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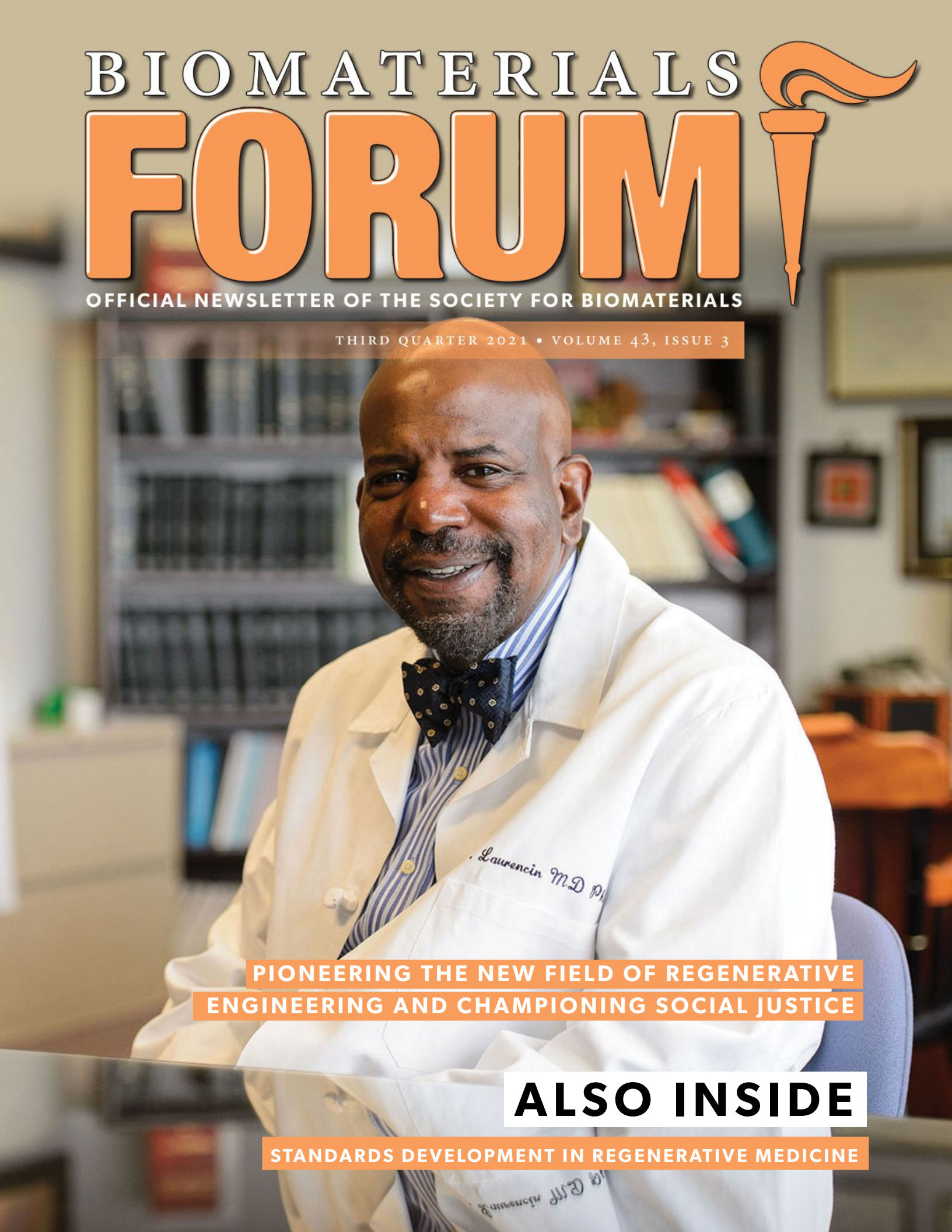

PIONEERING THE NEW FIELD OF REGENERATIVE ENGINEERING AND CHAMPIONING SOCIAL JUSTICE

ALSO INSIDE

STANDARDS DEVELOPMENT IN REGENERATIVE MEDICINE

Biomaterials Forum, the official news magazine of the Society For Biomaterials, is published quarterly to serve the biomaterials community. Society members receive *Biomaterials Forum* as a benefit of membership. Non-members may subscribe to the magazine at the annual rate of $48. For subscription information or membership inquiries, contact the Membership Department at the Society office (email: info@biomaterials.org) or visit the Society's website, biomaterials.org.

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BIOMATERIALS FORUM

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 43, Issue 3

SPECIAL INTEREST GROUP REPORTERS

ON THE COVER

The cover image shows Dr. Cato T. Laurencin, trailblazer in regenerative engineering and social justice. Dr. Laurencin is a university professor at the University of Connecticut.
Photo credit: Peter Morenus

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THE TORCH

NEWS & UPDATES

From the Editor

By Roger Narayan, Biomaterials Forum Executive Editor

I hope that all of you and your families are staying healthy and safe this summer. This issue features a profile of Dr. Cato T. Laurencin, one of the giants of our field. His discussion of equity, mentoring and social justice is important for all of us to consider as we work to support students and young professionals who are starting their careers. Carl Simon and SuPing Lyu share their views on standards development in regenerative medicine. I want to give profound thanks to Gopinath Mani, Carl Simon and Gerry Koons for sharing industry, government and student chapter news, respectively.

I have received promising information from Matt Peterson, NC State University's director of federal affairs, about increases in federal support of agencies and institutes that support biomaterials research. For example, the House Appropriations Committee has approved a fiscal year 2022 appropriations bill that includes $3 billion for ARPA-H, an Advanced Projects Research Agency for Health. The National Institutes of Health's traditional institutes will receive $3.5 billion more than in fiscal year 2021, which would translate to a 5% increase in budget (if the funding level is maintained in the final bill). The National Science Foundation (NSF) for the Future Act will support a doubling of the agency's budget over the next five years. The funds will support STEM workforce development at emerging research institutions and minority serving institutions, increased funding of the Mid-Scale Research Infrastructure program and a new Directorate for Science and Engineering Solutions that will facilitate collaborations and partnerships related to translational research. I hope to bring additional information about these exciting developments to the biomaterials community in upcoming issues of the *Forum*.

