

BIOMATERIALS

FORUM



OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

First Quarter 2014 • Volume 36, Issue 1



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BIOMATERIALS FORUM



The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 36, Issue 1

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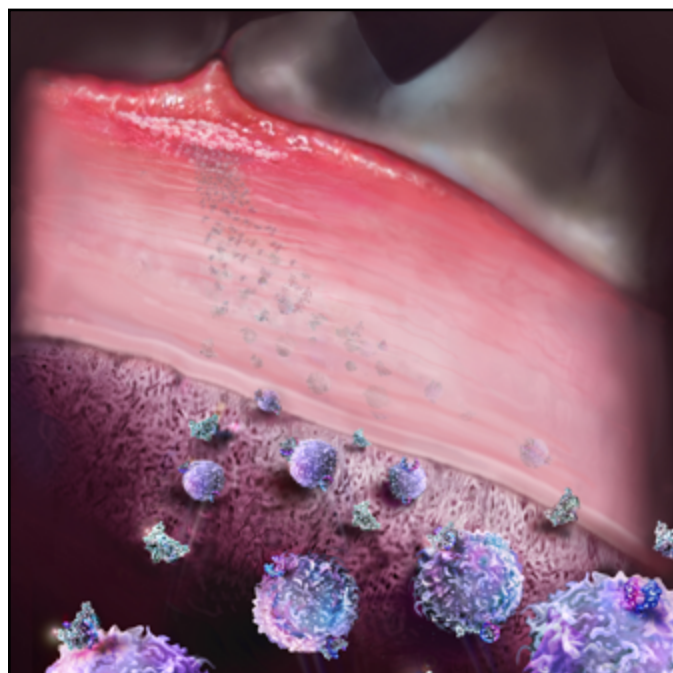
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On the cover: Pictured is an illustration of regulatory T cells (blue/violet) migrating through canine gum tissue, guided by a gradient of chemokines that originates from implanted controlled release microspheres in the periodontal pocket. Gum disease is an inflammatory disease that leads to the breakdown of gum tissue and tooth supporting bone, and is associated with a number of diseases including heart disease, stroke, and even premature childbirth. Current clinical treatments are focused on the temporary removal of bacteria that initiate the disease. Glowacki et al. explore an alternate treatment strategy by promoting local immunological homeostasis in the gums through the local recruitment of regulatory lymphocytes. The tooth in this image is portrayed from microCT scans of treated canine molars. See the full article by Glowacki AJ, Yoshizawa S, Jhunjhunwala S, Vieira AE, Garlet GP, Sfeir C, Little SR. Prevention of inflammation-mediated bone loss in murine and canine periodontal disease via recruitment of regulatory lymphocytes. *PNAS*, (2013), 110, 46, 18525-30. Image courtesy of Randal McKenzie, McKenzie Illustrations.



Greetings fellow biomaterials scientists,

Welcome to the news magazine of the Society For Biomaterials! Our goal is to keep you up to date on the latest activities within our Society and within the broader biomaterials community. The *Forum* provides a platform for discussion of scientific, business, philosophical and legislative matters related to biomaterials. In the *Forum*, you'll find short reviews highlighting the latest biomaterials developments, announcements of key business deals between corporations, tips for improving biomaterials education, highlights of our impressive member achievements, book reviews, career stories and more. Here's a sampling of what you'll find within this issue:

- It's election time! Please read the officer nominee biosketches and cast your vote today for the next President-Elect and Member at Large of the Society For Biomaterials. Information about the nominees can be found starting on page 8.
- The 2014 SFB Award recipients are announced in this issue and will be awarded at the upcoming SFB meeting in Denver, April 16-19, 2014. Don't forget to register early to take advantage of reduced registration fees.
- In the Member News section you'll find announcements of recent prestigious professional awards, advancements and relocations of our SFB members.
- A letter from the SFB Student President describes the ways in which students can participate within SFB and reap the rewards that activity and networking within a professional society can provide. Students: don't forget the upcoming Biomaterials Education Challenge 2014, in which student teams are challenged to develop an educational module for middle school science classes.
- Read about the impact of open on-line courses in the Education News column. It might surprise you to learn that up to 46 percent of all

students have now participated in one or more on-line courses.

- There will be a number of interesting panel discussions at the upcoming meeting in April. One of them I'd like to draw your attention to is about how to make a retrieved implant archive a reality. While the value of retrieved implants, such as total joints, for educational and research purposes is undeniable, the dark side of legal investigations has tainted and retarded previous efforts to establish such an archive. Please share your opinion about how to make a retrieved implant archive a reality by participating in this panel at the annual meeting or by sending in your comments to me at the *Forum*. I'll be compiling information about this topic and publishing a review in a future issue.
- The Industrial News includes an overview of the latest mergers and acquisitions and other notable corporate decisions, as well as highlights of policy decisions being made in this country and others that may affect your ability to conduct biomaterials-related business. Also, see the first SFB Business Plan Competition announcement under SIG news.
- In the book review corner, two books about bio-ethics are reviewed. The clinical use of biomaterials is slowly expanding from a device to a combination product with living cells, and it's important to have an informed, ethically sound strategy to conduct research in this field. These books can help inform your opinion and process.

Best wishes,

Biomaterials Forum Executive Editor

Associate Professor
University of Connecticut Health Center

CONTRIBUTE TO THE FORUM

Biomaterials is a diverse and fascinating field. Help us to make sure this publication reflects news of interest to you. I invite you to prepare a biomaterials-related article or opinion piece or cover art and send it to me at Lkuhn@uchc.edu for inclusion in one of the next issues of the *Biomaterials Forum*.



Making Progress

A main goal of our Society is to maintain and enrich our membership. As a Society we benefit tremendously from the expertise and varied backgrounds of our members. A diverse and healthy-in-numbers membership helps all of us identify and promote activities that reflect the interests and aspirations of our community. In an effort to increase our membership and enhance the benefits offered to our members, we have implemented a number of measures over the last year. These measures have emerged from many discussions of our members.

First, we endorsed a recommendation of the Special Interest Group (SIG) Representative Steve Little and we are offering one free SIG subscription with every new or renewed membership. SIGs provide a great way to get involved with the Society as they bring together members with similar interests. We have witnessed over the years many grass-root activities of SIGs serve as forums for fruitful interaction between academia and industry. Importantly, SIGs are heavily involved in shaping the program of our annual meeting. Participation in a SIG has been a successful way to make members realize the benefits of membership. We hope that the infusion of SIGs with new members will help expand the activities and outreach of SIGs, and consequently our Society.

Second, we approved a proposal from the Membership Committee and the registration fee to the annual meeting can now optionally include the annual membership fee to facilitate expense justification and tracking for our members. We also hope that this option will attract new members who will experience the benefits of membership and renew their membership together with their registration fee to the annual meeting for years to come.

Third, starting in 2015, we will have two program chairs for our annual meeting: one from academia and one from industry. Such a move will bring much needed expertise for making the meeting even more relevant to our colleagues from industry. The annual meeting can serve as a catalyst for progress in our field, progress that cannot be achieved by academia or industry only.

Fourth, we supported a recommendation from the Liaison Committee and initiated discussions with the Americas Chapter of the Tissue Engineering and Regenerative Medicine International Society to explore future opportunities for joint annual meetings of the two Societies. The huge success of the 2006 annual meeting of our Society in Pittsburgh, which had one overlapping day with the Regenerate World Congress on Tissue Engineering and Regenerative Medicine, clearly showed the added value of joint activities for both memberships.

Last but not least, for the past three years the Long Range Planning Committee has been instrumental in crafting the mission and vision of our Society and identifying its goals and also proposing the activities and strategies associated with these goals. Thanks to Nick Ziats and the rest of the committee, we are in the process of prioritizing and implementing these proposals for the benefit of our Society.

Our warmest congratulations are due to Joo Ong, Chair and the rest of the Program Committee of our 2014 Annual Meeting and Exposition. They have put together an exceptional program on Pioneering the Future of Biomaterials including 16 symposia, 38 general sessions, 5 panel discussions, and 2 tutorials of what promises to be a most successful meeting in Denver. Participants will also be able to select from a number of very interesting workshops including a workshop on “US vs. China – Regulation, Standard, and Innovation,” which continues the tradition of a very successful workshop of last year, and a “Research and Product Development from an Industry Perspective,” among others.

I look forward to seeing you in Denver. Denver can be the start of a series of meetings with very broad attendance from academia and industry where all voices are heard, and where our Society grows stronger. We have a fantastic meeting to look forward to.

Antonios G. Mikos
President, Society For Biomaterials
January 30, 2014

Hello from Society For Biomaterials headquarters! As we gear up for SFB's 2014 Annual Meeting in Denver, the committees are working on the initiatives established at the fall board and council meeting.

Awards, Ceremonies and Nominations – Chair Nicholas Peppas

The 2014 award recipients have been notified and a press release issued announcing their selection has been issued. The full article can be found starting on page 6 in this issue. In addition, the slate of officer candidates is on p. 8. The committee reminds all members to vote for the 2014-15 officers.

Bylaws – Chair Jiro Nagatomi

The committee is preparing to seek feedback from council and the membership before proposing any amendments to the bylaws allowing for a board structure that might permit extending the terms of the presidency or adding additional Members-at-Large.

Devices & Materials Committee – Chair Andy Doraiswamy

The committee is working on a self-guided tutorial on “what to disclose” that would become a requirement upon acceptance of an oral presentation assignment. Additional information about this idea will be presented for approval at the spring council meeting, with adoption to be executed in conjunction with the 2015 annual meeting.

