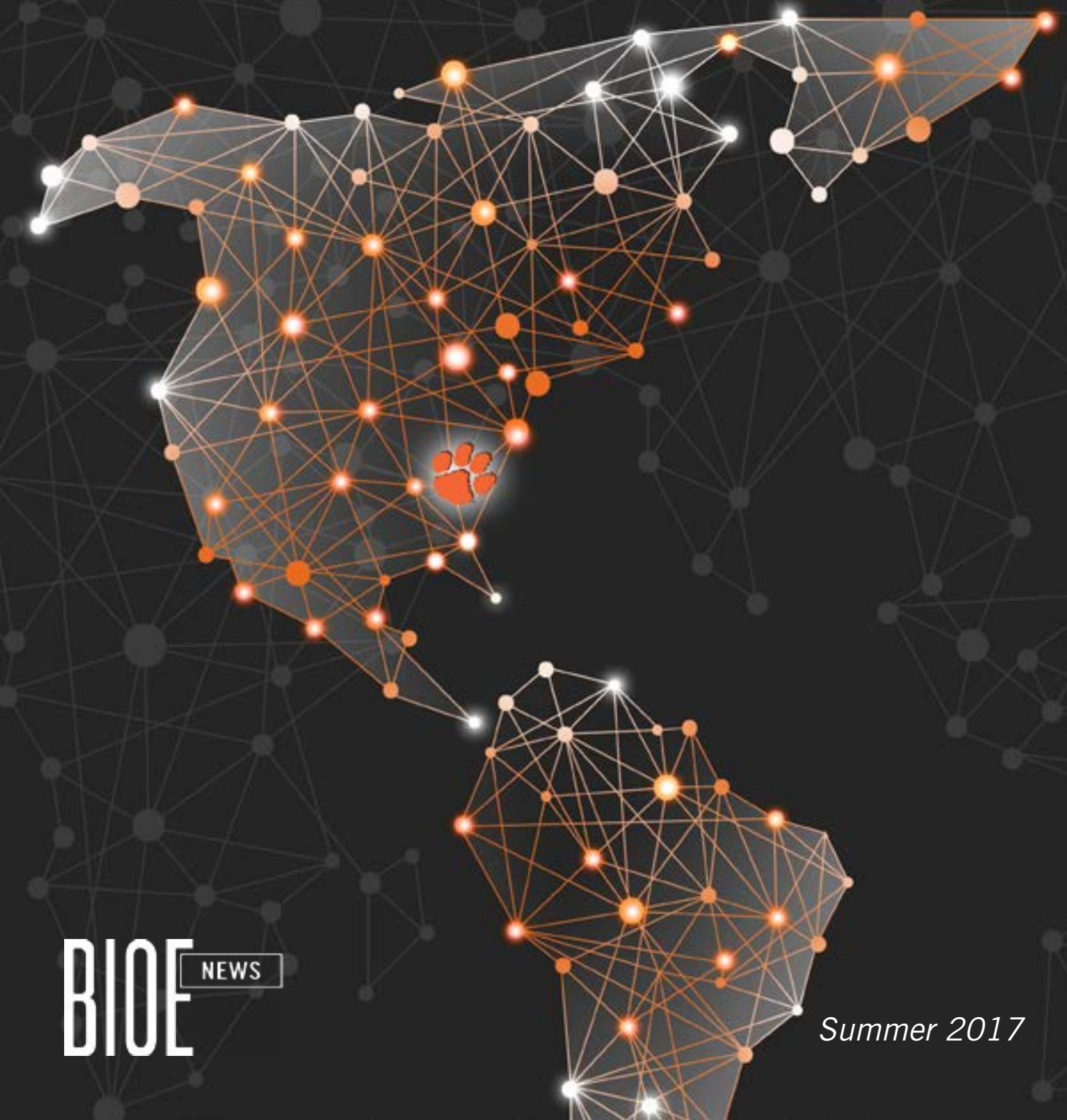
CLEMSON

BIOENGINEERING

Educating Thinkers, Leaders, and Entrepreneurs



BIOE NEWS

Summer 2017






CUBEInC

Open. For Business

CUBEInC

- Clemson University Bioengineering—Groundbreaking research and discoveries in health care delivery and outcomes
- Transferring medical device technology from bench to bedside
- A unique platform to train a highly qualified workforce
- Supported by a robust clinical trial program at the Greenville Health System and by Institutional Review Board resources for the use of humans in research

29,615 sq. ft. of research and training facilities

- Startup company space for lease
- Support labs adjacent to each research lab, each approximately 400 sq. ft.
- Bioskills surgery training center managed by Hawkins Foundation
- Office space for researchers and students adjacent to labs
- Networking and meeting space
- Shared facilities for microscopy, histology, rapid prototyping and material processing, among others

Contact: Leigh Humphries lcartee@clemson.edu for lease information

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Clemson Bioengineering, a Gateway to the Biomedical Technology World

Message from the Chair, Martine LaBerge, PhD

Since the instigation of Clemson's bioengineering doctoral program and graduation of the first doctoral students in 1968, Clemson Bioengineering graduates have led biomedical research and technological enterprise around the world. Our platform for educating leaders has been a culture focused on discovery, where innovators and knowledge workers are trained to take on the world's healthcare challenges with socially relevant and economically viable means. This issue of BioE-NEWS celebrates our contributions to the global biomedical technology development and research landscape through research, education and partnerships.

We assist in the creation of a competitive knowledge-based economy focused on development and translation of technology for healthcare by providing our students with immersive and integrative training experiences through study abroad programs in Singapore, Thailand, Japan and Spain; Creative Inquiry immersion in Tanzania; industrial internships in Japan; and research internships in Europe. Our faculty-led research collaborations and partnerships span six continents. The recently launched "Clemson Partnership for Global Biomedical Engineering Innovation and Regulatory Science" is aimed at educating industry-ready biomedical engineers. With their understanding of the global economy and regulatory science, they will have an immediate and positive impact on the global medical device industry and healthcare research. We educate international engineers about best practices for medical device design and product development and commercialization through the FDA regulatory process. Our effort catalyzes a worldwide network of biomedical engineers with a unique skill set for market-driven product design and development. World-class integrative learning and inventing experience equip trainees with technical competencies, societal awareness and entrepreneurial sensitivity toward building and promoting a global biomedical economy.

From Asia to North America, Clemson Bioengineering graduates have taken root around the world, contributing to establish an adaptable biomedical enterprise through entrepreneurship and leadership. We look forward to continue fulfilling our mission as a gateway to the biomedical technology world.