Yours truly,
Roger Narayan

From the President

By Guigen Zhang, SFB President

Happy summer, everyone! Hope you all found the time to enjoy the summer amid the still-lingering worries about the resurgence of the COVID-19 infection rate. I also hope that you found the time to tune in to the joint, virtual screening of the documentary film *Picture a Scientist,* hosted by the Society For Biomaterials (SFB) and the Tissue Engineering and Regenerative Medicine International Society (TERMIS) on Thursday, July 29, 2021, and joined the panel discussion afterward. Please let us know what you think of such joint events, or if you have any suggestions for similar events.

I am writing to connect and update you on what we have been working on since the 2021 virtual Annual Meeting. By we, I mean the Executive Committee, all SFB committees — the 2022 Annual Meeting Program Committee, the Awards, Ceremonies and Nominations Committee, the Publications Committee, etc. — and Dan and his staff at AH. With a front-row seat, I have the rare opportunity to witness the non-stop nature of the behind-the-scenes work by these committees, coupled with amazing support from Dan, Shena, Ashton and others, to keep the SFB moving forward.

We recently conducted a survey among the members of the SFB governing Board and Council utilizing the American Society of Association Executives (ASAE) ForesightWorks initiative. The ASAE ForesightWorks is a deliberate, evidence-based research initiative that identifies a list of 50 societal trends that are likely to impact associations in the future.

We used the member survey results to inform and guide our strategic planning discussion held during the August 2021 SFB Council Meeting and to help us prioritize action items for the coming years. The Executive Committee also examined the charges of all SFB committees in a holistic view and will ask each committee to prioritize their objectives and tasks.

We have also made good progress in working with colleagues from the Office of the Chief Scientist and the Office of Regulatory Science at the U.S. Food and Drug Administration (FDA) on developing a Memorandum of Understanding (MOU) toward establishing and expanding formal collaborative channels between the SFB and the FDA. At this moment, a drafted MOU has been developed for comments and input on both sides.

In a separate initiative, the Biomaterials and Medical Products Commercialization SIG officers, and the SFB Industrial Affairs Committee are also compiling feedback for the Center for Devices and Radiological Health (CDRH) on their recent request regarding conveying materials information about medical devices to patients and healthcare providers.

The theme for the 2022 SFB Annual Meeting and Exposition has been set, and it is "The Perilous Fight to Translate Innovative Research to Commercial Viability." In responding to the call for program ideas, we have received an overwhelmingly large number of proposals from our members, a strong indication that we are all eager to gather in-person to share our scientific breakthroughs and progresses and catch up with friends and peers next year in Baltimore, MD — let us keep our fingers crossed on that. The Program Committee, led by co-chairs Cherie Stabler and Carl Simon, joined by two past program committee chairs, two future program committee chairs, the SIG representative and Diversity, Equity and Inclusion (DEI) committee representative, among others, is busy in reviewing these proposals and making recommendations and decisions toward building a successful program truly reflective of the chosen theme.

I also want to brief you on the proactive actions taken by the Awards, Ceremonies and Nominations (ACN) Committee this year, led by Andrés García. The committee has developed a solid plan to improve transparency in the committee's functions, including: 1) posting the name and affiliation of all ACN Committee members on the SFB awards page; 2) publishing a written summary of the criteria used to evaluate the nominations, and the process by which the committee's input is compiled; and 3) providing guidelines for standardizing the information that should be contained in a letter of support for an award or officer nomination. As you may know, the committee has an

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appointed DEI committee member on board to assure SFB's committeemen to DEI is truly reflected in the ACN process. Let us know if you have any other suggestions.

In addition, we have formed a working group in collaboration with the Materials Research Society to host a series of webinars beginner October 2021. There will be a series of four MRS and SFB Joint Webinars held on Tuesdays at 11:00 am Eastern, on October 5, 12, 19 and 26, 2021. Be on the lookout for announcements concerning the topics and speakers included in this exciting new program.

Finally, I want to remind you about the joint symposium planned for January 8-10, 2022 in Honolulu, Hawaii, to honor the seminal contributions of four biomaterials luminaries: James Anderson, Art Coury, Tadashi Kokubo and Teruo Okano.

Thank you again for your devotions and contributions to the SFB!

Best wishes and stay safe,
Guigen Zhang
SFB President, 2021-2022

For more information on ASAE's ForesightWorks, visit https://www.asaecenter.org/resources/asae-foresightworks.

Staff Updates

By Shena Seppanen, Assistant Executive Director

Hello from Society For Biomaterials (SFB) Headquarters! SFB's governing Council held a Strategic Planning Call on August 17, 2021 with an eye on the future. As the new program year gets underway, the Society's Board of Directors, governing council, committees and SIGs will be working to advance the Society's strategic plan.

AWARDS, CEREMONIES AND NOMINATIONS COMMITTEE – CHAIR: ANDRÉS J. GARCÍA, PHD

The committee solicited nominations for 2021. Award nominations closed on September 17, 2021 and officer nominations closed on September 24, 2021. Award nominations are currently under review for announcement of selected recipients to be made in late November. Officer nominations, once formalized by the committee, will be forwarded to the council for ratification, and the approved candidates will stand for election in early 2022.

BYLAWS – CHAIR: C. LASHAN SIMPSON, PHD

The committee will be reviewing the by-laws and discussing any possible amendments.

EDUCATION & PROFESSIONAL DEVELOPMENT – CHAIR: THOMAS DZIUBLA, PHD

The committee is conducting an audit of those student chapters who received 2020 Biomaterials Day Grant funding but were delayed or postponed due to the COVID-19 pandemic, encouraging them to reschedule their events if they are able. The committee will also be considering the opportunity to offer continuing medical education programming in the near future.

FINANCE – CHAIR: DANIELLE BENOIT, PHD

SFB is preparing the 2022 budget to include the 2022 Annual Meeting and associated activities, the Biomaterials Day Program and a website update and rebuild.

INDUSTRIAL AFFAIRS – CHAIR: SUPING LYU, PHD

The committee has been in discussion in regard to future collaboration with the Food and Drug Administration to position the Society as a primary resource when it comes to fundamental science and the translational hurdles of medical device development and other biomaterials related issues. The committee also worked with the Biomaterials and Medical Products Commericalization SIG to provide feedback to a recent request from Center for Devices and Radiological Health on labeling requirements.

LIAISON – CHAIR: BINGYUN LI, PHD

The committee is evaluating endorsement requests and considering potential collaborations with other organizations.