Education and Professional Development – Chair William Murphy

The committee is supporting the second Biomaterials Education Challenge in which student chapters will compete in creating study modules aimed at eighth grade science students. Details are available on the 2014 meeting website.

Congratulations to the following chapters on being selected to receive a fall 2013 student chapter award:

- Columbia University
- UCLA
- North Carolina State University
- University of Florida
- Colorado School of Mines

Finance – Chair Lisa Friis

Because the total reserves (both operating and long term) are healthy—in excess of \$1.4 million—the Society has

invested in several new initiatives for 2014. One of these is the launch of a new website, which is scheduled to go live in March. Members have already started taking advantage of the ability to join one Special Interest Group for free, and the inclusion of

membership dues with meeting registration was initiated with this year's meeting.

Liaison – Chair David Puleo

The Liaison Committee is working with MRS to formalize collaborations on an ongoing basis. A joint task force is also being created with TERMIS-NA to discuss possibilities for co-locating future meetings.

Long Range Planning – Chair Nicholas Ziats

SFB is evaluating its stature on the public stage and looking for ways to increase its reach and expand its membership. The inclusion of membership dues in the 2014 meeting registration is one way this expansion will be implemented. The Liaison and Membership Committees' work complements this goal as well.

Meetings – Chair Antonios Mikos

A recommendation will be made to council at the April meeting on possible options for a 2016 event, such as a small, narrowly-focused symposium at a university, or possibly a collaboration with an existing event.

Membership – Chair Horst Von Recum

Several initiatives have begun to increase membership, including recruitment campaigns at Biomaterials Days, other society meetings and including membership as a component of meeting registration, effectively eliminating the non-member registration category. The committee will study the impact of these initiatives later in the year to see which should be continued or expanded.

2014 Program – Chair Joo Ong

The program planning meeting was held on January 14, 2014 and the schedule of sessions prepared. Late-breaking abstracts for poster presentations only were accepted until February 3. The final program book has been redesigned for 2014 to make all of the information easier to find and the program easier to follow.

Publications – Chair Alan Litsky

Social Networking: In addition to the normal eblasts and printed materials, updates and reminders about the 2014 meeting in Denver will be posted on SFB's LinkedIn site and Facebook fan page to reach those who frequent social media.

Biomaterials Forum (Editor Liisa Kuhn): Over the past year, a steady stream of content solicited from the membership and the SIGs has helped make each issue interesting and meaningful to our readers. Thank you! The full-color version of each issue is now posted on the SFB website.

Website (Editor Tom Webster): The new Society website is projected to launch in March. It will feature enhanced member

profiles and more interactive community pages for the SIGs and committees. It is planned that research being done by members will be featured throughout the year.

Book Series (Editor Jeffrey Hubbell): Volunteers are still being sought for more books for the series. Please contact SFB headquarters if you have an idea for a book in the biomaterials field!

Biomaterials Bulletin (compiled by Multibriefs): The *Bulletin* e-newsletter continues to feature a compilation of relevant articles about the field of biomaterials from across the Internet. It is sent to members bi-weekly.

Special Interest Groups – Representative Steve Little

Seven of the 14 SIGs volunteered to experiment with holding their meeting in Denver during a concurrent session time slot, provided that none of the concurrent sessions are related to that SIG’s area of specialization. The remaining SIGs will continue to meet before the sessions start. SIGs have also been working on updating their websites prior to having them transition to the new SFB website. They have provided keywords to use as metatags on SFB’s new website SIG pages.

SUGGESTIONS?

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

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Advances in Tissue Engineering

Rice University

**Center for Excellence in Tissue Engineering,
BioScience Research Collaborative,
Institute of Biosciences and Bioengineering,
Department of Bioengineering**

**Houston, Texas
August 13 – 16, 2014**

Twenty-second annual short course with leading scientists from Rice University, the Texas Medical Center, industry, and other institutions on advances in the science and technology of tissue engineering. Be informed on the latest technology in the world of patient-specific therapeutics, from transplantation of cells and tissues to artificial organs.

For biomaterialists, biomedical engineers, physicians, technical managers, and others involved in research in the areas of:

- Stem cell biology
- Cell & tissue culture
- Applied immunology
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- Organ & cell transplantation
- Vascular surgery
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- Reconstructive surgery
- Gene therapy
- Nanobiotechnology



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The Society For Biomaterials proudly announces its 2014 award recipients. These Society professionals are recognized for their outstanding achievements in and contributions to the biomaterials field. Each award recipient will be honored during the opening ceremonies of the 2014 Annual Meeting and Exposition, April 16-19 in Denver, Colo.

Founders Award

Rena Bizios, PhD, University of Texas at San Antonio

Dr. Bizios is the recipient of the 2014 Founders Award for her long-term landmark contributions to the discipline of biomaterials. Professor Bizios's research activities have established her as a pioneer and leader in cellular engineering and cell-biomaterial interactions, including nanostructured materials.

"Professor Bizios has been an early and relentless advocate for applying knowledge from the biological sciences to the discipline of biomaterials," says nominator David Puleo, PhD.

Professor Bizios has tirelessly served the SFB and the field of biomaterials for more than four decades. She has devoted her time and seemingly endless energy to activities spanning meetings that established bioengineering and biomaterials within the NIH to recently helping to launch a student chapter of the Society at UTSA.

C. William Hall Award

Robert Hastings, MS, PE, Depuy Orthopaedics

Mr. Hastings was nominated by Alan S. Litsky, MD, ScD, for the C. William Hall Award for his significant contributions to the SFB and his outstanding record in establishing, developing, maintaining and promoting the objectives and goals of the Society.

"Bob is committed strongly to the Society as THE place for study and discussion of orthopedic biomaterials and to assuring that orthopedic medical devices are the best they can be given the science and understanding as we know it," says colleague Jeremy L. Gilbert, PhD.

Mr. Hastings has been an active member of the Society for more than 20 years and served in many capacities, including abstract reviewer, session moderator, Membership Committee chair, Council member, president's Long-Range Planning Committee member and Orthopaedic Special Interest Group chair.

Society For Biomaterials Award for Service **Anne Meyer, PhD, The School of Dental Medicine** **at The University of Buffalo**

Dr. Meyer is the recipient of the Society For Biomaterials Award for Service for her significant service to the Society by establishing, developing, maintaining and promoting its objectives and goals.

"I am particularly impressed in Anne's leadership roles within our organization, as well as her serving as an important role model for women in our Society," says nominator Nicholas P. Ziats, PhD.

Dr. Meyer has published a significant number of publications in biomaterials research, particularly in the area of biofouling, with many prominent members of the Society over the past 30 years.

Technology Innovation & Development Award **Kishore Udipi, PhD and the Medtronic Resolute Integrity Team**

Dr. Udipi and his team are receiving the 2014 SFB Technology Innovation and Development Award. The award recognizes an individual or team who provided key scientific and technical innovation and leadership in a novel product in which biomaterials played an important and enabling role.

"The Resolute Integrity™ DES, based on the BioLinx™ polymer system, is well received by clinicians globally and is a great polymer innovation story," says nominator Josiah N. Wilcox, PhD.

The Medtronic Team has creatively developed a biocompatible drug eluting polymer blend, BioLinx, which is used today in the Medtronic Resolute Integrity drug eluting stent. It is the only drug eluting stent approved by the FDA for a diabetic indication.

Clemson Award for Applied Research **Ravi Bellamkonda, PhD, Georgia Institute of Technology**

Dr. Bellamkonda will receive the 2014 Clemson Award for Applied Research for his significant utilization and application of basic knowledge in science to accomplish a significant goal in the biomaterials field.

"To know Professor Ravi Bellamkonda is to appreciate a gentleman respectful of the personalities, potential and contributions of all, yet personally intense in his focus on benefiting society at large," says nominator Arthur J. Coury, PhD.

Professor Bellamkonda is a thought leader and seminal contributor to the literature and the basic knowledge of interaction of polymeric materials and the nervous system. As a teacher, he recently received the best professor award from undergraduate students in biomaterials education at GIT—an honor that has only been conferred upon four professors in the last 12 years.

Candidates for the SFB Young Investigator Award must be within 10 years of receipt of their terminal degree (PhD or equivalent) and, if they work in an academic institution, must not be tenured at the time of nomination.

“Brendan has not yet peaked as an independent investigator,” says nominator William L. Murphy, PhD. “His already impressive productivity is just the tip of a large iceberg.”

Dr. Harley’s more recent studies exert a higher level of biochemical control over new tissue formation via innovative spatial patterning schemes. His initial studies have led to significant insights into the balance between hematopoietic stem cell quiescence versus self-renewal and lineage specification.

2014 Student Awards for Outstanding Research Adam Young, PhD candidate, University of California, San Diego

In addition to his lab work, Mr. Young is passionate about getting involved and having an impact on others, including increasing diversity in science and engineering. He is very involved in the UCSD BioBridge program, which works to encourage young students to go into STEM fields. He has worked in classrooms across San Diego as a mentor and given talks in summer conferences to aspiring young scientists. Mr. Young has also received the prestigious National Science Foundation (NSF) graduate research fellowship as well as an additional fellowship from NSF as part of the Engineering Innovations Fellows Program, which is allowing him to do a paid internship this summer at Cytograft, Inc.

“Adam is an extremely bright and motivated student who was developing his own ideas and planning his own studies even in his first year in graduate school, which is rare,” says nominator Karen L. Christman, PhD. “Adam is an outstanding graduate student both in and outside of the lab and will undoubtedly be a leading engineer in the field.”