Clemson Bioengineering Announces the Establishment of the Harry G. Berry Endowment for Biomedical Technology Innovation

It is an honor for the department to be the steward of this endowment that integrates education, research and economic development in medical technology. *Dr. Martine LaBerge*

Established by Ethelyn Berry Smith to honor her brother Harry G. Berry '41, the $1.2M endowment is dedicated to support the education of bioengineering students with a focus on innovation of biomedical technology. Clemson Bioengineering has led the field of medical devices and biomaterials since the mid-1960s. In 2011, the Clemson Biomedical Engineering Innovation Campus (CUBEInC) was inaugurated to support biomedical technology innovation from applied research to commercialization. The Harry G. Berry Biomedical Technology Innovation Program will be used to support translational research at CUBEInC and provide the essential environment to further development of clinically relevant technology to improve patient care and disease diagnosis. CUBEInC is strategically located above three floors occupied by clinical vascular surgery and orthopaedic surgery at the Greenville Health System and houses multi-investigator research and education facilities; company incubator space; meeting and networking accommodations for industry, scientists and clinicians; and state-of-the-art surgical-skills facilities. The Harry G. Berry Endowment will support novel experiential opportunities for bioengineering students through the clinically embedded undergraduate biomedical engineering capstone design program led by Dr. John DesJardins and the graduate design rotation in the Master of Engineering in Biomedical Engineering degree program led by Dr. Jeremy Mercuri. Both initiatives have resulted in a large number of innovations in the practice of medicine that enhance patient-oriented outcomes while stimulating economic growth through entrepreneurship. "It is an honor for the department to be the steward of this endowment that integrates education, research and economic development in medical technology," said Dr. Martine LaBerge, chair of the Bioengineering Department. "It will assure that the essential environment for discovery and its translation are provided to our students."

The 30,000 square feet CUBEInC facility is located in Greenville, SC.

Clemson BIOE: From South Carolina to the World

Dr. Ruikai Chen
Joining J&J in Suzhou, China

Ruikai Chen

Clemson BIOE Ph.D.

"I have worked at JNJ Suzhou for more than 2 years; I run projects to transfer joint products from Depuy Synthes to China. So far, we have completed a clinical trial for one total hip replacement system and have just started a clinical trial for one total knee replacement system. We believe by obtaining a local registration license, we will be able to benefit Chinese patients by providing high quality local products with lower cost and higher reimbursement rate."

Drs. Aggie and Dan Simionescu
Expanding Collaborations in Romania

Clemson BIOE Faculty

"Our satellite lab, the Tissue Engineering and Regenerative Medicine Lab (TERMLab), was formed in 2012 at the University of Medicine and Pharmacy in Targu Mures, Romania, and has been funded by grants from the Romanian Government and the European Union. TERMLab's goal is to bridge basic research and clinical applications of regenerative medicine approaches by performing large animal preclinical testing of in vitro engineered cardiovascular tissues. The main attributes of TERMLab are the outstanding expertise in experimental and clinical cardiovascular surgery and the large-animal facility at the University.

Drs. Aggie and Dan Simionescu

Students, technicians, surgery residents and veterinarians from TERMLab were invited to the Biocompatibility and Tissue Regeneration Laboratory at Clemson Bioengineering for training sessions to learn and work together with our students on cardiovascular projects. The group participated in daily lab operations and group meetings, audited a few BIOE classes and toured the Godley Snell Animal facility. Some of our students also visited the TERMLab in Romania and thus cross-pollinated culturally and professionally.

The bidirectional impact was significant: The basic scientists and engineers from Clemson interacted directly with surgical residents and enriched their knowledge by expanding their horizons, while the Romanian surgeons got to work in the lab doing cell cultures and bioreactor studies.

This collaboration was solidified by the signing of a Memorandum of Understanding between Clemson University and the University of Medicine and Pharmacy in June of 2013. This set the official basis for further collaborations between the two institutions. Altogether, our work in Romania has been an added advantage to our students and to those in Romania."

Our research has contributed to increased national and international recognition of the vulnerability of the upper limb to work and task demands and helped to develop strategies to prevent injury in diverse populations. *Dr. Clark Dickerson* *(See pg. 6.)*

Clemson has opened my eyes to entrepreneurship. *Dr. Martin Alejos (See pg. 6.)*

Dr. Thomas Moore
With Adolphe Merkle in Switzerland

Dr. Thomas Moore

Clemson BIOE Ph.D.
"Currently I'm a senior researcher at the Adolphe Merkle Institute in Fribourg, Switzerland. Here we do basic science research on soft matter, and my research is focused on understanding fundamental interactions of nanomaterials with biological systems. Our group works closely with government agencies to understand the potential ramifications of nano-sized materials entering the human body (for example, inhaled particulate matter from combustion engine exhaust), and we're working to understand what kind of effects particles might otherwise have on the body. I also try to tie in my bioengineering background by working on side projects such as microfluidic multicellular systems to study particle transport across biological barriers, and developing functional nanoparticles for biomedical applications!"

Dr. Delphine Dean
Mentoring and wellness in Tanzania

Drs. Delphine Dean and John DesJardins and team in Dar es Salaam, Tanzania.

Clemson BIOE Faculty
For years, Drs. Delphine Dean, John DesJardins, their collaborators and students have spent periods of weeks in Tanzanian to give Clemson students the opportunity to work directly with residents who daily face challenges associated with wellness and healthcare. This past summer, the group worked in cities (Dar es Salaam and Arusha) and rural areas (Kisarawe): Dr. Dean and the team collaborate with Medical University of South Carolina's Dr. Michael Sweat, Director of the MUSC Center for Global Health, to support rural health care centers through a number of projects. Dr. Dean said, "This past summer, students assessed the baseline infrastructure and technologies available in Kisarawe, Tanzania, for their health centers. The goal is to determine what technologies need to be brought in or newly designed to help support noncommunicable chronic disease diagnosis and self-management for patients in rural Tanzania. This is part of our NIH R01 with Dr. Sweat. In addition, students helped repair equipment in Kisarawe Referral Hospital to help support the local community."

"We are also collaborating with Arusha Technical College (ATC). Dr. John DesJardins, students Zach Hargett, Scott Slaney, and Elizabeth Dawson and I met with our collaborators in July to organize joint initiatives. ATC has the first biomedical engineering bachelor's program in East Africa. In August, we sent two faculty members, Drs. Will Richardson and Brian Booth, and two graduate students and a postdoctoral fellow, Hannah Cash, Meredith Owen, and Hobey Tam, respectively, to ATC. The team taught design thinking and anatomy/physiology for the engineer short courses over two weeks." In 2018, student teams at Clemson and ATC will collaborate on design projects, meeting via Skype once monthly to discuss project progress and experience professional development. The projects are funded through grants (a VentureWell program grant and an NIH R01) and support from the College

Martin Alejos
Improving Clinical Strategies in Argentina

Dr. Martin Alejos

Clemson BIOE Ph.D.
"Clemson has opened my eyes to entrepreneurship. In Argentina, I've put on hold my corporate career and co-founded a firm that collaborates with medical device companies in clinical research projects and regulatory affairs. Helping out local companies to improve their clinical strategies has been very rewarding, as well as partnering with disruptive start-ups in clinical trial projects. We are now kicking off the first collaboration with a US-based start-up to plan and execute clinical studies to validate their products and hope we can add high value to their initiatives."

