who garnered national attention for using her lemonade stand to raise money for cancer research. Recently, the organization established in her memory, the Alex's Lemonade Stand Foundation (ALSF), awarded University of Maryland (UMD) Fischell Department of Bioengineering (BioE) Assistant Professor Christopher M. Jewell a three-year, $375,000 research grant to support the pre-clinical development of a cancer vaccine technology that could give children like Alex a better chance to live a long and happy life.

Neuroblastoma, the third most common pediatric cancer, causes nerve cells to turn into tumors. The prototype vaccine uses a unique combination of nanotechnology and immunology to "raise an army" of tumor-hunting immune cells, equip them to attack neuroblastoma, and leave them ready to reactivate if the cancer returns.



The lymph nodes are the body's immune system "command centers," packed with different types of immune cells. Each cell is equipped with a protein that responds to a particular disease or infection. Fragments of viruses, bacteria, and tumors collected in the lymph nodes are presented to these cells as antigens, molecules that provoke a response to a specific threat. When an immune cell encounters an antigen that it is designed to respond to, the cell "activates" and multiplies. These cells are then released into the blood and tissue to hunt their specific pathogens.

One type of activated immune cell, the central memory T cell, is particularly effective at infiltrating tumors. These cells start life as ordinary, inactive T cells in the lymph nodes that have the potential to become one of a number of active T cell types. Jewell's goal is to enhance the immune system's natural response by encouraging T cells to multiply and become central memory T cells specific for tumor antigens.

Jewell is an expert in immunomodulation, an emerging field that explores directing the body's immune system response to target a specific disease. And, earlier this year, he was selected for a five-year, $438,000 National Science Foundation (NSF) Faculty Early Career Development (CAREER) award for his vaccine design and immunotherapy research.

Jewell believes crafting a biomaterials-based vaccine that not only provides T cells with the weapons to fight neuroblastoma, but also instructions on how to do so, will give oncologists a new, more specific treatment option

Lymph nodes are the tissues that coordinate immune response. The fluorescent image shows the B cell zone (blue) at the edge of the lymph node, and the T cell zone toward the center (green). During infection or vaccination, these zones become intermingled to generate cells and antibodies that migrate out of the lymph node and combat or protect against infection. The Jewell lab is using new delivery tools to study how polymeric vaccine carriers (shown in red) impact lymph node signaling, and how these interactions can be exploited for biomaterial-based vaccines to treat cancer and autoimmune disorders.

that relies more on the patient's own defenses than radiation and chemotherapy.

Creating any successful vaccine is difficult. Once injected, its components are dispersed around the body. Just a fraction of the vaccine reaches the lymph nodes, and its components are often so damaged or degraded by the trip they're no longer functional. Engineered microparticle and nanoparticle vaccines face additional challenges, because they are either too large to drain into lymph nodes or they become too large because they stick to cells, proteins, or other particles.

Jewell's research group is developing a unique system in which controlled-release, biodegradable polymer "depots" are injected directly into the lymph nodes. The depots protect the vaccine components inside, control when they are released, and direct what happens next.

The vaccine contains two elements: the antigen that stimulates the T cells to attack neuroblastoma cells, and "immune signals," small molecules that mimic the chemical signals immune cells use to communicate. The message, like the antigen, is another call to action: transform into central memory T cells, and multiply. Jewell hopes this approach will result in an army of central memory T cells prepared to destroy neuroblastoma tumors and capable of "remembering the enemy" later.

The cells' mission continues after the existing tumors are cleared. "Establishing these large populations of immunological memory cells could also help keep patients in remission by rapidly destroying tumor cells that might arise during relapse events," Jewell explains.

He adds that, while the work is in the early stages, this technology could lead to new therapeutic technologies for treating other types of cancer.

"High-risk tumors like neuroblastoma are treated with multiple therapeutic strategies with poor outcomes," said Dr. Anthony Sandler, chief of surgery at Children's National Medical Center, who is collaborating with Jewell on the project. "Cancer vaccines add another therapeutic option, but so far have had very limited success. The novel approach proposed in this work may provide the spark that stimulates effective immunity against the tumor."

"Cancer vaccines represent a new class of therapies, and biomaterials have great potential to treat cancers like neuroblastoma," says Jewell. "The ALSF's support and the clinical training we will receive through our collaboration with Children's National Medical Center have created an amazing opportunity. This investment will have a lasting impact on my lab's ability to contribute to the pediatric cancer field."

As principal investigator for the Jewell Research Lab, Jewell and his team also study polymeric carriers that are important to the vaccine field, as well as new materials they are testing as improved vaccines. Through this research, the team hopes to uncover the reasons why some polymers work effectively as vaccine carriers, while others do not. Additionally, Jewell and his team study how the effectiveness of traditional vaccines – those that do not feature polymeric carriers – compares with that of vaccines that harness these new materials.

Looking Ahead to the Next Generation of Bioengineers

In late 2013, Jewell was named Outstanding Young Engineer by the Maryland Science Center and the Maryland Academy of Sciences. As one of Maryland's highest professional honors, the title of Outstanding Young Engineer is awarded to engineers who have pioneered and implemented new approaches to solve difficult problems. Jewell was presented with the award's Allan C. Davis medal, which is given to "encourage the important work of young scientists and engineers residing in the State of Maryland and increase public awareness of their accomplishments."

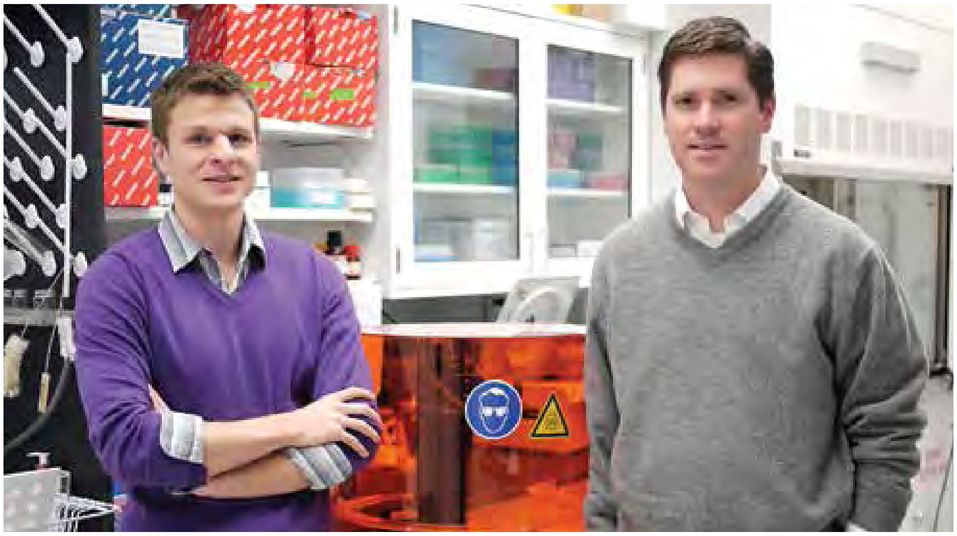
Encouraging young engineers is certainly a goal Jewell aims to achieve. In fact, along with his contributions to the biomaterials vaccine field, Jewell has played an integral role in the push to launch two new bioengineering programs at Wheaton High School in Silver Spring, Md.

The first program, established for the Biosciences Academy at Wheaton, featured a three-week module through which nearly 70 high school students worked in partnership with Fischell graduate students and postdoctoral researchers, who served as mentors, to create lessons about vaccines and conduct experiments in the Jewell lab.

