

SFB PAST QUARTER HONORS AND AWARDS

AIMBE REPORT

# BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

THIRD QUARTER 2020 • VOLUME 42, ISSUE 3



REMEMBERING ED MERRILL (1923-2020)

# BIOMATERIALS FORUM!

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 42, Issue 3

*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](mailto:info@biomaterials.org)) or visit the Society's website, [biomaterials.org](http://biomaterials.org).

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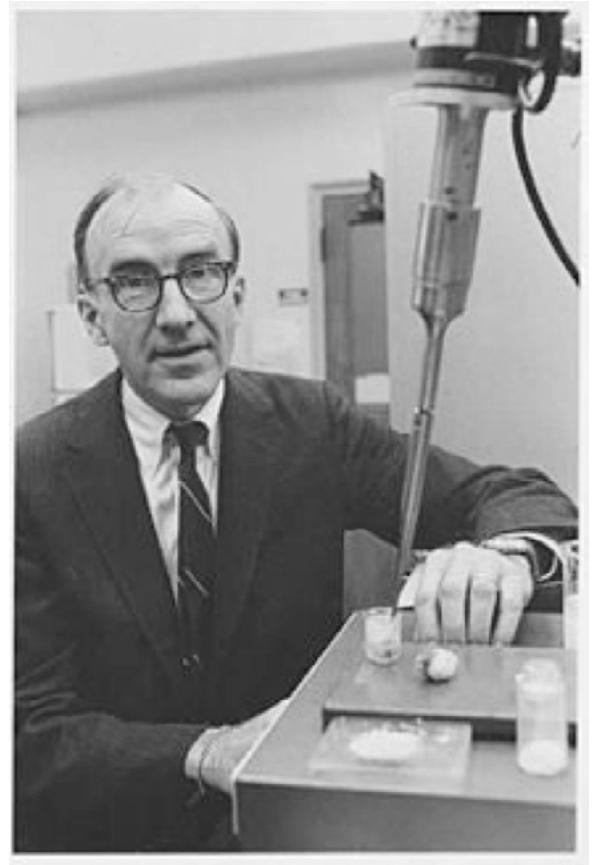
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### ON THE COVER

Professor Edward Merrill, a pioneer in bioengineering and co-inventor of the GDM viscometer, is shown here using the probe of the GDM viscometer to show its action in a small sample of a viscous fluid (1966).

Credit: MIT Museum General Collection

# From the Editor

By Guigen Zhang, *Outgoing SFB Forum Executive Editor*, and Roger Narayan, *Incoming SFB Forum Executive Editor*



**Guigen Zhang:** As the outgoing Executive Editor of the *Society For Biomaterials Forum*, I would like to take this opportunity to say farewell and thank many who have contributed to the *Forum* in the past five years. It was a great honor for me to serve the SFB in this role through which

I got to know many of you and learned about your fascinating research and educational activities, or the unique roles you play in leading the R&D efforts at your company. While the amount of names is too long to list individually, I do want to mention a few to express my sincere gratitude for their constant contributions as various column editors.

Lynne Jones, as the book review editor, has periodically brought to us critical and unbiased reviews of many books that are not only by members of the SFB community, but also of interest to many more. Reading her reviews, you also have the benefit of seeing her unique insights and wisdoms built upon her many years of teaching, research and consulting experiences. Steve Lin, as the Industry News Editor, has been a *Forum* fixture, running the Industry News column over several decades. For each of his columns he first digests the latest developments in the industry relevant to biomaterials and then summarizes them into concise headlines. Reading his column makes us appreciate the connections between what is going on in our research labs and what is happening in the biomedical marketplace. Carl Simon, as the government news editor, has also been a fixture for many years to remind us the roles government agencies such as NIST, FDA and others play in our translation efforts. LaShan Simpson, as the education column editor, has the magic power to assemble expert teams to address challenging issues in education, including the issues of access and equity in the digital classroom. Aside from working with six SFB Presidents, I also had great support from six Members-at-Large, including Elizabeth Cosgriff-Hernandez, Andres Garcia, Helen Lu, Rebecca Carrier, Cherie Stabler and Joyce Wong. Their contributions over the years are greatly appreciated. Finally, I want to introduce to you our newly-named Executive Editor, Roger Narayan. Roger was selected through a vigorous search process by the Publications Committee with approval by the SFB Board. I've asked Roger to share with you his vision for the *Forum* in the next five years.



**Roger Narayan:** As the incoming Executive Editor, I would like to thank the Committee and the Board for giving me the opportunity to serve as the Executive Editor of the *Forum*. In particular, I would like to thank Guigen for mentoring me during the onboarding process. I have been a

Professor in the Joint Department of Biomedical Engineering at the University of North Carolina and North Carolina State University since 2009. My team works on the use of laser techniques such as pulsed laser deposition, laser micromachining, matrix-assisted pulsed laser evaporation and laser-based additive manufacturing techniques for processing of biomaterials.

Here, I want to share with you my vision for the *Forum*. First, the diversification of the U.S. student population and workforce makes it imperative that our community supports efforts to recruit, retain and promote underrepresented groups. We will highlight partners who support efforts to broaden participation in science and engineering and shine a spotlight on role models who inspire us to do more and better. Second, the current COVID-19 pandemic has stressed the importance of biomaterials for diagnosis, protection from and treatment of COVID-19 and related medical conditions. We will highlight activities in academia, industry and government to address this challenge of our generation. Third, to help biomaterials scientists understand the processes underlying commercialization and clinical translation of their work, we will feature stories on how biomaterials scientists can better participate in the innovation ecosystem, including small business innovation research programs and venture capital. Fourth, as the competition for federal research funding becomes stiffer with every passing year, we will feature success stories on how to navigate the changing federal funding landscape. The COVID-19 pandemic has reminded us that despite all of the day-to-day conflicts, humanity is one interconnected family. We will consider some of the global challenges that have connections to biomaterials and medical device research.

Please don't hesitate to reach out if you have thoughts on appropriate content for future issues. I look forward to working with you to share your stories and successes with SFB members over the coming year.

Stay safe and healthy!

Sincerely,  
Guigen Zhang and Roger Narayan

# From the President

By Shelly Sakiyama-Elbert, SFB President



Dear SFB Colleagues,

As summer 2020 comes to an end and many of us have returned to a fall unlike any other, I hope this message finds you well. I would like to update you on what is new for the Society

For Biomaterials. We held our first virtual Business Meeting in July to formally mark the transition to our new Board and Council.

I would like to wish a warm welcome to our new President-Elect, Guigen Zhang and our new Member-at-Large, Joyce Wong. I would also like to thank Guigen for his service as the Forum Editor as his term ends and welcome our new editor, Roger Narayan.

In August, SFB voted to amend our Bylaws to add a standing Diversity, Equity and Inclusion Committee to coordinate current diversity activities and expand our ability to highlight the outstanding work of underrepresented scientists in biomaterials. I would like to thank the Diversity Task Force that set all this in motion: Elizabeth Cosgriff-Hernandez (Chair), Sarah Stabenfeldt, Anirban Sen Gupta, Brain Aguado, Ana Maria Porras, Brendan Harley, Joel Baumgardner, LaShan Simpson and Dan Lemyre. Also, thank you to Ashley Brown for guiding this effort through as Bylaws Committee Chair. The Diversity, Equity and Inclusion Committee will also work to expand training on mentorship of diverse research groups and increasing the nominations for SFB awards and elected offices. Please feel free to reach out if you have additional suggestions for activities or action.

Planning for the April 2021 Annual Meeting in Chicago, "Biomaterials Research: Hitting All the Right Notes and Avoiding

the Translational Blues," is in full swing. This year's program will focus on research that has direct patient impact and will expand the traditional definition of biomaterials to address challenges related to the development, manufacturing and use of PPE.

