

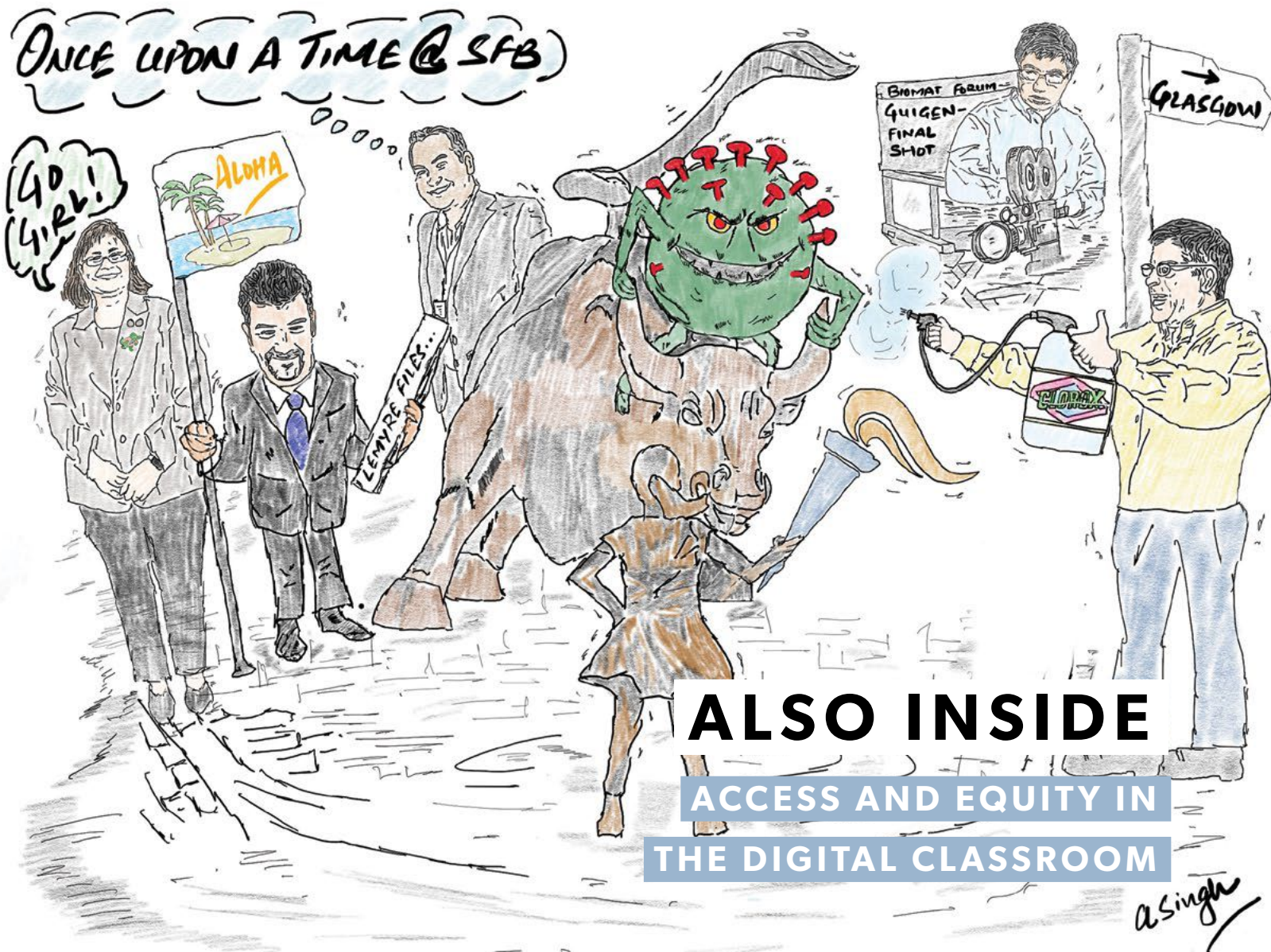
SPECIAL ISSUE: IN TIMES OF THE COVID-19 PANDEMIC

LETTER FROM THE NEW PRESIDENT

BIOMATERIALS FORUM!

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

SECOND QUARTER 2020 • VOLUME 42, ISSUE 1



ALSO INSIDE

ACCESS AND EQUITY IN

THE DIGITAL CLASSROOM

a.singh

BIOMATERIALS FORUM!



The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 42, Issue 1

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.

It is the policy of the Society For Biomaterials that all articles reflect only the views of the authors. Publication of articles or advertisements within *Biomaterials Forum* does not constitute endorsement by the Society or its agents of products, services or views expressed herein. No representation is made to the accuracy hereof, and the publication is printed subject to errors and omissions. Articles that do not have an author byline may originate from press releases. The Society For Biomaterials retains press releases on file for a period of one year from the date of publication.

Editorial contributions to *Biomaterials Forum* are always welcome. Contributions should be sent to the Executive Editor and are subject to the terms and conditions of the Editorial and Publication Release. Authors should refer to the Author Guidelines, which are available on the Society's website, when writing submissions. The publisher accepts no responsibility for return or safety of artwork, photographs or manuscripts. Submission of editorial content does not guarantee acceptance or publication.

Address corrections should be sent to *Biomaterials Forum*, 1120 Route 73, Suite 200, Mt. Laurel, NJ 08054.

Requests for advertising information should be directed to Lisa Howard-Fusco at lfusco@ahint.com or 856-380-6905. Information is also available on the Society's website, biomaterials.org.

Unauthorized reproduction of this magazine in whole or in part is prohibited without the permission of the publisher. Requests for permission should be directed to the Managing Editor.

Scientific photos may be submitted for cover consideration in future issues. Submit color photo, no larger than 4" x 6", along with credit information and scientific description, to the Executive Editor.

Copyright © 2020 • ISSN 1527-6031
Society For Biomaterials
All rights reserved

Executive Editor Guigen Zhang, University of Kentucky
Phone: 859-323-7217 • Fax: 859-257-1856
Email: guigen.bme@uky.edu

Managing Editor Lisa Howard-Fusco, Society For Biomaterials
1120 Route 73, Suite 200, Mt. Laurel, NJ 08054
Phone: 856-380-6905 • Fax: 856-439-0525
Email: lfusco@ahint.com

**Government News
Contributing Editor** Carl G. Simon Jr., NIST
Biosystems & Biomaterials Division
Email: carl.simon@nist.gov

News Contributing Editor Steve T. Lin, Exactech Inc.
Email: steve@exac.com

**Society Business & Membership
News Contributing Editor** Cherie Stabler, University of Florida
Email: cstabler@bme.ufl.edu

**Special Interest Group News
Contributing Editor** Danielle Benoit, University of Rochester
Email: danielle.benoit@rochester.edu

**AIMBE News
Contributing Editor** Lynne Jones, Johns Hopkins University
Department of Orthopaedic Surgery
Email: ljones3@jhmi.edu

Student News Contributing Editor Jason Guo, Rice University
Email: JLG19@rice.edu