Dr. Clark Dickerson
Increasing international awareness in Waterloo, Ontario

Dr. Clark Dickerson

Dr. Clark Dickerson is a Professor of Kinesiology and Canada Research Chair of Shoulder Mechanics at the University of Waterloo (Waterloo, ON). His research focuses on human musculoskeletal biomechanics, particularly of the shoulder. He earned his BSME at Alfred University, his MS in bioengineering from Clemson University, and his PhD in biomedical engineering from the University of Michigan. Dr. Dickerson's current research interests include the development and experimental evaluation of computational shoulder models; digital ergonomics; age- and disease-related shoulder disorder prevention, assessment, and mitigation; in vitro tissue mechanical characterization and comparative and developmental shoulder mechanics. The current past-president of the Canadian Society for Biomechanics, Dr. Dickerson is a member of the Board of the International Shoulder Group. He is the Scientific Director of the Centre of Research Expertise for the Prevention of Musculoskeletal Disorders, which promotes evidence-based improvement of working life across Ontario through generating and communicating ways to limit harmful occupational exposures. Dr. Dickerson said, "Our research has contributed to increased national and international recognition of the vulnerability of the upper limb to work and task demands and helped to develop strategies to prevent injury in diverse populations.

Department adds Publication Director and Academic Publicist position

Olga Reukova's broad experience in design and publications make her a perfect fit for the department's needs. Here, she will design, specify and manage production of newsletters, brochures, posters, flyers and websites. Olga hopes that she may also be called upon to deliver her favorite area of design, scientific illustration. "I'm glad that my expertise includes not only design of promotional materials, graphical elements and websites, but also creation of illustrations and infographics for abstracts and articles. I think that it's extremely important that scientists and researchers present their work in a beautiful and tasteful way."

Asked about her new position, Olga said, "I look forward to my work with the department; I know it will be stimulating. I am very happy to be a part of the Clemson University family."

Dr. Naren Vyavahare Leads the Field in Treatment for Abdominal Aortic Aneurysms

In addition to directing an NIH COBRE center to fast-track new biomedical researchers, Dr. Vyavahare now is Principal Investigator on a grant to fund innovative research to improve diagnosis and treatment of abdominal aortic aneurysms. The culmination of decades of research in this and related areas by Dr. Vyavahare and his groups, this grant addresses diagnosis and treatment of a condition that the National Center for Biotechnology Information classifies as the 14th leading cause of death in the US. When ruptured, abdominal aortic aneurysms can bleed at a lethal rate. In such cases, only 50% of patients reach the hospital; of those, 50% or fewer survive surgery, the only treatment.

According to Dr. Vyavahare, aortic rupture occurs when wall stress exceeds wall strength. Degradation of the elastic laminae leads to focal weakening and high stress concentration, but there presently is no way to measure the degree of weakening. Onset of abdominal aortic aneurysms is associated with extracellular matrix degradation, primarily elastic lamina degradation by proteolytic enzymes such as matrix metalloproteinases (MMPs) and cathepsins, which are produced by activated vascular cells and infiltrating inflammatory cells.

Based on his preliminary data, Dr. Vyavahare hypothesizes that elastic laminae degradation can be measured by site-specifically targeting gold nanoparticles to the degraded laminae and that the spatial distribution of gold nanoparticle binding will correlate with wall weakness: Thus, relative rupture risk can be predicted. He further hypothesizes that targeted delivery of drugs that increase the strength of the aneurysmal aorta (by stabilizing residual extracellular matrix and regenerating lost elastin), will prevent expansion and rupture of abdominal aortic aneurysms.

> We have developed an effective nanoparticle delivery system that targets only degraded vascular elastin, a hallmark of early stage aneurysms. We also have shown that polyphenols such as pentagalloyl glucose can stabilize and regenerate elastin in the aneurysmal aorta.
> *Dr. Vyavahare*

This systemic therapy, to be delivered by an injection, would be far less invasive than surgery. Therapeutic application of the proposed methods will require several more years of research. As this proceeds, Dr. Vyavahare said there are two unique aspects of the research he believes will affect healthcare more broadly. “While both wall stress and wall strength are important to estimate rupture risk, to date there has been no way to determine wall strength at high stress points in vivo. Aortic degradation, as indicated by the presence of elastin-targeting gold nanoparticles, will be correlated with mechanical properties, and the ratio of wall stress to strength, called the ‘Rupture Potential,’ will be identified and used as a risk stratification tool.”

The second unique aspect involves targeted-delivery nanoparticles carrying agents to regress aneurysms; no such use of targeted nanoparticles has been made, to Dr. Vyavahare’s knowledge. “We were the first to show that NPs coated with elastin antibody could target the aneurysmal site. This innovation alone could be used to deliver drugs, gene vectors, proteins, or imaging agents to the site and could open avenues for other researchers. Past pharmacological approaches focused on reducing inflammation or enzymatic activity; such approaches can only arrest aneurysmal growth, not restore healthy function. Our approach focuses not only on stabilization of aortic extracellular matrix, but also on restoration of healthy extracellular matrix in the diseased aorta by allowing assembly of newly deposited elastic fibers with innovative treatment. We will image elastin distribution before and after treatment and in nontreatment controls to observe the progression or regression of local elastin degradation at the aneurysmal sites.”

Holder of Hunter Endowed Chair of Bioengineering, Dr. Vyavahare’s decades of research and service to NIH have given him experience that has led to his being an informal mentor to numerous new assistant professors. Jenny Bourne, departmental Program Administrator for Academic and Research Services noted, “When new investigators have difficult questions about proposals, including strategy, I refer them to Naren. He makes time for new investigators and provides the reasoning underlying his recommendations so they are better able to make decisions for themselves.”

When asked about the value of training in entrepreneurship, Dr. Vyavahare said, “Bioengineering research by default is translational in nature: Engineers work to find solutions to biomedical problems. Faculty, with years of experience in an area, generally are at the cusp of new discoveries. However, to take laboratory discoveries to first-in-human requires a lot of research that is not exciting, but important, and cannot be done at the University (due to its mission of education first). Generally, large companies will not invest in projects that are too risky and at an early stage. That is where small start-ups by faculty can make a big difference. The researcher can tap into SBIR/STTR grants and angel investors to get the preliminary safety and efficacy data. Most technologies are developed at small start-up companies, and then they become attractive to larger companies. So entrepreneurship is an essential step in taking your discovery to market.”

Team Receives $6 Million for Research that could Lower Drug Prices

Paul Alongi

Sarah W. Harcum of Clemson University is leading a team that has received $6 million for research that could help lower the cost of several drugs that run into the thousands of dollars per treatment and fight some of the world's most debilitating ailments. The team brings together researchers from three states to seek better ways of engineering Chinese hamster ovary cells, which are used to manufacture more than half of biopharmaceuticals.

Sarah W. Harcum, professor of bioengineering, works in her lab at Clemson University. The potential impact is immense. Products from these cells represent more than $70 billion in sales each year and include drugs for Crohn's disease, severe anemia, breast cancer and multiple sclerosis.