The second program, established for the Biomedical Magnet Program at Wheaton, provided a select group of 20 students with a yearlong opportunity to learn about the research process by focusing on a bioengineering topic of their choosing. Selected topics include the use of stem cells to treat brain damage, therapies for multiple sclerosis, and biomechanics in sports medicine. Additionally, each program participant is partnered with a Fischell student or postdoctoral mentor, and tasked with interviewing experts, reading scientific literature and writing a review article.

The goal of the program is to not only provide high school students with an opportunity to delve into bioengineering topics, but to also help students learn about science and engineering career opportunities, and to provide opportunities for research internships, Jewell said. Additionally, the program provides Fischell graduate students and postdoctoral researchers with an opportunity to gain invaluable scientific management and mentorship experience.

Researchers Achieve Breakthrough in 3D Printing for Heart Implants



2011 Fischell Fellow Anthony Melchiorri (left) and Professor of Bioengineering and Associate Chair John Fisher (right) set out to develop a better material for vascular implants.

In recent years, the benefits of 3D printing have transformed countless concentrations in engineering, not the least of which is medical implant design.

While 3D printing has revolutionized the customization of medical implants for everything from bones and cells to skin and eyes, Fischell Department of Bioengineering Professor John Fisher and 2011 Fischell Fellow Anthony Melchiorri recently set out to use the latest technology to help tackle the nation's leading killer.

Claiming nearly 600,000 U.S. lives each year and accounting for approximately one in every four deaths in the nation, cardiovascular disease has proven one of today's most costly health problems. Knowing this, the duo worked to develop a unique biocompatible polymer that FormaSTEM, the company they co-founded, uses to create vascular grafts, which act as artificial blood vessels.

> Cardiovascular disease claims nearly 600,000 U.S. lives each year, accounting for approximately one in every four deaths in the nation.

Once implanted, the grafts support and serve as a template for the growth of blood vessel tissue. Its mechanical properties, strength and elasticity mimic those of actual blood vessels. And, because Fisher and Melchiorri's graft is biodegradable, the patient's own tissue replaces it over time. By the time the graft is gone, a new, real blood vessel segment has taken its place, reducing or eliminating the need for further surgeries.

Even more, because the grafts are produced on a 3D printer loaded with their special polymer, every patient can have one custom-made before surgery. Biomedical imaging techniques are used to create a 3D digital model of the patient's heart, and the graft is designed in the computer to fit precisely in the damaged area.

Then, the graft is "printed out."

This flexibility, Melchiorri explained, makes the FormaSTEM system an especially strong candidate for the treatment of congenital heart defects, which affect one percent of all live births. These defects are challenging to correct because each child's problem is unique – there is no single implant or graft that can help them all. Currently, surgeons fabricate custom grafts based on adult models during the operation, adding time to the procedure. The grafts don't grow with the children, meaning most will face multiple open-heart surgeries before they reach adulthood. FormaSTEM grafts could address all of these problems.

"With biodegradation and by encouraging native cell growth, you potentially reduce the number of surgeries throughout a patient's life, which relieves a huge financial and emotional burden, as well as additional burden on the patient's health," Melchiorri said. "If we can get a graft that fits the patient right away and that encourages cells to grow right away in their life and then degrade, the patient is not left with a prosthetic that needs to be replaced every several years because that graft is either a.) failing or b.) because the child has outgrown it."

Melchiorri noted that he and Fisher have incredible drive to push on with their research as, currently, nearly 1,350,000 vascular graft procedures are performed each year in the U.S. alone.

Not surprisingly, the duo's efforts have garnered quite a bit of attention in recent months, earning them UMD's Office of Technology Commercialization "Invention of the Year" award for the life science category this spring. The two also received the "Best Inventor Pitch" award at the 2013 Professor Venture Fair, held as part of Bioscience Research & Technology Review Day last fall.

Melchiorri noted: "It's great to see that all this work we're doing in the lab – that, largely, we talk about for hours, we develop for hours and we do the experiments and get all this data and we spend all this time within our own little circle creating, in this case, this polymer resin – people appreciate it and understand the impact of what we're doing."

UMD and JHU Students Host Research Fair

Undergraduates from the Fischell Department of Bioengineering (BioE) and Johns Hopkins University's Department of Biomedical Engineering (JHU BME) joined forces to host the second annual JHU-UMD Undergraduate Research Fair on March 28. Designed to showcase the impact and quality of undergraduate research, as well as to encourage classmates to pursue their own laboratory experiences, the event was held this year at the Jeong H. Kim Engineering Building on the University of Maryland's campus in College Park, Md. Guest speakers included Clark School benefactor Dr. Robert Fischell, Department Chair and Robert E. Fischell Distinguished Professor William Bentley, and Director of the Mtech Maryland Industrial Partnerships (MIPS) program, Dr. Martha Connolly. Following the success of last year's event, held on the JHU Homewood campus in Baltimore, the two universities' student chapters of the Biomedical Engineering Society (BMES) coordinated this year's event under the leadership of chapter presidents Luke Peterken (BioE) and Anvesh Annadanam (JHU BME).

Liu Receives Whitaker International Undergraduate Program Scholarship

Winston Liu

This spring, BioE junior Winston Liu embarked on a semester abroad to study bioengineering at the Universidad Carlos III de Madrid (UC3M), thanks to a scholarship awarded by the Whitaker International Undergraduate Program and the Institute of International Education (IIE). Liu is the first University of Maryland student to receive one of the Whitaker international scholarships.

The Whitaker International Undergraduate Scholarship Program was established to increase the number of bioengineering and biomedical engineering students who study abroad. The program provides participants up to $7,500 for a semester or as much as $10,000 for an academic year to enroll in biomedical engineering courses, complete an internship or conduct research.

Liu, who studied Spanish from third grade until recently, has always wanted to study abroad in a Spanish-speaking country. As such, UC3M is particularly tailored to his interests.

"One of the things that was really exciting to me about Carlos III was that they had core focuses on bioimaging and bioinstrumentation. And, bioimaging is something that I'm very interested in," he said, adding that he would like to pursue a career in either that or bioinformatics.

Liu enrolled as a full-time bioengineering student for the semester abroad, taking courses on fluids, biomaterials and imaging.

Barber, Iacangelo Awarded Olatunji Godo Biomedical Research Scholarships

BioE juniors Nathan Barber and Abigail (Abby) Iacangelo have been named 2013 recipients of the Olatunji Godo Biomedical Research Scholarship.

Established in 2012 by alumnus Olatunji Godo (B.S. '11, materials science and engineering), the scholarship fund supports undergraduates conducting research in BioE, the Department of Chemical and Biomolecular Engineering, or the Department of Materials Science and Engineering. Godo established the scholarship so other students could have the opportunities he had as a Clark School student.

Barber, who has been a member of BioE professor and chair William E. Bentley's research group since the summer after his freshman year, focuses on metabolic and genetic engineering. His current research, conducted under the mentorship of BioE graduate student Jessica Terrel, uses modified E. coli bacteria that fluoresce when they encounter signaling molecules excreted by harmful bacteria. This ability to respond to a specific type of molecule allows them to be used as a diagnostic tool capable of detecting contamination in complex biological samples. The E. coli sensors also carry nanoparticles that are used to magnetically separate them out of a solution when their work is done.

Iacangelo works in BioE associate professor Adam Hsieh's Orthopaedic Mechanobiology Lab, where she is comparing the mechanical properties of various tendon types used in anterior cruciate ligament (ACL) replacement.

With an interest in the design of prosthetic limbs, Iacangelo first got involved in research as a sophomore. After examining the Clark School's bioengineering and mechanical engineering labs, she ultimately felt Hsieh's was the best fit, and was happy to discover he was "more than willing" to have her join his team. She has since participated in a variety of Hsieh's studies, which she says has enhanced and broadened her skill set.