SPECIAL INTEREST GROUP REPORTERS

**Biomaterials & Medical Products
Commercialization** Puneeth Shridhar • pus8@pitt.edu

Biomaterials Education Sarah Rowlinson • sarcorow@gmail.com

Biomaterial-Tissue Interaction Antonio Merolli • antonio.merolli@rutgers.edu

Cardiovascular Biomaterials Chris Bashur • cbashur@fit.edu

Dental/Craniofacial Biomaterials F. Kurtis Kasper • Fred.K.Kasper@uth.tmc.edu

Santiago Orrego • sorrego@temple.edu

Drug Delivery Eun Ji Chung • eunchung@usc.edu

Engineering Cells & Their Microenvironments Scott Wood • scott.t.wood@gmail.com

Immune Engineering Yaoying Wu • yw195@duke.edu

Nanomaterials Eno Ebong • e.bong@northeastern.edu

Ophthalmic Biomaterials Frances Lasowski • lasowsfj@mcmaster.ca

Orthopaedic Biomaterials Roche C. de Guzman • roche.c.deguzman@hosftra.edu

Protein & Cells at Interfaces Rafael Ramos • ramos.rafael93@gmail.com

Surface Characterization & Modifications Shaunak Pandya • pandyasg21@gmail.com

Tissue Engineering Abby Whittington • awhit@mse.vt.edu

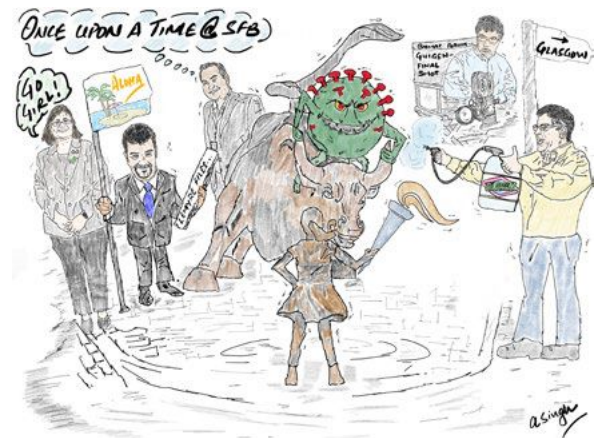
Contents

THE TORCH

- 4 FROM THE EDITOR
- 5 FROM THE PRESIDENT

NEWS & UPDATES

- 6 MEMBER NEWS
- 7 STAFF UPDATE
- 9 STUDENT CHAPTER NEWS
- 10 ENGINEERING CELLS AND THEIR MICROENVIRONMENTS SIG UPDATE
- 11 ACCESS AND EQUITY IN THE DIGITAL CLASSROOM
- 13 INDUSTRY NEWS
- 15 GOVERNMENT NEWS
- 16 HAPPENING DURING THE COVID-19 PANDEMIC: REVEALING YOUR INNER HERO
- 18 HAPPENING DURING THE COVID-19 PANDEMIC: PROVIDING REGULATORY GUIDANCE FROM THE DINING ROOM
- 19 HAPPENING DURING THE COVID-19 PANDEMIC: CONTRIBUTING IDEAS AND TECHNOLOGY TO THE CDC



ON THE COVER

The cover image, titled, “Once Upon A Time at SFB,” is the artwork by our very own artist, Ankur Singh, Associate Professor, Georgia Institute of Technology. Here is what Ankur intends with his art: “The novel coronavirus disease (COVID-19) has disrupted the lives of scientists at all levels. As the virus spreads around the world, impacting lives and the economy, scientists, including those at the Society for Biomaterials, have raced to develop solutions and tests in order to curb the infection. COVID-19 has caused conference organizers to cancel and/or reschedule scientific meetings across the world. At the same time, in these unprecedented times, the scientific leaders are thinking about how different identities and social structures come together and are cheering up or supporting those in need, as they try to navigate professional careers and personal lives. I sketched this cover just to bring smiles to your faces and to thank all the leaders in the field.”

From the Editor

RISE TO THE CHALLENGES

By Guigen Zhang, SFB Forum Editor



On March 20, we issued a call for a special issue of the *Biomaterials Forum*:

"We are living through the pandemic of COVID-19 that has swept through over 152 countries around the globe and all 50 states in the United States.

In deciding whether to cancel the Q2 2020 issue of the Forum or use the issue to document how the SFB community rises to the challenges of this still-developing crisis, the leadership team decided to do the latter.

We would make it a special issue to provide an opportunity for all SFB members, your colleagues and students alike, to share stories, experiences, creative ideas and actions in which we — while taking all necessary reactionary steps to keep the operations and teaching/learning activities going — proactively turn this crisis into the best laboratory or classroom for solutions to save the world.

This is an unprecedented crisis. Have you heard about the United States Food and Drug Administration's (USFDA) unusual "flexible regulatory approach" to allow companies to begin marketing coronavirus test kits directly to the public before asking for approval? Let us not let the crisis go to waste.

Some relevant topics to the SFB community may cover matters on the scientific, technical, legal, ethical and moral, as well as social/societal measures. For students, non-peer-reviewed information in the repository (www.medrxiv.org/archive) may provide something extra to digest and analyze, remotely in your home workshop or makerspace, to design and develop crisis-counteracting engineering solutions. For professors, you might want to consider modifying your initial course plans for the lectures, labs, final exams and even capstone projects. Students who pass this real-world test shall do well on any exam!

*We ask our regular and scheduled contributors, and all SFB members to lean in and help make this special issue a documentation of how the SFB, **especially the students in the SFB community**, step up and turn this still-unfolding crisis into a world-saving experience."*

We now bring to you this special issue. As you will note, all the contents are related to COVID-19. From the cover, we have the artwork by our very own artist, Ankur Singh, trying to lighten us up during these stressful pandemic times. In their article titled, "Access and Equity in the Digital Classroom," Simpson, Gomillion and Huang-Saad bring our attention to the "digital divide" in the wake of COVID-19 and online teaching. Even regular columns such as "Industry News" by Steve Lin and "Government News" by Carl Simon are also related to the pandemic.

Just weeks before the release of this special issue, another crisis hit the country - the tragic killings of George Floyd, Ahmaud Arbery, Breonna Taylor, and Rayshard Brooks. The letter from our new president, Shelly Sakiyama-Elbert, reflects where we stand in the fight against a painfully long history of dehumanizing, racist acts. Her letter also shares with us her plans for the SFB in the coming year.

With best wishes,

Guigen Zhang

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, 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.



From the President

By Shelly Sakiyama-Elbert, SFB President



Dear Friends and Colleagues,

It is an honor to assume the role of President of the Society for Biomaterials at our upcoming business meeting on July 15 (see page 8 for details), where I have been an active member for over 20 years. 2020 has certainly been an eventful year already. I was sad to miss seeing many of you in Glasgow at the World Biomaterials Congress due to the COVID-19 pandemic, and I look forward to a time in the (hopefully) near future when we can gather again in person. The past few months have been an unprecedented time of universities moving classes online, shutting research labs and much of the economy grinding to a halt to slow the progression of disease. As we wait to see how things progress, I know many labs are beginning to reopen and companies are resuming work under new and different conditions. I have been inspired by the efforts of the Biomaterials community in pulling together to support each other and to identify areas where we can be of assistance to develop new treatments, testing, vaccines and equipment to help healthcare providers and patients. Many of these efforts are highlighted in this issue of the *Forum* thanks to Guigen's efforts to publicize this impactful work by our Biomaterials community.

We have also been devastated by the tragic killings of George Floyd, Ahmaud Arbery and Breonna Taylor, some of the latest Black victims of a painfully long history of dehumanizing, racist acts plaguing the United States. The Society for Biomaterials stands in solidarity with the Black community and now more than ever we remain committed to supporting an equitable and inclusive community in which racist acts of violence, hate and intolerance are actively combatted.

In July 2019, SFB formed a Diversity Task Force that is charged with developing an action plan to reduce and resolve disparities within SFB. This action plan will become the charge for a standing Diversity & Inclusion Committee that will allow us to

coordinate current diversity activities and expand our ability to highlight the outstanding work of underrepresented scientists in Biomaterials. Formation of a formal committee will require a change in the bylaws, so be on the lookout for that this year. Other areas of focus for the Committee will include training on mentorship of diverse research groups, increasing the diversity of the nominations for SFB awards and elected roles and developing an SFB diversity award. We welcome your suggestions for other ways that SFB can continue to improve the diversity of our membership and to support all of our members.

Through these challenging times, we have been working to connect with our members in new ways. We have been hosting a number of webinars to virtually share expertise on topics including materials science research for the COVID pandemic (jointly with MRS), biomaterials for studying lung disease and biomaterials for cardiovascular disease (jointly with ISACB). We have a number of upcoming webinars, including a talk by David Mooney on Biomaterials for T cell Immunity, and a panel on Smart Dental Biomaterials.

We are already actively planning for the April 2021 Society for Biomaterials Meeting in Chicago and our joint symposium with the Japanese Society for Biomaterials in Hawaii that is now scheduled for July 2021. I hope to see you in person at one of these meetings! I challenge you all to continue your involvement with the Society for Biomaterials and to enhance the impact of our work in improving 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.