The focus for Harcum and her team will be on the Chinese hamster ovary "cell line." A cell line is developed from a single cell culture and starts with uniform genetic composition that would ideally remain unchanged. But that genetic composition drifts as the cells reproduce, and they become less effective at creating the drug they have been engineered to create. As a result, manufacturing becomes more expensive, said Harcum.

"We expect by the end of the study we will have identified some genes that cause the instability," she said.

> What would be even better is if we can prove by modifying those genes we can make a genome that is more stable. With success, the Chinese hamster ovary cell line will stay more stable during the manufacturing. We hope to get that drift to be reduced; that's the ultimate goal.

The four-year grant was among eight awards totaling $41.7 million announced Wednesday by the National Science Foundation's Established Program to Stimulate Competitive Research, or EPSCoR. The Harcum-led research strikes at the heart of one of the toughest challenges in manufacturing biopharmaceuticals.

Biopharmaceuticals are different from more conventional drugs, such as ibuprofen and acetaminophen, which are based on what researchers call "small molecules" and are relatively easy to manufacture. Biopharmaceuticals, however, are 1,000 times larger than the small molecules and have structures that are more complicated.

While biopharmaceuticals can treat disease that small-molecule drugs cannot, manufacturing these large-molecule drugs are more difficult. They require more monitoring, control and analysis throughout the manufacturing process. Harcum and her team are aiming to improve the process not for a single drug, but for a wide range of biopharmaceuticals. The project is expected to increase patient access to expensive medicines, while helping educate the professionals headed for the advanced biomanufacturing workforce.

As part of the project, researchers are planning to promote diversity on the research team by including several undergraduate and graduate students who are from groups underrepresented in engineering. Also, three tenure-track faculty members from underrepresented groups will be mentored by more senior researchers.

Harcum is the principal investigator on the grant, and she is collaborating with researchers from the University of Delaware, Tulane University and Delaware State University. They are calling the project "Advanced Biomanufacturing: Catalyzing Improved Host Development and High Quality Medicines through Genome to Phenome Predictions." Co-principal investigators are Kelvin H. Lee, the Gore Professor of Chemical Engineering at the University of Delaware, and Anne S. Robinson, chair of the chemical and biomolecular engineering department at Tulane University.

Robert Jones, executive vice president for academic affairs and provost at Clemson, said the project underscores the value of collaboration. "The grant is helping build a sustainable research infrastructure in three EPSCoR-eligible states, enabling each of the four institutions involved to build on each other's strengths," he said. "Further, the grant helps prepare a diverse talent pool for the biomanufacturing industry. We are well positioned for lasting impact."

Each project in the latest round of EPSCoR awards is focused on understanding the genome-to-phenome relationship. The projects are under EPSCoR's Track-2, which promotes collaboration across jurisdictions.

Chinese hamster ovary, or CHO, cells are used to manufacture biopharmaceuticals because these cells are highly adaptable to growth in different environments, bear no human viruses and are capable of high-level production, Harcum said. "However, the ability to continually adapt is also a negative attribute because clones may lose the desirable cellular and product phenotype even during short-term culture," she said. "This is known as cell line instability and is rooted in a relatively unstable genome. Here, we will develop approaches to relate CHO cell genome stability to the phenome and apply this knowledge to improve control over instability of the CHO genome."

Martine LaBerge, chair of the bioengineering department at Clemson, said Harcum's extensive work with CHO cells uniquely qualifies her to lead the project. "Dr. Harcum has 20 years' experience working with CHO cells and has used genomic approaches to study CHO cells for quite some time," LaBerge said. "She is very well aware of the industrial issues that affect CHO cells."

Anand Gramopadhye, dean of the College of Engineering, Computing and Applied Sciences, said the project addresses some of the nation's most critical needs, while building research infrastructure in three states, with Clemson taking the lead for South Carolina. "By seeking to engineering better medicines, Dr. Harcum and her team are focused on one of the 21st century's grand challenges," he said. "They are also using this project to enhance diversity in the talent pipeline. The size of the award attests to its crucial importance."

Lee said the grant will help accelerate biopharmaceutical manufacturing in the United States. "This project will help us address the challenges we face in making these medicines more widely available, which could prove transformational for thousands of patients," he said. "This is a natural extension of the work we are doing as part of NIIMBL."

Lee leads NIIMBL, which is short for the National Institute for Innovation in Manufacturing Biopharmaceuticals. The institute was established in March with a $70-million grant from the National Institute of Standards and Technology in the U.S. Department of Commerce and with support from more than 150 collaborators, including Clemson, Tulane and Delaware State.

Robinson said the EPSCoR project will help create a more diverse workforce in biopharmaceutical manufacturing. "This team has deep experience in supporting underrepresented groups and is well-suited to mentor diverse junior faculty members and students," she said. "The grant will help support programs that deepen our commitment to creating a more diverse workforce."

Douglas Hirt, associate dean for research and graduate studies in the College of Engineering, Computing and Applied Sciences, said the project helps lay the foundation for a sustainable research enterprise. "This project strengthens existing collaborations among academics and provides mentoring and development for students and tenure-track faculty at four institutions in South Carolina, Delaware and Louisiana," he said. "The work that Dr. Harcum and her team have initiated has set the stage for success and is to be commended."

Tanju Karanfil, the vice president for research at Clemson, said the grant helps build Clemson's reputation as a world-class research university. "This EPSCoR grant underscores that the University's researchers continue their pursuit of bold ideas and innovative answers, while affirming Clemson's role as a leader in health innovation," he said. "I congratulate Dr. Harcum and her team on a job well done."

The Perry Initiative at Clemson University: A Bridge to Communities

In May, Associate Professor Melinda Harman led the Orthopaedic Outreach Program developed by the Perry Initiative. The Perry Initiative's mission is to inspire young women to be leaders in the fields of orthopaedic surgery and engineering. At Clemson, the outreach program was sponsored through Clemson PEER/WISE, designed to increase and retain women and underrepresented minorities in engineering and science majors, and South Carolina Project Lead the Way, a nonprofit that provides the K-12 system with programs in science, technology, engineering and math.

Dr. Harman said, "The Perry Initiative emphasizes engineering applications with societal impacts, like healthcare applications, as a proven means of improving participation of students from populations underrepresented in science and engineering. As the host institution, we broadly impacted approximately 40 young women from South Carolina and the southeastern USA by bringing together diverse educational communities, such as Project Lead the Way, high schools, Women in Science and Engineering (WISE), and professional women working in orthopaedic surgery and bioengineering."

> Clemson University and our surrounding network of technical colleges provide numerous educational pathways that enable young women to become leaders and entrepreneurs in the medical technology sector.
> *Dr. Melinda Harman*

During the day-long Orthopaedic Outreach Program, student participants completed four hands-on activities related to joint replacement, fracture fixation, ligament repair, and wound suturing using realistic anatomical models, hand tools and surgical instruments. According to Dr. Harman, "The young students really responded to the college-aged female engineers and medical students who volunteered to lead the hands-on activities. The unique projects highlighted key applications in orthopaedic surgery, stimulating creativity and fostering a teamwork approach to problem-solving that made for an exciting day of interaction for everyone."