STUDENT AWARDS

Congratulations to the following students, who have demonstrated outstanding academic and research performance, and have made contributions to the Fischell Department of Bioengineering and the field.

THE FISCHELL DEPARTMENT OF BIOENGINEERING'S OUTSTANDING SENIOR AWARD:
Xinyi Zhou

THE FISCHELL DEPARTMENT OF BIOENGINEERING'S OUTSTANDING JUNIOR AWARD:
Jonathan Kozlowski

THE FISCHELL DEPARTMENT OF BIOENGINEERING'S OUTSTANDING RESEARCH AWARD:
Jeff Rappaport

THE FISCHELL DEPARTMENT OF BIOENGINEERING'S OUTSTANDING CITIZEN AWARD:
Emily Guerra

THE FISCHELL DEPARTMENT OF BIOENGINEERING'S VOLUNTEER AWARD:
Mian Khalid

OUTSTANDING ENGINEERING CO-OP/INTERN AWARD:
Alexandra Paraloglou

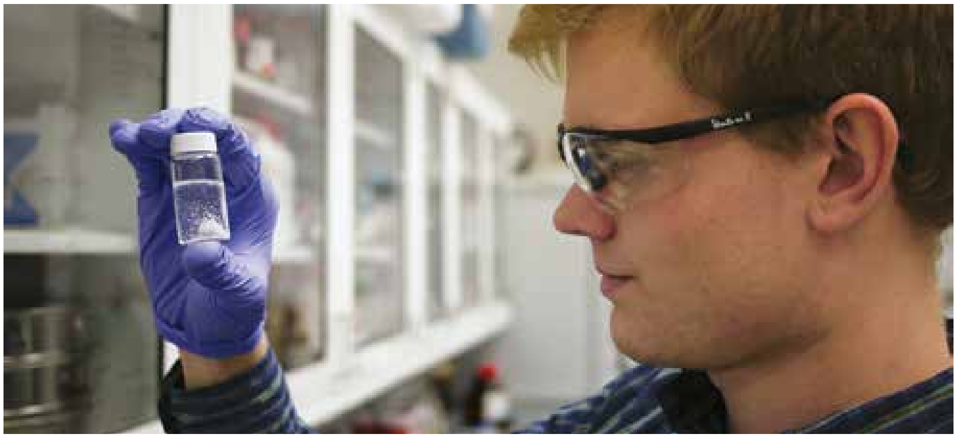
WOMEN IN ENGINEERING SERVICE AWARD:
Savannah Vogel

CENTER FOR MINORITIES IN SCIENCE AND ENGINEERING LEADERSHIP AWARD:
Whitney Wilson

CENTER FOR MINORITIES IN SCIENCE AND ENGINEERING SERVICE AWARD:
Eduardo Solano

A. JAMES CLARK SCHOOL OF ENGINEERING LEADERSHIP AWARD:
Jeff Rappaport

A. JAMES CLARK SCHOOL OF ENGINEERING INTERNATIONAL STUDENT AWARD:
Maggie Prendergast



Sikorski Named a 2014-2015 Philip Merrill Presidential Scholar

Fischell Department of Bioengineering (BioE) undergraduate Michael Joseph Sikorski has been named a 2014-2015 Philip Merrill Presidential Scholar.

The program honors the University of Maryland's (UMD) most successful seniors and their designated university faculty and K-12 teachers for their mentorship. Sikorski will be recognized along with other Merrill Scholars finalists and alternates at a special ceremony and luncheon to take place this fall.

Sikorski works in the Functional Macromolecular Laboratory under the mentorship of BioE Professor and Associate Dean Peter Kofinas and graduate student Adam Behrens. Their project aims to develop a new platform for topical and surgical sealants that utilizes the direct deposition of polymer nanofibers using a simple commercial airbrush. This technique allows for conformal nanofiber coatings to be generated on any surface, making it potentially very useful in difficult surgical procedures. Even more, the coatings can act as a supplement or replacement for traditional sutures.

With plans to attend medical school after he completes his undergraduate degree, Sikorski may one day find himself using the platform he helped create in the hospital setting.

"It is exciting to work on this research because it directly applies to the medical field, and could someday be used to help save lives," he said.

Belyaeva Awarded Amgen Scholars Summer Research Internship

BioE junior Anastasiya Belyaeva was recently awarded a 2014 summer research internship with the Amgen Scholars Program at the University of Washington's computational chemistry department.

The prestigious program allows students to take part in important university research projects and gain hands-on lab experience while interacting with faculty mentors, including some of the world's leading academic scientists. A signature component of the summer program is a mid-summer symposium held in California, where students hear firsthand from leading scientists working in industry and academia.

Belyaeva, a student in Assistant Professor Silvina Matysiak's Molecular Modeling Laboratory, has focused her recent research on determining the molecular mechanism of Huntington's disease using computational molecular dynamics.

Huntington's disease is a disorder passed down through families in which nerve cells in certain parts of the brain degenerate, resulting in cognitive decline and psychiatric disorders.

Belyaeva has studied the aggregation behavior of a small peptide in the amino terminal region of Huntington protein (N17). By simulating molecular driving forces between N17, water and the lipid bilayer, she hopes to elucidate the conformational and secondary stricture changes N17 undergoes upon contact with the lipid bilayer.

With the summer Amgen Scholars Program, Belyaeva will work on modeling the biophysical interactions between proteins and cell membranes in order to study the process of their aggregation. Using computer simulations, she hopes to characterize the structural changes of the lipid bilayer and proteins as they interact.

Tostanoski Receives NSF Graduate Research Fellowship

Second-year Ph.D. student Lisa Tostanoski, a member of Fischell Department of Bioengineering (BioE) Assistant Professor Christopher Jewell's research group, was recently awarded a $132,000 National Science Foundation (NSF) Graduate Research Fellowship for her work designing therapeutic vaccines to induce immunological tolerance for the treatment of autoimmune disorders.

Most recently, Tostanoski has worked on generating specific therapeutics for multiple sclerosis (MS), an autoimmune disease that affects 2.5 million people worldwide and has no known cure. MS causes the immune system to unpredictably attack a nerve-insulating protein called myelin as if it were a foreign invader, disrupting communications throughout the central nervous system. Sufferers may experience a wide variety of mild to debilitating symptoms, including vision problems, pain, weakness, loss of balance and concentration, and numbness.

Many of the typical clinical interventions today rely on general immune suppression, which has proven effective – but, these treatment options can leave patients immunocompromised, Tostanoski noted.

Knowing this, she and members of the Jewell research team are working to apply biomaterial strategies to enhance current therapies by regulating the way in which the body responds to self molecules such as myelin. In particular, Tostanoski has focused her efforts on designing polymer coatings that incorporate myelin, along with regulatory immune signals that, when delivered together in biomaterials, could help control MS without broad immunosuppression.

"I'm really excited that the research could potentially have a lot of implications for the treatment of autoimmune diseases," Tostanoski said. "The NSF Fellowship provides opportunities to promote dissemination of our work, not just through scientists and journal articles, but also through outreach programs."

Tostanoski noted that, in addition to work done in the lab, the lab has an extensive outreach program with high school students interested in bioengineering that has given her an opportunity to become involved in mentoring. Lisa also plans to connect with the local chapter of the National Multiple Sclerosis Society to build awareness of the disease and promote the involvement of researchers from non-traditional backgrounds

"I'm grateful for Dr. Jewell's guidance, and I received a lot of support on campus through some of the available resources for fellowship applications and from other graduate students," she said. "It's been a great experience."