Stephanie Tzouanas, senior bioengineering major at Rice University

Ms. Tzouanas’ accomplishments include proficiency in the analysis of nano-scale samples derived from a novel drug delivery system consisting of genetic material (siRNA) and a polymer carrier, investigations towards the synthesis and characterization of thermally and chemically gelling hydrogels for bone tissue engineering applications, and, most recently, investigations towards the development of novel injectable stem cell-based therapies leveraging thermally and chemically gelling hydrogels with enormous implications in tissue engineering and regenerative medicine.

“Stephanie is the most talented, dynamic, and innovative undergraduate student I have worked with in my 21 years at Rice,” says nominator Antonios Mikos, PhD. “She has exceptional intellectual promise, drive, self-discipline and an insatiable appetite for new knowledge.”



Clemson Award for Basic Research Elazer Edelman, PhD, Harvard-MIT Biomedical Engineering Center

Dr. Edelman is being honored with the Clemson Award for Basic Research for his contributions to basic knowledge and understanding of the interaction of materials with tissue.

“Elazer is the rare chimera of engineering and medicine, science and biology,” says nominator Robert S. Langer, ScD. “He is the model of how engineering principles, techniques and practices can be made to change medicine, drive healthcare innovation and lead to the life-saving and life-enhancing solutions.”

Dr. Edelman is a prolific research scientist, having written 240 articles, 32 patents and 240 abstracts and conference proceedings. His work has founded nine start-up companies and developed many healthcare products.

Clemson Award for Contributions to the Literature Rui Reis, PhD, University of Minho

Dr. Reis is the recipient of the 2014 Clemson Award for Contributions to the Literature for his significant contributions to the literature on the science and technology of biomaterials.

“Rui enjoys challenging the institutional conventional wisdoms,” says nominator Buddy D. Ratner, PhD. “In doing so, he is cognizant of the risks and follows his own vision—he believes that the values of competence, hard work, talent and strategy should be valued equally to the well-trodden paths to success.”

Over the years, Professor Reis has made outstanding contributions to the biomaterials field in the development and engineering of natural-based biomaterials, and in proposing several new strategies in the fields of tissue engineering and regenerative medicine.

Young Investigator Award Brendan Harley, ScD, University of Illinois

Dr. Harley is the recipient of the 2014 SFB Young Investigator Award for his achievements in the field of biomaterials research.

President-elect

The President-elect shall become familiar with the duties of the President and shall, at all times, cooperate and assist with the duties of that office. In the absence of the President, the President-elect shall preside at the meetings of the Society, the Council and the Board of Directors, and perform the duties and exercise the powers of President. The term of office is for a period of one year without succession. The President-elect is the chairperson of the Long Range Planning Committee.

Nominees for President-elect



Kinam Park, PhD
Showalter Distinguished
Professor of Biomedical
Engineering
Professor of
Pharmaceutics
Purdue University, West
Lafayette, Ind.

Biographical Sketch: Kinam Park received his PhD in pharmaceutics from the University of Wisconsin in 1983. After postdoctoral training at the Department of Chemical Engineering of the same university, he joined the faculty of Purdue University in 1986 and was promoted to Full Professor of Pharmaceutics in 1994. Since 1998, he has also had a joint appointment in the Department of Biomedical Engineering, and became Showalter Distinguished Professor of Biomedical Engineering in 2006. His research has been focused on the use of polymers and hydrogels for controlled drug delivery and biomedical applications. His current research includes microparticles for long-term drug delivery, polymeric micelles and drug crystals for enhanced drug bioavailability and drug-eluting stents and balloons. He has published more than 240 peer-reviewed papers, 90 book chapters and 100 JCR cover stories. He published 11 books in the area of controlled drug delivery, and trained 100 PhD graduate students, postdoctoral fellows and visiting scientists. He founded Akina, Inc., specializing in drug delivery technologies, in 2001. He is currently the editor-in-chief of the *Journal of Controlled Release*.

Vision Statement: We must be bold again. In the early 1980s, the first total artificial heart was implanted in a human patient. At that time, the biomaterials scientists predicted that the tissue-engineered heart would be developed within 10 years. That bold dream still remains a dream even three decades later. We ask ourselves: What is necessary to achieve that dream? Advances in science and technology are incremental and take time. But can we accelerate the process so that we can achieve the dream in

the next two decades? Let's set a goal of building a total tissue-engineered heart by the year 2034. Achieving that goal will require much more than the technologies available now and in the next several years. It will require much more than smart materials, 3D printing, organ on a chip or stem cell engineering. The vast expanses of the unknowns in creating a tissue-engineered heart is beyond our current grasp, but such efforts will organize the best of our abilities to create new technologies and knowledge necessary. The efforts will also propel the scientists to move forward beyond the comfort zone. Let's build the environment where a new generation of biomaterials scientists can build what we can only dream of today. The Society For Biomaterials has to be the agent for leading this effort. Making a fully functional heart is not just an engineering problem, rather, it requires active participation of scientists of various disciplines including cellular and molecular biologists. The Society For Biomaterials has to expand its member basis beyond traditional engineers. If elected, I will focus on setting up specific goals for the next 20 years of biomaterials research, recruiting scientists from other disciplines critical for achieving the goal, and starting a new journal to promote the cause. To do this and do other things right, we must be bold again.



Thomas J. Webster, PhD
Chair and Professor
Chemical Engineering
Department
Northeastern University,
Boston, Mass.

Biographical Sketch: Tom's degrees are in chemical engineering from the University of Pittsburgh (B.S., 1995) and in biomedical engineering from Rensselaer Polytechnic Institute (M.S., 1997; Ph.D., 2000). He is currently the Department Chair of Chemical Engineering and helping to form a new Department of Bioengineering at Northeastern. His research explores the use of nanotechnology in medical applications. He has graduated over 109 visiting faculty, clinical fellows, post-doctoral students and thesis completing B.S., M.S. and Ph.D. students. To date, his lab group has generated more than nine textbooks, 58 book chapters, at least 403 peer-reviewed literature articles, at least 567 conference presentations, 306 invited presentations and 32 provisional or full patents. His H index is 58 (Google Scholar). He has formed nine companies, which are currently improving the health of patients around the world. He has appeared on MSNBC (October 10, 2005), NBC Nightly News (May 14, 2007), PBS (from the winter of 2008 to the present), ABC Nightly News via the Ivanhoe Medical Breakthrough Segment (covered across the U.S. during the winters of 2008 and separate

research segments in 2010 and 2011), the London and Boston Science Museums (2009 to present) and Fox News (December 16, 2013) discussing how biomaterials can improve medicine. He is the founding editor-in-chief of the *International Journal of Nanomedicine* (an open access journal with a five year impact factor of 4.97), serves on the editorial board of 15 additional journals, has helped to organize 22 conferences and has organized more than 53 symposia at numerous conferences.

He has received numerous honors including, but not limited to:

- 2002, Biomedical Engineering Society Rita Schaffer Young Investigator Award
- 2003, Outstanding Young Investigator Award Purdue University College of Engineering
- 2005, American Association of Nanomedicine Young Investigator Award Finalist
- 2005, Coulter Foundation Young Investigator Award
- 2006, Fellow, American Association of Nanomedicine
- 2010, Distinguished Lecturer in Nanomedicine, University of South Florida
- 2011, Outstanding Leadership Award for the Biomedical Engineering Society (BMES)
- 2011, Fellow, American Institute for Medical and Biological Engineering (AIMBE, representing the top 2 percent of all medical and biological engineers)
- 2013, Fellow, Biomedical Engineering Society

Tom has been an active member of SFB since he was a graduate student, attending his first annual meeting in 1996. He has served on the Society's Council since 2007 as the Web Editor, now in his second term. As Web Editor, in 2008, Tom oversaw revamping of the SFB website with added features such as the "Biomaterial of the Month," which has served as an educational source for students around the world. This year, he is leading another SFB website reorganization to add features such as chat rooms, webinars and other interactive features. Tom's other contributions to SFB include: organizing nine symposia at SFB annual conferences throughout the years, forming the Nano SIG and serving as Chair and Vice-Chair of the PCI SIG, where he started the first SIG newsletter and student research awards which later become the current STAR awards. Tom is also the Founding Faculty Advisor for the Northeastern University SFB Student Chapter.

Vision Statement: When you find the right balance of enthusiastic people, cutting-edge science and life-lasting memories, you know you found a place where you belong. As a graduate student, I still vividly remember my first SFB conference when I realized this is where I belonged. I sat in the audience listening to world experts

talk about the past, present and future of biomaterials, always optimistic, always leaning forward, but questioning research every step of the way. I learned. I met life-long colleagues. I even gave a couple of presentations along the way. The bright lights, the podium, the microphones, the SFB banner, and yes, even the red lights that tell you to stop talking—this is the formality of a SFB presentation. This is the "seriousness" that SFB installs in biomaterials' research and education. It was these events and this Society that motivated me to pursue a lifelong career in biomaterials.

Each of us has our own experiences and reasons why SFB is our home. In my own way throughout the years, I have tried to keep the strong SFB tradition going. We have all seen what is happening with on-line education, webinars, electronic posters at conferences, journal video abstracts, asynchronous learning tools and open access journals. As the SFB Web Editor since 2007, I lead efforts to continually revamp our website to reach a broader audience and to meet our changing membership needs. Our "Biomaterial of the Month" and "Surgical Video Library" features are some of the most accessed sites on our revamped website. As President, I will continue and expand our efforts to make our website a role model that other Societies will surely follow.