The program featured three speakers. Dr. Harman addressed the topic of educational pathways and careers in engineering. She noted, "The medical technology sector is experiencing tremendous growth and demands continuous innovation to address challenges in healthcare. As a professional bioengineer, I can inspire young women through the Perry Initiative to identify engineering and medical technology as their "dream" career."

Lauren Hyer, MD, an orthopaedic surgeon from Shriners Hospitals for Children — Greenville, spoke on orthopaedic surgery. Perry Initiative co-founder, Dr. Jenni Buckley, discussed the need for students from diverse backgrounds to help solve problems in engineering and orthopaedic surgery.

Participating as mentors in the hands-on activities were current bioengineering students (Hannah Cash, VeeAnder Mealing) and two former bioengineering students who are now in medical school (Anna Tarasidis) or completing orthopaedic fellowships (Dr. Shea Ray) at Greenville Health System.

2017 Bioengineering Senior Design EXPO Represents 50 Clinical Partnerships

Dr.John DesJardins

On May 5, 2017, the Clemson University bioengineering department hosted its annual Senior Design Expo at TD Convention Center in Greenville, SC. The annual event attracted its largest attendance to date: Over 300 people from academia, industry, healthcare and the community came to celebrate the culmination of two semesters of design work in biomedical device innovation. In the 2016-2017 academic year, more than 100 bioengineering seniors partnered with over 50 clinicians to produce cutting-edge device innovations. Teams of seniors showcased their final designs, the result of 9 months of rigorous design effort mentored by faculty and graduate students. Their outcomes mirror industry standards for the design of biomedical devices.

The student senior design experience begins with a solid foundation in design theory, industry best-practices, FDA regulation, intellectual property and healthcare economics. Students then translate this theory into practice, exploring and evaluating clinical problems that have the potential to significantly impact health care. In partnership with clinicians in Upstate SC, the student teams strictly assess potential problems through a process of strategic focus, needs-finding, needs-statement development, disease state fundaments, needs filtering, clinical cycle of care analysis, stakeholder analysis, market analysis and gap analysis. They then begin to develop solutions to these well-vetted problems, using design inputs and outputs development, requirement and specification selection, risk analysis, competitor assessments, prior art analysis and design targets.

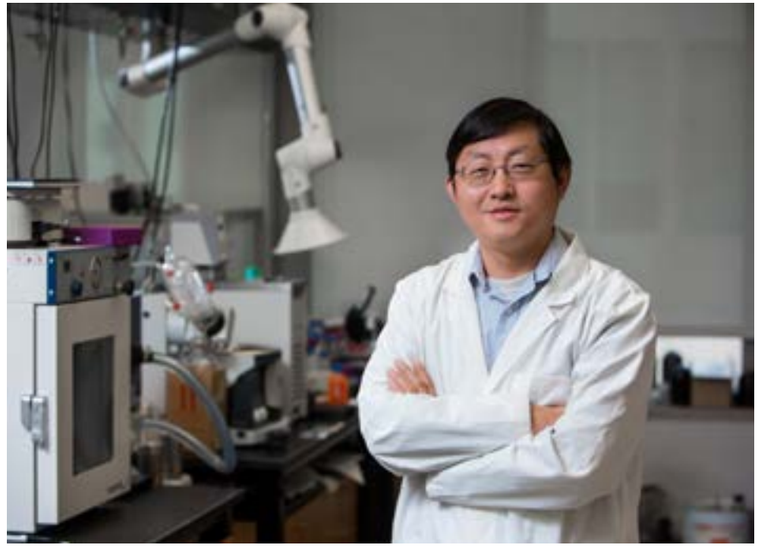
The development of final, working products is a hallmark of the program. Students learn to fail early and often, generating numerous low-resolution shoestring prototypes that often are just that, made from shoestrings. Slowly, the final design solution emerges, 3D printed versions are scrutinized, and the students work with industry professionals to manufacture a final device. These devices are then tested to national standards and evaluated for safety, efficacy and user satisfaction.

The Clemson bioengineering design program does not start or end with the senior year. Numerous other undergraduate and graduate groups are constantly imagining the next great biomedical innovation. The number of creative inquiry groups and active faculty in the department are among the highest at Clemson; they have produced numerous design solutions and national design awards. The new Masters in Engineering program takes the design program to the next level, training our graduate students in advanced industry best practices in biomedical device design and manufacturing. The department actively supports these efforts through faculty and graduate student mentoring, makerspaces, design studios, and our state of the art translational research facility at Clemson University Biomedical Engineering Innovation Campus (CUBEInC) located at the Patewood medical campus in Greenville, SC.

Accolades for Clemson's design program are numerous, including an award-winning design curriculum that is recognized and funded by the National Science Foundation. In the last six years, our undergraduate design teams' awards have included the following: 1st place in the Lemelson-MIT Cure-It Prize, 1st place in the VentureWell Design Competition, 2nd place in Engineering World Health, and 3rd place in the Collegiate Inventors Competition. Our faculty and design program are nationally recognized for productivity, innovation and educational excellence. Even more importantly, the design program prepares students for industry leadership as design engineers.

Newly Appointed Dean's Faculty Fellow Dr. Ying Mei Awarded NIH Funding to Biofabricate Nanoengineered Microtissues to Treat Cardiovascular Disease

Cardiac muscle cells have a very limited ability to divide, and the human heart has no effective means of replacing damaged or dead muscle cells after heart attack.



In addition to receiving research funding through the NIH RO1, Dr. Mei's sustained excellence in teaching, research, scholarship and service to the College of Engineering, Computing and Applied Sciences was recognized by his being named a Dean's Faculty Fellow. Dr. Mei said, "This award will allow me to further my commitment in teaching, research, scholarship and service. I now have a special obligation to the academic community to promote research and education programs that increase the national and international prominence of Clemson University and the Department of Bioengineering."

Regarding the research his RO1 will fund, Dr. Mei said "My RO1 aims to biofabricate nanoengineered human cardiac microtissues as cell-delivery vehicles to treat cardiovascular disease, the leading cause of death worldwide. The completion of the research will promote biofabrication capacity in South Carolina and establish the state's prominence in biofabrication. My long-term goal is to develop nanoengineered human cardiac microtissues as a clinical therapy to treat cardiovascular diseases. To achieve this, we need to use/develop biofabrication technologies to produce nanoengineered microtissues.

"Cardiovascular disease is the leading cause of death and disability worldwide. Cardiac muscle cells are responsible for contracting the heart to pump blood through the body. To initiate each contraction, cardiac muscle cells receive electrical signals from the heart's pacemaker cells. Early in life, human cardiac muscle cells exit the cell division cycle. Thus, they have a very limited ability to divide, and the human heart has no effective means of replacing damaged or dead muscle cells after heart attack. Another cell type, the stem cell, has the capacity to become other kinds of cells. Recent developments in stem cell biology have made the development of new regenerative medicine therapies for restoring damaged heart muscle following heart attack seem more promising. These technologies take human cells from blood, fat or skin tissue and manipulate them in the laboratory to form patient-specific stem cells. One benefit of this technology is that we can use these stem cells to derive new heart muscle cells for each patient.