Dr. Jewell noted, "Lisa is a talented and meticulous engineer, who couldn't be more deserving of the NSF fellowship."

Behrens, Manthe Join Future Faculty Program

Graduate students Adam Behrens (advised by Professor and Associate Dean Peter Kofinas) and Rachel Lee Manthe (advised by Associate Professor Silvia Muro) were among only 25 students recently named to this year's Future Faculty Program cohort.

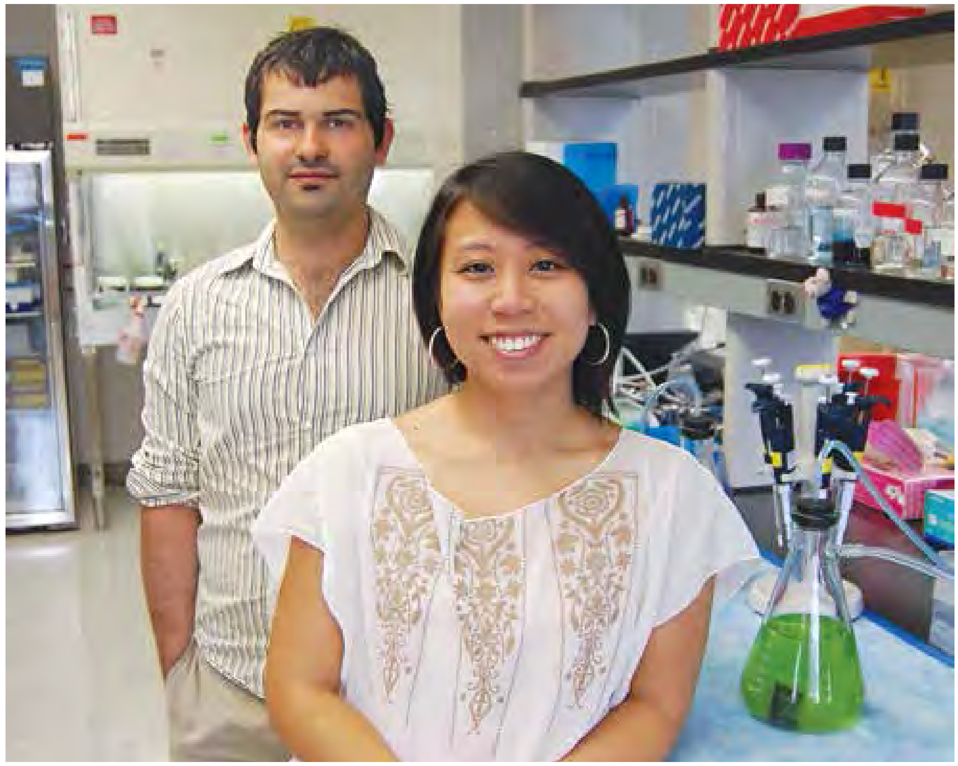
Much of Behrens' research has centered on how functional polymer materials can be used by surgeons and first responders to halt bleeding, repair hernias, and perform intestinal anastomosis.

Manthe's research focuses on overcoming the difficulty of transporting drugs across impermeable cell barriers and into diseased tissues. She is currently studying nanocarriers targeted to ICAM-1, a cell surface molecule known to transport substances across cell layers, and the role two particular enzymes play in the process. A thorough understanding of these mechanisms will enable researchers to design more effective drug delivery systems.

Hsu Receives ASNM Young Investigator Award

Fischell Department of Bioengineering (BioE) graduate student Janet Hsu was recently awarded a Young Investigator Award by the American Society of Nanomedicine for her work on the transport of intercellular adhesion molecule 1 (ICAM-1)-targeted carriers across the blood-brain barrier (BBB) – a semi-permeable barrier that separates the brain from the circulatory system. Formed by capillary endothelial cells (EC), the BBB protects the brain from potentially harmful chemicals, but, by nature, it can also inhibit drug delivery to the brain.

ICAM-1 is a cell surface molecule known to transport substances across cell layers. As such, under the advisement of Assistant Professor Silvia Muro (joint, BioE and Institute for Biotechnology and Bioscience Research) and the Muro Group laboratory, Hsu works to investigate how ICAM-1-targeted nanoparticles have the potential to improve drug delivery across the BBB and into neurons.



Janet Hsu and fellow Muro Group member Daniel Serrano (BioE)

Hsu's aim has been to treat cells that are affected by lysosomal storage disorders (LSDs), commonly caused by a genetic deficiency of functional lysosomal enzymes. LSDs affect all organs in the body and current treatment is considered suboptimal as it poorly distributes enzyme therapeutics to all affected organs and is inefficiently uptaken by cells.

But, recent tests have shown that the group's targeted drug delivery system can improve delivery of enzymes in all peripheral tissues and the brain in mice, Hsu noted.

"We've achieved this by targeting the enzyme to ICAM-1, which is involved in the inflammatory process and is naturally upregulated in pathology, as seen in LSDs," she said. "This makes ICAM-1 a good candidate to target to improve the delivery of therapeutics to the sites affected by the disease."

Ferlin Awarded Graduate Dean's Dissertation Fellowship for 2014-15

Doctoral candidate Kimberly Ferlin was recently named one of just 13 University of Maryland doctoral students awarded the Graduate Dean's Dissertation Fellowship for the 2014-15 academic year.

A student in BioE Professor and Associate Chair John Fisher's Tissue Engineering and Biomaterials Laboratory, Ferlin also conducts research at the Food and Drug Administration's (FDA) Center for Devices and Radiological Health under Dr. David Kaplan.

The main goal of Ferlin's research is to tailor cell-substrate interactions to simplify mesenchymal stem cell (MSC) enrichment, proliferation and differentiation. MSCs have tremendous therapeutic potential as they are capable of differentiating into various mesenchymal lineages such as bone, adipose and cartilage; however, MSCs represent only a fraction of the cells that are found in bone marrow and lack unique identifying markers, proving them difficult to isolate precisely.

In fact, there are currently few strategies that are capable of capturing and culturing MSCs in one step. As such, Ferlin aims to use a polymer fabricated in the lab – propylene fumarate (PPF) – as a base for the attachment of specific proteins and growth factors that will promote the adhesion and differentiation of a desired cell population. PPF is a hydrophobic polymer that can be used for rapid prototyping fabrication methods, such as 3D printing. As such, Ferlin and fellow members of the Tissue Engineering and Biomaterials Laboratory are working to develop a 3D printed PPF scaffold that can be modified to encourage MSC isolation based on adhesion to the material surface, resulting in the capture, culture and differentiation of MSCs for engineered cartilage tissue applications.

Native articular cartilage has very limited ability for repair, resulting in cartilage defects costing an estimated $60 billion annually in the United States alone. As such, Ferlin hopes that her team's work will provide an alternative to current repair techniques, contributing significantly to the field of cartilage tissue engineering.

Shapiro's Otomagnetics Recipient of BioMaryland Center Award


Ben Shapiro

Otomagnetics, a startup with roots in the Clark School, was recently named one of seven innovative life sciences companies to receive a Biotechnology Development Award through the BioMaryland Center, an office within Maryland's Department of Business and Economic Development.

The BioMaryland Center awarded up to $200,000 to each of the companies and one educational institution, totaling $1.5 million in funding to accelerate the commercialization of a wide range of treatments and technologies.