MEMBERSHIP – CHAIR: NATALIE ARTZI, PHD

Current membership stands at 1168, which is significantly less than in prior years, likely due to the effects of the pandemic — particularly the 2020 World Biomaterials Congress and the 2021 Annual Meeting both being virtual events. The committee continues to develop strategies to increase membership, especially focusing on industry and clinical sectors.

SFB/JSB JOINT SYMPOSIUM PROGRAM – CHAIRS: ELIZABETH COSGRIFF-HERNANDEZ, PHD AND NICHOLAS P. ZIATS, PHD

The Committee is finalizing plans for the joint symposium with the Japanese Society For Biomaterials to be held in Honolulu, Hawaii January 8-10, 2022. Please plan to join us!

2022 ANNUAL MEETING PROGRAM – CHAIRS: CARL G. SIMON, JR., PHD, AND CHERIE STABLER, PHD

The Committee is busy preparing for the 2022 Annual Meeting to be held in Baltimore, MD, April 27-30, 2022. We received a record number of ideas for programming, which bodes well for a robust meeting in 2022! They are currently in the call for abstracts phase, with a deadline of November 10, 2021.

PUBLICATIONS COMMITTEE – CHAIR: JAN P. STEGEMANN, PHD

The Publications Committee has undergone extensive review and negotiation of the Society's next contract agreement with Wiley to continue publishing JBMR Parts A & B. They are also continually considering the impact of open access publications on the Society's financial model, and the scientific community in general. This societal trend may well impact the way the Society operates in the future.

SPECIAL INTEREST GROUPS – REPRESENTATIVE: ASHLEY BROWN, PHD

Each SIG met during July and August 2021 and had great discussions around program ideas for the 2022 Annual Meeting. They also recently submitted their budget plans for the 2022 membership year.

NATIONAL STUDENT CHAPTER

The National Student Chapter hosted their Annual Business Meeting on Tuesday, September 14, 2021, and is actively developing programming for the 2022 Annual Meeting. All undergraduate students are to be reminded that the Society offers two scholarships — the C. William Hall Scholarship and the Cato T. Laurencin, MD, PhD Travel Fellowship — with application deadlines on December 3, 2021.

If you have any questions, require additional information or have suggestions for improved services, please feel free to contact the Society's Headquarters Office:

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Pioneering the New Field of Regenerative Engineering — and Championing Social Justice

(Photo by Peter Morenus)

Dr. Cato T. Laurencin has established preeminence in science, engineering, medicine, technology and social justice. A master of multiple fields, Dr. Laurencin, holds University of Connecticut's highest academic title: University Professor.

(This article originally appeared in *UCONN Magazine*.)

Please tell us about yourself and how you got to where you are today.

I work at the interface of medicine and engineering and am also someone that is very much involved in issues of social justice. I grew up in Philadelphia, PA and became interested in medicine at a very early age, and decided I wanted to become a doctor. I started college at Princeton, where I met people who were fantastic mentors in engineering. At that time, I was not quite sure how I was going to combine engineering and medicine, but I pursued chemical engineering.

When I completed college, I went on to medical school at the Harvard Medical School in Boston, MA, and partway through I decided to revisit my scientific and engineering routes. I met Robert Langer, who was a young assistant professor at that time and decided to join his laboratory. I subsequently took on a combined MD–PhD program combining work at Harvard with work at MIT. This program was unusual, and I realized that to do a comprehensive job on both would take a long, long time!

With the support and help of Noreen Koller, who was a fantastic registrar at Harvard, I was allowed to move back and forth for my training, so I would do clinical rotations and then I would do work in the laboratory. This enabled me to complete my MD and PhD combined in seven years, which really helped me on my journey because I became very, very used to working in both the clinical and research realms. I then began a residency in orthopedic surgery and opened my laboratory at MIT.

Pioneering the New Field of Regenerative Engineering (continued)

Since then I have been working in both areas — a common theme in all my research has been combining the principles of material science and engineering with physics and clinical medicine to allow us to be able to create new information and new science.

You have been recognized numerous times for your achievements in bioengineering. Could you talk about your work in this field?

I essentially defined what is now a new field — regenerative engineering, which is the convergence of technologies that we can utilize for the purposes of regeneration of complex tissues.

I first outlined this vision for the new field of regenerative engineering in 2012 and since then we have continued to work and expand the field. We now have a society called the Regenerative Engineering Society and our work has been successful in terms of developing new science, new technologies, and new ways of thinking for the regeneration of complex tissues and organ systems. We have been fortunate to be funded by the NIH Director's Pioneer Award, and the National Science Foundation has awarded us two Emerging Frontiers in Research and Innovation awards for this new field.

You have recently been awarded the Herbert W. Nickens Award by the AAMC — congratulations! Please tell us briefly about that award, why you won it, and how that makes you feel.

I was very excited and very proud to receive the Herbert W. Nickens Award. It's the American Association of Medical Colleges' highest award for social justice and equity, and it recognizes the work that I have been involved in over the past almost 40 years in the area of social justice and equity.

It recognizes my efforts to create a fairer society for all in work that has ranged from boots-on-the-ground programs seeking to increase the numbers of Black and Brown people working in engineering, science and medicine, to larger programs such as the creation of The W. Montague Cobb National Medical Association Institute program looking at ways in which one can address disparities in health, medicine and science for Black people, to launching a new journal — the *Journal of Racial and Ethnic Health Disparities* — which is now the leading journal working in the space, to our new work in terms of Chairing the National Academy of Sciences, Engineering and Medicine Roundtable on Black Men and Black Women in Science, Engineering and Medicine.

I have been involved in a broad gamut of endeavors that have at their core the aim of making the U.S. and the world a more fair, just and equitable society.

You have received singular honors for your years of work. You were the first individual in history to receive both the oldest/highest awards from the National Academy of Engineering (the Simon Ramo Founder's Award) and the National Academy of Medicine (the Walsh McDermott Medal). The American Association for the Advancement of Science recently awarded you with the prestigious Philip Hauge Abelson Prize for your innovative research, contributions to national policies regarding science and dedication to supporting diversity in the field. How will regenerative engineering shape the future?

At the Connecticut Convergence Institute our main focus is on regenerative engineering, which as I mentioned is defined as the convergence of advanced materials sciences, stem cell science, physics, developmental biology and clinical translation, for the regeneration of complex tissues and organ systems. Our institute aims to regenerate human limbs, not robotic limbs, but rather real, organic, flesh-and-blood ones that grow on the person receiving treatment. This type of breakthrough will have a tremendous impact on global public health and in the lives of those with amputations due to bone cancer, diabetes, dangerous infections, trauma accidents or children born with missing or impaired limbs.