The Program Committee has been busy reviewing applications for Symposia, Workshop and Special Events, so thank you to everyone for submitting wonderful ideas for the meeting. At this time, we are still planning for an in person meeting in Chicago (April 21-24), but we also acknowledge that travel issues may continue with the pandemic, and we are actively planning for contingencies in case the meeting needs to move to a virtual platform. Regardless of format, it will be a wonderful meeting filled with the latest biomaterials research, so please submit your abstracts! The call for abstracts is now live at [2021.biomaterials.org](https://2021.biomaterials.org) so please get your abstracts in for the early bird (Nov. 10 - \$25) or late deadlines (Nov. 20 - \$50).

Also mark your calendars for our [joint symposium](#) with the Japanese Society for Biomaterials in Hawaii that is now scheduled for July 29-31, 2021 at the Hilton Waikiki Beach.

I hope to see you in person at one of these two meetings! I challenge you all to continue your involvement with the Society For Biomaterials and to enhance the impact of our work to improve healthcare through the use of biomaterials while supporting and continuing to build a diverse community. I welcome your suggestions for ways to engage over the coming year (please email me at [sakiyama@utexas.edu](mailto:sakiyama@utexas.edu)).

## CALL FOR COVER ART

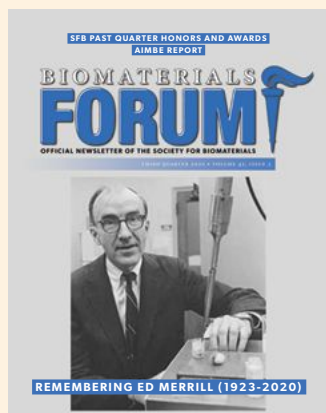
### WE WANT TO FEATURE YOUR EXCITING BIOMATERIALS ARTWORK ON THE COVER OF *BIOMATERIALS FORUM*.

**Deadline:** Accepted on a rolling basis.

**Instructions:** Please email artwork (digital images, artistic creations, etc.) to [info@biomaterials.org](mailto:info@biomaterials.org), to the attention of the Executive Editor of the *Biomaterials Forum*. All artwork with biomaterials relevance that have not appeared as a *Forum* cover are welcome. Multiple submissions are permissible.

**Description:** Selected artwork will appear as the cover of a future issue of *Biomaterials Forum* along with a brief "On the Cover" description of the subject and name/affiliation of the creator.

**Format:** High-resolution electronic version in .gif, .tiff or .jpeg file format.





# Member News

By Joyce Wong, Member-at Large



I am honored to serve as your 2020-2021 Member-at-Large representative! I will need your help to ensure that we spotlight *all* of our members' news and accomplishments. You can submit your own news or amplify other SFB members' work at any time using this [form](#). You can also email me at [jywong@bu.edu](mailto:jywong@bu.edu) or help us by tagging SFB in your posts on [Twitter](#) (@SFBiomaterials), [Facebook](#) and [LinkedIn](#). Also, please contact me with suggestions to help me advocate for the broad membership of SFB.

It is with great sadness to report the passing of a giant in our field, **Ed Merrill**. Please see a special remembrance from **Nicholas A. Peppas** and **Michael V. Sefton**, on page 14.

## SFB MEMBER NEWS AND ACCOMPLISHMENTS, PAST QUARTER HONORS AND AWARDS

**Rena Bizios**, the Lutchter Brown Endowed Chair Professor in Biomedical Engineering (University of Texas at San Antonio), is the recipient of the 2020 BioMedSA Award for Innovation in Healthcare and Bioscience. The BioMedSA Award for Innovation in Healthcare and Bioscience celebrates local and national innovators in the healthcare and bioscience industry, including patient care, education, research and development, leadership, public policy and medical technology and is one of the most prestigious international BME awards. Bizios is a globally-recognized researcher making groundbreaking contributions to the understanding of cell-material interactions at the tissue/implant interface with applications in implant biomaterials, tissue engineering and tissue regeneration. She has been honored in a ceremony that was held virtually on September 17, 2020. Bizios was elected a corresponding member to the prestigious [Academy of Athens](#), Greece – the most prestigious recognition scientists, engineers, intellectuals and artists can attain in Greece. This Academy harkens back to the Academy started by Plato in the fifth century. She is recognized for her contributions to biomedical engineering education, training and advising, for mentoring the next generation of scientists and engineers and for service to several professional scientific and engineering societies.

**Noam Eliaz**, Professor of Materials Science & Engineering (Tel Aviv University, Israel), was elected by the National Academy of Inventors, USA, as a [Senior Member](#), in recognition of his development of [technologies](#) that have “brought, or aspire to bring, real impact on the welfare of society,” and for contributions to the “innovation ecosystem.” This makes him the first scientist based outside the United States to attain the status.

**Robert S. Langer**, David H. Koch (1962) Institute Professor at MIT, is the recipient of the 2020 Maurice-Marie Janot Award. This award recognizes an individual researcher “also in the context of a team” for their contributions to the fields of Pharmaceuticals, Biopharmaceuticals and Pharmaceutical Technology. Langer is also the 2020 recipient of the Excellence in Biomaterials Science Award by the Surfaces in Biomaterials Foundation. This award recognizes an individual who has made significant contributions to the biomaterials science field, and is the highest award given by the Foundation. Langer also thrilled the virtual audience with his magic tricks with four lucky assistants chosen by lottery at the July 2020 Controlled Release Society (CRS) virtual meeting.

**Cato T. Laurencin**, Albert and Wilda Van Dusen Distinguished Professor of Orthopaedic Surgery and Chemical, Materials and Biomedical Engineering at the University of Connecticut School of Medicine, is the recipient of the 2020 Herbert W. Nickens Award. The award is bestowed on an individual who has made monumental contributions to promoting justice in medical education and health care equity throughout the nation. Laurencin is the recipient of the 2020 Von Hippel Award of the Materials Research Society – the Society’s highest and most prestigious honor.

**Antonios (Tony) Mikos**, the Louis Calder Professor of Bioengineering, Chemical and Biomolecular Engineering at Rice University, was elected into the 2020 Class of Academia Europaea. He was recognized for his contributions in the research area of biomaterials and tissue engineering in the Chemical Sciences section. Mikos was awarded an Honorary Doctorate from the University of Thessaloniki in Greece.

**Nicholas A. Peppas**, the Cockrell Family Regents Chair in Engineering and Professor of Chemical Engineering, Biomedical Engineering, Pediatrics, Surgery and Pharmaceuticals at The University of Texas at Austin, was elected a corresponding member of the Korean Academy of Science and Technology. Peppas received Honorary Doctorates from the University of Santiago de Compostela in Spain and from the University of Thessaloniki in Greece. He also received the IEEE/EMBS Academic Career Achievement Award, and is a recipient of the 2020 Ellis Island Medals of Honor. Recipients of this honor are “the leaders taking our nation powerfully into the 21<sup>st</sup> century. They are the innovators and visionaries who are defining their generation and shaping our future. They also respect the value of their ethnic heritage and appreciate the importance of America’s immigrant history.” In addition, Peppas received the [Sigma Xi Monie A. Ferst Award](#). He was honored for his contributions to research through his efforts to mentor and support several generations of graduate students. He has supervised the theses

## Member News (continued)

of 115 PhD students and has been the research mentor of 990 postdocs, visiting scientists and graduate and undergraduate researchers who have worked in his laboratory and his UT Institute for Biomaterials, Drug Delivery and Regenerative Medicine. At the awards, it was noted, "That most of his former students and collaborators continue interacting with him even 40 years later speaks to his strong support and mentorship to his family of trainees, or the 'Peppamers.'"