Led by Fischell Department of Bioengineering (BioE) and Institute for Systems Research (ISR) Professor Benjamin Shapiro, Otomagnetics is a magnetic particle drug delivery system for treatment of sudden hearing loss and, eventually, common ear infections. Along with ISR Associate Research Scientist Dr. Didier Depireux and the rest of the Otomagnetics team, Shapiro has worked to design a minimally invasive platform technology that directs and delivers therapeutics to the middle and inner ear to enable treatment of conditions such as sudden hearing loss, tinnitus and middle ear infections.

Since its inception in 2010, the BioMaryland Biotechnology Development Awards program, a key component of Maryland Governor Martin O'Malley's Bio 2020 initiative, has provided more than $6 million to 32 Maryland life sciences companies.

Prior to receiving the Biotechnology Development Award, Shapiro received the Fischell Department of Bioengineering 2013 Outstanding Teaching Award in fall 2013.

Lab on a Chip Journal Highlights Atencia's Microfluidics Research

BioE Research Assistant Professor Javier Atencia and National Institute of Standards and Technology (NIST) Research Bioengineer Gregory Cooksey were recently featured in *Lab on a Chip*, a journal published by the Royal Society of Chemistry, for their work with microvalves in folded 2D and 3D fluidic devices, known as microfluidic devices.

Cooksey and Atencia developed a prototyping technique that expands elastomeric valving capabilities to devices made from thin materials such as plastic films and double-sided tapes.

Typically, microfluidic devices are tiny apparatuses with fluid-carrying channels used in medical diagnostics, among other purposes. They are most often fabricated using photolithography, a process often used to create microchips. Additionally, microfluidic devices are traditionally designed as a pattern of miniature channels and ports over a silicon substrate, and the process used to replicate these patterns can take days to complete and often requires specialized equipment.

But, because the microfluidic devices Cooksey and Atencia have developed over the past few years are manufactured using plastic films and tapes, they can be fabricated in hours, rather than days.

The duo's microfluidic devices are also very thin – typically measuring less than 0.5 mm in thickness – which allows them to have many layers. Narrow slits are cut into the double-sided tape, which permits folding of the devices into 3D structures that have fully functional valves. Even more, because Atencia and Cooksey's microfluidic valves are made from cut-out laminates and tapes, the devices are cheap to buy and the technologies used to design and fabricate them – razor cutters and laser machines, for example – are widely available and affordable.

"Because the technology is so simple and cheap, I also believe it can easily be incorporated in undergraduate lab courses to help students explore the physics of fluid flow at the micro scale and transport phenomena," Atencia added.

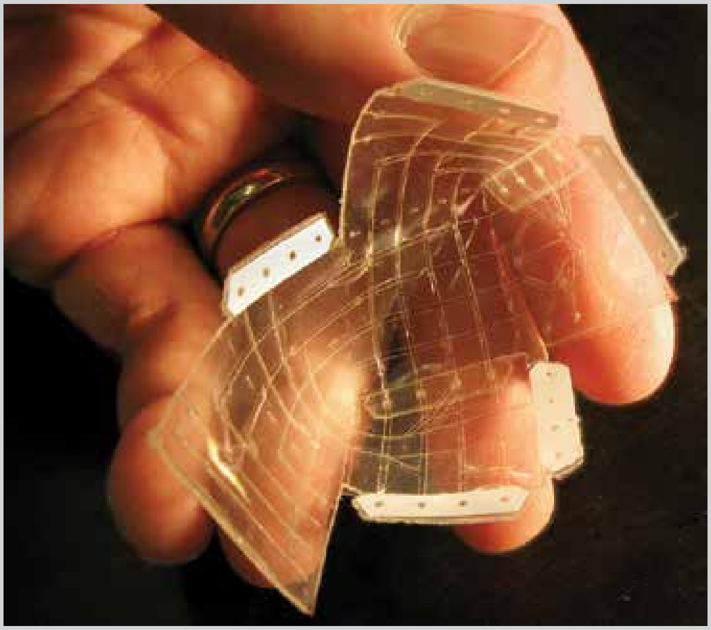


PHOTO COURTESY OF DR. GREGORY COOKSEY

A microfluidic chip built with plastic films, tape and, inside, elastomeric valves

He and Cooksey have also used their microfluidic device in complex configurations, such as devices with different designs for performing different tasks simultaneously. The duo even applied their technique to a cube-shaped device, in which the researchers placed agar and grew smooth-skinned threadworms, called nematodes (*Caenorhabditis elegans*). Using microchannels, ports and valves built into the cube's walls, Atencia and Cooksey injected chemicals at controlled concentrations that either attracted or repelled the worms. This demonstrated that their microfluidic devices could be used to study a living organism's response to chemical stimuli within a closed environment.

Diagnostic anSERS Launches Affordable Trace Technology

Diagnostic anSERS co- founders Eric Hoppmann (left) and Sean Virgile (right).

Diagnostic anSERS, the Fischell Department of Bioengineering-based start-up company founded by graduate students Eric Hoppmann and Sean Virgile, both advised by BioE and Institute for Systems Research Assistant Professor Ian White, has introduced a groundbreaking Surface Enhanced Raman Spectroscopy sensor – otherwise known as a SERS sensor – that enables trace chemical detection for only a few dollars per test. The sensor is poised to bring SERS into the mainstream.

SERS enables measurement of a molecule's uniquely identifying Raman "fingerprint" at trace levels. While Raman alone can only identify bulk materials, SERS enables the sample's molecular fingerprint to be obtained at millions of times lower concentrations than would be possible using Raman alone.

By applying a sample to a SERS substrate (sensor) and measuring the fingerprint with a handheld spectrometer, molecular identification can be carried out at the parts per billion level in less than a minute.

P-SERS™ is the first SERS sensor that is both cost effective – at a few dollars per test – and highly sensitive. While existing substrates are rigid sensors on silicon wafers, P-SERS™ substrates are flexible and can be used as dipsticks or surface swabs as well as a cost-effective alternative to existing silicon wafer substrates. Diagnostic anSERS is able to achieve this combination of high sensitivity without high cost through a patent-pending technique in which roll-to-roll ink-jet printing is used to precisely deposit special nanoparticle ink onto paper and other flexible support materials.

These easy-to-use sensors can be used for detection of a wide variety of molecules, including drugs, explosives, food contaminants and taggants for anti-counterfeiting. Additionally, there are custom sensors available that can be optimized for detection of targets which are difficult to measure and/or require ultra-high sensitivity, such as biological markers. Tests which previously would have required samples being sent to centralized labs, with the consequent multi-day wait and high price tag, can now be performed on-site. Affordable access to this class of ultra-trace detection enables practical screening in a wide variety of applications.

P-SERS™ research was recently featured as the cover article in the analytical chemistry journal, Analyst. In the piece, the researchers demonstrated detection of malathion, an organophosphate – or class of insecticides and nerve agents – at 413 picograms. They also demonstrated detection of heroin and cocaine at nine and 15 nanograms, respectively. Notably, these dipsticks and surface swabs were shown to provide repeatable, quantitative measurements, reporting the amount of drug residue on the surface (not merely presence/absence).

Fischell Alumna Joins Faculty


Kimberly Stroka

Earlier this spring, The Fischell Department of Bioengineering (BioE) and the A. James Clark School of Engineering named Assistant Professor Kimberly M. Stroka a new member of BioE faculty. Her official start date is slated for January 2015.

Stroka, who specializes in cell engineering, nano/microtechnology and quantitative mechanobiology, received her Ph.D. in Bioengineering from the Fischell Department of Bioengineering in 2011.

Prior to joining the Clark School, Stroka was a postdoctoral fellow in the Department of Chemical and Biomolecular Engineering and the Institute for NanoBioTechnology at Johns Hopkins University.