But obviously, online tools can never replace the importance of face-to-face meetings. As President, I will work very hard to explore innovative ways to increase membership and attendance at our meetings. Establishing SFB sponsored co-operative or summer research fellowships between SFB student members and SFB industry, clinical and academic members would go a long way improving education, collaborations and value to SFB membership. Establishing "Company Start-up Challenges" would also highlight the breadth of innovative translational research that is presented at our annual meeting. Building upon the very successful Biomaterials Day program, we could expand such efforts into regional mini-conferences (on-site or via the Internet). Establishing SIG sponsored mini-conferences in specific research breakthroughs could also promote collaboration in an informal "Gordon Conference" format. Establishing more awards (such as Diversity and Government Policy Awards) would also continue to highlight our members excelling in these critical areas.

Having served on Council since 2007, I have seen how the SFB President is critical to move the Society forward. I am honored to even be considered to follow some of the prestigious individuals who have held this office. It is from listening to them when I was a student that made me want to belong to SFB and, now, to make it an even better society.

Member-at-Large

The Member-at-Large shall serve as an unencumbered representative of the membership at meetings of both the Board of Directors and Council. The Member-at-Large shall serve for a period of one year.

Nominees for Member-at-Large



Sachin Mamidwar, MS
CEO, Orthogen, LLC
Springfield, N.J.

Biographical Sketch: Sachin Mamidwar has been involved in biomaterials research and development for a decade and a half. He received a medical degree from the University of

Pune, India, and a Master of Science from the joint Biomedical Engineering Program of Rutgers University and The University of Medicine and Dentistry of New Jersey. Upon graduation, he worked as a research engineer at the Orthogen Corporation. Sachin rose through the ranks to become first the Director of Product Development and Clinical Affairs followed by General Manager, and eventually to the position of CEO of Orthogen, LLC, which was spun off from the company in 2007. He was inducted as a fellow in the American Institute of Medical and Biological Engineering in 2012.

Sachin’s research focuses on developing novel technologies for bone regeneration and delivery of growth factors/drugs to bone defects. His research is funded by the National Institutes of Health and the New Jersey Commission on Science and Technology. He played a lead role in developing the NanoGen™ technology that was approved by the U.S. FDA for dental bone grafting applications and later in the commercialization of this product. He successfully took the company and its products through the ISO and CE certification process. He serves on the editorial board of the *Journal of Biomedical Materials Research (JBMR) Part B*, *Critical Reviews in Biomedical Engineering*, and the *Journal of Tissue Sciences and Engineering*. He was guest editor of a special issue of *JBMR Part B* on Dental Biomaterials and another special issue of the *Journal of Long Term Effects of Medical Implants* on Bone Graft Materials.

Sachin is an active member of the Society For Biomaterials. He either has served or is currently serving on the Awards, Ceremonies and Nominations Committee (2012-2013), the Bylaws Committee (2010-2014), the Devices and Materials Committee (2011-2013), the Liaison Committee (2007-2009, 2011-2012), the Long Range Planning Committee (2013-2014), the Program Committee (2013-2014), the SIG Chairs Committee (2011-2015) and the Education and Professional Development Committee (2012-2014). Additionally, he is a member of the Academy of Osseointegration, the American

Association of Implant Dentistry, ASTM International (F 04 committee), the Orthopedic Research Society and is a lifetime member of the Society For Biomaterials and Artificial Organs of India. He was one of the two SFB members who attended the Association Headquarters Leadership Workshop in 2013. This workshop educates current and prospective volunteer leaders of societies like SFB about how they can work toward making their societies successful.

Vision Statement: I became a member of the Society For Biomaterials (SFB) in 2002 when I first presented my research at the annual meeting held in Tampa, FL. Since then, I consider the Society to be my scientific home. I have learned a great deal at the Society’s annual meetings, through their various publications and through my interactions with members of the Society. I have sought the counsel of fellow SFB members concerning my research activities and the regulatory filings of my company’s products. I have presented my research and organized sessions at the Society’s annual meetings, served on various committees (Long Range Planning, SIG Chairs, Liaison, Devices and Materials, Awards, Ceremonies and Nominations, Bylaws, Program, Educational and Professional Development) and acted in a leadership role in the Dental/Craniofacial and Orthopedic SIG. Obviously, the Society has a special place in my heart.

Two outstanding traditional outcomes of the Society’s activities have been its annual meeting and the publications (*Journal of Biomedical Materials Research Parts A and B* and *Biomaterials Forum*). Recently, Biomaterials Days being held at various schools throughout the country have added much value to the membership of the Society. Student chapters provide strong guidance to the students. We, as a society, need to build upon these successful activities. Membership in the Society plays an important role in ensuring the Society and its activities are successful. A Member-at-Large is an interface between the Board and the members, taking feedback from members and presenting it to the Board. My goals as a Member-at-Large include the following:

- **To present the views of members to the Board.** Although basic, this is the most important job of the Member-at-Large. It is important to proactively solicit members’ views concerning the Society’s activities and present them to the Board and the Council. This leads to developing activities that reflect the will of the members, its main constituency.
- **To encourage and increase the participation of members in the activities of the Society.** SIGs have been the pioneers on this front. The grass-roots membership of the SIGs puts together most of the sessions at the SFB’s annual meeting. Having organized some of these sessions, I have first-hand experience in this activity. Participating in this way has provided me with a sense of increased responsibility and commitment to the Society.
- **To increase interaction among the members from academia, government and industry.** Although emphasis is expanding in this area, more interaction between these

sectors is needed. The sectors of academia, government, and industry are strongly interconnected. However, unless the new discoveries coming from academia can be commercialized by industry in a way that can be approved by government, these discoveries will never come to fruition. Stronger interaction between these sectors will help us develop technologies that will improve the lives of patients.

- **To increase the participation of members from industry and government in leadership roles of the Society.** Although the membership of the Society is equally split between industry and academia, of the 22 members who serve on the Council, 21 were from academia, one was from industry and none were from the government in 2013-14. No board members were from industry or government. Increasing the participation of members from industry and government in the Society's leadership roles would ensure that a diversity of views are represented at the board meetings, ensuring a broadly accepted vision of the SFB.

I am deeply honored to be nominated for the position of Member-at-Large of the Society For Biomaterials. If elected to the position of Member-at-Large, I promise to do my best to ensure that every member of the Society has an opportunity to present his/her views in an honest and transparent fashion.



Horst A. von Recum, PhD
Associate Professor
Biomedical Engineering
Case Western Reserve
University, Cleveland, Ohio

Biographical Sketch: I have been active in the Society since I attended my first meeting as

a graduate student in 1993 (and was probably attending meetings even before then).

In the Society, I have played multiple roles, most recently as Chair of the Membership Committee, a role I served in under three different Presidents (2011-2014). One of my major goals as Membership Chair has been to change the composition of the committee to better reflect the membership of the Society, and areas of focus to improve membership. This had led to including three industry representatives and two student/post-doc members on the committee of six. Changes proposed by this new committee are already underway to ensure that the Society continues to survive, grow and thrive in this new funding climate we all face. Before this leadership role, I was a regular member of that committee. I also served in an at-large position in the Bylaws Committee (2009-2010), and served in a number of roles in SIGs.

I played a highly visible role as Program Chair of Cardiovascular Biomaterials (2006-2008), and as Program Chair of Drug Delivery SIGs (2008-2010), putting together a large number of SIG-specific sessions for the meetings over which I presided.

Outside of formal leadership roles, I feel that I have been an extremely active and highly visible contributing member of the Society, encouraging strong attendance from my lab (one year students from my lab won both the MS and PhD student awards), as well as participation from my colleagues. As such, I feel that I am ideally suited to be our next Member-at-Large.

I believe my recent selection as Co-Chair for the 2017 Biomaterials Gordon Conference, as well as playing leadership roles in other societies, further demonstrate my high commitment to the biomaterials field.

Vision Statement: A recent publication on the changing role of societies entitled "The End of Membership As We Know It" demonstrates the changing role societies play in our field and others. Two features of that article are that a successful society today has to have an appropriate niche, and a well-defined culture. We are extremely fortunate (and grateful to our predecessors) that the Society For Biomaterials has extremely strong track records in both of these areas. We know our niche well (biomaterials) and represent one of the strongest, most active communities in the larger field, making SFB my favored home (and hopefully yours as well).

However, these goals are a moving target, and I feel it is the role of the Member-at-Large to have a finger on the pulse of the Society's members to identify the pivots the Society needs to make and new directions in which to head to ensure that we stay on top. As Membership Chair, I have enacted changes that ensure that student/post-doc members as well as industry members continue to be a growing, vibrant part of our society. Similarly another change brought forward by Society members and implemented by our Membership Committee will change the way dues and registration are paid in the future, hopefully making this easier for everyone. These changes would not have been possible without your voice.

Previous Members-at-Large, including Nick Ziats and Jan Stegemann, have been exceptional in maintaining good communication with the Society's members and representing their voice in Board and Council meetings. I have big shoes to fill, and, if elected, I promise to similarly present your thoughts fairly and actively to the Society's leadership.

To do this, I will seek out your input both in meetings and outside of meetings (the other 362 days of the year). I pledge to ensure that the voice of SFB is heard outside of the Society and in the larger biomaterials community. My ultimate goal is that this outreach will bring back enthusiastic new members who contribute and grow our Society so that we continue to define the niche and community that makes SFB so wonderful.

