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BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

Fourth Quarter 2011 • Volume 33, Issue 4

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 (e-mail: info@biomaterials.org) or visit the Society's Web site, www.biomaterials.org.

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The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 33, Issue 4

Special Interest Group Reporters

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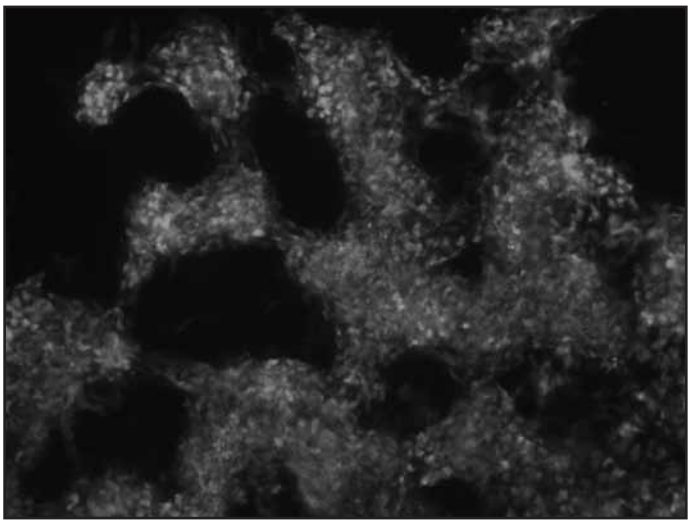
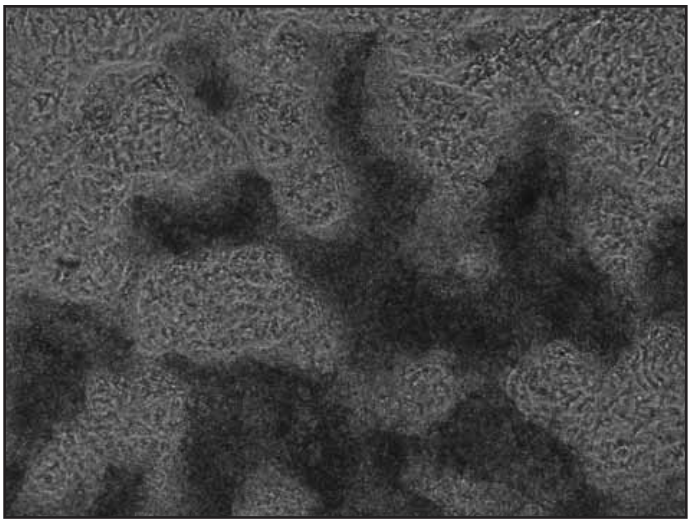
Departments

The Torch

Special Interest News



On the cover: Progenitor cells from transgenic mice that have been genetically manipulated to only express green fluorescence when they become mature osteoblasts capable of producing a mineralized matrix can be used for screening osteogenic biomaterials. The orange areas are positive xylenol orange (XO) staining of mineralized matrix. The co-localization of the GFP expression with the XO staining confirms that the cells have produced the mineralized matrix thereby discounting the possibility of non-physiological mineral deposition that often confounds interpretation of these types of cultures. The image below is a standard phase contrast image that is typically used to view mineralized nodules in osteoblast cell cultures. Notice not all cells in the culture are all at the same stage of differentiation. Photo courtesy of Sylvain Catros, Liisa Kuhn and David Rowe at the University of Connecticut Health Center.



From the Editor

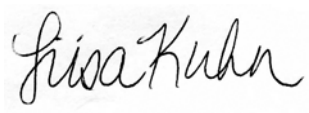
Greetings,
We've got another great issue for you! This issue contains some of the new content I talked about in my first Letter from the Editor—an interview with a Society For Biomaterials member about their career and their thoughts about the importance of biomaterials, a short review highlighting new technologies and an interview with an NIH program director. This new content is possible because a few members are generously donating their time to contribute the items—thank you! Along with Professor Bob Baier's provocative opinion/editorial piece about biocompatibility and the excellent contributions from the regular staff of the *Forum*, there's plenty of interesting material in this issue. I hope you enjoy it.

Thinking ahead to the content for the next issue, please take a moment to drop me a line about an SFB member you'd like to see interviewed in a future issue (my e-mail is lkuhn@uchc.edu). Are there any NIH program directors you think would be willing to be interviewed? This issue contains an interview with Dr. James Drummond from the NIH NIDCR program, but there are many other NIH institutes with active biomaterials programs we could all benefit from knowing. I'd still like to receive more short reviews from Special Interest Group members about new technologies of interest to their sub-specialties.

I'd like to start featuring advertisements from contract research organizations (CROs) and regulatory consultants who can help faculty and small businesses get more quickly through product development. If you're involved with corporate preclinical testing programs, please share with me your recommendations of high quality CROs you've used. Please contact Dan Lemyre at dlemyre@ahint.com at Association Headquarters if you are a consultant or organization wishing to let our members know about your services. We can feature short advertisements.

Lastly, are there any troubling work issues that are plaguing you at the moment? There's a group of experienced SFB members willing to consider your particular situation and provide advice in the form of a "Dear Labby" column in the *Forum*. Since "Dear Labby" is an American Society For Cell Biology moniker, I'm looking for witty suggestions of a biomaterials-themed female name. (PEG-y?) Regarding confidentiality, I'd like to do this in a safe manner, so if you've got a question, please send your concern directly to Leslie Clark at lclark@ahint.com, and she will remove all identifying information and forward your concern anonymously to me. Selected queries and concerns with the associated advice will be published without using real names in order to maintain confidentiality. I'm still looking for a few additional people with expertise in diplomatic handling of difficult work situations, so please contact me if you'd like to serve on the advice board for this proposed column.