The ultimate goal of the Hartford Engineering A Limb (HEAL) project, under active research in my laboratory, is aimed at helping wounded warriors as well as others who have lost limbs or experienced joint damage. Other patients who could benefit from the future breakthroughs are those with amputations due to bone cancer, diabetes, dangerous infections or trauma accidents, or even children born with missing or impaired limbs.

"IT'S THE AMERICAN ASSOCIATION OF MEDICAL COLLEGES' HIGHEST AWARD FOR SOCIAL JUSTICE AND EQUITY, AND IT RECOGNIZES THE WORK THAT I HAVE BEEN INVOLVED IN OVER THE PAST ALMOST 40 YEARS IN THE AREA OF SOCIAL JUSTICE AND EQUITY."

Pioneering the New Field of Regenerative Engineering (continued)

What would you say are the main challenges still hindering equity in healthcare?

Our main challenge in terms of equity for Black people in both the U.S. and the world is the persistence of racism. We know that there are excess deaths each year of Black people linked to racism and we have known this for a very, very long time — this is not new news. In the 1990s, the National Medical Association had a consensus report examining racism and its effects on health and the creation of health disparities. The National Academies followed up with a study called "Unequal Treatment," which examined the unequal treatment of Black people and others in the U.S. and found racism to be a primary reason why this is happening.

"IT IS NOT NECESSARILY THAT THE PERSON HAS TO AGREE WITH WHAT THEIR MENTOR SAYS, BUT THERE HAS TO BE A CLEAR RELATIONSHIP IN WHICH THE COUNSEL OR GUIDANCE IS PROVIDED AND HAS BEEN WELL THOUGHT THROUGH."

Recently, we have seen the murders of George Floyd and Breonna Taylor garner widespread media attention. This injustice translates to the medical establishment, too, in terms of medical care, which translates to higher mortality for Black people. That is the major challenge we have to address in terms of healthcare and something that I am very passionate about.

We recently made the case for why we need to see more Black professionals working in medicine, along with science and engineering. On the medical side, Black physicians treating Black patients obviously do not exhibit the levels of unconscious bias and conscious racism that take place among white physicians and some new studies — for example in COVID-19 — have suggested that clinical outcomes are improved where Black physicians have taken care of Black patients.

So what challenges are still faced by Black and Brown students who aspire to careers in STEM industries, such as healthcare?

Number one is that there are so many systemic racism issues. It was extreme when I was growing up — I still remember walking into a classroom at MIT and having a professor block me from coming into the door. Is it still this extreme? Probably not as blatant, but just as damaging.

As an active mentor helping address this, what are your top tips for others hoping to be good mentors?

I was very fortunate to win the Presidential Award for Excellence in Science, Math and Engineering mentorship from President Obama and the American Association for Advancement of Science Mentor Award, so mentoring is a big component of my life.

I think for mentors it is important that there is a dedication to that individual and to their long-term future. I have been fortunate to have mentorships that have been lifelong — I am still in contact with people I have mentored who are now full professors and chairs or deans. I think it is also important that the mentorship is a two-way relationship, meaning that there are expectations from both the mentor and the mentee. The mentees have to follow up with and listen to their mentors. It is not necessarily that the person has to agree with what their mentor says, but there has to be a clear relationship in which the counsel or guidance is provided and has been well thought through. Finally, there has got to be an open dialogue about successes, setbacks and plans.

You touched earlier on studies showing the availability of Black physicians reduces unconscious bias and improves care. Do you think that a representative workforce is requisite for equitable healthcare?

Yes, I think you do need to have a representative workforce in order to be able to have equity in medicine, for a number of reasons. Number one, because, as we alluded to, when you have Black and Brown physicians, you reduce the levels of unconscious bias and racism in the system as a whole and that results in better quality of care. Number two is that to a great extent the under-representation of Black physicians in medicine right now is a symptom of a system that has at its roots systemic racism.

Pioneering the New Field of Regenerative Engineering (continued)

One marker for how we progress is to examine the numbers of Black people who are in medical school. We had a historic low in terms of Black men in medicine around 2014–2015. Those numbers have rebounded a bit, but that shows that even in a world in which we talk about diversity and equity, such a phenomenon can happen. That's why I published my piece "The Context of Diversity" in the journal *Science*. You cannot think of diversity as an old Kumbaya general feeling. We have to look at what's happening with specific groups and with the specific challenges that are taking place in specific groups. With Black people, especially in the U.S., we know that racism plays a role in every aspect of their lives.

I wrote a paper recently on racial profiling as a public health issue speaking to how racial profiling by police in America has serious health effects. This is an area that really needs to be addressed.

You've done much for the state of Connecticut. You were the faculty architect for Bioscience Connecticut, which revamped UConn Health, and even serve as a Commissioner for Boxing for the state. You've been awarded the Connecticut Medal of Technology and Innovation for your work not only in research, but in entrepreneurship. You have a large social justice footprint in the state. You serve on the Connecticut Racial Profiling Prohibition Advisory Board and you were recently named a Connecticut Magazine Healthcare Hero. Tell us about your work that earned you that title and what your vision is for the future.

In the "Healthcare Hero" article I discussed how and why the coronavirus was and still is disproportionally affecting Blacks. I recall that when COVID-19 first hit, there was a myth of Black immunity that was circulating on the internet and social media, so I set out to examine that because I was really concerned if that misinformation got out it could be disastrous for the Black community.

I published the first peer-reviewed study in the nation with these findings in April 2020. It exploded the myth and created an early warning that the disease could be particularly bad for the Black community.

It's important to understand that the reason the levels that we're seeing are this high is because of the history of discrimination that has taken place in this country.

When thinking about remedies for the issue at hand, I developed the concept of the IDEAL Pathway to creating a just and equitable society. Currently, we're in a world of discussions about diversity, inclusion and equity. While we have had some gains in these areas, they have not really sufficiently addressed the issues of racism that we see in this country. So my belief is that we need to move to inclusion, diversity, equity, anti-racism and learning (IDEAL). Understanding ways in which Black people are affected by the specific kinds of racial discrimination called anti-Blackness. Understanding the history of Black, Indigenous and all people of color. Moving from ally to what I would call a ride-or-die partner in the anti-racism movement — these are some of the ways that I believe learning can be used in a constructive way to bring about the ideal pathway to move forward.