**Buddy Ratner**, Joint Professor of Bioengineering and Chemical Engineering and Michael L. & Myrna Darland Endowed Chair in Technology Commercialization at the University of Washington, along with several colleagues, won a \$500,000 [KidneyX](#) (the Kidney Innovation Accelerator) Phase 2 from the U.S. Department of Health and Human Services and the American Society of Nephrology. They are donating the prize to their University of Washington Center for Dialysis Innovation (CDI) of which Ratner is co-director. He and his colleagues created a tubular AV graft with similar mechanical compliance to a native artery, which is designed to perform better than those currently available and to reduce the rate of failure. The new graft type, Pro-Regenerative, Integrative Dialysis Egress (PRIDE), was demonstrated in sheep models to have significantly reduced thrombotic deposition.

**Amy Wagoner Johnson**, Professor of Mechanical Science and Engineering at the University of Illinois, was awarded the Society of Women Engineers Distinguished Engineering Educator "for being an impactful and inspiring teacher, whose students excel in engineering fields; for cutting-edge research in bone repair and coral regeneration and for leveraging STEM to positively affect humanity."

### FELLOWS

#### Election to American Chemical Society (ACS) 2020 Class of POLY Fellows:

*Recognizing outstanding achievements and contributions to polymer science and the profession.*

- **Stuart Cooper**, Ohio State University
- **Nicholas A. Peppas**, University of Texas at Austin

#### Election to International Academy of Medical and Biological Engineering

*Congratulations to our members who were elected to the 2020 Class of IAMBE Fellows!*

- **Lisa Brannon-Peppas**, PeppChem Consulting
- **Ashutosh Chilkoti**, Duke University
- **John P. Fisher**, University of Maryland
- **David L. Kaplan**, Tufts University
- **Cato T. Laurencin**, University of Connecticut

#### Election to the National Academy of Inventors

*Congratulations to our members who were elected to the 2019 Class of NAI Fellows!*

- **Guillermo Ameer**, Northwestern University
- **Rena Bizios**, The University of Texas at San Antonio
- **Jason Burdick**, University of Pennsylvania
- **Balaji Narasimhan**, Iowa State University
- **Ebru Oral**, Harvard Medical School

### PROMOTIONS AND APPOINTMENTS

**Chien-Chi Lin**, Thomas J. Linnemeier Guidant Foundation Endowed Chair & Professor, Department of Biomedical Engineering at Indiana University-Purdue University Indianapolis, was recently promoted to Full Professor in Biomedical Engineering at Indiana University-Purdue University Indianapolis. He was also appointed as the holder of Thomas J. Linnemeier Guidant Foundation Endowed Chair in Biomedical Engineering. This endowed position was created by The Guidant Foundation, a subsidiary of the Boston Scientific Corporation.

### RECENT PUBLICATIONS FROM OUR MEMBERS

It is always great to see SFB members citing so many other SFB members' work, showing the strength of our community. It is also good to see research in the area of developing biomaterial-based technologies for underserved communities.

**Sandra Musu Jusu**, PhD Candidate in Materials Science and Engineering at African University of Science and Technology in Abuja, Nigeria, is developing targeted treatment for triple negative breast cancer, an aggressive form of cancer that predominantly affects women of color.

**Jusu SM**, Obayemi JD, Salifu AA, et al. Drug-encapsulated blend of PLGA-PEG microspheres: in vitro and in vivo study of the effects of localized/targeted drug delivery on the treatment of triple-negative breast cancer. *Sci Rep.* 2020;10:14188. [doi.org/10.1038/s41598-020-71129-0](https://doi.org/10.1038/s41598-020-71129-0).

Increasingly, biomaterials, in particular nanoparticles, are being used to monitor disease progression and tissue regeneration, as shown in the review article below.

**Mallika Modak**, MD/PhD Candidate in Biomedical Engineering at Northwestern University, recently published a review on recent advances in the use of nanoparticles for imaging cellular processes in cardiovascular disease.

## Member News (continued)

**Modak M**, Frey MA, Yi S, Liu Y, Scott EA. Employment of targeted nanoparticles for imaging of cellular processes in cardiovascular disease. *Curr Opin Biotechnol.* 2020;66:59–68. [doi.org/10.1016/j.copbio.2020.06.003](https://doi.org/10.1016/j.copbio.2020.06.003).

**Terry W.J. Steele**, Associate Professor in Materials Science & Engineering at Nanyang Technological University in Singapore, after a 5-year collaboration with local surgeons, published in *Biomaterials* work demonstrating repair of arteries, faster surgical times, anesthetic drug release and anti-platelet blood clotting.

Researchers developed CaproGlu, a multifunctional tissue adhesive, and report preclinical trials in the following publication with associated news stories.

Djordjevic I, Pokolenko O, ... **Steele TWJ**, et al. CaproGlu: Multifunctional tissue adhesive platform. *Biomaterials.* 2020;260:120215. [doi.org/10.1016/j.biomaterials.2020.120215](https://doi.org/10.1016/j.biomaterials.2020.120215).

(See also news reports on [CNA](#) and [MSN](#) ).

Biomaterials can be used as immunomodulators in the context of transplantation and in stem cell therapy, as seen respectively in the articles below.

**Maria Coronel**, Postdoctoral Fellow in Mechanical Engineering at the Georgia Institute of Technology, and colleagues demonstrate that an off-the-shelf biomaterial is capable of mediating immune acceptance of a transplant after a single dosage delivered locally with the graft. This proof-of-principle work illustrates how this platform technology can be implemented to improve organ transplantation by reducing the need for systemic immunosuppression.

**Coronel MM**, Martin KE, Hunkler KD, et al. Immunotherapy via PD-L1-presenting biomaterials leads to long-term islet graft survival. *Sci Adv.* 2020;6(35):eaba5573. [doi:10.1126/sciadv.aba5573](https://doi.org/10.1126/sciadv.aba5573).

**Omid Veisheh**, Assistant Professor in Bioengineering at Rice University, and colleagues have developed an immunomodulatory alginate-based hydrogel and demonstrated that it can enhance stem cell therapy after myocardial infarction.

Ghanta RK, Aghlara-Fotovat S, ... **Veisheh O**, et al. Immune-modulatory alginate protects mesenchymal stem cells for sustained delivery of reparative factors to ischemic myocardium. *Biomater Sci.* 2020 Sept;18:5061-5070. [doi:10.1039/DOBM00855A](https://doi.org/10.1039/DOBM00855A).

## CONFERENCE ORGANIZATION

**Kent Leach**, Professor of Biomedical Engineering & Orthopaedic Surgery, UC Davis, is a Co-Chair (with Debra Auguste and Tanmay Lele) of the upcoming Annual Biomedical Engineering Society Meeting, which will be virtual this year (October 2020). The theme of the conference is “A 20/20 Vision of Biomedical Engineering.”

**Scott Taylor**, CTO of Poly-Med, Inc., is organizing a [meeting](#) in January 2021 with ASTM entitled, “Workshop on the Use of Absorbable Polymers for Medical Devices,” a two-day, fully virtual event that will help advance ASTM standardization objectives for absorbable polymers.

## COVID-19-RELATED RESEARCH

Our members continue to work hard to address the COVID-19 pandemic.

**Cato T. Laurencin** and colleagues came up with a method to fabricate 3D-printed, custom-fit mask frames to optimize protection from the spread of COVID-19 and has a licensing deal with a Connecticut manufacturer (Connecticut Biotech) to produce them under the brand Secure Fit.

**Todd McDevitt**, Senior Investigator, Gladstone Institutes; Professor, Bioengineering & Therapeutic Sciences, UCSF, and colleagues recently [identified](#) a pathogenic signature of SARS-CoV-2 in human heart muscle cells *in vitro* that [predicted similar features](#) in autopsy heart samples of COVID-19. This suggests [potential cardiac damage due to the virus](#) that could have longer term effects afterward.