Best wishes from Connecticut,



Liisa Kuhn, PhD

From the President

The SFB Council and Board of Directors meet each year in person approximately "mid-term" between the annual meetings. This year we met in Hartford, Conn., to capitalize on the high presence of SFB leaders in attendance at the Biomedical Engineering Society (BMES) meeting. Here are some highlights of the meeting.

By now you have responded to or are at least aware of the recent call for abstracts (deadline now past) for the 9th World Biomaterials Congress in Chengdu, China, next June. We will be represented by two members of the Society For Biomaterials 2012 International Scientific Advisory Committee at the program planning meeting in China this December. Updates regarding program content and related events will be posted to the Congress website (www.wbc2012.com). Monty Reichert, program chair of the October 4-6, 2012 New Orleans SFB symposium, has been working with his program committee members to develop an exciting Grand Challenges theme-based event. Meanwhile, I am pleased to announce SFB member Dr. Timmie Topoleski has agreed to serve as the program chair for the April 2013 annual SFB meeting, which will be held in Boston.

Working toward the goal of building a broader base of corporate participation in SFB, the Devices and Materials Committee has labored diligently to provide a comprehensive survey of industry members, and the results are being discussed by the SFB leaders. This valuable input gives us an opportunity to develop new educational initiatives and enhance membership benefits and opportunities for all members. Look for a panel discussion at the upcoming symposium or the next annual meeting that will give corporate members a chance to introduce themselves to non-corporate members and begin healthy discussion about the "drivers" in their respective worlds. It is only through these types of discussions that we can more effectively work together to reach common goals.

An exciting development from our special interest groups (SIGs) is *SIGnal*, a new monthly newsletter designed by and for the SIG leaders to provide updates of new developments and opportunities for the SIGS. SIG leaders, for example, are discussing the possibility of offering SIG-focused/sponsored webinars. A big thank you to SIG representative Jeff Schwartz for facilitating these communications!

Regarding SFB marketing and information delivery, and as approved by Council, all abstracts accepted for presentation at an SFB annual meeting or symposium will be made publicly available six months after that meeting, with permission of the authors. Abstracts whose authors opted out of broader dissemination will be available, as always, in electronic form to all SFB members through the searchable index on the SFB website. This option is particularly timely and exciting as our ability to educate, convince and influence others of the crucial importance of biomaterials significantly increases with broader dissemination of our meeting content.

Lastly, we are in preliminary discussions with BMES regarding biomedical engineering curriculum development and the idea of partnering with BMES to provide relevant input. The SFB Biomaterials Education SIG and the Education and Professional Development committee will be pursuing this opportunity.

These highlights are a few of the many discussions relevant to SFB direction and mission. As always, your involvement in these discussions and initiatives is crucial to the ongoing success of our Society.

Best wishes from Clemson,

Karen J.L. Burg
Hunter Endowed Chair & Professor of Bioengineering
Interim Vice Provost and Dean of the Graduate School
Clemson University

Staff Update

Hello from Society For Biomaterials headquarters! The Society's Board of Directors and governing Council met on October 16, 2011 in Hartford, CT and shared the following updates on committee activity:

Awards Ceremonies and Nominations - Chair Anne Meyer

The proposed slate of officers and award nominations were presented and passed unanimously. Results will be announced in the first quarter 2012 issue of *Biomaterials Forum*. The Committee recommended the Clemson Award nominations be specific to the award, with the final disposition of the individual Clemson awards remaining within the Committee's purview.

Devices and Materials – Chair Bruce Anneaux

Results of a recently conducted survey were presented, and additional data analysis will be available soon. Two areas at the forefront were a significant interest in information on regulatory processes and industry concern over the perception that the Society's focus is shifting away from traditional and clinically relevant materials and applications and toward tissue engineering.

Education and Professional Development – Chair William Murphy

Two mentoring luncheons are planned for the New Orleans symposium, with registrants indicating their area of interest to facilitate better matching of mentors and mentees. The Committee evaluated the 2012 Biomaterials Days grant applications and recommended the awarding of five grants, which were approved by Council.

Finance – Chair David Kohn

The Long Term Reserve Fund now stands at more than $500,000, and 2011 is on track to meet or exceed budgeted expectation. The Committee has recommended the board increase investments that deliver value to the membership.

Long Range Planning – Chair Joel Bumgardner

The Committee reviewed three recently conducted surveys: the Membership Exit Survey; Annual Meeting Evaluation and Website Development. There is a desire to have some presentations from the annual meeting made available on the website. Others have called for a web-based itinerary builder for the annual meeting. There is some concern that the new patent legislation might affect the presentation of information at the meeting. Keynote speakers for the 2012 Fall Symposium will be advised that their presentations will be made available on the website—they may wish to submit a redacted version of their presentations if necessary.

Meetings – Chair Karen Burg

An overview of upcoming meetings was presented:

2012 World Biomaterials Congress – The Society will be represented at the December planning meeting by Helen Lu. The abstract deadline was extended to October 20, 2011.

2013 Annual Meeting in Boston – Tim Topoleski has been named Program Chair for this meeting.

2020 Pitch – Planning for this continues. So far, Seattle does not have an appropriate venue. San Diego was unable to offer accommodations this far in advance without a trackable room night history, and San Francisco has been flexible—some dates are available at this point. Work will continue on this, but there is a chance SFB may have to pitch for the 2020 WBC without a contractual guarantee.