Finally, what have been some of your proudest moments during your career thus far?

The proud moments are too numerous to count. I am blessed and highly favored. The moments surrounding my family (meeting and falling in love with my wife and the birth of my children probably count as the best moments).

Speaking of moments, I want to share some of my philosophy. There are actually three "most important" dates of your life. They are the day you are born, the day you realize your purpose in life and the day you are truly carrying out your life on purpose.

For me, starting the new field of regenerative engineering, taking care of patients as a surgeon, working for social justice and mentoring the next generation, all while doing the most important thing: staying connected to my family, my values and my God collectively represent my purpose.

A life on purpose is where I am, which is the ultimate goal.

Portions of this interview originally ran in the journal *BioTechniques*.

Standards Development in Regenerative Medicine

By Carl Simon and SuPing Lyu

WHAT ARE STANDARDS?

Standards are often divided into three categories: written, physical and data.[1,2] Written standards, also called documentary standards, are documents drafted by teams of experts and voted upon at standards development organizations such as ASTM (formerly known as American Society of Testing and Materials) or International Organization of Standardization (ISO). Documentary standards define terms, describe test methods and provide guides on the best way to do things, such as characterize a product. Physical standards, also known as reference materials, are physical artifacts that can be developed in house, or by a certifying organization, and have stable, homogenous properties that are useful for calibrating instruments or to confirm that a measurement system is working properly. Data standards are sets of carefully collected data that can be used for comparisons, such as reference spectra for chemical compounds. This article focuses primarily on documentary standards.

WHY HAVE STANDARDS? RELIABILITY AND COMMON LANGUAGE

The promise of standards is reliability and trustworthiness. Standards have extra vetting and review, making them more likely to be more dependable, feasible, operationally consistent or rigorous than other sources of information. Standards development organizations must follow a process of openness, balance, due process, an appeals mechanism and consensus. Publishing requires a vote, and at ASTM all negative votes must be addressed. ASTM committee F04, where many medical device standards reside, has more than 400 members that review and vote upon each standard.

Without standard test methods, when different people do the same testing, they often get different results. Differences can be greater if the testing is done by different institutes, e.g., suppliers of goods and users of them. A standard test method can improve comparability of results. A result obtained with a standard test method may bring regulatory reviewers, product manufacturers, physicians and materials suppliers to the same table with the same understanding of the result for them to make critical decisions. Standards may also save time because the users do not have to develop duplicated methods on their own. Many users of standards are not experts in the test methods and may not be capable of developing the methods they need. Standards can provide objective, consensus, technically rigorous test methods to support product development and characterization in the tissue engineering and medical device community.

Great Discussions

A key benefit of participating in standards development is the high-quality and deep dialogue about fundamental scientific issues. Standards development provides a unique, neutral forum where open, respectful scientific discussions can occur. If you want to talk candidly about technical or analytical aspects of product development and characterization, then you would probably enjoy standards. You meet other scientists that may be facing similar challenges in their product development journey and have the opportunity to learn from the insightful experiences they share. Regulatory agencies have a large stake in standards, since use of standards during product development can streamline review. Regulators enjoy standards forums since they can speak more openly in these generalized discussions than, for instance, when a specific product is being discussed. Standards discussions do not touch upon proprietary information and focus on topics and information that are available to all.

Standards Coordinating Body

The 21st Century Cures Act provided the Food and Drug Administration (FDA) with support to establish the Standards Coordinating Body (SCB) to coordinate the development of regenerative medicine standards.[3] Regenerative medicine products draw from many disciplines causing the relevant standards to be developed in a wide range of standards development organizations (SDOs). Some examples are ASTM, ISO, American Society of Mechanical Engineers (ASME), United States Pharmacopeia (USP), Foundation for the Accreditation of Cellular Therapy (FACT), American Association of Blood Banks (AABB), American Type Culture Collection (ATCC), Parenteral Drug Association (PDA) and IEEE (formerly known as Institute of Electrical and Electronics Engineers). SCB coordinates activities between the SDOs by serving as a liaison, recruiting subject matter experts to serve on working groups, and educating stakeholders on how standards are developed and used. SCB maintains an interactive portal for searching regenerative medicine standards, publishes stakeholder surveys regarding standards needs and develops helpful educational tools.[4-6]

The Journey

I, Carl Simon, thought I would describe my own journey in standards development so that you might better appreciate how things progress. Earlier in my career I did a lot of research on tissue engineering scaffolds, developing some expertise on the topic. Colleagues urged me to organize an ASTM workshop on scaffold characterization. I thought to myself, "I know a little bit about the topic, but it is so broad, how could I possibly lead a workshop?"

It was overwhelming. I was clearly out of my comfort zone, but

Standards Development in Regenerative Medicine (continued)

we did it in 2013 in Indianapolis, IN. We had about 80 attendees. I learned about a lot of new methods for scaffold characterization, I engaged with many new stakeholders in the tissue engineering industry and we published a report to summarize discussions.[7] The workshop inspired several attendees to lead new standards on polymerized collagen (Sherry Harbin), cell-catheter interactions (Michael Hiles and Will McRoy) and decellularized extracellular matrices (Nikhil Gheewala).[8-10] What I learned from the workshop caused me to realign my research priorities leading to a new project in scaffold characterization.[11]

In 2018, we organized a follow-up workshop at the ARMI|BioFabUSA facility in Manchester, NH, but this time the focus was on fiber-based constructs.[12] It was still overwhelming and pushed me out of my comfort zone, but the experience was rewarding. I learned a ton about characterizing fiber scaffolds and engaged many new industry stakeholders. Attendees were motivated to form a working group to write a standard on fiber-based scaffolds that was published this year.[13] I was again to redirected my research focus to address needs uncovered at the workshop. This work is still in progress and I hope to provide a report sometime in the future!

Experts Needed

Subject matter experts are needed to develop standards to facilitate translation of regenerative medicine products. Please contact Carl Simon (carl.simon@nist.gov) if you are interested in participating. We especially need people who like technical writing! Participants can be from any stage of their careers and from a wide range of backgrounds such as students, technicians, industry scientists, professors, non-profits, regulatory, statistics, biologists, quality control, CEOs, research, computer scientists, post-doctoral, engineering, etc. Some examples of working groups that would be delighted to have your participation are given in Table 1.