Members in the News



Greetings and best wishes for the New Year to all Society members! I thought this would be a good opportunity to remind you that as Member-at-Large, I represent the broader membership of the Society through service on the Board of Directors and the Council of the Society, as well as several committees. These

arrangements are in place so that the membership always has a clear voice in the direction of the Society, and my participation in these committees and governing bodies ensures that your voice can be heard. I encourage you to bring forth your ideas to me about the Society, our meetings, and anything else you think is relevant to making our Society better.

Once again it is my pleasure to use this column to highlight recent accomplishments and news about our membership. I hope it helps you keep track of what is happening in our community, and to see how our membership is impacting the field. Please send me your news for future issues (you can email me directly at jpsteg@umich.edu)! As usual, our members have been very active and productive in the past quarter.

Honors and Awards:

Dr. Jin Whan Lee, Dr. Hai Bo Wen and their team at Zimmer Dental were recently awarded a Silver Medal at the 2013 Medical Design Excellence Awards (MDEA) in the category of “Dental Instruments, Equipment, and Supplies” for their work on Trabecular Metal™ Dental Implant. The MDEA competition targets the “medical technology community, recognizing the achievements of medical product manufacturers and the many people behind the scenes—engineers, scientists, designers, and clinicians—who are responsible for the groundbreaking innovations that are changing the face of healthcare.” The Trabecular Metal™ Dental Implant features an osteoconductive mid-section designed for ingrowth, as well as ongrowth, of bone. Dr. Lee is Manager of Research at Zimmer Dental and is an Editorial Board Member of the *Journal of Biomedical Materials Research, Part B*. Dr. Wen is Director of Research at Zimmer Dental.

Dr. Bingyun Li has been awarded a Collaborative Exchange Award from the Orthopaedic Research Society, which awards two applicants from the orthopaedic research community worldwide each year. With this award, Dr. Li will make several trips in 2014 for collaborative exchange with the lab of Dr. Ali Khademhosseini at Harvard-MIT’s Division of Health Sciences and Technology. Dr. Li is Associate Professor in the West Virginia University Department of Orthopaedics and is Director of the WVU Biomaterials, Bioengineering and Nanotechnology Laboratory.

Dr. Heinz Redl was awarded the 2013 Wilhelm Exner Medal from the Austrian Association for Small and Medium-sized Enterprises in recognition of promoting cooperation between science and industry in the area of biomaterials and its application. This annual award is dedicated to Wilhelm Exner, a renowned Austrian professor of engineering with an outstanding impact on educational and industrial policies. It is awarded to scientists and researchers whose scientific achievements have directly boosted or enhanced business and industry. Dr. Redl is Director of the Ludwig Boltzmann Institute for Experimental and Clinical Traumatology and the Austrian Cluster for Tissue Regeneration.

Dr. Thomas Webster was selected for the 11th Sahaj Memorial Lecture Award by the Indian Ceramic Society for his expertise in bioceramics. Dr. Webster also recently spoke on Fox News about New England Patriot’s football player Rob Gronkowski’s season-ending ACL and MCL injury and how nanomedicine is being used to treat cartilage injuries. In addition, Dr. Webster was covered on NBC News talking to high school students about future careers in nanotechnology. Dr. Webster is the SFB Web Editor and Chair and Professor in the Department of Chemical Engineering at Northeastern University.

The following SFB members were inducted as 2013 Fellows of the American Association for the Advancement of Science (AAAS): **Dr. Kevin Healy** (UC Berkeley), **Dr. Ali Khademhosseini** (Harvard U.), **Dr. Robert Langer** (MIT), **Dr. Cato Laurencin** (U. of Connecticut), and **Dr. Peter Ma** (U. of Michigan). The AAAS seeks to “advance science, engineering, and innovation throughout the world for the benefit of all people.”

The following SFB members were inducted as 2013 Fellows of the National Academy of Inventors (NAI): **Dr. Joachim Kohn** (Rutgers U.), **Dr. Cato T. Laurencin** (U. of Connecticut), **Dr. Kam**

Leong (Duke U.), **Dr. Samir Mitragotri** (UC Santa Barbara), **Dr. Glenn D. Prestwich** (U. of Utah), **Dr. Joseph C. Salamone** (U. Mass Lowell), **Dr. Kathryn E. Urich** (Rutgers U.). NAI fellows are “academic inventors who have demonstrated a highly prolific spirit of innovation in creating or facilitating outstanding inventions that have made a tangible impact on quality of life, economic development, and the welfare of society.”

Other news and recognitions:

Simon Longela will represent the SFB chapter of the University of Oslo at the Higher European Research Course for Users of Large Experimental Systems (HERCULES 2014) at the University Joseph Fourier of Grenoble, including a week at the synchrotron in Paris and Switzerland. This course will provide training in tools for molecular dynamics and spectroscopy measurements. Simon Longela is a PhD student in the Biomaterials Department of the University of Oslo, Norway.

Dr. Tom Horbett recently returned from China, where he gave two invited presentations. One was at the International Conference on Zwitterionic Biomimetic Materials (ICBZM) at Zhejiang University in Hangzhou on the invitation of Prof. Jiacong Shen of Zhejiang University and Prof. Shaoyi Jiang of the University of Washington. The second was to the biomaterials group headed by Prof. Hong Shen at Souchou University in Souzhou. Both presentations were titled “Blood (in)compatibility of biomaterials: A failure of biomaterials science?” Tom reports he “enjoyed seeing the country from which so many fine past students and current colleagues in biomaterials originated and was duly impressed with the tremendous vitality and growth in the country as a whole, and in biomaterials science.” Dr. Horbett is Professor Emeritus in the Department of Bioengineering at the University of Washington.

Dr. Jiro Nagatomi recently returned from a seven-month sabbatical at the University of Tokyo, working with Professor Kazuhiko Ishihara, recipient of the 2009 SFB Clemson Award for Applied Research. The visit served to establish a research collaboration and to extend the academic exchange relationship between the University of Tokyo and Clemson University. Dr. Nagatomi is Associate Professor in the Department of Bioengineering at Clemson University.

Robert Torgerson was featured in a recent Qmed (qualified medical device supplier directory) article for helping to establish a medical device cluster in the northern California area by starting up RxFiber. The company recently released a new biomaterial, RxFibron HT, “the first commercially available smallest, strongest PET, medical grade fiber developed for implantable medical devices.” RxFibron HT was nominated for UBM’s Golden Mousetrap award, the winner of which will be announced at the MD&M trade show in February. Rob is also assembling a group of leading medtech biomaterial experts to discuss medical grade standards for fibers used in implantable devices. This group of experts will convene during the SFB Annual Meeting in Denver. If anyone is interested in being considered to participate in this forum, please contact Brenda at Brenda@rxfiber.com. Robert Torgerson is President of RxFiber, a medtech biomaterial start up in Windsor, Calif.

New positions:

Dr. Martin O’Toole, was promoted to Assistant Professor in the Department of Bioengineering at the University of Louisville.

James Roma was promoted to Product Engineering Manager, Engineering Services, at B. Braun Medical Inc., Allentown, PA.

Dr. Jessica Winter was appointed Associate Director of the OSU Center for Emergent Materials, an NSF-funded Materials Research Science and Engineering Center (MRSEC). In this role, Winter will serve as the industrial outreach liaison for the center’s more than 50 members. Dr. Winter is Associate Professor in the William G. Lowrie Department of Chemical Engineering and Department of Biomedical Engineering at The Ohio State University.

DO YOU HAVE OTHER MEMBER NEWS?

Contact me with Member News at jpsteg@umich.edu
or 734-764-8313

Winning the Race to the Surface: Local Delivery of Infection Control Agents from Biomedical Implants

By Scott A. Guelcher, PhD, Vanderbilt University

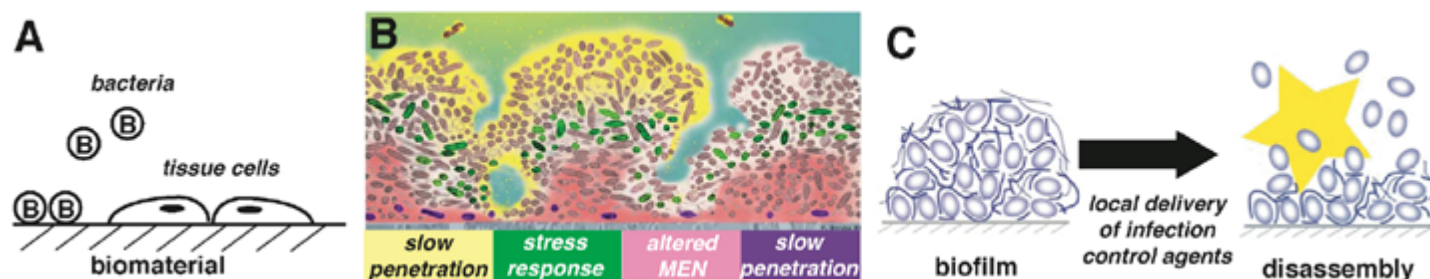


Figure 1. Implantation of a biomedical device initiates a race between integration of the surface with host tissue and colonization of the surface by bacteria. (A) Bacteria and tissue cells compete for domains at the surface of the inanimate biomaterial [1]. (B) Stages of biofilm development. Due to slow penetration of systemic antibiotics, bacterial cells in the biofilm have sufficient time to initiate stress responses and become metabolically inactive. As a result of the altered microenvironment, a small number of persister cells survive the systemic antibiotic challenge and remain viable, resulting in colonization of the surface of the implant by bacteria. Adapted from the Center for Biofilm Engineering (<http://www.biofilm.montana.edu/node/2410>). (C) Schematic summarizing the strategy of biofilm disruption by local delivery of infection control agents [2].