2014/2015 Site Selection – The Committee has refined the list of potential sites to San Diego, Denver, Crystal City and Baltimore. They have been asked to add Cleveland to the list, as that city has recently expanded its conference capabilities.

Membership – Chair Horst von Recum

Retention is the major issue affecting the Society's growth. In the Membership Exit Survey, cost and value concerns were most frequently cited as reasons for non-renewal. The Committee suggests easing the transition between member categories and streamlining the application process. The Committee is also planning outreach to some of the larger universities lacking active student chapters.

Program – Chair William Reichert

Twenty-eight session proposals were received for the 2012 Fall Symposium. The preliminary program can only accommodate 20 sessions, so some merging will be requested, and some proposals will not be accepted. In an effort to create the best possible meeting, some of those decisions will not be made until the abstracts have been reviewed. The graphic theme for the symposium was presented and approved.

Publications – Chair Ashutosh Chilkoti

***JBMRB*:** Manuscript submissions have increased 30-40% to between 750 and 800 for the year. Half the editorial board has turned over in the past year. Systems to detect and prevent plagiarism are being investigated, and some special topic issues are being developed.

***Biomaterials Forum*:** An editorial board has been created. The Member Spotlight feature from the website is being repurposed for use in the *Forum*. Articles or reviews are being solicited from the Special Interest Groups. A new column and methods to increase ad sales are being considered.

Website: A recent website survey showed more than 50% of respondents visited the website more than once a week. More content is needed for K-12 outreach and updates on the 510(k) regulatory process. A motion was approved to make all abstracts submitted to the annual meeting available to the public six months after the meeting. In the future, authors will be given the opportunity to opt out.

Book Series: Two books have been approved by the review committee; one proposal is being revised; one submission was declined.

Liaison – Chair Molly Shoichet

Call for Volunteers: The Committee will be identifying groups to work with targeted organizations to develop programming over the next few years.

AIMBE Activities—Current activities include:

- **Nominations for Fellows** – Members are urged to consider colleagues who might be nominated.
- **Mentoring** – AIMBE's Committee on Underrepresented Minorities (CURM) and the Women in Medical and Biological Engineering (WIMBE) Committee will be jointly hosting a leadership symposium on November 17-18, 2011 at the Crystal City Marriott.
- **Congressional Briefing** – The Society has been invited to exhibit technology at a table outside the congressional briefing room where AIMBE will be represented.

President's Advisory Committee – Chair Jeremy Gilbert

The Committee helped name the new Society award: The Society For Biomaterials Award for Service

National Student Chapters – President Scott Cooper

The national student chapters have five initiatives for the coming year:

- Five $1,000 grants to student chapters for assistance with travel to the World Biomaterials Congress in Chengdu.
- Sixteen $250 grants to student chapters (eight in the fall, eight in the spring) for assistance with operating expenses and local activities.
- Continuing publication of a newsletter highlighting student activities in local chapters across the country.
- Four $500 grants to support student chapter travel to the 2012 Fall Symposium.
- Mentoring luncheon to be held in New Orleans.

Special Interest Groups – Representative Jeff Schwartz

For the first time ever, all of the SIGs submitted a 2012 budget. A new monthly newsletter, the *SIGnal*, has been created. SIGs are encouraged to develop webinar content. Council approved requests from two SIGs to change their names: Cell/Organ Therapies is now Engineering Cells and Their Microenvironments, and Biomaterials Availability and Policy is now Biomaterials and Medical Products Commercialization. These SIGs are redefining their missions. More will be heard from them about their rebranding plans.

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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Interview with the Director of the Dental Materials Program at NIDCR

Interviewed by Liisa Kuhn, Editor

Dr. James L. Drummond, Director, Dental Materials and Biomaterials Program at the Integrative Biology and Infectious Diseases Branch of the National Institute of Dental and Craniofacial Research (NIDCR) National Institutes of Health kindly agreed to be interviewed by *Forum* Editor Liisa Kuhn this fall.

Liisa Kuhn: First, about you, Jim—How long have you been working at NIDCR, and what attracted you to a position at NIDCR? What are some of your favorite aspects about working at NIDCR?

James Drummond: I have been here three years, and I was attracted by the opportunity to have an impact on the future of dental materials and biomaterials research.

LK: In your particular specialty, what do you think are the most exciting new biomaterials developments?

JD: That's tough to answer in one sentence. The Dental Materials and Biomaterials Program supports basic and translational extramural research on dental materials and devices, dental implants, biocompatibility of dental restorative materials and biomaterials for craniofacial reconstruction. In addition, this program encourages research that is responsive to the product development efforts supported by the SBIR and STTR program. Additional information can be found at the Dental and Biomaterials Program website at NIDCR.

http://www.nidcr.nih.gov/Research/DER/IntegrativeBiologyAndInfectiousDiseases/DentalBiomaterialsProgram.htm

LK: Are the number of grants being submitted to NIDCR continuing to rise every year? Does this mean it will only get harder to get a grant from NIDCR?

JD: Underlying NIDCR's financial management plan is the Institute's goal to provide stable levels of support for high-quality scientific research. This is consistent with NIH's funding policy (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-077.html). Funding for new and early stage investigators remains an Institute priority. The NIDCR provides individual consideration to all applications. As the year progresses, the Institute adjusts its plans to accommodate changes in the projected number of applications, the scientific merit of applications as reflected in the scores assigned during peer review, projected award costs, new scientific opportunities and other relevant factors.

LK: When it is appropriate for a research faculty member to contact an NIDCR program official, and in what way can the NIDCR program officials be helpful to an investigator?