**Rafael Ramos**, MD-PhD student at Wayne State University School of Medicine, over the course of the COVID-19 pandemic, used his desktop 3D printers to produce PPE for hospitals, clinics and other volunteer organizations. Having done this since the stay-at-home orders went into effect in Michigan, he had the privilege of receiving a [Board of Governors Warrior Unsung Hero Award](#) for his efforts. Wayne State University recently established this award to honor “Warriors” whose selfless efforts reflect the university’s mission of meaningful engagement.

**Thomas J. Webster**, Art Zafiropoulo Chair and Professor in Chemical Engineering at Northeastern University recently had his self-assembled nanomaterials [licensed by Audax Medical, Inc.](#) for commercialization as a therapy for COVID-19. The molecules were designed to bind to several regions on COVID-19 and encapsulate the virus, keeping it from entering cells to replicate.

## DIVERSITY, EQUITY & INCLUSION (DEI)

Our members are taking a stand against racism and promoting equity.



## Member News (continued)

**Pat Stayton**, Washington Research Foundation Professor of Bioengineering and Director of the Molecular Engineering & Sciences Institute, University of Washington; **Ed Botchwey**, Associate Professor of Biomedical Engineering, Georgia Tech; and colleagues held a two-day, nationwide event called, “Experiences of Black STEM in the Ivory: A Call to Disruptive Action” with panelists from multiple points of view (staff, student, faculty, deans) to share their unique perspectives on current barriers facing Black scholars in STEM fields with the goal of inspiring and challenging participants to take action to address racial inequities in STEM. If you missed the event, you can watch the panel discussions here:

- Day 1 – <https://youtu.be/Be3NCsBsl-H>. Staff, students, and faculty share their experiences as Black scholars and professionals in STEM.
- Day 2 – <https://youtu.be/eUc2jnsWcRA>. College of Engineering Deans discuss ways in which colleges might take action to make real change. Following this final panel, all panelists participate in a more open-ended Q&A discussion on ending racism in academia.

**Kelly Stevens**, Assistant Professor of Bioengineering, University of Washington, and colleagues (Naomi Chesler, Lola Eniola-Adefeso and Princess Imoukhuede) have started a Biomedical Engineering (BME) Faculty Equity Session, which is a virtual forum to discuss how racism permeates the academic institution. Based on these discussions, the goal is to develop action item-based themes for the most impact on equity in our profession. Please email [ksteve@uw.edu](mailto:ksteve@uw.edu) if you would like to become involved.

Here are some examples of how some SFB members are adding DEI into their lab groups and their institutions:

**Todd McDevitt** and colleagues (Megan McDevitt, Lisa Accardi) hosted Manu Platt in a conversation on “Gaslighting in the Academy: Actually Making Black Lives Matter.” You can watch the talk [here](#). This talk is part of a new series of “Critical Conversations,” launched in 2020, as a way for Gladstone Institute community members to challenge and empower themselves by considering different ways of thinking through the lens of others. Past and upcoming discussions can be found [here](#) and encourage reframing or shifting your perspective.

**Phil Messersmith**, Class of 1941 Endowed Professor of Bioengineering and Materials Science and Engineering at University of California at Berkeley, conducts a “DEI minute” in his lab group meeting. He assigns a student/postdoc to present “DEI minute” topics and gives them the freedom to choose

the topic. Sometimes they use slides, other times it is an open discussion. Some recent examples of DEI minute topics in his group meeting include:

- Discussion of the [article](#):
  - ◆ Gewin V. The Time Tax Put on Scientists of Colour. *Nature*. 2020;583:479-48. doi: [10.1038/d41586-020-01920-6](https://doi.org/10.1038/d41586-020-01920-6).
- Discuss what the book *Life on the Color Line* by Gregory Howard Williams meant for each of the lab members.
- Bias in academic peer review.
- Stereotyping.
- Interruptions in academic talks and meetings.
- Work-life balance.
- Machines inherit human biases.

**Kelly Stevens**, University of Washington, does an activity called “equity.” Their activities have generally focused on racism. They previously organized conversations about sexism, especially at the height of the #metoo movement. Some examples:

- Listening to podcasts together (e.g., “Seeing White” podcast), one 30-minute episode per month.
- Readings and small group discussions about racism.
- Journal club on papers relevant to equity (e.g., [Disparity in NIH review](#)).
- Optional activities, such as:
  - ◆ A book club, rotating through antiracism books, one book every two months.
  - ◆ Lab “happy hours” commonly replaced with volunteer events and/or outreach activities.

*If you have any questions,*

need any information or have suggestions for improved services, please feel free to contact the Society’s Headquarters office:

**SOCIETY FOR BIOMATERIALS**

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# Staff Update

By Dan Lemyre, Executive Director



SFB staff continues to work remotely and will continue to do so for the remainder of this calendar year. Our offices are expected to reopen on January 4, 2021. Our thanks go out to the Board, Council, SIG Officers and volunteers who have helped to make these past few months productive and fruitful!

The following is a brief summary of the actions and plans for the Board, Council, Committees and Task Forces:

## **BOARD/COUNCIL – PRESIDENT: SHELLY SAKIYAMA ELBERT, PHD**

The SFB Board and Governing Council will convene via Zoom twice in the coming months to discuss 2021 programming, member benefits and of course, the 2021 budget.

## **AWARDS, CEREMONIES AND NOMINATIONS COMMITTEE – CHAIR: DAVID KOHN, PHD**

Currently, SFB is still planning on presenting the Society's 2020 Awards during the World Biomaterials Congress. 2021 Award and Officer nominations have been collected, and the Committee's deliberations will be conducted over the next few weeks.

## **BYLAWS – CHAIR: ASHLEY CARSON BROWN, PHD**

The Committee prepared an amendment that was voted upon via electronic ballot in August 2020 that codified the formation of a Diversity, Equity & Inclusion Committee. The amendment was approved with a vote of 97 in favor, 10 opposed and 3 abstained. With 110 votes cast, the approval rating was 88%, and the bylaws have been amended on the SFB website.

## **DIVERSITY, EQUITY AND INCLUSION – CHAIR: ED BOTCHWEY, PHD**

The Committee is in the process of forming and will appoint representatives to the Awards, Ceremonies and Nominations Committee and the Program Committee in the near future. The Committee will also be working to formalize an action plan and create a space within the SFB website dedicated to increasing awareness of, and participation in, their efforts.

## **EDUCATION & PROFESSIONAL DEVELOPMENT – CHAIR: TOM DZIUBLA, PHD**

The 2020 Biomaterials Days have all been postponed to either the fall or winter of 2020 or spring of 2021. As such, only new chapters will be invited to submit a Biomaterials Day application for 2021. The E&PD Committee is also helping to curate the webinar offerings, and encourages all members and student chapters to [submit an idea for a webinar](#).

## **FINANCE – CHAIR: SARAH E. STABENFELDT, PHD**

As we prepare for 2021, a litany of issues loom large over the budget process. SFB remains committed to offering an annual meeting in 2021 — whether it be an in-person event in Chicago, a virtual event or some hybrid of the two, remains to be seen. As the meeting is typically the Society's greatest source of revenue, the Finance Committee is exploring options for additional revenue streams, and ways of curtailing expenses that do not affect membership benefits.

## **INDUSTRIAL AFFAIRS – CHAIR: SUPING LYU, PHD**

The Committee participated in their second Biomedical Engineering Materials and Applications Roundtable with the National Academies on September 16, virtually. The Committee is planning to organize a forum for device companies, suppliers and government agencies to harmonize regulatory efforts and stabilize supply chains. These efforts will culminate with programmatic offerings during the 2021 Annual Meeting.