Warm regards,
Shelly Sakiyama-Elbert, PhD
SFB President

Member News

By Cherie Stabler, Member-at-Large



I am so honored to serve as your 2019-2020 Member-at-Large representative! In this role, I strive to provide your collective voice to the SFB Board and Council. I am actively working to support and expand our supportive and engaging community with broad and diverse membership engagement. Please feel free to share your ideas and concerns with me directly at cstabler@bme.ufl.edu.

Some of this quarter's exciting member news and accomplishments:

Ashutosh Chilkoti, the Alan L. Kaganov Distinguished Professor of Biomedical Engineering at Duke University, was recently awarded an NSF Rapid Response Research grant to adapt their current rapid testing assay, designed to detect Ebola, and to detect SARS-COV-2 antigens. While in the early stage of adaptation, such a tool could be useful to quickly detect infected patients using a higher sensitivity than current approved assays.

SFB members **Stuart Cooper**, Professor, Chemical & Biomolecular Engineering at Ohio State University, and **Nicholas Peppas**, Cockrell Family Regents Chair in Engineering and Professor of Chemical Engineering at the University of Texas, Austin, were recently recognized as 2020 POLY Fellows, awarded through the POLY division of the American Chemical Society. This award recognizes excellence advancements in the field of polymer science, either through scientific accomplishments, service to the profession, or both.

Jordan Green, Professor of Biomedical Engineering, Ophthalmology, Oncology, Neurosurgery, Materials Science & Engineering and Chemical & Biomolecular Engineering at the Johns Hopkins University School of Medicine and his colleagues recently published an article in the journal *Science Advances* where they developed a nanoparticle that mimics the shape and cell membrane of red blood cells to serve as a means to enhance the detoxification of blood. DOI: 10.1126/sciadv.aay9035

Ali Khademhosseini was recently appointed as CEO and director of the Terasaki Institute for Biomedical Innovation, an independent non-profit research foundation affiliated with the University of California, Los Angeles.

Robert Langer, David H. Koch Institute Professor at the Massachusetts Institute of Technology, was recently highlighted by *The Boston Globe* for his efforts in COVID-19 research. The article highlights his role in consulting for vaccine development, mask prototyping and designing microneedles for blood samples.

www.bostonglobe.com/2020/05/04/nation/common-denominator-several-coronavirus-efforts-mits-bob-langer/

Cato 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, and **Joanne Walker** recently published an article that outlines six ways (four direct and two indirect) police profiling and racial discrimination impacts African-American health. The goal in conducting this research was to shine a light on an uncharted but highly prevalent societal issue, and in turn, propose potential remedies that address the clinical health effects of racial profiling. DOI: 10.1007/s40615-020-00738-2

Krishnendu Roy, Robert A. Milton Chair and Professor, and **Johnna Temenoff**, Carol Ann and David D. Flanagan Professorship II and Associate Chair for Translational Research, both at the Joint Department of Biomedical Engineering of Georgia Tech and Emory, were recently awarded Georgia Tech's Award for Outstanding Achievement in Research Program Development in 2020 for their efforts in leading the National Science Foundation (NSF) Engineering Research Center for Cell Manufacturing Technologies (CMaT) based at Georgia Tech.

Congratulations to all the 2020 inductees to the National Academy of Engineering, including current SFB member **Michael Sefton**, University Professor & Michael E. Charles Professor, Institute of Biomaterials and Biomedical Engineering, University of Toronto. <https://www.nae.edu/224584/National-Academy-of-Engineering-Elects-87-Members-and-18-International-Members->

The American Institute for Medical and Biological Engineering (AIMBE) inducted its **2020 Fellows** in an online ceremony on June 5. AIMBE is the authoritative voice and advocate for the value of medical and biological engineering to society. Its mission is to recognize excellence, advance the public understanding of, and accelerate medical and biological innovation. AIMBE also drives advocacy initiatives into action on Capitol Hill and beyond. At AIMBE College of Fellows, Fellows are nominated each year by their peers and represent the top two percent of the medical and biological engineering community. They are considered the life-blood of AIMBE and work toward realizing AIMBE's vision to provide medical and biological engineering innovation for the benefit of humanity. Congratulations to the SFB Members who were inducted as 2020 Members of the AIMBE College of Fellows:

Jianjun Guan, PhD, Washington University in St. Louis
SuPing Lyu, PhD, Medtronic

Jon P. Moseley, PhD, Wright Medical

Angela Panoskaltis-Mortari, Ph.D, University of Minnesota

Josephine Allen, PhD, University of Florida

Themis Kyriakides, PhD, Yale University

Qiaobing Xu, PhD, Tufts University

Lauren D. Black, PhD, Tufts University

Jaime E. Ramirez-Vick, PhD, Wright State University

Yunzhi Yang, PhD, Stanford University

Christopher Bettinger, PhD, Carnegie Mellon University

Staff Update

By Dan Lemyre, Executive Director



During the quarantine, SFB staff has been working remotely and continuing our efforts to deliver value to SFB members through the delivery of webinars. We've also recently completed a Member Needs Analysis survey, the results of which will be discussed with governing Council members during the strategic planning meeting

to be held over the summer. We eagerly await the return to normal operations, with our headquarters office slated to reopen sometime in July. 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, HORST VON RECUM, PHD

The changeover in administration will occur at the Annual Business Meeting, which will be held virtually on July 15, 2020. SFB Welcomes incoming President Shelly Sakiyama Elbert, PhD, from the University of Texas in Austin as the incoming President.

AWARDS, CEREMONIES AND NOMINATIONS COMMITTEE – CHAIR: LIISA KUHN, PHD

The Society's 2020 Awards are still planning to be presented during the World Biomaterials Congress. The 2021 Award nominations are being solicited with a deadline of September 18, 2020. Please visit the awards description page on the website for detailed information and a nomination form.

BYLAWS – CHAIR: ASHLEY CARSON BROWN, PHD

The Committee prepared an amendment which was voted upon via electronic ballot in May 2020 which allows SFB to hold an annual business meeting online. The amendment passed with 122 members voting to approve, 3 votes not to approve, and 1 abstention. The Committee will also be discussing amendments, including the addition of a Diversity and Inclusion Committee for presentation at the 2021 Annual Meeting.

EDUCATION & PROFESSIONAL DEVELOPMENT – ANIRBAN SEN GUPTA, PHD

The 2020 Biomaterials Days have all been postponed to either the Fall or Winter of 2020, or Spring of 2021, dates to be determined. The E&PD Committee also helped curate the SIG webinar offerings. Evaluation of 2021 Biomaterials Days grants and planning for student activities and the mentor program continue.

FINANCE – CHAIR: SARAH E. STABENFELDT, PHD

With the global pandemic affecting organizations of all sizes, SFB has seen a dramatic reduction in dues renewals. Please encourage your colleagues to support SFB and please don't hesitate to contact headquarters directly if we may be of any assistance in recruiting or following up with potential new or lapsed members.

INDUSTRIAL AFFAIRS – CHAIR: SUPING LYU, PHD

The Committee helped to co-organize a Biomedical Engineering Materials and Applications Roundtable with the National Academies on March 9 at the Keck Center in Washington DC. Please see Carl Simon's article on page 15 of this issue for more information. 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 include a panel discussion at the 2021 Annual Meeting.

LIAISON – CHAIR: TIM TOPESKI, PHD

SFB has delivered a webinar co-sponsored by the Materials Research Society and another co-sponsored by the International Society for Applied Cardiovascular Biology. We are also working to host another with the Materials Research Society on Synthetic Biology in the near future. In addition, SFB will be pitching to host the 2028 World Congress, timing to be determined by the IUSBSE.

MEMBERSHIP – C. LASHAN SIMPSON, PHD

The committee has executed three separate member surveys of SFB members to gauge satisfaction of SFB's benefits to current members and ask for ideas on improvement and added value. These ideas will be discussed by Council at a strategic planning meeting this summer.

CHICAGO PROGRAM – GUILLERMO AMEER, PHD AND KRIS KEISWETTER, PHD

The Society For Biomaterials has issued a Call For Ideas for the 2021 Annual Meeting which is scheduled to take place in Chicago, IL, April 21-24, 2021. Full Proposals will be due in July, and the call for abstracts will be issued just before Labor Day.

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, HI, July 29-31, 2021. The call for abstracts will be issued in the fourth quarter of 2020.