JD: It is appropriate for research faculty to approach a program official early in the development of their research proposal. Through discussions of the applicant's research concepts and provision of information, program staffers can provide advice to investigators to develop their applications. After the summary statement is made available at eCommons, the assigned program official is the point of contact. The program official uses the information from review meetings and summary statements to make funding recommendations, and he or she provides the Institute's scientific administration of grants and contracts once they have been awarded. Program officials also monitor progress with research based on annual progress reports and other interactions with grantees, and they evaluate possible changes in research directions and other issues raised by grantees. In the event an application is not funded and a decision is made to resubmit, program officials work with applicants, providing both scientific and technical assistance as needed.

LK: What particular research directions are of high priority to the NIDCR?

JD: NIDCR has placed a high priority on funding scientific meritorious ideas as outlined in NIDCR Strategic Plan 2009-2013.
http://www.nidcr.nih.gov/Research/ResearchPriorities/StrategicPlan/

LK: What is the best way to increase the probability of funding from NIDCR? Are there contacts to be cultivated? Certain topics to pursue? What advice would you give the inexperienced new faculty member?

JD: NIDCR has always encouraged people to get to know potential program officers and talk to them about how their research areas map to the Institute's priorities. After examining the websites of the appropriate institute and becoming familiar with their areas of research and envisioning a preliminary research focus, contact the most appropriate program officer and discuss the topic. The program officer can then discuss your idea or refer you to the most appropriate person if the topic is not housed in their program. Also, look at the NIH Funding Opportunities Announcements for each respective Institute, as well as NIH-wide opportunities such as those provided by the Common Fund. Also, it is a good idea to develop a mentor within your own research area/institution who can provide seasoned advice.

LK: Is there any possibility of a budget increase at NIDCR in the near future? What about a budget decrease? Or will it stay flat-lined?

JD: NIDCR cannot predict the budget outcomes. It is up to the President and Congress to determine the budget for the current and future fiscal years.

LK: Why are the paylines at NIDCR not published?

JD: Institutes that choose to publish paylines in advance calculate the payline based on expectations about the availability of funds, application loads, and the average cost of research project grants during the current fiscal year. Other institutes, such as NIDCR, prefer to describe the process for selecting applications for funding and then report on the number of applications funded at the end of the fiscal year. Because the NIH is currently operating on a continuing resolution and funding levels for the remainder of this fiscal year are uncertain, most of the NIH institutes have offered less detail this year than in the past. The NIDCR sees no benefit to publishing their payline, because applications outside of the payline can be paid under justified circumstances if these applications are a high priority.

LK: Dr. L. Tabak, Director of NIDCR said in an interview, "We must continue to place a higher priority on some areas of research than on others. In short, we must use our resources wisely, and we can't stop taking some risks." What areas do you think are high priority? Translational research?

JD: The NIDCR strategic planning process gathered public and stakeholder input about prospective activities, areas of research emphasis, future research approaches, needs, and opportunities. The result of this input is outlined in the NIDCR Strategic Plan 2009-2013. http://www.nidcr.nih.gov/Research/ResearchPriorities/StrategicPlan/

LK: How does NIDCR decide to commit millions of dollars in a fiscal year to support meritorious projects solicited through FOAs?

JD: The NIDCR prioritizes scientific opportunities on the basis of their potential impact to improve health, the readiness of the scientific community to accomplish them and their alignment with NIDCR's mission. The NIDCR strongly believes in the peer review system. NIDCR carefully considers the scores applications receive from study section, and extramural staffers weigh them against Institute priorities, including mapping them to public health needs and scientific opportunities. NIDCR also integrates input from the National Advisory Dental and Craniofacial Research Council in making funding decisions.

LK: Please describe briefly how FOAs, RFAs, etc, are created. How does NIDCR make sure that the highlighted areas of research are well aligned with the community's true interests?

JD: As part of the budget planning process each fiscal year, the NIDCR identifies topical themes for development into research initiatives. The NIDCR begins the initiative development process each year by identifying broad research topic areas. NIDCR then develops a specific initiative proposal for each theme, taking into consideration the input received. During this process, input is welcomed from our scientific advisory boards, the extramural community, interested organizations and the public at large.

IN MEMORIAM

Edwin Salzman, M.D.

Dr. Edwin Salzman, vascular and thoracic surgeon, medical researcher, Harvard professor and deputy editor of the *New England Journal of Medicine* died October 3 at the age of 82. His research demonstrating how aspirin reduces venous thrombosis is a key reason why many Americans take daily aspirin tablets.

Salzman attended Washington University in St. Louis for college and medical school and began a residency in surgery at Massachusetts General Hospital, where Edward Churchill, chief of surgery, was instrumental in moving the practice of surgery onto firm scientific ground. After his internship year in 1954, he married the former Nancy Lurie and spent two years at Wright-Patterson Air Force Base in Dayton, Ohio, in the research group developing the G-suit.

He returned to MGH in 1956 to complete his training as a general surgeon and then spent 2 years working with R.G. Macfarlane at the Radcliffe Clinic in Oxford, England, investigating how blood clots, a scientific question that would animate the rest of his career. After his training, he joined the MGH staff and Harvard Medical School faculty where he taught for 35 years, moving in 1965 to become chief of vascular surgery to Harvard's Beth Israel Hospital.

His research career focused on blood coagulation and means to produce and implant materials that would not induce thrombosis. His laboratory established that von Willebrandt's disease, a clotting disorder, was caused by platelets malfunctioning. He also showed that molecules of cyclic AMP and ions of calcium within the platelet cell play key roles in platelet function. His most clinically significant finding may have been the demonstration of aspirin's antithrombotic effect in venous disease and the discovery that aspirin could prevent post-operative venous thrombosis.