Significant progress has been made toward using stem cells to create human cardiac muscle cells to repair damaged hearts, but major hurdles remain. The two most commonly employed strategies using stem cell-derived cardiac muscle cells for cardiac repair are 1) injection of individual stem cell-derived cardiac muscle cells into the damaged muscle, and 2) using the stem cell-derived cells to create a patch to transplant to the damaged heart. Success has been limited. The problem with cell injection is that very few of the cells actually become a functional part of the heart muscle: Most are washed away or die because they are not integrated with the surrounding environment. Some that do integrate into the heart muscle are immature, which can cause life-threatening arrhythmias. The transplanted patches do survive, but they, too, are immature. By not integrating electrically with the surrounding muscle, they do not provide contractile support for the damaged heart.

My lab's focus over the past several years has been to 1) improve the maturity of stem cell-derived cardiac muscle cells and 2) to improve their integration in the heart. To this end, we have optimized how these cells are manipulated in the laboratory prior to injection into the damaged heart. First, we grow the cells together to form what we refer to as spheroids (i.e., spherically shaped microtissues) that can be injected through a small needle. Due to their size (> 100 μm) these microtissues do not easily get washed away after transplantation into hearts. In addition, we added electrically conductive silicon nanowires (e-SiNWs) in the cardiac microtissues to improve electrical interaction between the stem cell-derived cardiac muscle cells. Lastly, we used electrical stimulation to condition nanowired cardiac microtissues so that they contract as they would in the heart. Our recent studies have shown that these constructs can promote maturity of stem cell-derived cardiac muscle cells and reduce the likelihood that they will cause arrhythmias.

In our RO1 application, we proposed to pursue the following three Aims: 1) Elucidate the mechanisms of the interactions between e-SiNWs and stem cell-derived cardiac muscle cells, 2) Further advance maturation of stem cell-derived cardiac muscle cells through long-term electrical stimulation of the nanowired cardiac microtissues, and 3) Examine efficacy of the nanowired cardiac microtissues in both healthy and injured rat hearts. The completion of the proposed research would, for the first time, allow us to produce stem cell-derived cardiac muscle cells with controlled maturity, develop a set of quantitative criteria to assess maturity of stem cell-derived cardiac muscle cells for transplantation, and identify a suitable range of maturity of stem cell-derived cardiac muscle cells for transplantation. We will lay down a solid foundation to establish the use of electrically stimulated, nanowired cardiac microtissues as an innovative platform to deliver stem cell-derived cardiac muscle cells to treat heart failure."

My lab's focus over the past several years has been to improve the maturity of stem cell-derived cardiac muscle cells and to improve their integration in the heart.

Dr. Aggie Simionescu Awarded American Heart Association Grant

Dr. Aggie Simionescu's research has been chosen for an American Heart Association Institutional Research Enhancement Award for a period of two years, during which Dr. Simionescu will study mitral valve tissue engineering. According to Dr. Simionescu, "Mitral valve insufficiency is the most common cause of regurgitation referred for surgical repair or replacement in the western world, but currently available substitutes do not adequately comply with the performance and flow pattern requirements of the left ventricle. Tissue engineering and regenerative medicine approaches using scaffolds, cells, and bioreactors could provide viable implant solutions. Our goal is to develop a tissue engineered mitral valve with ideal characteristics: large orifice, rapid opening and closure, no rigid support, maintenance of mitral annulus–papillary muscle continuity, extended durability, biocompatibility, normal function at any change in the left ventricle size in time, and also, easy to produce and construct." Goals of the AHA award are to support meritorious research, expose students to research and strengthen the research environment of the institution.

He has a Passion for It: Dr. John W. Gilpin

Dr. John Witherspoon Gilpin '82 is a philanthropist and leader in providing for students and institutions in medicine and higher education, a runner and hiker in venues around the country and life-long friend to Clemson University and those who attended with him. And recently, he chose to befriend the department by establishing an endowed associate professorship in bioengineering with a three-year term limit and a provision for additional terms.

According to former classmate Doug Gray '82, now Director of Development for the College of Engineering, Computing and Applied Sciences, Dr. Gilpin has long been a leader and philanthropist with a commitment to service. A microbiology major at Clemson, Dr. Gilpin was student body vice president and president of the Student Alumni Council in 1980, when the council hosted a national gathering of all student alumni councils.

Dr. Gilpin's typical day at Clemson included classes, meetings and running. Because he and his roommate spent evenings working for student organizations, both studied long into the night. "Being a microbiology major helped me learn how to think and solve different problems," Dr. Gilpin said.

While at Clemson, Dr. Gilpin was director of Blue Key Tigerama, a beloved traditional gathering celebrating the current and all previous homecomings. Proceeds from the event benefit Blue Key's Tigerama Scholarship Fund. And 1982 was huge for Dr. Gilpin: He graduated, and he was presented the Norris Medal, awarded annually to the graduating senior judged the best all-around student by the Scholarships and Awards Committee. It is the highest honor a Clemson undergraduate can receive. And to crown his college years of friendship, scholarship and service, the Tigers won their first national championship in football!

> We were a group of seven friends; most of us finished Clemson in 1982. We pooled our money to endow a scholarship for a talented young person.
> *John W. Gilpin, MD*

Now, Dr. Gilpin continues to proactively involve himself with the people and institutions in this area. He enjoys philanthropy, and has developed a detailed process for deciding where to give. His recent decision to establish an annuity trust for scholarships to the USC School of Medicine Greenville was partially due to the fact that the new medical school lacked alumni at that time.

The problem-solving skills Dr. Gilpin learned studying microbiology still serve him in his work as a radiologist and Clinical Assistant Professor of Radiology with Greenville Health System and the University of South Carolina School of Medicine Greenville. Dr. Gilpin still enjoys running; he travels around the country for a run or a hike. Some of his favorite athletic pursuits are competing in marathons and 10k races. He has run the Boston Marathon ten times and the Peachtree Road Race multiple times, and his hikes have included national parks like Yosemite and Acadia. He also enjoys an occasional white water excursion with friends.

Just recently, Dr. Gilpin and six friends from his college days rode a raft down western North Carolina's Nantahala River, which flows at 45° Fahrenheit year round. By the time they could feel their toes again, they had reflected on the Clemson 7 Endowed Scholarship that they funded to benefit students from SC and NC. Of philanthropy, Dr. Gilpin said, "You have to have a passion for it. You just want to give back."

This friend, physician, runner and hiker is a devoted uncle to nieces and nephews from Greenville, Florence and the western US. And, it seems Dr. Gilpin's eye is always on Clemson University, and maybe, his heart has never left.

The professorship will be integrated with the Bioengineering Economic Development Activities at CUBEInC, the Clemson University Biomedical Engineering Innovation Campus in Greenville, SC.

Professors of Practice: Mike Gara and Steve Johnson

Clemson Bioengineering is very pleased to announce its inaugural professors of practice.