Staff Update (continued)

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

The SIG webinar program is in full gear with more than six webinars scheduled for delivery between April and July 2020. For more information, please visit www.biomaterials.org/webinars.

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

The SFB National Student Chapter will be scheduling a virtual meeting for late June 2020. Please see the official announcement below.

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

Society For Biomaterials
1120 Route 73, Suite 200
Mount Laurel, NJ 08054
Phone: 856-439-0826
Fax: 856-439-0525
Email: info@biomaterials.org

OFFICIAL ANNOUNCEMENTS**ANNUAL BUSINESS
MEETING ANNOUNCEMENT**

**WEDNESDAY, JULY 15, 2020, 12:00 NOON (EDT)
LIVE VIA GOTOWEBINAR**

The Society for Biomaterials recently passed a bylaws amendment via electronic ballot to allow the Annual Business Meeting to take place virtually.

Nominations for the Awards, Ceremonies and Nominations Committee will be requested. Please be sure to check with any nominee to be sure they would accept the position before making a nomination.

To register for the Annual Business Meeting, please see the link from the email that was sent to all active members with the subject line, "SFB 2020 Annual Business Meeting Registration" and log in to the SFB website: www.biomaterials.org, or you can email headquarters at info@biomaterials.org.

**NATIONAL STUDENT
CHAPTER MEETING
ANNOUNCEMENT**

**WEDNESDAY, JUNE 17 AT 5:00 PM (EDT)
LIVE VIA GOTOWEBINAR**

The SFB National Student Chapter Meeting will be combined with a webinar, and SFB's Young Scientists are invited to attend. The webinar will be a panel discussion on online branding, networking and job applications during the COVID-19 pandemic. Panel members include:

- Bob Bullard, Director of the Office of Career Advancement at Rowan University
- Dr. Lisa Volpatti, Postdoctoral Scholar in Hubbell Lab at the University of Chicago
- Dr. Ritu Raman, Postdoctoral Scholar in Langer Lab at Massachusetts Institute of Technology
- Woojin Han, Postdoctoral Fellow in García/Jang Labs at Georgia Tech

To register for the webinar, please see the link from the email sent to all SFB members with the subject line, "SFB: National Student Chapter Meeting Announcement & Webinar for Young Scientists" and visit www.biomaterials.org/webinars, or email headquarters at info@biomaterials.org.

Jason Guo, President, SFB National Student Chapter



Society For
Biomaterials

Student Chapter News

GRADUATE HEALTH AND PRODUCTIVITY IN THE TIME OF QUARANTINE

By Jason Guo, National Student Chapter President



Greetings SFB student members and young scientists! You may likely be reading this article from home, if you're doing remote work like myself. The onset of the COVID-19 pandemic has prompted many creative solutions on the part of universities and research groups, including transitions to entirely remote work as well as the pursuit of novel scientific and clinical solutions to COVID-19. So how do we adapt to a highly fluid and demanding situation? How do we make the most out of a difficult time? It can be a challenge to stay productive in these situations, but it's all the more important to do so for the sake of maintaining good mental health and resilience.

There's no one-size-fits-all solution, but I'd like to share what's worked for me in terms of staying productive and most importantly, healthy.

MAINTAINING A ROUTINE

It's easy to fall into the trap of Netflix and other distractions when you're working from home. It's sustainable for a day or two, perhaps, but then we become restless. So how do you truly keep your mind busy? I would argue that one of the best solutions is to maintain a routine.

Do you have a thesis proposal or review paper you've been meaning to work on? Set aside a dedicated block of time each day to write! Have you been meaning to look into internships and future career plans? Set aside dedicated time for that as well. A transition to remote work doesn't have to mean the end of a structured day, and you can still use Google Calendar and any other tools you normally use to organize your professional and academic needs. The more consistent we keep our working time, the sharper our minds and the saner we keep ourselves.

It's not just academic and professional work that benefits from a routine, either. Physical exercise doesn't have to fall by the wayside when working from home, and plenty of routines involving bodyweight exercise or running/biking outdoors can be done without a gym. It's more important than ever to find ways to stay physically active and maintain good health.

LEARNING FROM THE EXPERIENCE

To make something positive of the present, we can utilize the unique factors of remote learning and research to develop new tools that will be helpful even after in-person work resumes. For instance, if you've now utilized Zoom or other conferencing tools for your lectures and meetings, think of how these tools could be used to create more effective meetings with distant collaborators

and colleagues in the future. If you've discovered that many in-person meetings could be efficiently converted to remote communication, consider how this may be applicable moving forward as well.

Have new elements been introduced to your research due to remote work? As an experimentally-focused researcher myself, I've found new time to delve into literature and assess common patterns in the research outcomes of certain materials and 3D printing techniques. These beneficial lessons will certainly be applied to my experimental work as soon as it resumes, and I encourage everyone to also consider how their remote work can introduce improvements or positive changes to their usual approach in research.

"TO MAKE SOMETHING POSITIVE OF THE PRESENT, WE CAN UTILIZE THE UNIQUE FACTORS OF REMOTE LEARNING AND RESEARCH TO DEVELOP NEW TOOLS THAT WILL BE HELPFUL EVEN AFTER IN-PERSON WORK RESUMES."

Less time for experimental work also means more time for introspection and reflection on our academic and professional goals. We're often so occupied with our deadlines and tasks that we lose the time to strategize and plan how we want to proceed in the long term. The present situation is a rare opportunity to truly consider and contemplate our future steps once everything resumes.

CONNECT WITH US!

Hopefully, this piece can be helpful as you develop your own routine and ideas on how to best manage your time during the COVID-19 outbreak. Personally, I've found that concretely organizing my time with Google Calendar and extracting any positive lessons that I can from my remote work have been critical practices in maintaining good productivity and health. Have any ideas for the national student chapter? Are you interested in participating or taking on a leadership position? Contact me at JLG19@rice.edu. You can also find SFB and its members on social media, including Facebook, LinkedIn and Twitter. More information on these social media outlets can be found here: www.biomaterials.org/about-about-society/sfb-social-media. Stay safe and keep busy!

Update from the Engineering Cells and Their Microenvironments (ECTM) SIG

By Scott Wood, PhD, Nanoscience and Nanoengineering Program and Biomedical Engineering Department, South Dakota School of Mines and Technology



In this time of unprecedented international disruption due to the necessity for social distancing to combat COVID-19, many challenges and opportunities have arisen throughout the scientific and engineering community. Members of the ETCM SIG are actively responding to these in a wide variety of ways.

Many ETCM members have stood in solidarity with their local healthcare providers by working to engineer novel solutions to the projected shortages of personal protective equipment (PPE) and medical devices. One example of these efforts is in the widespread collection of donated PPE items and disinfectants. These efforts have been so successful at the University of Texas-Austin that the donation carts were routinely filled to the brim daily until the shelter-in-place orders were given. Members at several universities have been working diligently to produce respirator masks and face shields, ventilators and ventilator splitters, hand sanitizer and more.

Danielle Benoit (SIG Representative) of the University of Rochester, has served as a consultant to hospitals in the Rochester, NY area to reverse engineer the Battelle system, recently approved by the FDA to sterilize N95 masks for re-use. Scott Wood (ECTM *Forum* Reporter) has likewise been working as part of a team from the South Dakota School of Mines and Technology to identify effective respirator mask materials and alternative ventilation strategies for Monument Health in Rapid City, SD, which is the hospital with the largest geographic coverage area in the United States. Dr. Wood's efforts have also included optimizing and validating techniques for making a nanoparticle-embedded antiviral respirator mask alternative which can be produced entirely by using household materials and equipment.

Other ETCM members are taking advantage of the newly-imposed online teaching mandates to explore the challenges and pedagogical intricacies of distance learning. Surveys of engineering students at Texas A&M University have revealed significant challenges for students, including disparities of internet access. To address these challenges, Daniel Alge (ECTM Vice-Chair) of Texas A&M University has been ramping up his efforts to develop content and tools for his undergraduate biocompatibility students to engage in self-directed learning,

which include an interactive course mind map and an AI-based teaching assistant.