He retired from surgical practice at the age of 47, in 1976, after learning he had Parkinson's Disease, and devoted himself to full-time research. He ran an active laboratory and collaborated with Edward Merrill at MIT on artificial surfaces with specialized anti-thrombotic properties. These materials are now widely used in coronary stents and other implanted medical devices. He also worked with the editors and authors of the *New England Journal of Medicine* to keep the weekly publication at the forefront of medical research. His 1994 editorial, Living with Parkinson's Disease, describing the personal challenges from chronic illness, received a world-wide response from physician-readers and has been incorporated into medical school curricula.

During his research career, he wrote hundreds of journal articles and co-authored a standard text on hemostasis and thrombosis. He chaired the Thrombosis Council of the American Heart Association, served as president of the New England Society for Vascular Surgery, and participated in several national and international professional societies. Among his honors, he received the American Heart Association's Distinguished Achievement Award and Washington University Medical School's Alumni Achievement Award.

The Society For Biomaterials sends its sincere condolences to the Salzman family and salutes his substantial contributions to our discipline.

Monitoring and Modulating the *in situ* Biochemistry of the Foreign Body Reaction

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Various types of materials chemistry (i.e., hydrophilic, hydrophobic or charged surfaces) and properties (i.e., porosity and roughness) have an influence on the extent of the Foreign Body Reaction (FBR). While the role of different cell types in FBR is being investigated by many groups, the macrophage has emerged as the predominant cell believed to significantly direct the foreign body reaction. These cells release numerous chemicals into the extracellular matrix that serve different functions from destroying the object (oxidants), degrading the extracellular matrix to allow cellular migration (proteases such as the matrix metalloproteases [MMPs]) to cell-to-cell chemical communication via the release of signaling chemicals including leukotrienes and cytokines. The signaling proteins known as cytokines are believed to be vitally important in driving the end result of the foreign body reaction [1].

Since the FBR is a dynamic continuum of biochemical and cellular changes, many researchers have attempted to monitor the temporal evolution of cell types present at the foreign body site and the resulting biological milieu in the extracellular fluid (ECF) surrounding implanted materials. The most widely-used approach to these types of studies is the cage implant system. In the cage implant system, a piece of material is placed into a stainless-steel cage of approximately 1 cm^2 external diameter. The cage with material along with an empty cage that serves as a control is implanted into an experimental animal, typically the rat. At various time points, the cages are removed and the fluid from the cage is analyzed for cell types and cytokine protein content. While much information has been gained over the years regarding how material surface chemistry affects the cell types that are attracted to the cage as well as the possible differences in protein expression, the cage implant has limitations with respect to performing a continual bioanalysis of the chemical signaling molecules that affect the FBR.

One technique that is available for studies of tissue biochemistry is microdialysis sampling (Figure 1). Microdialysis sampling has been widely used for more than 30 years for collection of low molecular weight chemicals such as glucose and neurotransmitters (dopamine, glutamate, etc.) from mammalian brain [2]. Microdialysis sampling devices are typically referred to as either "probes" for basic research studies or "cannulas" for clinical research studies. The microdialysis probe has a semipermeable hollow fiber dialysis membrane that is available with different molecular weight cutoff (MWCO) values ranging from 5 kDa to 100 kDa for most commercially available devices. Others have reported the use of membranes with MWCO as high as 3,000 kDa. The hollow-fiber membranes are typically the same materials cut from kidney dialyzer units and have external diameters of 240 to 600 μm. Inlet and outlet tubing is attached to the membrane to allow for a perfusion fluid to pass through the membrane at microliter/min flow rates. Chemicals that can diffuse through the semi-permeable membrane are collected into the perfusion fluid. These chemicals can then be quantified with appropriate bioanalytical chemistry methods. For basic research studies, the membrane lengths vary between 1 and 10 mm. For clinical research, membrane lengths are available up to 30 mm.

Conceptually, the implantation of a microdialysis sampling probe has been compared to implanting an artificial blood capillary that allows for the collection of chemicals residing in the extracellular fluid space of tissues. It is critically important to note that as a diffusion-based sampling method, microdialysis probes can only collect solutes that are in the ECF. Any chemical that is residing within the cell or attached to cellular membranes (e.g., integrin proteins) cannot be sampled with microdialysis sampling.

Our research group is interested in monitoring different chemicals in relation to the foreign body reaction and how this response can be modulated to provide different outcomes to implanted objects. This interest has its origins in the field of glucose sensing where even today commercially-available glucose sensors are only FDA approved for clinical decision making (e.g., does the person have to inject insulin) for up to 5-7 days. There are many different reasons for the choice of this time frame, but one of the issues is the effect the FBR has on the sensor signal and output after the sensor has been implanted 5 to 7 days. There has been considerable interest in modulating the FBR to these sensor-materials via the controlled release of chemical agents including either small molecules (e.g., dexamethasone) or proteins (e.g., VEGF) [3].

Despite these important advances in controlled-release chemistry, the measured outcomes for controlled-release of drugs from materials are typically histological analyses. The biochemical changes (e.g., cytokine or other signaling molecules) that have led to alterations in the histological outcomes have not been measured in real time. In our view, a clear understanding of these biochemical changes involved in the FBR can be used to more completely understand the role of macrophage or other immune cells observed using histological analyses. This knowledge can be used to design and evaluate approaches for modulating the outcome of the FBR.