Her recent work has focused on cancer metastasis, cardiovascular disease and the immune response and, more specifically, how physical properties of the cell's microenvironment – such as stiffness and dimensionality – affect cellular behavior.

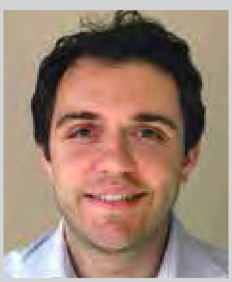
Stroka's new lab will address questions at the interface of nano/microtechnology and blood-brain barrier mechanobiology; the cell cycle, nuclear mechanics and their role in disease; and stem cell engineering. Additionally, Stroka is interested in developing microfluidic-based "organ-on-a-chip" models for complex biological systems such as the blood-brain barrier, which can then be used to unravel pressing questions such as how tumor cells metastasize to the brain.

"My goal is to develop an innovative research program that combines microfabricated devices, cellular engineering via molecular biology, live cell imaging and quantitative analysis in order to create relevant in vitro models of multi-scale biological systems," Stroka said. "Subsequently, my goal is to understand the mechanobiology of the interactions between cells and their microenvironment in the context of cancer and cardiovascular disease."

By taking a highly interdisciplinary approach, her lab will be able to develop regenerative and/or drug-based therapies for diseases, she noted.

"I am extremely excited to join the Fischell Department of Bioengineering," she said. "I completed my Ph.D. in the Fischell Department of Bioengineering, so I know firsthand how excellent the environment is. The energy and vibrancy of the department drew me in as a graduate student, and that same energy and vibrancy have drawn me to become part of the faculty."

Scarcelli Joins Fischell Faculty


Giuliano Scarcelli

The department also named Assistant Professor Giuliano Scarcelli as a new member of BioE faculty. His official start date is also slated for January 2015.

Scarcelli, who specializes in biophotonics with strong emphasis on optical sciences and technology development, received his Ph.D. in Applied Physics from the University of Maryland, Baltimore County (UMBC) in 2006.

Prior to joining UMD and the Clark School, he served as an instructor with the Harvard Medical School and Wellman Center for Photomedicine at Massachusetts General Hospital in Boston. At Wellman, Scarcelli worked on developing a new optical technology that enables the measurement of the stiffness of material without touching it; rather, it is an imaging technology that simply requires shining a light on the material to map its stiffness. Scarcelli's demonstration of the feasibility and potential of this technology earned him the Tosteson Postdoctoral Fellowship Award, a NIH K25 Career Development Award and a Young Investigator Award from the Human Frontier Science Program.

"In the past few years, I am proud to say that we have brought this new technology from first principles all the way to clinical trials," Scarcelli said. "In particular, our new imaging technology [at Wellman] has had an impact in ophthalmology, where the biomechanical properties of the cornea and crystalline lens had been long sought-after but never measured noninvasively."

Scarcelli is the inventor in four patents, all licensed to industry, and he has published approximately 30 publications with more than 1,000 citations.

Born and raised in Italy, Scarcelli completed his undergraduate in physics from the University of Bari Aldo Moro before receiving a European Union international graduate student fellowship to pursue his Ph.D. at UMBC.

"Having lived in the [College Park] area before, I knew from personal experience and personal interactions how strong the Clark School of Engineering is," he said. "I immediately realized I wanted to join the Fischell Department of Bioengineering because it is a great environment, with top-level research in all the fields that are complementary to mine. There is strong potential of synergistic research, and I think my research program will highly benefit from this environment."

Bentley Receives Marvin J. Johnson, Charles Thom Awards


William Bentley

This March, the American Chemical Society's (ACS) Division of Biotechnology (BIOT) awarded BioE Department Chair and Robert E. Fischell Distinguished Professor William Bentley its Marvin J. Johnson Award in Microbial and Biochemical Technology at the ACS national meeting in Dallas, Texas.

In a letter to Bentley, BIOT Awards Co-Chairs Matthew DeLisa (Cornell University) and Todd Przybycien (Carnegie Mellon University) cited him for his many contributions to the biotechnology field, "in particular for [his] innovative molecular and metabolic engineering contributions advancing protein expression, quorum sensing, RNA inhibition, and biofunctional devices."

Prior to receiving the Marvin J. Johnson award, Bentley received the Society for Industrial Microbiology and Biotechnology's Charles Thom Award, which recognizes individuals who have made one or more outstanding research contributions in industrial microbiology or biotechnology. It is awarded to individuals of exceptional merit, who reflect originality that adds to scientific knowledge.

Connolly Named UM Ventures Director of Bioentrepreneurship

Dr. Martha J. Connolly

Earlier this year, the University of Maryland Ventures (UM Ventures) named Fischell Department of Bioengineering (BioE) affiliate faculty member Dr. Martha J. Connolly director of bioentrepreneurship, a new program supported by the Maryland Technology Enterprise Institute (Mtech) and the A. James Clark School of Engineering. This program is designed to enhance collaboration between the University of Maryland, College Park (UMD) and the University of Maryland, Baltimore (UMB) as part of the MPowering the State initiative.

"UM Ventures creates an integrated innovation ecosystem that includes entrepreneurial support resources," said James Hughes, Chief Economic Development Officer and Vice President at UMB. "Experts like Martha help turn novel ideas into sustainable businesses, and I'm pleased to have her as part of our enterprise."

Connolly joins the UM Ventures team whose goal is to foster entrepreneurship among faculty and students. Through her recent appointment, she led the first-ever course in entrepreneurship on the UMB campus, which launched in January 2014. Connolly is also working closely with 16 teams of engineering students from UMD who are paired with UMB clinical faculty to define problems in healthcare, then develop products to improve patient health and clinical outcomes. Increasingly, students look at careers beyond the traditional academic research path and these courses will prepare them for careers in private industry.

"Martha Connolly is a highly regarded and proven professional in technology-based economic development in the state of Maryland," said University System of Maryland Chancellor William E. "Brit" Kirwan. "As one of the state's first biotechnology advocates, she helped lay the foundation for the state's now-thriving bioscience economy."

Connolly has served as director of the Mtech Maryland Industrial Partnerships (MIPS) program since 2003. MIPS is a grant program that funds and connects Maryland companies with University System of Maryland faculty to develop commercially promising technology products.

As head of MIPS, where nearly 40 percent of funding is awarded to bioscience-related projects, Connolly connected faculty with companies such as MedImmune, CSA Medical, WellDoc, PharmAthene, GenVec, Innovative Biosensors, 20/20 Gene Systems, Alba Therapeutics, A&G Pharmaceutical and Gliknik to foster development of new products.

Prior to MIPS, Connolly directed business development activities at a publicly traded biopharmaceutical company, and co-founded a startup technology development and commercialization firm.

Before that, Connolly was the first-ever biotechnology advocate hired at the state level at the Maryland Department of Business and Economic Development (DBED) to foster the state's then fledgling bioscience industry. During her time at DBED, she helped grow the Maryland bioscience community from 300 to 450 businesses.

Kofinas Featured in *Chemical & Engineering News*

Peter Kofinas

BioE Professor and Associate Dean Peter Kofinas was featured in *Chemical & Engineering News (C&EN)* for his work with polymer nanofibers for use in surgery as a sealant, hemostatic and buttress for tissue repair.

This work is led by BioE graduate student and Citrin Fellow Adam Behrens.

In the piece, "Airbrushed Polymers Could Seal Surgical Incisions," writer Katherine Bourzac discusses how researchers have proposed replacing sutures with sticky, biodegradable mats of polymer nanofibers to seal surgical incisions and promote healing. Bourzac highlights Kofinas' work with researchers at Food and Drug Administration and the Children's National Medical Center on surgical adhesives for sealing up blood vessels and intestinal tissue. Even more, she notes that Kofinas and his colleagues have established a process to make mats of polymer nanofibers using an airbrush technique commonly used to apply paint.