## **LIAISON – CHAIR: BINGYUN LI, PHD**

SFB has co-hosted two webinars with the Materials Research Society (MRS) over the last few months, both of which were successful. The Society is exploring ideas for co-hosting a lengthier virtual symposium with MRS in Fall 2021. If you're interested in getting involved in the planning of this virtual event, please contact Dan Lemyre ([delmyre@biomaterials.org](mailto:delmyre@biomaterials.org)). In addition, SFB will be pitching to host the 2028 World Congress, with the timing to be determined by the IUSBSE.

## **MEMBERSHIP – C. LASHAN SIMPSON, PHD**

The Committee will be exploring methods to enhance membership retention and recruitment in 2021.

## **CHICAGO PROGRAM – GUILLERMO AMEER, PHD AND KRIS KIESWETTER, PHD**

The Society For Biomaterials has issued the Call for Abstracts for the 2021 Annual Meeting, which is scheduled to take place in Chicago, Illinois, April 21–24, 2021. At this time, we are planning to hold the meeting in Chicago in person. In the event that pandemic-related travel restrictions persist, we will switch to a virtual meeting platform and will work to accommodate all accepted poster and oral presentations on that platform. We anticipate that virtual registration rates will be lower than in-person registration rates as food and beverage expenses will not be incurred. Any registration made at the in-person rate will be eligible for credit to the virtual rate, should that come to pass. More information and regular updates are available at: [2021.biomaterials.org](http://2021.biomaterials.org).

## Staff Update (continued)

**HAWAII PROGRAM – ELIZABETH COSGRIFF-HERNANDEZ, PHD, AND NICHOLAS P. ZIATS, PHD**

The Society For Biomaterials has rescheduled our joint symposium with the Japanese Society For Biomaterials, to take place in Honolulu, Hawaii, July 29-31, 2021. The Call for Abstracts will be issued in the fourth quarter of 2020.

**SPECIAL INTEREST GROUPS – DANIELLE BENOIT, PHD**

If your SIG would like to organize a webinar, please contact Dan Lemyre directly ([dlemyre@biomaterials.org](mailto:dlemyre@biomaterials.org)) or complete the [webinar proposal submission form](#). To access any of our previous webinars, please visit [www.biomaterials.org/webinars](http://www.biomaterials.org/webinars).

**STUDENT CHAPTER/YOUNG INVESTIGATORS – JASON GUO (STUDENT CHAPTER PRESIDENT) AND BRIAN AGUADO, PHD**

The SFB National Student Chapter held a virtual meeting on Thursday, October 22, 2020 where the results of the 2021 Student Chapter Officers election were revealed, activities for the year were recapped and an address was made by the incoming National Student Chapter President, Deanna Bousalis.

If you have any questions, require any information or have suggestions for improving services, please feel free to contact the Society's headquarters office:

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# Student Chapter News

## BUILDING YOUR PROFESSIONAL BRAND ONLINE

By Jason Guo, National Student Chapter President



Greetings SFB student members and young scientists! With the onset of COVID-19 and limited in-person contact, many are pursuing creative solutions to build their professional brand and network online. Thanks to website building services, social media and webinar-style conferences, there is now a plethora of online tools to build exposure as a scientist. In this article, we hope to introduce you to a few strategies that you can utilize as a student or young scientist to establish and further strengthen your professional brand online.

### MAKING A PERSONAL WEBSITE

The creation of personal, portfolio-style websites has become more and more common for aspiring young scientists. Whether you're interested in academia or industry, a personal website can help you stand out from the crowd and showcase your achievements in their best light. In effect, a personal website serves as a more user-friendly and visually appealing version of your CV/resume, helping potential employers and advisors see your best professional self.

There are countless website building services that are affordable, user-friendly, and don't require any technical knowledge of coding or website creation. Some of the most popular tools include Wordpress, Squarespace and Wix. For more information, I highly recommend the [article](#) published in Nature Index, on building your own website as a scientist.

### SOCIAL MEDIA AS A SCIENTIST

Social media can be a powerful tool to amplify your professional brand and to connect with other young scientists. Twitter, in particular, has become a popular outlet for young scientists in academia and industry to stay in touch, share the latest virtual and scientific events and promote their scientific output.

In fact, a fascinating study in the Annals of Thoracic Surgery recently demonstrated that sharing publications via Twitter resulted in increased citations and scholarly impact over time, supporting the scientific utility of Twitter and other social media. <https://pubmed.ncbi.nlm.nih.gov/32504611/>.

### WEBINARS AND VIRTUAL CONFERENCES

In place of in-person conferences, many webinars and virtual conferences have emerged to allow students and young scientists to continue sharing their research with others. These online events can be a great way to build exposure with a broader audience and

importantly, to stay connected with developments in your field. Personally, I've found that Twitter is one of the best ways to learn about upcoming virtual scientific events.

Interested in hosting a scientific webinar of your own? SFB is now hosting a call for webinar proposals. For more information, you can contact [info@biomaterials.org](mailto:info@biomaterials.org) or view the proposal form [online](#).

"...A FASCINATING STUDY... RECENTLY DEMONSTRATED THAT SHARING PUBLICATIONS VIA TWITTER RESULTED IN INCREASED CITATIONS AND SCHOLARLY IMPACT OVER TIME, SUPPORTING THE SCIENTIFIC UTILITY OF TWITTER AND OTHER SOCIAL MEDIA."

### CONNECT WITH US!

Hopefully, this piece can help spark ideas for how to build and strengthen your professional brand using online and virtual strategies. SFB is also active on social media, and you can find more information here: [www.biomaterials.org/about-about-society/sfb-social-media](http://www.biomaterials.org/about-about-society/sfb-social-media).

Interested in taking on a leadership position in the  
*National Student Chapter?*

We are now soliciting nominations for President-Elect, Secretary/Treasurer-Elect and Bylaws Chair. No prior experience or involvement is required, and you can contact [info@biomaterials.org](mailto:info@biomaterials.org) for more information.

# AIMBE Report

*By Lynne C. Jones, Alan Litsky, and Joel Bumgartner*

Who are, or what is, AIMBE? AIMBE stands for the American Institute for Medical and Biological Engineering. If you go to its website, it will say, "The American Institute for Medical and Biological Engineering (AIMBE) is a non-profit organization headquartered in Washington, DC, representing the most accomplished individuals in the fields of medical and biological engineering." As explained by Anthony Guiseppi-Elie, PhD, former Chair of the College of Fellows, "AIMBE's mission is to recognize excellence, advance the public understanding and accelerate medical and biological innovation. Our rigorous agenda this past year led to new collaborations, new programming and new innovations that were only possible with the support of AIMBE fellows (AIMBE Annual Report, 2019)."

AIMBE comprises a College of Fellows and several Councils. Members of the College of Fellows are leaders, engineers, scientists and educators as well as entrepreneurs, innovators and inventors. They represent the top 2% of the medical and biological engineering. There are 152 members of the Society For Biomaterials who have been selected as fellows of AIMBE. Many of our members have held leadership positions within AIMBE, including several past Presidents: Robert Nerem, Buddy Ratner, Arthur Coury, Linda Lucas, Ravi Bellamkonda and Christine Schmidt.

AIMBE is composed of three councils: Council of Societies, Academic Council and the Industry Council. The Society For Biomaterials is a member of the Council of Societies and members of SFB have served as chairs of the Council. The Council of Societies provides a collective voice to advocate for issues that are common to each of its members. This effort has been impactful in the establishment of the FDA Modernization Act (1997), the Biomaterials Access Assurance Act (1998), the National Institute of Biomedical Imaging and Bioengineering (NIBIB) in 2000 and the National Institutes of Health Bioengineering Consortium (BECON). In addition to our members advocating individually and in small groups on Capitol Hill, members of the Council of Societies have met with officials of NSF, NIH, FDA, the Medial Technology Leadership Caucus, the House of Representatives Appropriations Committee and the Senate Commerce, Science and Transportation Committee. The Academic Council is comprised of leaders from prominent educational programs in medical and biological engineering at the graduate and undergraduate levels. Many of our members are actively involved with the Academic Council. Discussions are held to determine how each institute can address and contribute to the current federal policies influencing education and research at their institutions. Recently, with the impact of COVID-19, this Council conducted fireside chats to discuss lessons learned related to hybrid teaching models and budget constraints, as well as addressing the need for PPE, returning to the lab and

transitioning lab research to COVID-19 research.