We have focused on developing bioanalytical chemistry methods to collect cytokines as well as determine the localized activity of matrix metalloproteinases (MMPs) near the probe site [4,5]. Cytokine proteins have been collected using implanted microdialysis sampling probes for up to 14 days post implantation. Using commercially-available bead-based

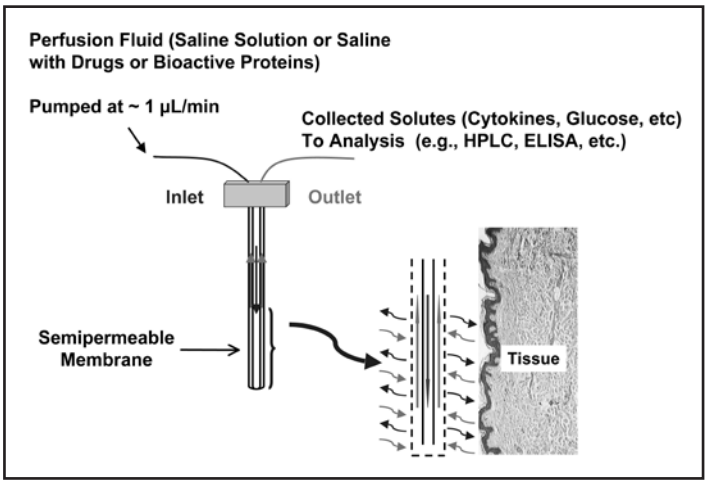

Figure 1. *Schematic of the microdialysis sampling process. Perfusion fluids (with or without bioactive agents) can be passed through the microdialysis probe at µL/min flow rates. Solutes diffuse into and out of the semi-permeable membrane.*

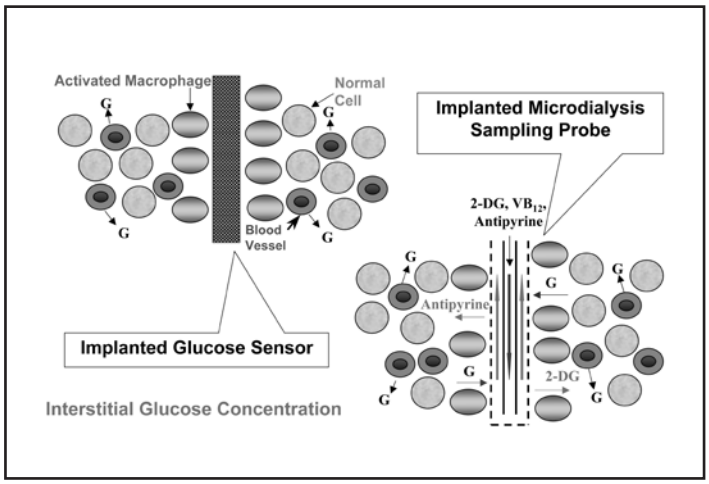

Figure 2. *Comparison of a glucose sensor vs. a microdialysis sampling probe. The microdialysis probe can deliver different internal standards such as antipyrine (AP), vitamin B12 (VB12) and 2-deoxyglucose (2-DG) to determine calibration changes as a function of implantation time.*

immunoassays (Luminex or BD), we have measured up to 13 separate cytokines within a single 25 µL microdialysis sample. Recently, we have collected cytokine proteins and have compared the collected protein content to the mRNA message quantified using qRT-PCR. For MMP analysis, we can infuse judiciously-chosen MMP substrates and collect their cleavage products in the dialysis perfusion fluid. In these studies, lower molecular weight cutoff membranes have been used to prevent the diffusion of the MMPs into the perfusion fluid and thus converting the substrates post analysis which would lead to complications with the analysis. However, larger MWCO membranes could be used to collect the MMP proteins from the ECF, as has been done in studies of MMPs in breast cancer tissue.

In another aspect of our research, the microdialysis probe serves as a mimic to an implanted glucose sensor since the two devices have approximately similar dimensions (500 µm o.d. for a dialysis probe vs. ~ 350 µm for different commercially available glucose sensors) (Figure 2). Because the collection of chemicals is diffusion-based, it is possible to also include different chemicals in the perfusion fluid and locally deliver these materials to the ECF to influence the localized tissue biochemistry. In this way, the microdialysis probe serves as a dual drug delivery/sample collection device that can allow for many different permutations with respect to delivery of prophylactic agents meant to influence the macrophage-released chemicals [6].

In the dual delivery/sample collection procedure, we have delivered different drugs (dexamethasone and nitric oxide releasing agents) as well as cytokines to modulate the FBR. We also have strategies to evaluate how the probe calibration is affected by these modulating agents while simultaneously collecting targeted cytokines.

In summary, microdialysis sampling has a unique potential to allow for biomedical studies of the FBR to be performed where modulation and monitoring of the biochemistry is desired. The drawback of this approach is that changes to the biochemistry inside cells (e.g., NF-κB activation or alterations in integrin binding proteins) cannot be observed. However, because so much of the FBR involves chemical communication between cells via the ECF, the biochemical aspects of the FBR which can be studied using this method are plentiful. Given the inexpensive nature of the microdialysis sampling approach with respect to equipment and supply costs, the technique can be rapidly set up in most research laboratories.

Acknowledgement. The work on microdialysis sampling for studies of the FBR has been supported by the NIH (EB 001441). The author thanks the many students and postdocs who have worked on these projects over the years.