The CDC estimates that 1.7 million hospital-acquired infections occur each year, resulting in nearly 100,000 fatalities³ and approximately \$5 billion in costs.⁴ While surgeries after trauma and tumor resections have a relatively high incidence of infection⁵, simpler surgical procedures, such as insertion of a catheter⁶, also present a significant risk of infection. New rules effective in 2008 stipulate that the Center for Medicare and Medicaid Services will no longer reimburse providers for hospital-acquired conditions not present on admission, including selected surgical site infections⁷. Furthermore, hospitals are required to report hospital-acquired infection rates to Medicare. These radical changes in reimbursement are anticipated to change clinical practice by incentivizing hospitals to reduce infection rates. Biomedical device-related infections are typically associated with the formation of a biofilm, in which adherent bacteria are embedded in a viscous polysaccharide extracellular matrix on the surface of the device¹. Upon implantation of an avascular biomedical, a race to the surface commences between bacterial and host tissue cells (Figure 1A). If bacteria colonize the surface of the implant before tissue cells, an infection will result. Thus, an unintended consequence of implantation of a biomedical device is its potential to function as the nidus for biofilm formation and infection, since inanimate surfaces represent the eminent domain of bacteria and not tissue cells. While patients are frequently treated with systemic antibiotics, their efficacy is hindered by transport limitations associated with the biofilm extracellular matrix (Figure 1B)⁸. Recent studies have

highlighted the potential of local drug delivery from biomedical devices as an effective strategy for biasing the race to the surface in favor of tissue cells and consequently preventing infection (Figure 1C).

Protection of bone grafts from infection^{9,10} has attracted considerable interest due to the strong clinical correlation between bacterial contamination at the time of injury and the incidence of deep infection, osteomyelitis, and amputation¹¹. Open fractures will not heal without bone grafting, but unfortunately the unintended consequence of the surgeon placing the graft in a contaminated wound bed is the formation of a biofilm on the surface. Thus, recent studies have investigated local drug delivery strategies to reduce the risk of infection. Constructs comprising poly(methyl methacrylate) (PMMA), carboxymethylcellulose (CMC) and poly(lactic-co-glycolic) acid (PLGA) augmented with colistin supported release of the antibiotic at concentrations exceeding the minimum inhibitory concentration (MIC) for up to five weeks¹². When implanted in mandibular defects in rabbits, the PMA/CMC/PLGA constructs maintained space and supported tissue integration¹³. Silica sol-gels (xerogels) have also been reported to provide sustained release of vancomycin for up to six weeks¹⁴. The time scale of antibiotic release is critical for mitigating the risk of infection, as evidenced by a recent study reporting that sustained release of vancomycin at concentrations exceeding the minimum bactericidal concentration (MBC) for greater than eight weeks

reduced CFUs/g bone tissue compared to a five-to-six week release period¹⁵. To address the need for osseointegration as well as infection control, osteoconductive calcium phosphates have also been investigated as carriers for antibiotics. In one study, HA scaffolds incorporating ceftriaxone and sulbactam supported sustained release of the drug at concentrations exceeding the MIC for six weeks, reduced the risk of infection, and enhanced new bone formation compared to parenteral drug administration in contaminated rabbit tibia defects¹⁶. These studies point to the utility of local delivery of antibiotics from osteoconductive bone grafts for controlling infection and promoting bone healing in contaminated defects.

The increasing trend of antimicrobial resistance as well as the formation of biofilms on avascular biomedical implants have contributed substantially to device-related chronic infections and are major barriers to wound healing¹⁷. Thus, new approaches to infection control are under active investigation, including local delivery of biofilm dispersal agents and bacteriophages⁸. For both gram-positive and gram-negative bacteria, coordination of biofilm formation and dispersal occurs through the detection of self-produced soluble factors by quorum sensing systems¹⁸. Given their specificity, bacterial signaling molecules that trigger biofilm dispersal have gained considerable interest as therapeutic agents to treat chronic infections¹⁹. Molecules investigated as biofilm dispersal agents include cis-2-decenoic acid²⁰, quorum sensing inhibitors²¹, bismuth thiols²², D-amino acids²³ and recombinant DNAses²⁴. While recent studies have shown that the use of bismuth thiols can enhance the effects of antibiotics against biofilms in animal models of chronic disease²², the efficacy of these drugs may be limited by cellular cytotoxicity and lack of specificity of the dispersal agent for certain bacterial species. D-amino acids secreted by bacteria have been reported as a widespread signal for biofilm disassembly due to their low cytotoxicity and broad-spectrum activity against a variety of pathogens²³. In a recent study, local delivery of D-amino acids from resorbable lysine-derived polyurethane scaffolds was shown to reduce the probability of biofilm formation and infection in contaminated bone defects in rats²⁵.

The discovery of highly potent biomimetic biofilm dispersal agents² presents promising opportunities for the development of biofilm-dispersive devices that reduce the risk of infection. Synthetic molecules mimicking norspermidine have been reported to exhibit increased potency compared to mixtures of norspermidine and D-amino acids². In contrast to local delivery of antibiotics, the optimal doses and release kinetics that prevent biofilm formation or disperse existing biofilms are largely unknown for biofilm dispersal agents and warrant further investigation. Local delivery strategies for emerging biofilm dispersal agents offer considerable promise for reducing the risk of infection and improving patient outcomes for a broad spectrum of surgical procedures.

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Business Plan Competition

Prepared by Jim Curtis, Secretary/Treasurer of the Biomaterials and Medical Products Commercialization Special Interest Group

Did you know that the Annual Biomaterials Meeting in Denver will include an **exciting new competition** with cash prizes? If you have an entrepreneurial spirit, please plan to attend the SFB Business Plan Competition. The audience will have an important role in judging the business plans that have been pre-selected (by the abstract peer-review process) for podium presentation at

this session. This unprecedented event is co-sponsored by the Biomaterials and Medical Products Commercialization, Tissue Engineering, Drug Delivery, Dental/Craniofacial, Engineering Cells and Their Microenvironments, Cardiovascular Biomaterials and Biomaterials Education Special Interest Groups.

Trends in Ophthalmic Biomaterials: Toward Development of a 3-D Printed Retina

Contributed by Morgan V. Fedorchak, PhD
Research Assistant Professor
Departments of Chemical Engineering and Ophthalmology
University of Pittsburgh and the Louis J. Fox Center for Vision Restoration

Three-dimensional printing of cells and substrates is a technique that hopes to provide biomimetic structures for a variety of tissue engineering applications. This emerging technology has been tested on stem cells, muscle cells, and several embryonic neuronal cells among others^{1,2}. However, until very recently, these methods had yet to be tested for adult neuronal cell types. The January 2014 issue of the British journal, *Biofabrication*, details the use of an inkjet printer to print viable ocular cells, namely retinal ganglion and glial cells³. These cells are of particular interest, as age, disease, and trauma-related degeneration is very common and can cause irreversible loss of vision. Despite a low yield due to the processing steps involved, the authors demonstrated that the printing procedure did not affect survival or growth of the cells. To continue their work toward producing a 3-D inkjet printed retina, the next steps are to test these methods with photoreceptors and further improve the printing process for scale-up. Despite the long road ahead for demonstration of a true retinal graft, this work highlights the exciting possibilities for regenerative ophthalmology and next-generation ophthalmic biomaterials.

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A Report on the American Society of Testing and Materials (ASTM) Scaffolds Workshop

Contributed by Carl G. Simon, Jr.

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A workshop entitled “Standards & Measurements for Tissue Engineering Scaffolds: What Do We Have & What Do We Need?” was held on May 21, 2013, in Indianapolis, Ind., during the spring meeting of ASTM International (ASTM). The objective of the workshop was to identify the highest priority items for future standards development for scaffolds for tissue engineered medical products (TEMPs). The workshop hosted 18 speakers and 78 participants, comprising a diverse group of stakeholders, including industry (51 percent), academia (31 percent), government (8 percent), end users (5 percent, surgeons and dentists) and non-profit organizations (5 percent).

ASTM Committee F04 on “Medical and Surgical Materials and Devices” currently has seven published standards that focus on tissue engineering scaffolds and discussions highlighted many potential areas for future work. A key finding was that the F04 TEMPs groups have many guide documents for educational and advisory purposes, but that few standard tests or procedural methods have been published. Guide documents provide “an organized collection of information that does not recommend a specific course of action,” whereas test methods are more specific and describe “a definitive procedure that produces a test result.”

Overwhelmingly, the most clearly identified need was standards for measuring scaffold structure. The second was standards for

biological characterization including in vitro testing, animal models and cell-material interactions. Standards for scaffold mechanics, degradation, reference materials, composition, clinical outcomes, reporting and sterilization effects were also recommended. The workshop spawned several new work items including task groups to develop a standard for measuring stem cell response to catheters, a standard for advanced characterization of collagen-based products, a standard for measuring decellularization of extracellular matrices, a standard for characterizing bioglasses and reference materials for measuring cell-material interactions.

A Workshop Report is freely available at www.astm.org/COMMITTEE/F04.htm.

LEARN MORE

Please contact Carl Simon at carl.simon@nist.gov if you want to learn more about developing ASTM TEMPs standards.