For more information, please contact Carl Simon at **carl.simon@nist.gov**, and SuPing Lyu at **suping.lyu@medtronic.com**.

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Table 1. Examples of Working Groups that Would be Delighted to Have Your Participation

Existing working groups	Sampling methods of tissue engineered medical products for sterility assurance (ASTM)
	Bioinks used in bioprinting (ASTM)
	Test method for measuring cell viability in a scaffold (ASTM)
	Biobanking requirements for human mesenchymal stromal cells (ISO)
	Guide for software for 3D bioprinting (IEEE)
	Cryopreservation of cells (PDA)
Working groups just starting	Standards for microphysiological systems (ASTM)
	Guide for cell viability measurements (ISO)
	Tissue-engineered muscle (ASTM)
Areas of need	Characterization of scaffold materials
	Donor tissue sterilization
	Release criteria for regenerative medicine products
	Animal models for safety testing

Industry News

By Gopinath Mani, Industry News Editor

Stryker recently announced the Food and Drug Administration (FDA) clearance of the first balloon implant for arthroscopic treatment of massive irreparable rotator cuff tears.[1] The InSpace balloon implant is designed to restore the subacromial space without requiring sutures or fixation devices and has been demonstrated to improve shoulder motion and function.[1] This implant system is indicated for the treatment of patients with massive, irreparable, full-thickness torn rotator cuff tendons due to trauma or degradation, with mild to moderate gleno-humeral osteoarthritis in patients greater than or equal to 65 years of age, whose clinical conditions would benefit from treatment with a shorter surgical time compared to partial rotator cuff repair.[1] Thus, this implant system provides a new option for surgeons in their shoulder continuum of care that allows them to better meet the needs of their patients.[1]

Neurescue, a medical device company, recently announced that the FDA has granted 510(k) clearance to market the company's NEURESCUE® device for temporary occlusion of large vessels, including patients requiring emergency control of hemorrhage.[2] Hemorrhage is a substantial global unmet need, with more than 60,000 deaths per year in the U.S., and an estimated 1.9 million deaths per year worldwide, 1.5 million of which result from trauma, such as car accidents.[2] The NEURESCUE® device is an intelligent balloon catheter for aortic occlusion, an emergency technique that supercharges blood flow to the heart and brain within one minute from deployment.[2] This device consists of a catheter and a control unit, which houses patented sensor guidance and automated inflation technology.[2] The device's intelligent safety feedback system helps ensure safe catheter positioning and regulates balloon pressure to prevent over-inflation, rupture and damage to tissue while also monitoring blood pressure.[2] This device is delivered via the femoral artery, temporarily inflating a soft balloon in the aorta to redirect blood flow towards the upper body.[2] The procedure is performed to provide additional time to control blood loss and bridge patients to additional life-saving treatment options.[2]

Eclipse, a medical device manufacturer, recently announced FDA clearance of their latest medical-grade microneedling device, the MicroPen EVO.[3] Microneedling is a procedure that uses small needles to create controlled injuries to the skin, promoting natural increases of collagen for the improvement of facial acne scarring.[3] The new design and technology built into the MicroPen EVO will help practitioners treat patients more effectively, with more control and an improved field of view.[3]

AliveCor, a medical device company, recently announced that it has received 510(k) clearance by the FDA for healthcare professionals to use the KardiaMobile 6L device to calculate patients' QTc interval.[4] The QTc is a heart rate corrected interval that reflects the integrity of the heart's electrical recharging system.[4] QT prolongation can stem from congenital long QT syndrome, many disease states or electrolyte abnormalities.[4] Patients with a prolonged QTc are at greater risk for their hearts to go into a potentially dangerous arrhythmia called Torsades de Pointes which can lead to sudden cardiac arrest.[4] More commonly, QT prolongation is a potential side effect of more than 100 FDA-approved medications, including certain antiarrhythmic medicines, cancer therapies, antifungals, antipsychotics, antidepressants, antibiotics, multiple sclerosis (MS) medications and opioids, among other categories.[4] With this new FDA-clearance, in just 30 seconds, healthcare professionals can use the KardiaMobile 6L device to obtain an ECG which they can use to manually measure their patients' QT interval.[4]

New View Surgical, Inc., a medical device company, recently announced that it received 510(k) clearance from the U.S. Food and Drug Administration for its VisionPort™ System, which is a surgeon-controlled, multi-camera laparoscopic visualization system.[5] This system simplifies the laparoscopic procedures.[5] Its dual-camera design offers multiple, simultaneous views of the anatomy and surgical instrumentation — unavailable with conventional laparoscopic systems.[5] The VisionPort system is intended to be used in a broad range of diagnostic and therapeutic procedures within the thoracic and abdominal cavities.[5]

Rousselot® Biomedical recently launched X-Pure® GelDAT – Gelatin Desaminotyrosine, a purified and phenol-functionalized gelatin.[6] Until now, one of the go-to products for researchers requiring a biomaterial more adhesive than GelMA-Gelatin Methacryloyl, was GelTYR — Gelatin Tyramine.[6] However, GelTYR has several limitations, most notably its irreproducibility and the lack of a scalable production process.[6] The chemical reactions required to make GelTYR lead to uncontrollable side reactions, which can significantly delay product development and negatively impact the likelihood of success.[6] X-Pure® GelDAT offers guaranteed purity and consistency at scale, vital to the successful development of biomedical applications used in the human body.[6] Also, the X-Pure® GelDAT is unique because of its phenolic modification that grants superior adhesion properties to human tissues, and because it can be cross-linked by both enzymatic reaction or photo-induction.[6] These characteristics allow its combination with other biomaterials for the creation of more versatile and complex structures for drug delivery, tissue engineering, organ-on-a-chip and complex wound dressing applications.[6]

Industry News (continued)

MedPharm Ltd., a contract developer of topical and transdermal pharmaceutical products, is opening a new location in Raleigh-Durham, NC that will expand its CDMO services in topical and transdermal delivery.[7] This facility will support process development, clinical and small-scale commercial manufacturing for semi-solid and liquid pharmaceutical products.[7] This new site, located within a few miles of MedPharm's current Center of Excellence for topical and transdermal development, gives MedPharm's clients the opportunity to manufacture clinical batches and commercial scale products in the US.[7] The facility is designed to meet all FDA, EMA and GMP requirements with state-of-the art design, operational support systems, technology and resource management.[7]