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Summits for Cure

Blindness from cataracts remains the primary cause of blindness in our world. As people age, they develop cataracts, which can lead to blindness if left untreated. In the developing world, cataracts often remain untreated due to poor accessibility to healthcare, and we all know this is dependent on various socio-economic factors. Blindness can obviously be quite devastating—the damage is more profound in the developing world due to poor infrastructure, social stigma and inadequate support for the blind. Studies have shown unnecessary blindness from cataracts reduces the life-expectancy rate by at least 1/3. The irony is that blindness from cataracts can be easily treated. The treatment is often an out-patient surgery (less than 20 minutes) and involves the extraction of the cataract lens and replacement with an artificial intraocular lens or IOL.

Like most of us here at the Society For Biomaterials, my primary objective and focus is to contribute towards the advancement of healthcare for patients everywhere through scientific research and new product development. Advancement of biomaterials technology is arguably the primary facet in achieving this goal, and our professional society provides a unique and valuable platform towards this advancement. As Director of Research and Development with Advanced Vision Science Inc. (A Santen Company), I lead research and development of advanced solutions to treat cataracts.

I began a personal seven-summit quest by scaling Mt. Blanc (tallest in Western Europe) in 2005. Last year, I had plans to scale the tallest peak in Africa. My discussions with the founders of the Himalayan Cataract Project regarding the state of affairs on unnecessary blindness motivated me to initiate SummitforCure! I saw my mountaineering goals as an opportunity to align with my primary goal to address global healthcare needs.

SummitforCure! was born as a portal for summiting the tallest peaks in every continent on earth and dedicating/raising funds during the course to cure illness around the world. The concept for SummitforCure! is to raise contributions, funds and relevant medical equipment/devices that will go directly toward the project. For corporate and academic sponsors, this is a unique brand marketing opportunity (on top of every continent) for a worthy cause. This is a small step in addressing the looming issue of unnecessary blindness in our world.

For 2010-2011, our target was to raise $5,895—equivalent to the elevation in meters of the tallest peak in Africa (Uhuru Peak, Kilimanjaro, Tanzania.) With generous donations from supporters worldwide, we were able to raise the equivalent of $140,884, including 2,687 intraocular lenses for this fantastic cause. Our goal for 2012 is to raise $22,841 (equivalent height in feet of Aconcagua) toward curing global blindness. The next target summit is Mt. Aconcagua and target date is December 2012 and target cause is unnecessary blindness in sub-Saharan Africa.

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How Well do You Know Your MATES?

Joy Dunkers, Government News Contributing Editor

There is a group that quietly goes about the business of advancing the areas of tissue engineering and regenerative medicine. I say "quietly" because this group's work, while impactful, is not well known outside of government circles. How well do you know your MATES? MATES is an acronym for Multi-Agency Tissue Engineering Science Interagency Working Group (IWG). Federal agencies with very different missions participate in MATES including: the Center for Medicare and Medicaid Services (CMS), Defense Advanced Projects Research Agency (DARPA), Department of Agriculture (USDA), Department of Defense (DoD), Department of Health and Human Services (HHS), Department of Veterans Affairs (VA), Food and Drug Administration (FDA), National Institutes of Health (NIH), National Institute of Standards and Technology (NIST), National Air and Space Administration (NASA), National Science Foundation (NSF), and the Naval Research Laboratory (NRL).

The goals of the MATES IWG are:

- Facilitate communication across departments/agencies by regular information exchanges and a common web site.
- Enhance cooperation through co-sponsorship of scientific meetings and workshops, and facilitation of the development of standards.
- Monitor technology by undertaking cooperative assessments of the status of the field.
- Provide for support of Tissue Engineering research through an Interagency Announcement of Opportunities in Tissue Engineering.

According to Dr. Marcus Cicerone, Bioimaging Project Leader at NIST, the essence of the MATES mission is to "…identify critical scientific needs that are not supported elsewhere in Tissue Engineering and Regenerative Medicine (TE/RM) and to ensure those needs are addressed. In addition, the IWG actively seeks to expose the TE/RM community to science and technology normally outside its scope that has the potential to positively impact the field."

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Book Review

From Lynne Jones, book reviewer
Co-authored by Lynne C. Jones and Howard Winet

Popper

by Bryan Magee, originally printed by Fontana Press (London). ISBN 0006860087; Other printings: Penguin, 1973, ISBN 0670019674 (Viking Press, ISBN 0670411744; later titled *Philosophy and the Real World*)

Who was Karl Popper, and what did he have to say about the Scientific Method? Popper (1902-1994) was a professor at the London School of Economics who published more than 20 books. Karl Popper has been called "the greatest philosopher of science there has ever been." While this may be disputed in philosophical circles, he is known for his belief in empirical falsification and as a critic of basing the scientific method on induction. He is also known for his political philosophies against Marxism and for Democracy in a form that he calls the "Open Society."

Bryan Magee, the author, provides us with a glimpse into the man and his philosophical positions. However, this book is so much more than a line to line translation of Popper's teachings. This short book (111 pages) is a simple, coherent distillation of Popper's philosophies regarding the scientific method, politics and society. Magee has the ability to present complex concepts in everyday terms. His personal and professional relationship with Karl Popper provided him with insights into the reasoning behind the man as well as access to many unpublished writings, which provide an important contextual framework.

There are seven chapters in this book:

Chapter 1. Introduction

This chapter provides an overview of the life of Karl Popper in order to recognize the significance of Popper's work ranging from criticisms of Marxism to its impact on quantum physics.