Industrial News



Medtronic, Inc. (Minneapolis, MN) obtained FDA approval for its artificial pancreas. The MiniMed device can automatically stop delivery of insulin when a patient's glucose levels are within normal range. It is intended for use on patients over age 16 who are diagnosed with diabetes. The new artificial pancreas has several advantages

for patients suffering from diabetes. Since the new MiniMed 530G works with Medtronic's Enlite sensor, it can detect blood glucose levels with higher accuracy than earlier systems. On top of this, the system includes Medtronic's Threshold Suspend technology, which can automatically stop the delivery of insulin as determined by a preset threshold. With the device, patients can control their diabetes without the need for multiple injections.

Evena Medical (Los Altos, CA) is betting that smart glasses will help nurses when it comes to the classic problem of finding a vein in an obese or elderly patient's arm. A nurse can put on Evena's Eyes-On Glasses System and clearly see the veins underneath the skin. The next question is whether the hospital systems the nurses work for will choose to buy when Evena's Eyes-On Glasses System starts shipping next year. These may be helpful to graduate students conducting preclinical studies attempting to find veins in mice as well.

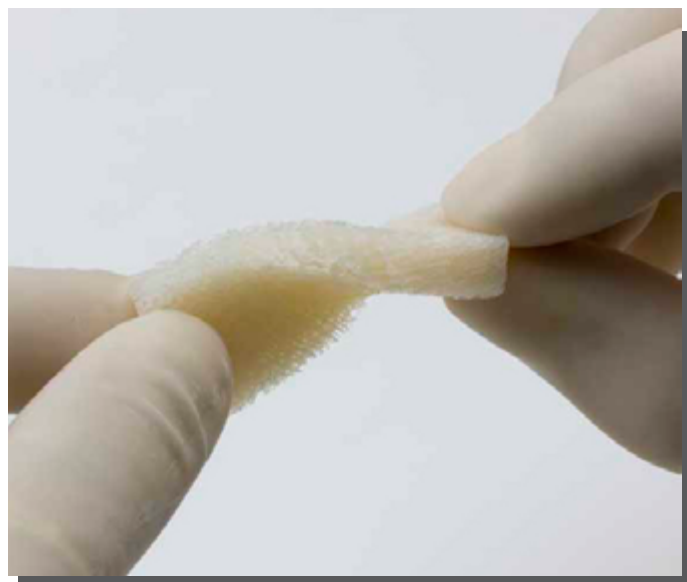
Texas is becoming a major medical device innovation hub. According to state officials, in 2012 approximately 800 firms—including more than a dozen Fortune 500 medtech companies—employed more than 15,200 workers in the medical technology sector. As a result, Texas is counted as one of the top 10 states in the nation in numbers of medical device workers. Governor Rick Perry's 2005 creation of the **Texas Emerging Technology Fund (TETF)** dealt the state itself a hand in the medtech game. While not solely interested in medical technology, in the past year alone TETF has announced assistance to five medtech startups as well as the creation of an academic Center for Cell and Organ Biotechnology, a collaboration between the Texas Heart Institute and Texas A&M College of Veterinary Medicine & Biomedical Sciences.

Stryker Corp. (Kalamazoo, MI) has completed its previously announced \$1.7 billion acquisition of **Mako Surgical Corp** and its

cutting-edge robotic arm assisted orthopaedic surgery technology. The exact price was \$1.68 billion, or \$30 per share of Mako stock, according to a Stryker SEC filing. The price per share is about double what Mako stock was trading at before the deal was first announced in late September last year. Mako's MAKOplasty robotic procedures are available for both partial knee resurfacing and total hip arthroplasty.

Boston Scientific (Natick, Mass.) is looking to boost its bottom line in China. The company is adding employees in China and is debuting surgeon-training centers there. The move comes even as the device giant slashes hundreds of jobs in the United States and elsewhere, with savings from the "strategic growth initiative" going toward developing new products and other initiatives. Boston Scientific is hiring where it expects growth in countries such as Brazil, Russia, India and China (the BRICs).

Depuy Synthes Spine (Raynham, Mass.) launched a new tissue implant for spine surgery: CONFORM SHEET™ in collaboration with **DePuy Synthes Biomaterials**.



It is a hydrated, pliable and totally demineralized cancellous bone matrix that fills voids during posterolateral spinal fusion surgery and provides a natural scaffold for new bone formation.

The new allograft implant, processed by the **Musculoskeletal Transplant Foundation** (MTF), has both osteoinductive and osteoconductive properties. Through a unique demineralization process, bone morphogenic proteins (BMPs) are exposed, providing CONFORM SHEET its osteoinductive properties, while the cancellous structure of the scaffold provides osteoconductive characteristics. *CONFORM SHEET and CONFORM CUBE are regulated as an HCT/P (Human Cells, Tissues, and Cellular and Tissue-Based Product; pursuant to 21 CFR 1271.

CDRH has placed developing a draft guidance on benefit-risk determinations in premarket notifications (510(k)s) among its top guidance priorities in 2014. Other top draft guidances to be developed include the following:

- Appropriate use of voluntary consensus standards in premarket submissions.
- Custom devices.
- Hearing aids and personal sound amplification products. The guidances under development are included in a new CDRH website (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm) mandated under the Medical Device User Fee Amendments of 2012. The website also lists priority draft guidances that will be finalized next year.

People often insist that the **Affordable Care Act** will bring monumental change to the U.S. healthcare industry. But beyond predicting cost cutting and accountable care, most don't offer many specifics about what that change will look like. Here are the predictions by Nicholas Donoghue, associate principal at the business advisory firm McKinsey & Co.:

- Hospitals' margins will improve in the short term but degrade in the long term.
- The poorest hospitals today will benefit the most, while the richest will suffer

- The cost of healthcare will become more transparent.
- Hospitals will band together and share data.
- Physicians' purchasing power will dwindle.
- There will be fewer hospitals.

The 2.3 percent medical device excise tax barely survived the budget battle this fall with an amendment to repeal the onerous levy making it all the way to the final reconciliation before being yanked out at the last minute. Yet there remain several good signs that the tax could be repealed in the coming year. First, the author and godfather of the medical device tax, Sen. Max Baucus, is retiring this year and is likely off to China as the next ambassador for the U.S. The Big Sky State's senior senator looms large over the medical device tax debate because of the considerable power he wields over the purse strings of the federal government as chairman of the Senate Finance Committee.

The Defense Department has awarded scientists at **Wake Forest Baptist Medical Center** \$24 million in funding to develop human organ systems as small as a quarter through the use of 3-D printing. The body-on-a-chip technology is expected to have the ability to assess the effect of chemical and biological agents on the human body and allow researchers to develop strong drug antidotes.

MOOCs: A Brief History and Summary of Massive Open Online Courses



Over the past decade, technological advances related to the Internet have been incorporated into classroom teaching more and more. Initially we and others termed it “e-learning” and it ranged from electronic lecture notes being available to students for download from university servers, downloadable audio-based lectures

paired with electronic slide presentations, live class lectures made available beyond the immediate classroom via videoconferencing to other sites, and, in some cases, actual online courses where instructors would narrate slides live to an audience of logged-in students beyond the borders of the university campus.

This idea has been maturing over the past 10 years as the notion of Internet-based distance learning has gained momentum. In 2008 surveys showed as many as 15 percent of students had participated in a class that was offered online. By last year, this number had risen to 46 percent¹. This concept of a course existing solely online and available to a wide audience that reaches beyond the university campus or the extended campus network has been termed a massive open online course, or MOOC, and has blossomed over the past few years largely through the efforts of a few well-known entities. The origin of MOOCs may be hard to pinpoint but there have been some notable milestones over the past decade in the area of widely available online educational content.

The Khan Academy (no relation) began compiling brief lectures on a variety of topics and making them available for free to the general public in 2006. To date, the founder, Salman Khan, and his team have amassed more than 3,000 short courses primarily in math and science, but also touching on economics and the humanities. The target audience seems to be largely pre-college, but there is some content that first or second year undergraduates in science and engineering may find useful. However, the notion of making course material available online has expanded to the university level.

In 2010, Stanford University professors Andrew Ng and Daphne Koller started developing a software platform specifically for

a web-based teaching program and continued to develop and improve it over the next two years². In 2012, Coursera was

launched with four other contributing institutions and offered online courses; less than two years later it has grown to include almost 100 institutions world-wide offering online content spanning a spectrum of topics including humanities, science, social sciences, mathematics, business, computer science and others.

MIT started opening up their course content through their OpenCourseWare (OCW) program in 2002 (when we still called it e-learning), with other institutions from more than 50 countries following suit through the OpenCourseware Consortium³. As of late 2012, MIT had made the content from more than 2,000 courses available online through their OCW program. In 2011, MIT launched MITx, their version of the MOOC that was developing at Stanford University. In 2012, Harvard and MIT combined forces and renamed their effort edX, a formalized MOOC, to make courses available online². In less than two years, edX has grown into a consortium of almost 30 schools from all over the world offering course content in more than 125 courses covering science, social science, health, business and many others¹. It seems that the recent past suggests MOOCs are more than a fad.

Education Quote of the Quarter:

“Teachers open the door, but you must enter by yourself.”

—Chinese Proverb

One indication that the growing interest of MOOCs may be here for a while is the way some institutions are incorporating them into their academic infrastructure. For instance, Georgia Tech is developing an online Master’s degree program in Computer Science; San Jose State University is beginning to offer college credit for certain MOOCs; MIT is recognizing MOOCs in their admissions application; and both California and Florida have enacted

legislation that considers the role of MOOCs in their education systems¹. Given the initial interest, the apparent popularity and the considerable potential of this educational template, many have begun to study and scrutinize MOOCs and have identified certain challenges that they present as well as opportunities that may arise.