Varian, a Siemens Healthineers company, recently announced that the FDA has granted the company "breakthrough device designation" for its cardiac radioablation (CRA) system, currently in development as a noninvasive therapy for select patients with refractory ventricular tachycardia (VT).[8] Ventricular tachycardia is a fast, abnormal heart rate and may lead to sudden cardiac arrest if not treated successfully.[8] Patients with VT may be treated with an implantable cardioverter-defibrillator (ICD), antiarrhythmic medications or an invasive catheter ablation procedure.[8] Often, these interventions are insufficient in controlling VT.[8] Varian's CRA system was designated a "breakthrough device" by the FDA because of its potential to offer a more effective treatment for select patients with refractory VT.[8] Unlike conventional catheter ablation for VT, the Varian CRA system is being developed to enable noninvasive targeting and delivery of ablative energy across the full thickness of the myocardium.[8] As a noninvasive therapy, CRA procedures may prove safer and require less time than current surgical modalities.[8] The FDA breakthrough device program is intended to provide patients with more timely access to medical devices that have the potential to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.[8] As part of the program, the FDA expedites the traditional review and assessment process to help accelerate the development, assessment and review of the device.[8]

UroViu Corporation, the developer of a suite of portable, self-contained and versatile single-use cystoscopy solutions, has received clearance from the FDA to market its third device — Uro-G, a flexible single-use cystoscope with a fully deflectable tip that enables physicians to perform interventional and diagnostic urologic procedures in their clinics conveniently in any room, anytime, without reprocessing.[9] This allows for practices to expand their cystoscopic capabilities and throughput without capital investments or service contracts.[9] Typically, the per-procedure cost of owning and using a UroViu device is lower than for traditional reusable platforms.[9]

Front Line Medical Technologies, Inc. recently announced that the FDA has cleared its control of bleeding, resuscitation, arterial occlusion system (COBRA-OS™).[10] The COBRA-OS™ is the first four French resuscitative endovascular balloon occlusion of the aorta (REBOA) device and it is the smallest on the market.[10] REBOA is a minimally invasive procedure used in emergency situations, that deploys an endovascular occlusion balloon in the aorta to temporarily stem blood flow below the device and increase blood flow above it to the brain and heart.[10] The COBRA-OS™ is a cost-effective, innovative, easy-to-use aortic occlusion device with an extremely low profile for temporary hemorrhage control and resuscitation.[10] Also, the COBRA-OS™ is capable of providing full occlusion, intermittent occlusion, or partial occlusion depending on the patient's need, and also has a unique Safety Shoulder Reservoir™ incorporated into the device to help prevent aortic rupture during inflation.[10] The medical device allows frontline personnel to save more lives by controlling patients' bleeding in fewer steps and less invasively, potentially decreasing complications.[10]

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NIH Releases 5-Year Strategic Plan

By Carl Simon, Government News Editor

The National Institutes of Health (NIH) published a strategic plan addressing fiscal years 2021-2025.[1] NIH's budget in 2020 was $42 billion, and 80% of this was used to support extramural research. The plan starts with 11 strategies, the first of which is "building data resources to enable research progress." It addresses databases for DNA, RNA, microbiomes, genomes, large cohorts of clinical data and mapping the mouse brain, highlighting the growing focus on sharing data, metadata and higher order analytical methods. The ninth strategy may be the most relevant to biomaterials scientists: "Catalyzing cell engineering, bioengineering and regenerative medicine." This section focuses on induced pluripotent stem cells, engineered tissues, organs-on-chips and 3D tissue models. A section called "Bold Predictions" sets 35 specific, ambitious goals, and the three most relevant for biomaterials are[1]:

- First-in-human clinical trials will demonstrate the efficacy of iPSC-derived products.
- Engineered biological cells and scaffolds will be successfully used to repair and replace tissue damaged by chronic wounds or such disorders as osteoarthritis.
- Insight will be gained into the ultimate ability to regenerate human limbs, using emerging technologies to activate the body's own growth pathways and processes.

The following terms are not used in the plan: biomaterial, ceramic, polymer, hydrogel. "Scaffold" is used once in the prediction quoted above. "Metal" occurs once, in an inset about biofilms on metal implants. "Engineer" is used about 12 times. Thus, 9% (1/11) of the strategies and 9% (3/32) of the bold predictions are highly relevant to biomaterials.

FDA APPROVES STRATAGRAFT FOR TREATMENT OF THERMAL BURNS

FDA approved StrataGraft for treatment of thermal burns in June 2021, via the biologics license applications (BLA) process.[2] The established name is "allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen." It is "a viable, bioengineered, allogeneic cellularized scaffold product that contains a fully-stratified epithelial layer comprised of differentiated, multilayered, epidermal keratinocytes from a single human donor. The keratinocytes are grown on a murine collagen matrix (rat-tail collagen type I) embedded with fibroblasts from a second human donor."

The product is an 8 cm by 12.5 cm rectangle of tissue that contains two layers of cells, an epidermis (keratinocytes) and a dermis (dermal fibroblasts). It may be trimmed to fit the wound area and is shipped frozen on dry ice. It is indicated for "treatment of adults with thermal burns containing intact dermal elements, for which surgical intervention is clinically indicated (deep partial-thickness (DPT) burns)." A DPT burn penetrates through the epidermis and deep into the dermis without going all the way through (not "full thickness"). The Food and Drug Administration (FDA) assigned an RMAT designation (regenerative medicine advanced therapy), which provided an expedited review process, since the product met "an unmet medical need for treatment of DPT thermal burns with products that decrease the need to obtain autologous skin tissues or biopsies."[3]

The final phase three clinical trial enrolled 71 adults with DPT thermal burns involving 3%-37% of total body surface area. "Two comparable wound sites of each subject were selected and randomized to receive either topical application of StrataGraft or autograft" (standard of care). Efficacy was established on the basis of two major outcomes. One was the difference in the percent area of the StrataGraft treatment and the control autograft that required additional autografting three months after the original StrataGraft or autografting. "Among the 71 StrataGraft-treated sites, three required autografting to achieve wound closure. Among the 71 autograft-treated sites, two needed repeated autografting to achieve wound closure. Therefore, 4% (3/71) of the StrataGraft treatment sites and 102% (73/71) of the autograft treatment sites were autografted by three months. The difference in the percent area of StrataGraft and control autograft treatment sites that required autografting by three months was 98% ± 17% ($p<0.0001$)." And, "Donor site harvest was eliminated in 96% of StrataGraft-treated DPT burns."