Although it may not get as much press as cancellations of in-person teaching, some new teaching demands also extend beyond the online environment. Many ETCM members have stepped up to meet the challenges of the COVID-19 crisis in a more domestic manner due to the loss of access to childcare options. For some, this has meant more time to spend caring for a preschooler or a newborn infant. Such demands, however, while edifying, can easily make it difficult to maintain work productivity.



Scott Wood integrates hands-on science demonstrations into his children's newfound homeschooling lessons, as he teaches them about copper oxide nanoparticles and how they can be useful to incorporate in homemade pandemic face masks.

(continued on page 14)

Access and Equity in the Digital Classroom

By C. LaShan Simpson, Ph.D.; Cheryl Gomillion, Ph.D.; Aileen Huang-Saad, Ph.D.



In the wake of the coronavirus pandemic, colleges and universities scrambled to rapidly

transition to online instruction, seemingly overnight. This certainly brought about drastic adjustments for all, but for some, the access to education was swiftly taken away. While it may seem improbable in today's technological world, there still remains an expansive "digital divide" and many Americans do not have access to broadband internet. The Federal Communications Commission (FCC) uses a download speed of at least 25 Mbps and an upload speed of at least 3 Mbps as the standard for broadband high-speed internet.¹ In a 2018 FCC report, it was indicated that 24.7 million Americans are without broadband internet access.² Many college students, especially those in rural areas, have limited internet access, which has been likened to an invisible barrier that those living in the most rural areas must face. According to the 2010 Census, 19.3 percent of the United States population lives in rural areas.³ Coupling this

with being from a low-income or disadvantaged background, many students now may not have the technology necessary for completing classes online.

"IN A 2018 FCC REPORT, IT WAS INDICATED THAT 24.7M AMERICANS ARE WITHOUT BROADBAND INTERNET ACCESS."²

This time of crisis has brought out impressive ingenuity and benevolence from the community. Many internet providers are offering free and reduced internet access for students. Some universities are even offering extended terms for laptop and hotspot rentals.⁴ These are all generous temporary solutions, but for some students, this gesture still provides little resolution for their immediate access needs to complete coursework

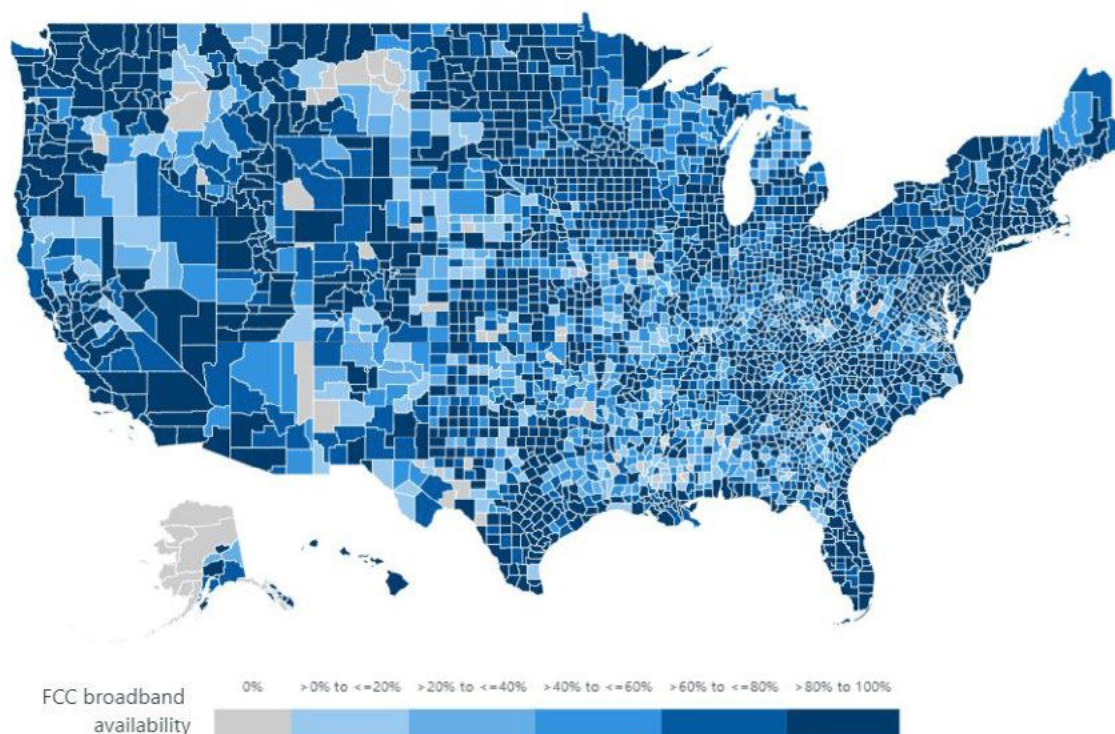


Figure 1. Map of population percentages with access to fixed broadband systems of download speeds of at least 25 Mbps and upload speeds of at least 3 Mbps.²

Access and Equity in the Digital Classroom (continued)

and assignments. For example, a mobile hotspot still requires access to cellular networks, which also may be limited in the most rural areas. Emerging accounts from students acclimating to this new reality have described having to venture to neighboring towns (while being advised to shelter-in-place or remain socially distant) or even to parking lots of buildings to access more reliable internet services.⁵ Our traditional classrooms have not only moved online, but to settings that faculty and administrators likely have not considered during this shift. Entering into this phase of “crisis management” in education, it was likely thought that, at least for a short time, faculty and students alike would “make it work;” but as the time away from traditional instruction increases, how will the less fortunate students be impacted in the long term?

**"OUR TRADITIONAL CLASSROOMS
HAVE NOT ONLY MOVED ONLINE,
BUT TO SETTINGS THAT FACULTY
AND ADMINISTRATORS LIKELY
HAVE NOT CONSIDERED DURING
THIS SHIFT."**

The concepts of the digital divide and digital equity have been a growing area of interest since the early 2000s.⁶ While there is a general consensus for the definition of digital equity, the digital divide is a more complicated construct. Digital equity seeks to ensure that “all individuals and communities have the information technology capacity needed for full participation in our society, democracy and economy.”⁷ The digital divide has evolved from a more narrow view of physical access to include access skills and competencies, motivations and attitudes.⁸ This evolution is critical, as research shows that even with access, students are less likely to be successful as a greater portion of their course load is online.⁸ In fact, these results are more pronounced for transfer students.⁸ Thus, as colleges and universities seek to continue to support students through online distance learning, we cannot solely depend on the temporary benevolence of corporations to address physical access. We must recognize that the solution must be more comprehensive, and look to address more obvious challenges of physical access and beyond if we want to ensure equity in the digital classroom.

Now that many universities are planning to continue online instruction for the summer and even fall terms, the digital divide has the potential to continue widening the education gap for many Americans.⁹ But with challenges come opportunities. In this case, the large-scale transition to online learning offers us the opportunity to seek out better approaches to addressing the digital divide for equity. Efforts to scale higher education outside the walls of residential colleges through technology and MOOCs have been faced with single digit completion rates and tend to draw educated career builders and education seekers.¹⁰ As higher education is faced with significant uncertainty over the next 18 months, we have the opportunity to explore the complexity of the digital divide and identify more effective ways to engage and support broad populations in online learning. Perhaps this is the call to action that we needed to move the needle on access and equity in the digital classroom.