One issue that has arisen with early data collection about MOOCs is the very high enrollment rate (one course claims as many as 270,000 enrolled students so far), but woven into that is the very low completion rate—about 15 percent². Further, as the rise in popularity for MOOCs seems steep, it has not necessarily caught hold with undergraduate students, with less than 10 percent of surveyed undergrads having taken one, and only about 30 percent having even heard of them. Also, given their relative newness, there is relatively little information about how effective MOOCs are as teaching tools, or what the best way to design an actual MOOC would be. A recent special issue in the *Journal of Online Learning and Teaching* examines many of the issues that are beginning to arise with MOOCs⁴.

While the challenges are apparent, great opportunities exist within the MOOC model. Clearly reaching large numbers of people who may have geographical or financial barriers to accessing course content is an advantage. Also, MOOCs have been useful in promoting new teaching strategies, the flipped classroom concept for instance. Flipped classrooms, where the students are required to view lecture material online outside of class and then come to class to either complete assignments or have group discussions on the content, are an ideal environment for MOOCs. Also, the software platforms that some of the large MOOCs use allow for a vast amount of data to be collected from the participants, well beyond the answers to homework and exam questions. Since the students taking the course do it at their own pace, data like mouse clicks, quiz answers, pauses in lecture videos, changes in lecture speed, rewinds, etc. can all be collected. This data can be analyzed to determine where

students are having problems or where the lecture content is being skipped or fast-forwarded. The instructor can adjust lectures in accordance with how the students interact with the videos to optimize the content. This is particularly valuable because it is not inherently obvious how to translate a live interactive lecture to a format that can be paused, rewound and replayed. Anyone who has ever prepared a lecture video to be viewed later can attest to the challenges this format presents beyond giving a lecture in person to an audience sitting before you.

MOOCs are here, but whether they remain has yet to be determined and the experts are just beginning to weigh in.

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HAVE YOU HAD EXPERIENCE WITH MOOCs?

Is your institution in the process of implementing them into the curriculum? How does online learning translate to the biomaterials education world? How do we approach laboratory classes when thinking about online learning? If you have any thoughts about MOOCs or related ideas, please contact me at ykhan@uchc.edu to share your experience, advice, suggestions or cautions in a future *Biomaterials Forum* article.

USEFUL LINKS

- www.edx.org
- www.coursera.org
- www.khanacademy.org
- www.ocwconsortium.org

Student Chapter News



2014 will be an exciting year for the Student Chapters of the Society For Biomaterials. The annual meeting in April, which is in Denver this year, will bring with it a slate of new officers for the student chapter. If you are looking for ways to be a bigger part of SFB, this is an exciting opportunity.

The positions open for election are:

- President-Elect
- Treasurer/Secretary
- Bylaws Chair

Serving in these roles is a great way to not only become more aware of the goings on within SFB, but also to become more involved in planning student activities and networking. If you are interested, watch your email closely, because student elections are held right before the conference and we will be emailing all student members to either run or nominate someone they know for open positions.

If you're looking for other ways to become involved in SFB, think about joining a Special Interest Group (SIG). SIGs are a great way to interact and network in your field of interest and are free for students to join. You can sign up for them when renewing your membership or by filling out a form on the SIGs website. If you're not shy, consider becoming a *Biomaterials Forum* reporter who interviews experienced researchers in industry and academia (contact editor-in-chief Liisa Kuhn at Lkuhn@uchc.edu). All of these are great ways to make contacts that may be valuable for your future.

2014 also brings with it new Biomaterials Days. These are happening all around the country, so there could be one close to you. On March 27, the University of Washington will be holding a Biomaterials Day, while the University of Florida hosts theirs the following day, on March 28. Following the conference, Texas A&M will be hosting the Biomaterials Day for Texas on June 9 that is a joint effort between Texas A&M, University of Texas at Austin and Rice University. More Biomaterials Days are scheduled for the fall, so visit www.biomaterials.org to find out what schools are hosting them. These are a great way to learn about the exciting research being performed in your area, as well as to network with people from industry, academia and the military. If you are interested in any of the Biomaterials Days listed, accessing the student section of the SFB webpage will link you to the hosting university's SFB student chapter officers. They can provide you with information about their Biomaterials Day and the specific activities planned for the conference.

May is both an exciting and a nervous time for students graduating in 2014. The possibilities can sometimes be overwhelming as graduation approaches. To help you consider available careers, the SFB student section website at www.biomaterials.org/student_section has a link to the SFB Career Center where jobs for various positions related to biomaterials are posted.

With new student chapters forming at many universities all over the United States, 2014 promises to be an exciting year for SFB. Be sure to sign up for the student luncheon and attend the Student Chapter meeting at the annual meeting to stay informed and help direct future events.

Principles of Biomedical Ethics (7th edition) **and What Would You Do? Juggling Bioethics** **& Ethnography.**

Principles of Biomedical Ethics (7th edition)

Tom L. Beauchamp and James F. Childress

Oxford University Press, 2012

ISBN-10: 0199924589

And

What Would You Do? Juggling Bioethics & Ethnography.

CL Bosk

The University of Chicago Press, 2008

ISBN-10: 0226066770 | ISBN-13: 978-0226066776



Bioethics have always been a part of the discussion regarding biomaterials science. Issues have ranged from the scientific conduct of research and development to the implantation of devices and other biomaterials into animals (including humans). Newer technologies involving tissue engineering and regeneration

raise new concerns. O'Mathúna (2007) expounded on this:

Biotechnology has the added capacity to produce products that literally do take on life. The technology humans developed in the past was inanimate and could be left unused if found to be ethically problematic—as difficult as that might have been. However, biotechnology now makes possible the creation of products that are themselves alive.

To appreciate the nuances related to bioethics and future biotechnological advances, it is important to have a solid foundation in the basics of ethical theory. Lectures and courses on bioethics are now standard fare at academic institutions. While the subject is not new to the fields of biomaterials and bioengineering, debate is ongoing as to how best to teach this topic to undergraduate, graduate and post-graduate students.

Several journal articles and books exist on this subject matter. In fact, the SFB-endorsed textbook, *Biomaterials Science. An Introduction to Materials in Medicine*, dedicates a subchapter to this topic. Additional suggested references are appended to the end of this review.

One book that should find a place on your bookshelf is *Principles of Biomedical Ethics*, written by Tom L. Beauchamp and James F. Childress (2012). The authors of this book are world renowned for their efforts in this field. Dr. Beauchamp is also known for playing a major role in the writing of The Belmont Report (1978), a major document outlining the ethical principles of human subjects research. Dr. Childress has also served on several national committees regarding organ sharing, human gene therapy, and data and safety monitoring boards.

Principles of Biomedical Ethics is written as a traditional textbook. Part I introduces the concepts of Moral Norms and Moral Character. Chapter 1 describes principles and rules and their role in “moral deliberation and decision-making.” Chapter 2 discusses moral virtues and ideals. Chapter 3 characterizes the theories of moral status and their significance. Part II characterizes the four basic groups of principles: respect for autonomy (Chapter 4), nonmaleficence (Chapter 5), beneficence (Chapter 6) and justice (Chapter 7). Chapter 8 discusses professional-patient relationships. I suggest that you read the subsection entitled “The Dual Roles of Physician and Investigator.” It is here that they discuss the conflict between healthcare and research:

As an investigator, the physician acts to generate scientific knowledge to benefit individual patients in the future. As a clinician, responsibilities for care require acting in the best interests of present patients.

The authors recognize that the physician must abide by the Declaration of Geneva of the World Medical Association and the Physician’s Oath, which states that “Concern for the interests of the subject [of research] must always prevail over the interests of science and society.” Part III contains chapters on moral theories

(Chapter 9) and method and moral justification (Chapter 10). The five types of moral theory include: Utilitarianism, Kantianism, Rights and Virtue.

The last two chapters lend themselves easily to any undergraduate or graduate course on the topic of biomedical ethics for use in

moral analysis. There is also a companion website at www.oup.com/us/beauchamp, which contains teaching resources within a downloadable instructor's manual and testbank. There is also a student resource section, which contains self-quizzes, web links, suggested readings and media and reading goals for each chapter.

Another book I suggest reading is *What Would You Do? Juggling Bioethics & Ethnography* by Charles L. Bosk. Charles Bosk is a well-respected sociologist and ethnographer. The book is based upon previously published essays, lending each chapter to be somewhat self-contained. I found the prose contained within this book to be refreshing and to stimulate thought "outside of the box" of traditional ethics curriculum. While the book is focused on medical care of patients, the principles discussed can also be applied to medical research—both clinical and basic science.

Examples of some of the points of discussion include:

- Are our consent procedures flawed? Is there such a thing as informed consent? Can subjects ever be fully voluntary and informed? (Several chapters touch upon this, especially Chapter 5—Bureaucracies of Mass Deception—and Chapter 8—Irony, Ethnography, and Informed Consent.)
- Can or should promises of confidentiality and anonymity ever be made? (I highly recommend reading the recounting of Charles Bosk's own experiences in Chapter 11—A Monument of Silence.)
- Do we have the tendency to overestimate the benefits and downplay the risks of treatments?
- Can you really be an observer without influencing the outcome?

Charles Bosk states that his essays are "good to think about." As scientists and engineers, we need to scratch deeper than the questions related to misconduct and actually discuss what we are doing and whether we should be doing this at all. For example, how should you introduce and test new medical implants in patients?

In conclusion, I believe that an open discussion by the members of the Society For Biomaterials relating to the bioethics of biomaterials science is important. We need to determine the limits that should be placed, if any, on our research before it is decided for us.

OTHER RECOMMENDED READINGS

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