The Industry Council provides a voice for industry members to discuss federal policies that have a significant impact on medical devices and instrumentation. These policies impact the translation of new innovations from bench to bedside. Again, the SFB membership is well represented here, including the current chair, Nadine Ding, PhD.

A major goal of AIMBE is to inform our Senators and members of Congress, and their staffs, of federal policies that have an impact on medical and biological bioengineering research and development. AIMBE members strive to remain impartial and apolitical, basing our educational efforts and recommendations on the underlying science. AIMBE has several initiatives to accomplish this goal. An important resource that AIMBE offers is guidance on how to engage your representatives and senators. This includes how to request a meeting with your elected officials as well as how to write influential letters. This information can be found at <https://aimbe.org/advocate/>. AIMBE has held Capitol Hill Days that provide training on how to advocate and meetings to speak with lawmakers in your state. Another initiative is a lecture series provided to colleges and universities across the country to discuss "The Science of Failed Public Policy – Why Congress Doesn't Fund Medical Innovation," hosted by AIMBE Executive Director Milan Yager. The AIMBE FDA Scholars Program provides an opportunity for post-doctorates in biomedical engineering fields to serve as expert advisors to policy makers at the FDA. The experiences of past scholars demonstrate the breadth of this program, as can be seen at <https://aimbe.org/scholars-program/>.

There is an annual meeting held in Washington, DC, each spring. This is an opportunity to listen to bioengineers, policy makers and other leaders as they provide scientific lectures on cutting edge innovations, current federal policies and other topics of particular relevance to this field. Throughout the year, the Fellowbooks describes the latest research of many of its members (<https://aimbe.org/fellowbook/>). I view this as similar to reading a magazine to keep up on advances being made across the wide array of medical and biological engineering. Another resource for up-to-date news is the AIMBE Flash. This is available to SFB members at <https://biomaterials.org/aimbe-advocacy>. In conclusion, be aware that many of our SFB members are advocating for you in Washington – speak with them about issues that are important to you. Write to your elected officials. Attend the annual meeting of AIMBE in Washington; you can also include a visit with your representatives and senators while you are there. Lastly, aspire to be a fellow of AIMBE – it is not only an honor that reflects positively on your research career, but creates opportunities to network with other leaders in your field.





From left to right: a young Ed Merrill; Ed's 95th birthday celebration at his home in 2018; Ed shoveling snow with his signature Sherlock Holmes cap and pipe.

# Remembering ED MERRILL

## (1923-2020)

By Nicholas A. Peppas and Michael V. Sefton

**On August 6, 2020, our PhD research advisor, Ed Merrill of MIT, passed away in his sleep after a wonderful life full of contributions to polymer science, biomaterials and bioengineering.**

Over a 66-year career, Professor Edward Merrill was a pioneer in several fields of bioengineering. Merrill's ideas on poly(ethylene oxide) (along with Ed Salzman of MGH) in 1979 as a non-fouling and non-thrombogenic biomaterial led to an explosion in the use of PEG- and PEO- decorated biomedical systems. He moved on to studies on blood compatibility through his expertise on blood rheology. In the 1950s and 60s he was the leading scientist in the blood rheology field, which included the invention of the GDM (Gilinson-Dauwalter-Merrill) viscometer. He investigated the effect of hematocrit and various plasma proteins on blood viscosity, and then went on to study the drag reduction effect associated with macromolecular solutions. In the 1960s and 70s Merrill was a pioneer in the development of the artificial kidney, and in the analysis of its transport characteristics and optimization of hemodialyzer membranes. Starting in 1964 and continuing into the early 1990s, he pioneered protein/polymer interaction studies under stagnant and flow conditions and made exceptional contributions to the development of hydrogels as biomaterials,

and to ionic or covalent heparinization techniques on polymer surfaces for antithrombogenic materials. He was also the inventor of the silicone-based contact lenses (1973) that became the basis of the hard, oxygen-permeable technology of modern contact lenses. In the 1990s (with W. Harris of Harvard) he developed a patented type of irradiation-crosslinked HDPE that has become the main material for total joint replacement. Overall Ed had 26 inventions in our field summarized in 65 US patents.

Both of us were drawn to MIT to study biomaterials with Ed in the early 1970s. We had read his paper on heparinized Cuprophane (in the Transactions of ASAIO) and had the opportunity to do our PhDs on new biomaterials based on poly(vinyl alcohol) and hydroxylated SBS-block copolymer systems (with Pat Wong as the postdoc in the lab). We became but two names on an "academic tree" that includes more than 4,400 scientists with PhD degrees associated with him directly, or through his academic descendants. Merrill was also a pioneer in educating several generations of current leaders of biomedical engineering, although in a 1971 letter to one of us, Ed expressed the opinion that "the general biomedical engineering degree is not of very great value and that MIT's method of concentration within one department continues to be a superior system."

## Remembering Ed Merrill (continued)

We remember Ed as a mentor because of his spectacular teaching. He introduced us to Paul Flory, both through his textbook and then in person when he came to MIT to teach an advanced polymers course (the same semester he won a Nobel Prize). He introduced us to the patent literature and what we now call translation, drawing from his experiences as a consultant to industry. He taught us to think like a polymer, to imagine a Maxwellian demon, and to connect polymer excluded volume to Lewis Carroll's Cheshire cat.<sup>1</sup> That same Transactions of ASAIO paper (previously mentioned on page 14) also tells the story of his Sherlock Holmes hat. Early in his career, grateful students presented him with an authentic Sherlock Holmes-style hat which was a famous trademark of his for many years thereafter. That hat, his Holmesian pipe, and his tall, lean appearance must have startled more than one MIT student. An impressionable undergraduate might well have thought that the famous detective was alive and well and now devoting his talents to unraveling scientific mysteries, and such a deduction would not have been far from the truth. One of us also discovered that he was a fan of the Marx Brothers, which seemed incongruous then for a PhD supervisor and highly literate teacher and professor, but now all seems to fit. Another had discovered that Ed was fluent in ancient Greek, and had greeted him with the first three strophes of Homer's Iliad when he first entered his office in 1971. In the 1990s and beyond he would gather his grandchildren around him during cold winter evenings at his and Ginnette's Belmont home, where he would play them Bach and Mozart and would read them ancient Greek and Latin stories.

But the most poignant summary of the special environment that existed when Ed Merrill was teaching came from David Tirrell,<sup>2</sup> Provost of CalTech, a distinguished member of all three U.S. academies, and his student at the same time we were in the lab. He said in an April 2010 seminar:

"... It won't surprise anyone to hear me say that Ed Merrill is without question the most influential teacher I've ever had. I am a polymer chemist because Ed is a polymer chemist, I work on biological problems because Ed works on biological problems, and I teach the way I do because Ed teaches the way he does. I've said many times that had I encountered Ed as a teacher of something else, I would now be doing something else ... Ed offered a [short] course on polymers in January 1972 and I became a polymer chemist just about half way through his first lecture ... Ed did many things at that time that were important to me and have remained important to me over the years. His classes were lively and his sense of humor and his flair for the theatrical were always on display. ... He made me feel as if what I was doing in the lab was important, despite the fact that I was mostly breaking stuff and spending his money. And he made me part of a family ... For all of those things I am very grateful."