REFERENCES:

1. Gallardo R. The Digital Divide in Mississippi. Mississippi State University Extension Service website. <http://extension.msstate.edu/sites/default/files/publications/publications/P2969.pdf>. Published no. 2969, July 2016. Accessed May 22, 2020.
2. Kahan J. Signs of progress on broadband mapping, but still more work to do. Microsoft website. <https://blogs.microsoft.com/on-the-issues/2019/07/31/signs-of-progress-on-broadband-mapping-but-more-work-still-to-do/>. Published July 31, 2019. Accessed May 22, 2020.
3. Ratcliffe M, Burd C, Holder K, Fields A. Defining Rural at the U.S. Census Bureau. United States Census website. <https://www.census.gov/content/dam/Census/library/publications/2016/acs/acsgeo-1.pdf>. Issued December 2016. Accessed May 22, 2020.
4. OIT Helping Students Who Need Laptops, Internet Access. University of Tennessee Knoxville News website. <https://news.utk.edu/2020/03/17/oit-helping-students-who-need-laptops-internet-access/>. Published March 17, 2020. Accessed May 22, 2020.
5. Donovan, S. Rural students search for internet as UGA moves to online instruction. The Red & Black website. https://www.redandblack.com/coronavirus/rural-students-search-for-internet-as-uga-moves-to-online-instruction/article_f399da44-7457-11ea-a374-bf36f3416664.html. Published April 1, 2020. Accessed May 22, 2020.
6. Davis T, Fuller M, Pittman J, Sweet J. A National Consideration of Digital Equity. 2016. https://www.researchgate.net/publication/234680441_A_National_Consideration_of_Digital_Equity. Accessed June 2020.
7. National Digital Inclusion Alliance. NDIA website. <https://www.digitalinclusion.org/definitions/>. Accessed May 22, 2020.
8. Dijk JAGM. Digital Divide: Impact of Access. *Int. Encycl. Media Eff.* 2017;(1–11).
9. Reis B, Wagner M. Universities Begin Considering the Possibility of Canceling In-Person Classes Until 2021. CNN website. <https://www.cnn.com/2020/04/14/us/university-may-cancel-classes-fall-2021-trnd/index.html>. Updated April 15, 2020. Accessed May 22, 2020.
10. Zhenghao C, Alcorn B, Christensen G, Eriksson N, Koller D, Emanuel EJ. Who's benefiting from MOOCs, and why. *Harv. Bus. Rev.* 2017;(1–11).

Industry News

By Steve Lin, Industry News Editor



AAOS cancelled its 2020 Annual Meeting due to the ongoing spread of the coronavirus disease (COVID-19). The Academy's board cited factors we've all grown accustomed to hearing—potential risks associated with a large gathering, increasing travel restrictions and the need for AAOS members to protect and help their local institutions and patients prepare for and respond to the spread of COVID-19.

The **European Parliament** voted in favor of the European Commission's proposal to postpone the **Medical Device Regulation (MDR)** until May 26, 2021. The vote is one of the last hurdles to MDR's postponement and is considered the death of the 2020 deadline. The final steps to postponement involve approval by the member states and publication of the postponement in the Official Journal before it will enter into force. The postponement has been expected since Stella Kyriakides, the European Commissioner for Health and Food Safety, [announced in March](#) that the commission would propose delaying MDR, due to the resources needed to combat COVID-19.

While medical technology is front and center in the fight against COVID-19, medical device companies are far from immune to the economic impact of the pandemic. **Boston Scientific** is "significantly reducing" the salaries of its CEO, board of directors and executive committee members as part of its mitigation plan for managing the financial impact COVID-19. **Conformis** recently [furloughed](#) one-third of its workforce (about 80 employees) and withdrew its 2020 guidance. Previously the Billerica, MA-based company was expecting to see a product revenue growth this year between three and six percent. **Second Sight Medical Products** is [laying off 84 of its 108](#) employees and said it intends to wind down operations. The Sylmar, CA-based company develops implantable visual prosthetics that are intended to create an artificial form of useful vision for blind individuals. Weight loss company **Obalon Therapeutics** is

exploring [financial and strategic alternatives](#). Such alternatives could include equity or debt financing, a sale of the company, a business combination or a merger or reverse merger.

COVID-19 is wreaking havoc on employers; layoffs and bankruptcies are inevitable. On March 18, the **Centers for Medicare & Medicaid Services** announced that all elective and non-essential procedures should be delayed during the COVID-19 outbreak to preserve hospital beds and supplies. Procedure deferrals impact all orthopedic market segments. Joint replacement and many types of spine procedures will have to wait. Trauma cases will continue, but the effects of social distancing and shelter-in-place orders will undoubtedly reduce the number of trauma incidents. Companies are bracing for excessive disruption. Revenue decline is estimated anywhere from a manageable four percent to a jarring 18 percent for 2020. The orthopaedic market is expected to recover eventually, due to demographics and the lasting economic need to keep us all active and productive.

Lima Corporate (Lima) and the **Hospital for Special Surgery (HSS)** will co-found what is reported to be the first additive manufacturing 3D printing facility for custom complex orthopaedic implants in a hospital setting. Operations are expected to begin by early 2020. The facility will be operated by Lima and reside on the HSS main campus in New York, and will combine Lima's manufacturing experience with HSS's clinical care and biomechanical engineering expertise. It will initially serve hospitals in the region, with plans to make devices available to all providers in the U.S., and will be accessible to all who need complex implants (not just HSS patients).

Startup company **Fusion Robotics** announced closure of an undisclosed sum of funding in 2019. Fusion Robotics seeks to introduce the world's first portable spinal robotic navigation offering. It can easily fit within a suitcase for simple travel. The full system comprises five parts, including a laptop, USB localizing camera, O.R. table mounting arms and a four-pound robot. A dedicated system also exists comprising the all-in-one computer, USB localizing camera, mounting arms, a four-pound robot and a system cart for storage. Fusion Robotics is in the process of finalizing their FDA 510(k) application with the expectation of receiving FDA clearance in the summer of 2020.

Joint replacement sales account for more than 35 percent of the total orthopedic market and surpassed \$19 billion in 2019. The joint replacement market is dominated by **Zimmer Biomet**, **Stryker**, **DePuy Synthes** and **Smith+Nephew**. These four major players hold a 73 percent market share with a combined growth rate around two percent yearly, while the next tier of

Industry News (continued)

players is growing at seven percent. A new **ORTHOWORLD®** report highlights the market leaders, procedure mix, surgeon comments and trends that will push joint replacement past the \$20 billion mark.

The “wait and see” period for enabling technology in orthopedics is over. Commentary from executives and spending patterns of the largest orthopedic companies affirmed that message in the first three months of 2020. Virtually all of the major players in orthopedics have shifted strategy to apply more focus and resources to enabling technology. Companies are allocating more R&D dollars to developing these internally, as well as pursuing acquisitions. Seven of the ten largest orthopedic companies have invested heavily in robotics. Companies like **Stryker** and **Medtronic** demonstrated the revenue-generating

power of enabling technology, and robotics specifically, throughout 2019. Stryker’s knee franchise grew 7.7 percent in 2019 over 2018, mainly contributed by their **Mako robot** as a primary driver.

IF YOU HAVE INDUSTRY NEWS TO SHARE
WITH *BIOMATERIALS FORUM* READERS,
SEND IT TO STEVE@EXAC.COM.

Update from the ECTM SIG (continued from page 10)

For many ECTM members in dual-income households with school-age children, trying to maintain some productivity while also developing and teaching homeschool lessons has been particularly challenging.

While nationwide lab closures have made research progress difficult, all ECTM members are doing their best to press forward. For example, Daniel Harrington (ECTM Industry Representative) of UTHealth in Houston was recently awarded SBIR Phase II funding alongside Mimetas US to develop 3D hydrogel models of patient-derived prostate cancer xenografts within their perfused microfluidic plates. Their team will develop racially diverse libraries of specimens to assay for drug sensitivity, and establish a platform for addressing questions of health disparities in the disease. Janet Zoldan (ECTM Secretary/Treasurer) of the University of Texas-Austin is gearing up to pivot her lab’s induced pluripotent stem cell (iPSC) research to investigate why age and comorbidities influence the mortality rate of COVID-19 so strongly. Ashley Brown (ECTM Chair) of North Carolina State University and UNC Chapel Hill has been working on developing novel material strategies to treat disseminated intravascular coagulation, which is emerging as an important contributor to mortality in COVID-19 patients.

Finally, the ECTM officers have been hard at work responding to the rescheduling of the World Biomaterials Congress by

organizing webinars for SFB members. Attendance is free, but advance registration is required, so register today at biomaterials.org/webinars! If you have an idea for a webinar that you would like to present or organize, please reach out to Ashley Brown (ECTM Chair) at aecarso2@ncsu.edu or Akhilesh Gaharwar (ECTM Program Chair) at gaharwar@tamu.edu to let them know.