Efficacy was also established on the basis of the proportion of subjects achieving durable wound closure of the StrataGraft treatment site at three months without autograft placement. "Wound closure was defined as complete skin re-epithelialization and the absence of drainage. Durable wound closure at three months was defined as wound closure at two consecutive study visits at least two weeks apart." Durable closure was achieved in 83% of the StrataGraft treatment sites and in 86% of the autograft control treatment sites. The presence of allogeneic DNA from StrataGraft was not detected in patients at three months. The FDA website provides several technical documents associated with the review process, such as the product insert and the clinical review memorandum, which nicely summarize the 10-year development timeline.[4]

For more information, please reach out to Carl Simon, carl.simon@nist.gov.

(References on page 18)

Young Scientist Group News

By Claudia Loebel, MD, PhD

We would like to annouce the 2021-2022 Society For Biomaterials Young Scientist Group leadership Chairs!

- Chair: Claudia Loebel, MD, PhD
- Vice Chair: Jason Guo, PhD
- Diversity, Equity and Inclusion Chair: Marian Ackun- Farmmer, PhD
- Programming Chair: Marissa Wechsler, PhD
- Industry Chair: Bhavya Singhi, PhD
- Communications Chair: Tochukwu "Tochi" Ozulumba, PhD

The main objective of the Society For Biomaterials (SFB) Young Scientist Group (YSG) is to facilitate and promote the entry, development and full participation of young scientists within SFB and the broader biomaterials community. Undergraduate students, graduate students, postdoctoral fellows, young industrial professionals, young faculty and other young scientists are included in SFB's Young Scientist Group.

SFB-YSG initiatives planned for the upcoming year include hosting scientific sessions, seminars, panels and mixers on the following topics: navigating early career transitions in academia and industry, speed networking/mentoring, promoting mental health and wellbeing as a scientist, fostering allyship and much more! In addition, the SFB-YSG plans to continue recognizing outstanding postdoctoral researchers with the Postdoctoral Achievement Award, and for the first time, recognizing early career insustry researchers with the Industry Young Scientist Award at the upcoming SFB Annual Meeting in Baltimore.

Please visit the YSG page on the SFB website for more information: **https://biomaterials.org/committees-committees-overview/young-scientist-group**.

AIMBE Update

Throughout August 2021, Congress was mainly focused on the infrastructure bill and getting home for their summer recess. However, many SFB members may have been following the Administration's push to form a new institute: Advanced Research Projects Agency for Health. AIMBE has supported the Administration's ARPA-H proposal with the understanding that funding will not be taken from existing NIH programs and will be "new" appropriations. This appears to be the approach the House of Representatives has taken when recently approving $49 billion for NIH, an increase of $6.5 billion above fiscal year 2021, and including $3 billion to establish the ARPA-H; this is only half of what the Biden Administration had requested. However, it should be noted that the appropriations for ARPA-H will be contingent upon Congress authorizing the program. In this regard, Representatives Diana DeGette (Colorado) and Fred Upton (Michigan) will be instrumental because they have included ARPA-H in their CURE 2.0 legislation (discussion draft of the Cures 2.0 Act from June 22).

Some Members of Congress have been skeptical and have pushed back on the Administration's draft. Many worry the culture of NIH is not a good fit for this type of program and have concerns that the funding is duplicative of the current programs at NIH. Republican members of the House have also suggested the mission of translational science is better achieved by the private sector.

AIMBE President Tejal Desai was asked to participate in an NIH listening session to gather feedback on the Administration's ARPA-H proposal. Her remarks are posted on the AIMBE home page, and can also be accessed here: https://aimbe.org/arpa-h-listening-session/

To view the most current AIMBE Flash news, please click here.

Student Chapter News

By Gerry Koons

As the incoming officers of the National Student Chapter, we are excited to introduce ourselves and our goals for the upcoming year.

OFFICER INTRODUCTIONS

President: Gerry Koons, BS, is an MD/PhD student in the dual-degree medical scientist training program at Rice University and Baylor College of Medicine in Houston, Texas. She is currently performing her thesis research on 3D printing with growth factors for bone tissue engineering in the lab of Dr. Antonios Mikos. Her career goals entail biomaterials-based innovation in the clinical specialty of pediatric craniofacial surgery.

Secretary-Treasurer: Bryan D. James, PhD, is a recent graduate from the lab of Dr. Josephine B. Allen in the department of materials science and engineering at the University of Florida in Gainesville, FL. In his dissertation research, Bryan investigated the sex differences of vascular cells in response to complex microenvironments and spearheaded DNA-collagen complex self-assembly for tissue engineering. He is currently a postdoctoral scholar at the Woods Hole Oceanographic Institution in Woods Hole, MA, working in plastic pollution. His career goal is to be a faculty member developing material solutions for the environment and the body.

Stay tuned for an email announcement regarding our newly elected Student Section Officers!

WHAT'S AHEAD

Inclusion: As our field offers an important intersection of scientific research with societal impact, equity and inclusion initiatives, recruiting and retaining biomaterials researchers of diverse backgrounds should be prioritized and featured in SFB events.

Upcoming Initiative: Recruitment webinar for students attending historically Black colleges and universities

Communication: Maintaining and expanding our presence and activity in various social media venues can enable continuous interaction with our student members and university chapters.

Upcoming Initiative: Instagram account featuring a "Meet Your Future Collaborators" series to highlight student researchers

Collaboration: Strengthening the cohesion among university chapters will facilitate the sharing of ideas, experience and resources to support their individual activities.

Upcoming Initiative: Quarterly meetings with leadership of university chapters, including a workshop about organizing Biomaterials Day events.

Be sure to follow the National Student Chapter on **Twitter** and **Instagram** for all the latest biomaterials and SFB news!

The Materials Research Society (MRS) and the Society For Biomaterials (SFB) are excited to announce the **Workshop Series on Innovation in Biomaterials Science**, a new collaboration in delivering education to our members. MRS and SFB will present a new webinar each Tuesday in October at 11:00 am EDT. The exciting lineup of topics and speakers can be found here.

Registration for all four webinars is only $150 for SFB and MRS Members! (Half price for student members!) You can also register for each webinar separately for $50. For more information, or to register for one webinar, or the entire series, please click the banner!

Government News (continued from page 16)

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