Ed was a member of the National Academy of Engineering, National Academy of Medicine, American Academy of Arts and Sciences and the National Academy of Inventors. We point you to his obituary<sup>3</sup> for details of his education and awards. One item that is singularly relevant is that Ed studied classics and chemistry at Harvard before finding himself in a chemical engineering basics course, and then went on to MIT to study and then teach chemical engineering. We were then not greatly surprised to learn later that Ed was a consultant to the Conservator, Department of Prints, Drawings and Photographs at the Museum of Fine Arts in Boston. While occasionally his classics background came through in his teachings, I recall more often an expression that I think came from West Roxbury or Buzzards Bay, "dollars to doughnuts."

So, dollars to doughnuts, we have lost an important pioneer of biomaterials and biomedical engineering, regardless of the caveat above. Quoting Herman "Fritz" Meissner,<sup>4</sup> who was the major research professor for his PhD thesis, "Ed Merrill is [was] truly a Renaissance man in the best sense of the phrase, with broad interests and the ability to inject ideas from one discipline into another, often with spectacular results."

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... should make it clear that, while you express interest in the general field of biomedical engineering and would like to work for a Masters and Doctoral degree in this field, there is no department at M.I.T. that offers a degree in Biomedical Engineering. We generally believe that our students are best served by being very strongly grounded in a field of engineering, such as chemical engineering, and in our department we therefore award degrees in chemical engineering, not biomedical engineering, although the subject of the student's research, as demonstrated in his thesis, can be obviously adduced to demonstrate his interest in biomedical engineering. So, if you are convinced that you want a degree in "biomedical engineering," you will not be able to obtain the same from M.I.T. My own experience has convinced me that the general biomedical engineering degree is not of very great value and that M.I.T.'s method of concentration within one department continues to be a superior system.

Merrill's 1971 letter expressing his opinion on the general biomedical engineering degree.

# Industry News

By Gopinath Mani, Industry News Editor



**Johnson & Johnson (J&J)** announced that it entered into an agreement to acquire **Momenta Pharmaceuticals, Inc. (Momenta)**.<sup>1</sup> Momenta discovers and develops novel therapies for immune-mediated diseases. This acquisition is seen by J&J as an opportunity for its **Janssen Pharmaceutical** subsidiary to broaden its work in immune-mediated diseases and drive growth through expansion into autoantibody-driven diseases. In autoantibody-driven diseases, the body's antibodies attack or damage its own proteins, cells and tissues, often with devastating consequences.<sup>1</sup> It is estimated that approximately 195 million people worldwide suffer from some form of autoantibody-driven disease.<sup>1</sup> This acquisition includes the full global rights to Momenta's nipocalimab (M281) anti-FcRn antibody, for which Janssen plans to pursue indications across autoimmune diseases with unmet medical needs in maternal-fetal disorders, neuro-inflammatory disorders, rheumatology, dermatology and autoimmune hematology.<sup>1</sup>

**Medtronic** announced its plans to acquire **Companion Medical**, the manufacturer of InPen, a smart insulin pen system paired with an integrated diabetes management app, already cleared by the U.S. Food and Drug Administration (FDA) and on the market.<sup>2</sup> The InPen system automatically records insulin doses, tracks active insulin and recommends mealtime and correction doses based on a bolus calculator, which may help simplify diabetes management.<sup>2</sup> Patients are also able to share data with caregivers and clinicians. Regarding this acquisition, Medtronic's vision is to build upon the success of the InPen system by combining it with their intelligent algorithms in order to deliver proactive and personalized dosing advice.<sup>2</sup>

A **Northwestern Medicine Bluhm Cardiovascular Institute** physician, Bradley Knight, MD, Medical Director of Cardiac Electrophysiology at Northwestern Memorial Hospital, was the

first in Illinois to use a new advanced imaging system during cryoablation, a minimally-invasive treatment for atrial fibrillation requiring precise images of the heart.<sup>3</sup> This was done using the **Phillips KODEX-EPD** system, which offers 3D high-definition images of a patient's heart during a procedure. It is estimated that more than 6 million Americans may have atrial fibrillation, a heart rhythm disorder when the upper and lower chambers of the heart beat out of sync, either too slowly, too quickly or irregularly.<sup>3</sup> A major risk of atrial fibrillation is stroke. In cryoablation, physicians use a thin, flexible tube called a balloon catheter to locate, freeze and disable the heart cells that are causing the irregular heartbeat.<sup>3</sup> Imaging is critical to help the physician guide the catheter (which typically enters the body through a blood vessel in the upper leg) to the heart and the tissue that they will be ablating.

**Therapixel** received FDA 510(k) clearance for MammoScreen,<sup>TM</sup> an artificial intelligence (AI)-based software assisting radiologists in reading screening mammograms.<sup>4</sup> The FDA clearance was received after submitting results from a multi-reader, multi-case study conducted last year.<sup>4</sup> Study findings revealed improvement in readers' performance in cancer detection in mammograms when paired with MammoScreen compared to radiologists alone.<sup>4</sup> MammoScreen automatically detects and characterizes suspicious soft tissue lesions and calcifications in mammogram images while assessing their likelihood of malignancy. The results are presented in a summary report that characterizes the suspiciousness of each lesion, scored on a scale of 1-10 (with one being least likely to reveal malignancy and 10 most likely).<sup>4</sup> Breast cancer is the second cause of cancer death worldwide. Early detection is the key to successful treatment.

**BrainsWay Ltd.**, a medical device company focused on the development of non-invasive neurostimulation products, announced that it has received 510(k) clearance from the FDA for its proprietary deep transcranial magnetic stimulation (Deep TMS) system for use in short-term smoking cessation in adults.<sup>5</sup> Smoking is one of the leading causes of death in developed countries. The addiction to nicotine involves modulation of the brain reward system and causes an uncontrollable desire to smoke.<sup>5</sup> The efficacy of the BrainsWay Deep TMS System with H4-coil as an aid to short-term smoking cessation was demonstrated in a prospective, double-blind, randomized, sham-controlled, multi-center trial which enrolled 262 eligible subjects.<sup>5</sup>

**Hyperfine Research, Inc.** has received 510(k) clearance from the [FDA](#) for its category-defining portable magnetic resonance imaging (MRI) technology, the Swoop<sup>TM</sup> Portable MR imaging device.<sup>6</sup> Hyperfine's Swoop<sup>TM</sup> system is a point-of-care MRI device that wheels directly to the patient's bedside, plugs into

## Industry News (continued)

a standard electrical wall outlet and is controlled through a wireless tablet, making MRI immediately accessible.<sup>6</sup> Magnetic resonance imaging uses a magnetic field, radio waves and a computer to produce detailed pictures of the body's internal structures that are clearer and more detailed in order to identify and accurately characterize disease; however, fixed MRI systems can be inconvenient and inaccessible for providers and patients, particularly when time is critical.<sup>6</sup> Transport to the MRI suite demands complicated scheduling coordination, moving patients and, often, four to six hour patient backlogs — all which compromise the utility of MRI as a diagnostic tool in time-sensitive settings such as intensive care units and emergency rooms.<sup>6</sup> Furthermore, high capital investments, electrical power needs and significant maintenance requirements present a barrier to adoption across all populations, especially for developing countries and rural geographies. Hyperfine's Swoop™ system was designed to address the limitations of current imaging technologies and make MRI accessible anytime, anywhere, to any patient.<sup>6</sup>

**CoreLink, LLC**, a surgical device manufacturer of spinal implant systems, announced the 510(k) clearance from the FDA for the F3D-C2 Stand-alone Cervical Spine System.<sup>7</sup> It features an additively-manufactured spacer with two bone screw anchors secured by a locking mechanism printed within the cage. Stand-alone cervical devices eliminate the need for a supplemental fixation plate, making anterior cervical discectomy and fusion (ACDF) procedures easier and faster to complete.<sup>7</sup> A patented and proven 3D-printed [Mimetic Metal® technology](#) is incorporated into the spacer to emulate key characteristics of natural bone.<sup>7</sup> The technology provides less stiffness than machined titanium and the reduced implant density minimizes imaging artifact. The system will be available in multiple footprints, heights and lordotic angles.