Professor of Practice ***Steve Johnson***'s interests lie in technology commercialization, medical device development, managing start-up companies, intellectual property management and financial analysis. He regards his specialties as technology transfer, new company start-ups and strategic planning and execution. Currently, Professor Johnson heads Compass Bioscience Advisors, a consultancy which focuses on strategic planning, market assessment and financial analysis in the life science field.

Of his professorship in bioengineering at Clemson, Professor Johnson said, "I believe this has been a two-way street. For me, it motivates and excites me to see very bright and committed students who are innovating in the life science field. For them, I hope it is a way to reach out beyond what they read in a textbook and get a real-world perspective on a range of subjects from FDA approval to how start-ups get funded."

Professor Johnson started the first technology transfer company in South Carolina over 20 years ago and has held executive management positions in both Fortune 500 companies and startups.

Professor of Practice ***Mike Gara*** is now a principal with Equinox Medtech Partners, a consultancy for medtech companies. Prior to this he was Director of Healthcare innovation for the Department of Bioengineering at Clemson University. He held numerous posts for Wallace Coulter Foundation, including foundation director.

Describing demands today's students may face, Professor Gara said, "As a scientist turned business person, I have had the challenge of dealing with innovation and product development from many different perspectives. I am encouraged by the nascent field of bioengineering, which brings together skill sets in engineering, science and biology to tackle today's challenges in the industry. Before the emergence of bioengineering, companies and disciplines were more often in silos, and communication and problem solving was more difficult. Today's bright faculty and students are better equipped and determined to meet those challenges."

BMES Distinguishes Clemson Bioengineering Society's Exceptional Mentoring Program

Clemson Bioengineering Society, the department's graduate student professional organization, is the winner of the Outstanding Mentorship Program Award given annually by the Biomedical Engineering Society. Students Sarah Helms, Alison Markley and Cody Dunton were instrumental in this success. Mr. Dunton said, "We decided a good way to approach a mentorship program is to facilitate numerous small and informal interactions between mentors and mentees. These small interactions allow for relationships to form between the mentors and mentees, thereby organically leading to pertinent discussions, solicitation of advice and mentorship." At the 2017 BMES annual meeting in October, Mr. Dunton will deliver a presentation on how the graduate students were able to attract the interest and participation of so many members of the department's undergraduate group, Clemson Undergraduate Bioengineering Society.

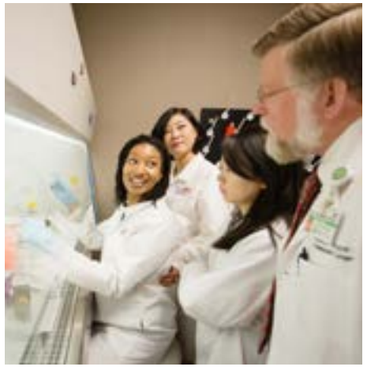
Clemson Pioneers Academic Workforce Generation

We study how multigene silencing affects cancer cell survival and sensitization to combination therapies using peptide, liposomal, and polymeric delivery systems. *Dr. Angela Alexander-Bryant*

The department is delighted to welcome two new assistant professors, Angela Alexander-Bryant and Jordon Gilmore. Having spent two years as departmental postdoctoral fellows through the former Tiger Talent program, these assistant professors are already a good fit in Clemson Bioengineering. Tiger Talent, initiated by the provost to attract postdoctoral fellows from groups underrepresented in science, was designed to ensure a successful relationship between the fellows and their departments. Tiger Talent mentors facilitated this outcome through regularly scheduled meetings and talks with fellows. Additional resources were made available as needed to promote a successful fit in target departments. According to Martine LaBerge, Chair of the Department of Bioengineering, "During the two postdoctoral years, fellows learn to be a faculty member. The time is an opportunity to really see if the career is really what they want."

Dr. Alexander-Bryant received her B.S. and M.S. from Johns Hopkins University in materials science and engineering with a concentration in biomaterials. She completed her Ph.D. in bioengineering in the Clemson-MUSC Joint Bioengineering Program. Dr. Alexander-Bryant's long-term scientific career goal is to develop novel, clinically translatable therapeutic delivery strategies to improve targeted treatment of disease. "My lab will study the effect of multigene silencing on cancer cell survival and sensitization to combination therapies using peptide, liposomal, and polymeric delivery systems. We will also actively collaborate with other laboratories to expand the applications of these drug delivery platforms to other diseases and tissue engineering applications."

Tiger Talent was invaluable in my development as a researcher and teacher. I able to explore new research areas, gain additional technical experiences, and learn critical insights from a team of academic mentors. I am thankful for the University and CECAS resources invested into my success as a Clemson faculty member and mentor for future Tiger Talent scholars. *Dr. Jordon Gilmore*



I am particularly interested in biofabrication, cell culture optimization and intelligent biosensing. *Dr. Jordon Gilmore*

Dr. Gilmore received his Bachelor of Science in electrical engineering from The Citadel. He received his Ph.D. in bioengineering at Clemson in 2015. Dr. Gilmore's interests are orthopedic tissue engineering, biomedical textiles and bioinstrumentation and control engineering. His research focuses on the integration of adaptive control systems with biomaterials, medical textiles, and stem cells in regenerative medicine applications. Dr. Gilmore said, "As a part of this work, I am particularly interested in biofabrication, cell culture optimization and intelligent biosensing. My research group will combine the expertise of scholars across bioengineering, material science, electrical engineering, and computing to generate interdisciplinary solutions for emerging biomedical challenges."

Awards Banquet and Senior Celebration

The following were recognized at the department's annual Awards Banquet and Senior Celebration

2017 College of Engineering, Computing and Applied Science Award Winners

J. Wesley Davis Leadership Award — Joey Wilson
Hambright Scholarship Fellow — Natalie Ivey

2017 Undergraduate Award Winners

S. W. Shalaby Outstanding Bioengineering Sophomore Award — Cassidy Barringer
Larry S. Bowman Outstanding Bioengineering Junior Award — Natalie Ivey
Poly-Med Outstanding Bioengineering Senior Award — Katelyn Ragland
Barry W. Sauer Outstanding Bioengineering Undergraduate Researcher Award — Taylor Rothermel
Jonathan Black Undergraduate Leadership in Bioengineering Award — Anna Lu Carter
C. William Hall Undergraduate Departmental Honors Award — Lauren Pruett
R. Larry Dooley Entrepreneurship Award — Carlie Van

2017 Graduate Award Winners

Austin T. Moore Leadership Award — Alan Marionneaux
Outstanding Graduate Bioengineering Teaching Assistant Award — Dmitry Gil
Page Morton Hunter Bioengineering Graduate Researcher Award — Dylan Richards
R. Larry Dooley Entrepreneurship Award — Bre Przestrzelski

NSF Graduate Research Fellowship Program

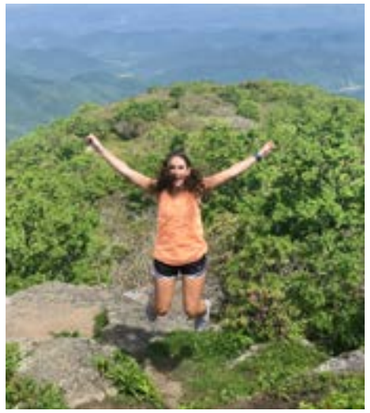
Seniors Lauren Pruett and Jacqueline Rohde were awardees in the National Science Foundation's Graduate Research Fellowship competition, and graduate student Meredith Owen was selected for honorable mention.