"The researchers showed that the mats could seal diaphragm hernias and cuts to the lung, intestine and liver in a pig," Bourzac writes, noting that Kofinas and his team are currently working to improve the materials for surgical trials in animals.

Behrens (B.S., '10, chemical engineering) is now a Ph.D. candidate in the final year of his dissertation research. He has been working with Kofinas since his sophomore year, when he was recruited from the professor's section of ENES 100: Introduction to Engineering Design. Today, much of his research focuses on how functional polymer materials can be used by surgeons and first responders to halt bleeding, repair hernias and perform intestinal anastomosis.

In addition to being featured in C&EN, Kofinas's work was highlighted on the global scale, with recognition of his research featured in publications across France, Japan, Spain, Colombia, Brazil, Portugal and Greece this spring alone.

Additionally, Kofinas was featured on a local radio spot with CBS affiliate All News WNEW 99.1 FM. The piece highlighted how Kofinas's work could transform how doctors close surgical incisions.

"Doctors and surgeons have wanted to use a sticky glue to close surgical incisions, but the old way of applying it was damaging good and living cells until researchers figured out something new," said WNEW reporter Rob Dawson. "Kofinas and his team spent a lot of time trying to get the chemical combination just right so that it could work in the airbrush."

"We paint fibers on top of wounds – something similar to a commercial paintbrush," Kofinas said in the interview. "It is portable, it can go into the operating room, and it uses a gas that's already in the operating room."

Along with being featured in recent publications, Kofinas has been recognized for his role as faculty mentor for 2014-2015 Philip Merrill Presidential Scholar Michael Sikorski. Along with Sikorski, a rising BioE senior, Kofinas will be honored at a luncheon for scholars, teachers and faculty this fall.

Dr. Fischell Awarded Inaugural ECEDHA Industry Award

University of Maryland Electrical and Computer Engineering Department Chair Rama Chellappa and Clark School benefactor Dr. Robert Fischell.

The Electrical and Computer Engineering Department Heads Association (ECEDHA) named A. James Clark School benefactor Dr. Robert Fischell a recipient of the inaugural ECEDHA Industry Award.

Given to companies or individuals in recognition of seminal contributions to engineering education that extend well beyond typical industry-university relationships, the award was presented to Fischell at the ECEDHA annual conference, which took place March 21-25 in Napa, Calif. The selection is based primarily on a qualitative evaluation of educational contributions to recognize and encourage effective engagement in engineering education by industry representatives. The ECEDHA noted that Fischell was chosen largely for his passion to create new devices for the sake of mankind, as well as for his activities and lifelong achievements in developing, mentoring and teaching students.

Fischell is the creator of several lifesaving medical devices and biomedical companies. He serves on the Clark School Board of Visitors and the University of Maryland Foundation Board of Trustees.

Fischell, who holds more than 200 patents, is the father of modern medical stents, lifetime pacemaker batteries and implantable insulin pumps. He received a Master's degree in physics from the university in 1953.

Spine Society Grant Supports Hsieh's Back Pain Research

Fischell Department of Bioengineering (BioE) Associate Professor and Associate Chair Adam Hsieh recently received a Basic Research Grant from the North American Spine Society (NASS) to explore and explain the exact biological mechanisms that lead to back pain.

"While there have been significant advances in identifying the risk factors of spinal disorders associated with lower back pain, they don't address the problem faced by those who are already afflicted," Hsieh explains. "Although recent studies have made progress toward understanding what factors might provoke chronic intervertebral disc pain, the precise biological mechanisms responsible for it remain poorly understood."

He describes the project, in which he is partnering with co-PI and former BioE professor Sameer Shah (University of California, San Diego), as an early step in a broader effort to improve the diagnosis and treatment of discogenic back pain through a more comprehensive understanding of what happens at the cellular and molecular levels.

Hsieh and his colleagues have recently developed a novel in vitro culture model of the spine's dorsal (back) root ganglions, the small bulb-like nodules to which nerve filaments extending from the spinal cord connect. The model allows them to study the cellular physiology and regulation behind the invasion of nerves called sensory axons into the extracellular matrix, the fluid found between the cartilage cells in intervertebral discs. When the nerves penetrate, the discs become sensitized to the mechanical pressures of their environment, resulting in pain.

Hsieh and Shah will explore how inflammatory conditions in the spine affect the communication between the dorsal root ganglions and the intervertebral disc's annulus fibrosis, the stiff ring of fibrous material around its gel-like center. It is this intercellular communication that is thought to stimulate the pain-inducing neural growth. Understanding how to control or block this chatter could stop it; however, Hsieh says, things aren't so straightforward, and are sometimes even contradictory.

"Not all discs invaded by nerves are painful, and some painful discs don't exhibit pronounced nerve penetration," he says. "This represents a critical gap in our knowledge, and suggests that the regulation of both neuronal growth and sensitization processes are complex. Inflammation inhibits neural growth, but stimulates disc cells to secrete nerve growth factor. The degradation of the extracellular matrix removes barriers to nerve ingrowth, but decreased tissue stiffness blocks it. Mechanical and nutritional considerations present additional complexities. Our hypothesis is that a confluence of biochemical and biophysical factors result in neuronal ingrowth, neurophysiological sensitization, and pain. While individual connections have been made between inflammation, disc cells, neurons, and extracellular matrix degradation, the complete picture has yet to be uncovered."

BioE Associate Professor Adam Hsieh (right) with fellow NASS grant recipients.

BioE and Mtech Partner with Children's National Health System to Form Pediatric Device Consortium

In the fall of 2013, the A. James Clark School and the Sheikh Zayed Institute for Pediatric Surgical Innovation at Children's National Health System received a grant from the U.S. Food and Drug Administration (FDA) to form the National Capital Consortium for Pediatric Device Innovation (NCC-PDI). The $700,000 grant represents the first part of an anticipated five-year award. Fischell Department of Bioengineering (BioE) Chair and Robert E. Fischell Distinguished Professor William Bentley serves as the consortium's co-principal investigator.

The grant was awarded by the FDA's Office of Orphan Products Development, which funds consortia that advance the development of pediatric medical devices. These consortia work with the FDA to help innovators effectively navigate existing laws, regulations and agency guidance that protect the health and safety of children.

The NCC-PDI partnership will include BioE, the Clark School's Maryland Technology Enterprise Institute (Mtech) and Mtech's Maryland Industrial Partnerships (MIPS) program.

In addition to providing a platform of experienced regulatory, business-planning and device development services to foster the advancement of medical devices for pediatric patients, the NCC-PDI partnership will also bring together individuals and institutions that can support pediatric medical device progression through all stages of development.

It will provide a platform of experienced regulatory, business planning and device development services (such as intellectual property counsel, prototyping, engineering, laboratory and animal testing, grant writing and clinical trial design) to foster the advancement of medical devices for pediatric patients; bring together individuals and institutions that can support pediatric medical device progression through all stages of development—ideation, concept formation, prototyping, preclinical, clinical, manufacturing, marketing, and commercialization; support a mix of projects at all stages of development, particularly the later stages of clinical, manufacturing, and marketing; and provide counsel on accessing various federal and non-federal funding resources while assessing the scientific and medical merit of proposed pediatric device projects.

For more information about NCCPDI, visit www.innovate4kids.org.