*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

1120 Route 73, Suite 200 | Mount Laurel, NJ 08054

Phone: 856-439-0826 • Fax: 856-439-0525

Email: info@biomaterials.org

Government News

By Carl Simon, Government News Editor



COVID-19 OPEN RESEARCH DATASET CHALLENGE (CORD-19): AN AI CHALLENGE

In response to the COVID-19 pandemic, the White House and a coalition of leading research groups have prepared the COVID-19 Open Research Dataset (CORD-19). The research groups include the Allen Institute for AI (AI2), in partnership with the Chan Zuckerberg Initiative (CZI); Georgetown University's Center for Security and Emerging Technology and Microsoft Research (MSR); as well as the National Library of Medicine - National Institutes of Health, in coordination with The White House Office of Science and Technology Policy.¹ CORD-19 is a resource of over 29,000 scholarly articles (including over 13,000 with full text) about COVID-19, SARS-CoV-2 and related coronaviruses. This freely available dataset is provided to the global research community to apply recent advances in natural language processing and other artificial intelligence (AI) techniques to generate new insights in support of the ongoing fight against this infectious disease. There is a growing urgency for these approaches because of the rapid acceleration in new coronavirus literature, making it difficult for the medical research community to keep up.

COVID-19 HIGH PERFORMANCE COMPUTING CONSORTIUM

The COVID-19 High Performance Computing Consortium is a unique, private-public effort spearheaded by the White House Office of Science and Technology Policy, the U.S. Department of Energy and IBM. The idea is to bring together federal government, industry and academic leaders who are volunteering free compute time and resources on their world-class machines in support of COVID-19 research.² The consortium currently includes access to over 330 petaflops, 775,000 central processing unit (CPU) cores and 34,000 graphics processing units (GPUs). A petaflop is a unit of computing speed equal to one thousand million million (10^{15}) floating-point operations per second. Researchers are invited to submit COVID-19 related research proposals to the consortium, which will be reviewed for matching with computing resources from one of the partner institutions. An expert panel comprised of top scientists and computing researchers will work with proposers to assess the public health benefit of the work, with emphasis on projects that can ensure rapid results. Fighting COVID-19 will require extensive research in areas like bioinformatics, epidemiology and molecular modeling to understand the threat we're facing, and can form strategies to address it. This work demands a massive amount of computational capacity. The COVID-19 High Performance Computing Consortium helps aggregate computing capabilities from the world's most powerful and advanced computers to help

COVID-19 researchers execute complex computational research programs and help fight the virus.

BEMA ROUNDTABLE ON BIOMATERIALS SUPPLY CHAIN

Biomedical Engineering Materials and Applications (BEMA),³ is a "roundtable" initiative of the National Academies of Engineering, Science and Medicine (NASEM) that is administered by the National Materials and Manufacturing Board.⁴ BEMA held a meeting on "Issues and Opportunities Regarding the Availability of Biomaterials and Services for the Medical Device Industry" on March 9th at the Keck Center at the NASEM in Washington DC. The meeting was co-sponsored by the Society for Biomaterials. Initiated in 2000, BEMA is charged with considering issues of importance to the broad field of biomaterials and medical devices and is the second longest-running National Academies Roundtable. Major institutions from academia, industry and government are affiliates of BEMA, and individual biomaterials leaders are members. The FDA maintains lists of current drug and biologics shortages.^{5,6} The low profit margins on many essential medical supplies (antibiotics, sterile saline, vitamins) has driven manufacturing overseas, and the U.S. is anticipating more shortages in the wake of the COVID-19 pandemic which has caused factory closures in China and India.⁷ Twenty-five industry leaders attended the event and discussed issues that included the following:

- ASM Medical Materials Database⁸
- Ways to avoid material shortages
- The value in the U.S. manufacturing key materials within the homeland
- The role of standards in maintaining stable supply chains
- The Biomaterials Access Assurance Act of 1998 which protects suppliers from undue liability
- The ripple effect that can follow the disruption in the supply of a single key material

FDA ISSUES EMERGENCY USE AUTHORIZATIONS (EUA) FOR COVID-19 DIAGNOSTICS, VENTILATORS AND SURGICAL MASKS

The FDA has taken actions to expedite the availability of medical supplies for the COVID-19 pandemic COVID-19.⁹ The FDA has granted "Emergency Use Authorizations" for Diagnostics, Surgical Masks and Ventilators, and several tests can now be marketed without regulatory review. Further, the FDA has authorized state health agencies to oversee the validation and marketing of tests within their state without interaction with the FDA. The FDA has a "hotline" that test developers can call for immediate

(continued on page 17)

HAPPENING DURING THE COVID-19 PANDEMIC:

Revealing Your Inner Hero

By Fanny Chapelin

Below, in her own words, are the actions taken by Fanny Chapelin, Assistant Professor, F. Joseph Halcomb III, M.D. Department of Biomedical Engineering, University of Kentucky, to help fight the pandemic.

My call for action emanated from video calls I had with friends in the medical field the weekend following the start of the case number explosion in the U.S. (in mid-March). The University of Kentucky had just shut down the labs, and I was left flabbergasted, not knowing how to transfer my teaching responsibilities to an online format, and with my research plans in complete disarray. Former colleagues of my husband (who is a medical doctor in Kentucky) shared their anxiety about the level of unpreparedness and the ill-equipped conditions they were about to face in the coming days. I felt powerless in my job and powerless to help those in need. Many have made the analogy that our doctors are standing on the front lines of this COVID war. It is true, and they go there too often without proper support and personal protective equipment. Seeing what was happening in Europe, it seemed like a vision of what might happen in the U.S. Unfortunately, this vision came true.

While my husband and I were looking into ways we could help, both nationally and in Kentucky, a friend of mine posted on social media that he would be spending the weekend sewing face masks for medical professionals as a means to keep himself busy while social distancing. That was what I needed to do! My lifelong hobby has been to hand stitch all types of wall decor, personalized baby patterns and Christmas cards. Nonetheless, face masks definitely cannot be stitched by hand, as it would probably take the entire epidemic to sew a handful. A couple

days later, I bought a beginner's sewing machine, spent the morning watching YouTube videos and taught myself how to machine sew. By the end of the day, I had four masks done.

"I DID NOT GET INVOLVED TO RECEIVE ACCLAIM OR FAME, BUT TO STIMULATE WIDER INVOLVEMENT. I DEFINITELY DID NOT EXPECT OPPOSITION, BUT I DIDN'T LET IT DEMOTIVATE ME."

Some say that the internet and social media is both a blessing and a curse, but in these times, and for the national effort, I'd say it's been a game changer. There've been numerous social media groups forming out there to help with smart designs and resource sharing which have been efficient and helpful. In particular I want to mention the Superhero Mask Project, based in Kentucky, which focused on efficiency and prioritizing more than advertising and fame. Getting involved in making masks I faced praise, opposition and politics. I did not get involved to receive acclaim or fame, but to stimulate wider involvement. I definitely did not expect opposition, but I didn't let it demotivate me. As I mentioned above, looking at Europe, I knew many people would change their minds when the real crisis situation hit. At first, most of us worked of our own accord, and when official requests came in, we were glad we'd been working for



Adult masks



Children's-sized masks

Revealing Your Inner Hero (continued)

several weeks. Getting in touch with several university task forces, social media groups and even local representatives taught me that you can spend countless hours sending emails to different groups, that everyone has different (and strong) opinions, but mainly that few are ready to do the hard work or take actions, and most are in it for the recognition. So I took a step back and focused on my handiwork, waiting for decisions to be made.

It's been a month of social distancing now. I've shipped over 50 masks to New Jersey and Kentucky, and I am now starting to stitch children's-sized masks for the local children's hospital.

The Superhero Mask project has shipped over 400 masks nationwide. I am also helping now with producing alternative swabs for COVID testing at the University. These are difficult times, but I've chosen to see it as a gift of time. And I've decided to share this gift in the most meaningful way possible. As Bob Riley said, "Hard times don't create heroes. It is during the hard times when the 'hero' within us is revealed." I hope this story will encourage you to find your 'inner hero' and to contribute to mitigate this crisis that affects each and every one of us, one way or the other.



Dr. Chapelin wearing a mask

Government News (continued from page 15)

support. As of March 26, 2020, there were 16 tests with EUAs. In addition, the FDA is granting EUAs for ventilators, anesthesia gas machines modified for use as ventilators, positive pressure breathing devices modified for use as ventilators, ventilator tubing connectors and ventilator accessories. EUAs are also being issued for respiratory protective devices such as surgical masks and face masks, including the authorized use of expired devices. These relief actions were deemed necessary in order to respond to the pressing public health emergency of COVID-19.