Jaqueline Rohde:

"I'm very excited to be attending Purdue University to earn a PhD in Engineering Education. My work will be on the postgraduation career paths of engineering students. I want to look at the progression of student identity development as engineers, especially with people who go into careers that are not typical industry-type jobs. I consider myself incredibly fortunate to have worked with great mentors in the Bioengineering department who supported me while I ran around trying to figure out what made me the most passionate. I feel honored to receive this fellowship from the NSF and look forward to jump-starting my career as a researcher and educator."

Lauren Pruett:

"I feel very honored to have received the NSF Graduate Research Fellowship to support my doctoral studies at the University of Virginia. I am very excited to start my graduate school journey and research career. I am confident that Clemson's bioengineering program has prepared me well for this next step. I will be performing biomaterials and stem cell research, and I plan to use the skills I gain in graduate school to work in industry or academia."



Meredith Owen:

"Being recognized by the National Science Foundation as an Honorable Mention for the Graduate Research Fellowship Program was a great honor. While I ultimately did not receive the scholarship, the process of applying for the award allowed me to gain a deeper understanding of the research I plan to conduct while pursuing my graduate degree in bioengineering. I am very grateful to all those who provided support and encouragement throughout the application process."

Cambridge Trust Scholarship to Joey Wilson

In late 2016, Joey Wilson, bioengineering major and a 2017 graduating senior, member of the Honors College and president of Clemson's Undergraduate Student Government, was named a Schwarzman Scholar. The honor includes a year of study at Tsinghua University in Beijing. There, he will be one of 129 students from 30 countries. Of Clemson's role in this opportunity, Joey said, "My Clemson experience has shaped me to be the person I am today and I'll carry Clemson with me for the rest of my life."

After a year of study in Beijing, Joey will begin research toward a Ph.D. in Oncology at Cambridge University. "I am thrilled to have the opportunity to earn a Ph.D. in Oncology at Cambridge University, where I will conduct research on how nanotechnology can be developed to better prevent and treat cancer under Dr. Daniel Munoz-Espin! I believe that Cambridge is like Clemson—with an amazing "family" environment and beautiful community that will provide opportunities for immense intellectual, professional, and personal growth inside and outside of the lab and classroom. I hope to take full advantage of my time there by joining a great college, meeting new people, and staying involved on campus—my ultimate dream would be to join the rowing team and compete against Oxford on the River Thames. I'm so thankful for all of the constant support given by Clemson's Bioengineering Department and the Honors College in my quest to attend Cambridge—I wouldn't be the person I am or have the opportunities I do without them."

Clemson-MUSC Program Students training through an NIH T32

Lindsay Stark and ***Robert Coyle***, students in the Clemson-MUSC Program, were awarded a National Institutes of Health T32 grant, Training in Craniofacial and Oral Health Research. Ms. Stark is studying the energy metabolism of human intervertebral disc cells to reveal the glucose consumption and lactate production of both healthy and degenerate discs. Her aim is to characterize the changes that occur during the degeneration process. Mr. Coyle's research focuses on development of injectable, pre-lumenized human cardiac organoids with enhanced survival rates and improved capacity for anastomosis post-transplantation for the treatment of injured hearts.

Dassault Systèmes Project 2017 Jury Prize Goes to Kyle Snethen: Predicting Clinical Outcomes in TKR

Kyle Snethen, graduate student in Dr. Melinda Harman's lab, was awarded the Dassault Systèmes Project 2017 Jury Prize. Kyle's winning entry demonstrated that finite element modeling of patient-specific simulations could inform surgical decisions and intraoperative technology.

Clemson Faculty and Staff Awards

Dr. John DesJardins, Robert B. and Susan B. Hambright Associate
Associate Professor in Engineering Leadership, was awarded the College of Engineering, Computing and Applied Science's 2017 Mentoring Award. According to Dr. DesJardins, this recognition affirms his belief that mentoring is a slow and consistent process of gaining and maintaining the trust of another person, placing their interests, aspirations and successes above your own, for the common good of everyone.

At the 2017 University-wide faculty meeting, ***Melissa McCullough***, the bioengineering's electrical and communication services coordinator, was awarded the Frank A. Burtner Award for Excellence in Advising. Presented by President James Clements, the annual award includes a cash prize. The Burtner Award recognizes an advisor of students (academic or nonacademic) or student organizations who excels in developing students in the area of leadership, devotion to duty and service.

Dr. Vladimir Reukov, received the 2017 Phil and Mary Bradley Award for Mentoring in Creative Inquiry. The University award is given to a faculty member in recognition of outstanding work with undergraduate students, who are the nominators for the award. In addition to receiving a monetary award, Dr. Reukov will act as an ambassador for the program and will be a plenary speaker at next year's Focus on Creative Inquiry. A research assistant professor and entrepreneur, Dr. Reukov has been named by President James P. Clements to the President's Leadership Institute. Dr. Reukov co-founded VRM Labs, where he serves as Chief Technology Officer, to pursue commercialization of his research findings.

Dr. Christopher C. Wright Accepts the 2017 Samuel F. Hulbert Award

Dr. Christopher C. Wright received the 2017 Samuel F. Hulbert Award at the department's annual awards ceremony in April. This award, instituted in recognition of the founder of the bioengineering program at Clemson University, is given to an individual outside the University who has made outstanding contributions to the department and significantly assisted its mission. Dr. Wright, a cardiothoracic surgeon at Greenville Health System, is Chief Medical Affairs Officer there and Chairman of its Institutional Review Board Committee.

An Adjunct Professor of Bioengineering since 2012, Dr. Wright works with graduate students on tissue regeneration projects, collaborates with faculty on funding applications and co-authors papers. He supports the SCBioCRAFT COBRE.

Dr. Wright's frequent collaborator Dr. Dan Simionescu, Dempsey Professor of Bioengineering, refers to Dr. Wright as "a cardiac surgeon with a heart of gold." At Clemson, Dr. Wright performs heart surgery on pigs, teaches a cardiovascular innovation class during the undergraduate/graduate cardiovascular course and works as a clinical mentor with groups of undergraduates for their design projects.

CLEMSON
BIOENGINEERING

Clemson University cordially invites you to be our honored guest at a reception celebrating the 2017 Biomedical Engineering Society Annual Meeting.

Camelback B
Sheraton Grande Phoenix
October 12, 2017
8:00 to 11:00 pm

Visit Clemson University in Booth 708!

See you in Atlanta for BMES 2018! #BMESfifty

50th Anniversary 1968-2018 BMES Biomedical Engineering Society
Celebrating the Past, Transforming the Future

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