**JEOL, Ltd.** announces the release of a new scanning electron microscope (SEM), the JSM-IT700HR.<sup>8</sup> The JSM-IT700HR is equipped with an in-lens Schottky field emission electron gun (FEG). Such FEG allows users to observe high-definition images with high spatial-resolution analysis. The JSM-IT700HR delivers a high resolution of 1 nm and maximum probe current of 300 nA

(15 times higher than previously), providing greater observation and analysis information.<sup>8</sup> The microscope also incorporates a new function to display the characteristic X-ray generation depth, which supports prompt understanding of the analysis depth (reference) for the specimen, making it useful for fast elemental analysis.<sup>8</sup>

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# Government News

By Carl Simon, Government News Editor



## FDA DATABASES

The US Food and Drug Administration (FDA) provides many useful online databases for regulated devices and biologics.

**Devices:** The Center for Devices and Radiological Health (CDRH) has a landing page with links to 25 different databases<sup>1</sup> including Product Recalls,<sup>2</sup> Advisory Committee Meetings<sup>3</sup> and products approved via the 510k,<sup>4</sup> De Novo<sup>5</sup> and Premarket Approval (PMA)<sup>6</sup> mechanisms. As an example of how the databases can be used, Figure 1a shows

a screen shot of the search window for De Novo-approved products for the date range of January 1 through September 9, 2020. Figure 1b shows the 14 entries that resulted from this search. Results include new approvals and regulatory actions for approved products, such as a change in testing, manufacturing or supplier. The links provide important information on how the product is regulated and the clinical indication.

**Biologics:** The Center for Biologics Evaluation and Research (CBER) has a web page with an extensive list of more than 300 approved biologics.<sup>7</sup> Clicking on an approved product leads to PDFs of package inserts, approval letters and review documents.

(a) **Search Database** [Help](#) [Download Files](#)

Denovo Number  [Product Code](#)

510(k) Number  Priority Review

Panel  Device Name

Center  Requester Name

Decision Date  to

Sort By

[Clear Form](#)

(b)

1 to 14 of 14 results results per page

Decision Date From: 01/01/2020  
Decision Date To: 09/09/2020

[New Search](#) [Download Files](#) [More About De Novo](#)

Device Name	Requester	De Novo Number	510(k) Number	Decision Date
<a href="#">Theranova Dialyzers, Theranova 400 Dialy</a>	Baxter Healthcare Corporation	<a href="#">DEN190042</a>		08/28/2020
<a href="#">Cell-Free DNA BCT</a>	Streck, Inc.	<a href="#">DEN200001</a>		08/07/2020
<a href="#">Cobas EBV, Cobas EBV/BKV Control Kit, Co</a>	Roche Molecular Systems, Inc.	<a href="#">DEN200015</a>		07/30/2020
<a href="#">EndeavorRx</a>	Akili Interactive Labs Inc.	<a href="#">DEN200026</a>		06/15/2020
<a href="#">NaviCam Capsule Endoscope System With Na</a>	AnX Robotica, Inc.	<a href="#">DEN190037</a>		05/22/2020
<a href="#">NP Screen</a>	Advance Sentry Corporation	<a href="#">DEN190031</a>		05/11/2020
<a href="#">ITEAR Neurostimulator</a>	Olympic Ophthalmics, Inc.	<a href="#">DEN190026</a>		05/01/2020
<a href="#">OGmend Implant System</a>	Woven Orthopedic Technologies, LLC	<a href="#">DEN180065</a>		05/01/2020
<a href="#">CARPEDIEM System</a>	Belco Srl (Now Part Of Medtronic, Inc)	<a href="#">DEN180055</a>		04/29/2020
<a href="#">MyCare Psychiatry Clozapine Assay Kit</a>	Saladax Biomedical Inc	<a href="#">DEN190028</a>		04/16/2020
<a href="#">ITind System</a>	Medi-Tate Ltd.	<a href="#">DEN190020</a>		02/25/2020
<a href="#">AmplideX Fragile X Dx &amp; Carrier Screen K</a>	Asuragen, Inc.	<a href="#">DEN190023</a>		02/21/2020
<a href="#">Surfacer Inside-Out Access Catheter Syst</a>	Bluegrass Vascular Technologies, Inc.	<a href="#">DEN190038</a>		02/10/2020
<a href="#">Caption Guidance</a>	Bay Labs, Inc.	<a href="#">DEN190040</a>		02/07/2020

Figure 1. (a) Search window for FDA database on products approved via the De Novo pathway. (b) Search results returned for the query of a date range of January 1 to September 9, 2020



## Government News (continued)

### NCATS 3D Tissue Bioprinting Program

The National Center for Advancing Translational Sciences (NCATS) has established a 3D Tissue Bioprinting Program whose goal "is to advance the process of discovery and development of new medicines by developing physiologically relevant 3D cellular models as test platforms that better predict the toxicity and efficacy of drugs in humans."<sup>8</sup> The program uses a range of tissue engineering and biofabrication technologies, including bioprinting, to create human 3D tissue models. The ability of 3D bioprinters to dispense viscous mixtures of cells and hydrogels in an automated, spatially-controlled manner is being leveraged to enable the reproducible biofabrication of native-like human tissues in microwell plates. Use of microwell plates allows the program to take advantage of the extensive suite of drug discovery tools that have been designed for this platform. The program has developed models for skin<sup>9</sup> and retina,<sup>10</sup> and is expanding to lung and brain. The skin models have been used to assess the irritation potential of topical drug compounds<sup>11</sup> and to develop skin disease models such as atopic dermatitis.<sup>12</sup> Tissue viability, trans-epithelial electrical resistance, cytokine secretion and imaging of disease biomarkers are used to assess the effects of test compounds on the tissue models. All the components, including bioinks, cells, scaffolds and measurement instrumentation, are from commercial sources to facilitate broader adoption of the models by the scientific community.

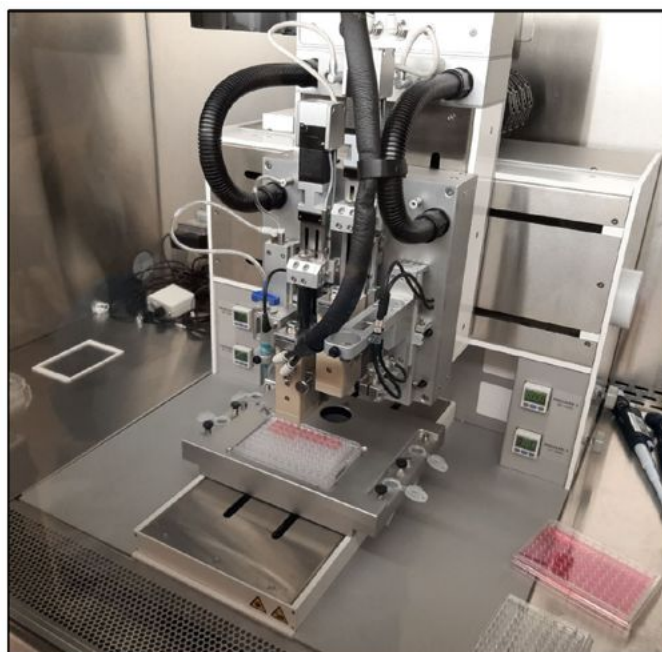


Figure 2. 3D bioprinter at NCATS

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