FDA WORKING WITH MANUFACTURERS TO ADDRESS SHORTAGES IN PERSONAL PROTECTIVE EQUIPMENT (PPE)

An increased use of PPE in response to COVID-19 could lead to shortages at some institutions. Manufacturers of PPE who may be considering increasing the availability of these products (especially surgical masks and isolation gowns) to the U.S. market should contact the FDA to inquire about the potential for expedited review.¹⁰ The FDA wants to hear from manufacturers that can help alleviate potential shortages.

REFERENCES

1. Allen Institute for AI. <https://www.kaggle.com/allen-institute-for-ai/CORD-19-research-challenge>. Accessed May 26, 2020.
2. The COVID-19 High Performance Computing Consortium. <https://covid19-hpc.mybluemix.net/>. Accessed May 26, 2020.
3. Roundtable on Biomedical Engineering Materials and Applications . National Academies of Science website. https://sites.nationalacademies.org/DEPS/NMMB/DEPS_060366 . Accessed May 26, 2020.
4. About the National Materials and Manufacturing Board. National Academies of Sciences website. https://sites.nationalacademies.org/DEPS/NMMB/DEPS_060363 . Accessed May 26, 2020.
5. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA. FDA website. <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm> . Accessed May 26, 2020.
6. CBER-Regulated Products: Current Shortages. FDA website. <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages> . Accessed May 26, 2020.
7. Government of India, Directorate General of Foreign Trade. Amendment in Export Policy of APIs and Formulations Made from These APIs. Notification No. 50/2015-2020; New Delhi, India, March 3, 2020. https://dgft.gov.in/sites/default/files/Noti%2050_0.pdf . Accessed March 16, 2020
8. COVID-19. ASM International website. <https://www.asminternational.org/> . Accessed May 26, 2020.
9. Coronavirus Disease 2019 (COVID-19). FDA Website. <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19> . Accessed May 26, 2020.
10. FAQs on Shortages of Surgical Masks and Gowns During the COVID-19 Pandemic. FDA website. <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns> . Accessed May 26, 2020.

HAPPENING DURING THE COVID-19 PANDEMIC:**Providing Regulatory Guidance From the Dining Room**

By Jeffery Toth

During the pandemic, Jeffrey Toth, Professor of Orthopaedic Surgery and Director of Biomaterials Research, School of Medicine at the Medical College of Wisconsin, provided regulatory guidance to a consortium of manufacturers who were springing into action to produce N95 masks. N95 masks are classified by the USFDA as Class II (intermediate risk) devices. As of late March, the FDA had listed three separate product codes for N95 masks governed by two different specific regulation numbers. In addition, on an emergent basis, the FDA issued a March guidance document entitled, "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency," and has since listed a

fourth product code for N95 masks on the FDA medical devices classification website. Although some requirements for N95 masks may be exempted in the face of the health crisis, 1) The necessity to assure the SAFETY and EFFICACY of the N95 masks as USFDA-regulated medical devices is not exempted, and 2) General controls – that is, registration with the FDA as a medical device manufacturer, proper labeling etc. are all still in play. Dr. Toth helped members of the consortium sort out these requirements and regulations during the public health crisis.



Jeff Toth was working in his dining room to provide regulatory guidance.

HAPPENING DURING THE COVID-19 PANDEMIC:

Contributing Ideas and Technology to the CDC

By Shannon Nargi

Since the outbreak began in late 2019, researchers have been racing to learn more about COVID-19, or SARS-CoV-2, a strain from a family of viruses known as coronavirus (named for their crown-like shape).

Thomas Webster, who specializes in developing nano-scale medicine and technology to treat diseases, is part of a contingency of scientists that are contributing ideas and technology to the Centers for Disease Control and Prevention to fight the COVID-19 outbreak.

The idea of using nanoparticles, Webster says, is that the virus behind COVID-19 consists of a structure on a similar scale as his nanoparticles. At that scale, matter is ultra-small, about ten thousand times smaller than the width of a single strand of hair.

Webster is proposing particles of similar sizes that could attach to SARS-CoV-2 viruses, disrupting their structure with a combination of infrared light treatment. That structural change would then halt the ability of the virus to survive and reproduce in the body.

"You have to think in this size range," said Webster, who is the Art Zafiropoulo Chair in Engineering at Northeastern, "in the nanoscale size range, if you want to detect viruses, and if you want to deactivate them."

Finding and neutralizing viruses with nanomedicine is at the core of what Webster and other researchers call theranostics, which focuses on combining therapy and diagnosis. Using that approach, his lab has specialized in nanoparticles to fight the microbes that cause influenza and tuberculosis.

"It's not just having one approach to detect whether you have a virus and another approach to use as a therapy," he said, "but having the same particle, the same approach, for both your detection *and* therapy."

SARS-CoV-2 spreads mostly through tiny droplets of viral particles — from breathing, talking, sneezing or coughing — that enter the body through the eyes, mouth or nose. Preliminary research also suggests that those germs may survive for days when they attach themselves to countertops, handrails

and other hard surfaces.

That's one reason to make theranostics with nanoparticles the focus of the COVID-19 outbreak, Webster said.

Nanoparticles can disable these pathogens even before they break into the body, as they hold on to different objects and surfaces. His lab has developed materials that can be sprayed on objects to form nanoparticles and attack viruses.

"Even if it was on a surface, on someone's countertop, or an iPhone," he said. "It doesn't mean anything because it's not the active form of that virus."

That same technology can be fine-tuned and tweaked to target a wide range of viruses, bacteria and other pathogens. Unlike other novel drugs with large molecular structures, nanoparticles are so small that they can move through our body without disrupting other functions, such as those of the immune system.

"Almost like a surveyor, they can go around your bloodstream," Webster explained. "They can survey your body much easier and with much longer times to try and detect viruses."

To do all that, the CDC needs to know the specifics about what kind of structure is needed to neutralize SARS-CoV-2, Webster said. That information isn't public yet.

"You have to identify what we need to put in our nanoparticle to attract it to that virus," he said. "The CDC must know that, because they've developed a kit that can determine if you have [COVID-19] versus influenza, or something else."

An alternative to nanomedicine is producing synthetic molecules. But Webster says that tactic presents some challenges. In the case of chemotherapies used to treat cancer cells, such synthetic drugs can cause severe side effects that kill cancer cells, as well as other cells in the body.

"The same thing could be happening with synthetic chemistry to treat a virus, where molecules are killing a lot more than just that virus," Webster explained.

Still, Webster acknowledges that there aren't many researchers focusing on nanoparticles to kill viruses.

One of the main reasons for the lack of those solutions is that the same benefits that make nanoparticles ideal to fight infectious diseases also make them a concern for the United States Federal Drug Administration.

Because of their size, nanoparticles are pervasive (too pervasive, maybe) to seep through other parts of the body. To reduce that risk, Webster's lab has focused on using iron oxide, particles that make up entail chemistry that is already natural to our bodies and diets.

"Even if you have a viral infection, you need more iron, because you could be anemic depending on how bad the infection is," Webster said. "We're actually developing these nanoparticles out of chemistries that can help your health."

And, he added, iron-based nanoparticles could be directed with magnetic fields to target specific organs in the body, such as the lungs and other areas susceptible to respiratory complications after contracting viral infections. That too, Webster said, is something that you couldn't do with a novel synthetic molecule.

"Really, what this all means is that we just have to do the studies to show those iron nanoparticles are not going into the brain or the kidney," Webster explained, "that these nanoparticles are going exactly where you want them to go-to the virus."



Thomas Webster is contributing ideas and technology to the Centers for Disease Control and Prevention to fight the COVID-19 outbreak.



Society For
Biomaterials

2021

ANNUAL
MEETING &
EXPOSITION

BIOMATERIALS RESEARCH:

*Hitting all the right notes, and
avoiding the translational blues*



CHICAGO

APRIL 21-24, 2021 • HILTON CHICAGO, IL

www.biomaterials.org