UMD, UMB to Offer Joint Degree in Medicine, Bioengineering

Dual degree program designed to promote human health through engineering principles and scientific method education

The University of Maryland's (UMD) School of Medicine and the A. James Clark School of Engineering have initiated a combined doctor of medicine/doctor of philosophy in bioengineering degree program to meet the demand for both medical sciences and bioengineering expertise among health professionals early in their careers.

This new offering is part of the MPowering the State initiative, designed to enhance collaboration between UMD and the University of Maryland, Baltimore (UMB) by focusing their collective expertise on critical statewide issues of public health, law, biomedical informatics, and bioengineering.

The goal of the dual degree program is to educate physician scientists in engineering principles and scientific methods to develop knowledge and products to promote human health.

"This is the latest of many educational offerings within bioengineering that serve to connect engineers with clinical environments and medical practice," said William Bentley, Chair of the Fischell Department of Bioengineering.

"This joint effort will help transform the workforce in the region by connecting the most populous engineering talent in the U.S. with the most expansive biomedical research enterprise in the world. Our partnership with UMB is absolutely essential," said Darryll Pines, Farvardin Professor and Dean of the A. James Clark School of Engineering.

Students enrolled in the M.D./Ph.D. program will begin the seven- to eight-year endeavor with two years of medical school at the University of Maryland School of Medicine and part one of the national licensure exam. During the summers before and after their second year of medical school, students will explore opportunities in laboratories affiliated with UMD's Fischell Department of Bioengineering. In their third year, students will matriculate to the Clark School, where they will complete two to three laboratory rotations, required coursework, dissertation research and defense, and a semester-long teaching assistantship.

Upon successful completion of the doctoral defense, students will return to UMB to complete clinical rotations and part two of the licensure exam. UMD and UMB will confer the Ph.D. and M.D. degrees, respectively.

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The M.D./Ph.D. in Bioengineering program is part of UMD's School of Medicine's Medical Scientist in Training Program (MSTP), which is funded by the National Institutes of Health to train the next generation of leaders in academic medicine and biomedical research.

"In addition to our established programs in neurosciences, microbiology and immunology, molecular medicine, epidemiology, biochemistry and toxicology, our students now have the option of pursing the Ph.D. in bioengineering," said MSTP Program Director Michael Donnenberg. "The partnership with the Clark School of Engineering is part of a continuing effort to expand the Medical Scientist Training Program to meet the challenge of educating the next generation of physician-scientists to find new treatments for human disease."

Tuition and fees of all MSTP students are covered by the MSTP training grant, individual training grants secured by the student, or the School of Medicine during the medical school portion of program. The Ph.D. in Bioengineering tuition and fees will be covered by the Fischell Department of Bioengineering, research grants obtained by the student's mentor, or training grants secured by the student.

Schultheis Leads New UMD Regulatory Science Initiative

Dr. Lex Schultheis

Last fall, the University of Maryland (UMD) appointed Dr. Lex Schultheis as Director of UMD's New Regulatory Science and Innovation Initiative to grow the regulatory science initiative at the university in partnership with the U.S. Food and Drug Administration (FDA).

Through this initiative, UMD researchers are helping to make Americans safer by developing innovative, science-based processes to improve consumer safety and streamline government regulations. Many of UMD's programs – including those in engineering – have great relevance to the current challenges that the FDA faces in transforming itself into a "science based, science led" regulatory agency.

UMD's Center of Excellence in Regulatory Science and Innovation (M-CERSI), awarded by the FDA in partnership with the University of Maryland, Baltimore (UMB), works to develop new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated drugs and medical devices. As such, the Regulatory Science and Innovation Initiative will foster further development of research and education programs in partnership with the FDA. As Director, Schultheis will plan and grow all facets of the initiatives' operations, including the development of new applications, products, academic programs and collaborations between faculty, researchers, students, corporate partners and government agencies.

A Maryland native, Schultheis completed his undergraduate and Ph.D. training in bioengineering at Johns Hopkins University, where he focused on studies of adaptive control systems and signal processing in the brain. In medical school at the University of Pennsylvania, his interests in modeling physiology expanded to studies of artificial environments, such as patients under anesthesia and humans in space flight.

Schultheis completed a residency in anesthesiology with a clinical fellowship caring for cardiac surgical patients at Johns Hopkins. He has more than 20 years of experience as an active physician, including direction of a subspecialty of cardiac anesthesiologists and work as Chairman of a Department of Anesthesiology at the Washington Hospital Center. Most recently, Schultheis served as an expert medical officer in the Center for Drug Evaluation and Research, and Branch Chief in the FDA Center for Devices and Radiation Health, where he reviews anesthesia and respiratory medical technology.

Regulatory Science Competition Winners Present Concepts to FDA

On Monday, April 28, University of Maryland (UMD) Fischell Department of Bioengineering (BioE) graduate student Chelsea Virgile and University of Rochester medical student David Brodell traveled to Silver Spring, Md. to present their respective award-winning "America's Got Regulatory Science Talent" competition concepts to the Food and Drug Administration (FDA).

First hosted in 2013 by the University of Maryland School of Medicine and the Center of Excellence in Regulatory Science and Innovation (M-CERSI), a collaboration with UMD, the "America's Got Regulatory Science Talent" competition is designed to promote student interest in the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.

Virgile was named the winner of this year's M-CERSI competition for her entry "Liquid Barcoding Pharmaceuticals for Counterfeit Pharmaceutical Drug Detection." Advised by BioE Department Chair and Robert E. Fischell Distinguished Professor William Bentley, Virgile pitched a new technology to augment the FDA's already powerful CD-3 devices by providing a means to test the drug itself in addition to its labeling. Currently, the FDA's CD-3 devices test for counterfeit drugs using an ultraviolet to infrared light shined on the drug's packaging to capture an image that can be compared to an image of an authentic sample to determine if the drug is genuine. Virgile's proposal is to use advanced liquid barcoding technology, which she believes could improve current good manufacturing practices and ensure the drug's authenticity by identifying its manufacturer, version and intended destination directly in its liquid filler.

A second year graduate student who has focused much of her recent research on synthetic biology and genetic engineering of E. coli as "smart" bacteria for detection and delivery of therapeutics, Virgile's competition entry dovetails on the efforts put forth by Maryland spinout company, Diagnostic anSERS, Inc.

The company's technology incorporates inexpensive Surface Enhanced Raman Spectroscopy (SERS) approaches for the detection of a variety of molecules in the defense and drug industries. SERS, a molecular fingerprinting technique, is most often used to detect trace amounts of explosives, drugs, toxins or other target substances.

"Counterfeit drugs are found not only in foreign countries, but in the United States as well," Virgile said. "According to the Center for Medicine in the Public Interest, approximately 10 percent of drugs sold around the world are counterfeits, and these drugs generate an estimated $75 billion per year in profits for counterfeiters.

"Since Diagnostic anSERS' liquid barcoding technology works by adding a molecular barcode at ultra-low concentrations, counterfeiting of these markers would not be feasible," she added.

David Brodell (UR), Dr. Stephen Ostroff (FDA), and Chelsea Virgile (UMD)

For the first time, in addition to M-CERSI's competition, an "America's Got Regulatory Science Talent" competition was also held at the University of Rochester Medical Center (URMC) as a component of their Regulatory Science educational initiatives, led by Drs. Scott Steele and Joan Adamo. Brodell's "Team Cardioid" was declared the winner for the entry, "Developing a High-Resolution 3D Heart Model for Drug Safety Assays."

Both Virgile and Brodell had the privilege of presenting their concepts to FDA Chief Scientist Dr. Stephen Ostroff, as well as other FDA staff members, at the agency's White Oak campus.

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