Chapter 2. Scientific Method – The Traditional View and Popper's View

This chapter introduces us to the concepts of verification and falsification. Magee states scientists search for natural laws via the Scientific Method. These general statements are based upon "accumulated observations of specific instances," known as induction, and this is the basis for the distinction between science and non-science. He references Hume's criticism of this noting "…No number of singular observation statements, however large, could logically entail an unrestrictedly general statement." Popper provided an alternative to induction, falsification. Falsification is a concept where circumstances are tested to determine when the empirical generalization does not hold true.

The following excerpt (p. 24) illustrates the benefit of this process:

> *Suppose we start by believing, as most of us are taught at school, that it is a scientific law that water boils at 100° Centigrade. No number of confirming instances will prove this, but we can nevertheless test it by searching for circumstances in which it does not hold. This alone challenges us to think of things, which, so far as we know, no one else has hit on. If we are at all imaginative we shall soon discover that water does not boil at 100° Centigrade in closed vessels. So what we thought was a scientific law turns out not to be one. Now at this point we could take a wrong turning. We could salvage our original statement by narrowing its empirical content to 'Water boils at 100° Centigrade in open vessels' And we could look systematically for a refutation of our second statement. And if we were rather more imaginative than before we should find it at high altitudes: so that to salvage our second statement we would have to narrow its empirical content to 'Water boils at 100° Centigrade in open vessels at sea-level atmospheric pressure.' And we could then begin a systematic attempt to refute our third statement. And so on…But to proceed in this way, through a series of statements with vanishing empirical content, would be to miss the most important features of the situation. For when we discovered that water did not boil at 100° Centigrade in closed vessels we had our foot on the threshold of the most important kind of discovery of all, namely the discovery of a new problem: 'Why not?'*

Chapter 3. The Criterion of Demarcation Between What Is and What Is Not Science

What is and is not science continues to be debated in today's philosophy classes. According to Magee, the traditional inductivist view is that science is based on "statements about the world, which have the maximum degree of probability." Popper refutes this based upon the reality that a statement can be so generalized as to have almost no informative content. The example given is the statement, "It will rain," which, although undeniably true, provides us with little insight.

One of the points raised in this chapter has had a significant impact on my thinking:

> *For all of us, in our activities, the notions that we can do better only by finding out what can be improved and then improving it; and therefore that shortcomings are to be actively sought out, not concealed or passed over; and that critical comment from others, far from being resented, is an invaluable aid to be insisted on and welcomed, are liberating to a remarkable degree.*

continued on next page

Embracing this concept can have a profound effect on scientific research from developing hypotheses to be tested to the final publication and presentation of our results.

Chapter 4. Popper's Evolutionism and His Theory of World

This interesting chapter delves into the theory of evolution. Popper states "All organisms are constantly, day and night, engaged in problem solving; and so are all those evolutionary sequences of organisms…" (*Objective Knowledge*, p. 242). One of the points Magee makes is Popper, like Darwin, offers no explanation of the genesis of life, and he believes that origination is not susceptible to rational explanation. The remainder of this chapter primarily focuses on Popper's musings on man and the development of civilization.

Chapter 5. Objective Knowledge

This chapter is based on the following:
P_1 (the initial problem) TS (trial solution) EE (error elimination) P_2 (the resulting situation)

He believes this type of process is evident in the behavior of animals and plants as well as in the development of scientific thought and theories. This is described as a feedback process, although "…It is not cyclic, for P_1 is always different from P_2." Magee suggests this approach allows one to 1) focus on problems and 2) realize"…complex structures are only to be created and changed by stages, through a critical feedback process of successive adjustments."

Chapter 6. The Open Society

Popper's teachings have both scientific and political implications. He is known as a critic of Marxism. Popper was an advocate for democracy, or the belief in free institutions. His concepts are a logical extension of his thoughts on the scientific method. He believed in an open society where "… incompatible views are expressed and conflicting aims pursued, a society in which everyone is free to investigate problem-solutions and to propose solutions, a society in which everyone is free to criticize the proposed solutions, most importantly those of government, whether in prospect or application."

Chapter 7. The Enemies of the Open Society

This chapter provides context for Popper's views on Marxism and politics and his views of other philosophers.

Our Musings

Bryan Magee was 43 years old when he published this book. He had already started his career as a proponent of philosophy and friend of Karl Popper. He had been trained as a philosopher at Oxford, and his biography shows no evidence of a scientific background. He has written a number of books since 1973, and he may reveal more familiarity with science in these. Thus, it may be forgiven that he does not describe why Popper had to construct a deductive epistomology for science. Understanding this context is critical if a scientist is to appreciate the magnitude of his contribution to operational science. Inductive logic was invoked by Francis Bacon in 1620 in his *Novum Organum*. He was forced into this epistemology by the damage Aristotelian deductive logic had caused through scholasticism. He was relatively safe in England when he published, but Galileo was brought before an inquisition, so the times were dangerous. Induction-based experimentation drove the growth of science during the enlightenment, and its practitioners grew more and more confident with each confirmed discovery. By the 1920s, the belief that physics and chemistry would eventually bring us complete understanding of the universe—reductionism—was the rule amongst scientists. Engineers and physicians had gradually jumped on the bandwagon during the 19th century, and the more academic among them wanted to be as "scientific" as possible. In 1927, Werner Heisenberg published his "Principle of Uncertainty" paper and brought reductionism to an end. Scientists who understood the implications of the work were concerned. Some thought causality was dead. Some philosophers concurred. Karl Popper, an Austrian, published his *Logik der Forschung* in 1934, where he proposed a new form of deductive logic to replace reductionistic induction. Unfortunately, the English translation did not appear until the 1959 publication of *The Logic of Scientific Discovery*. (There are a number of political reasons for this delay. The interested reader should read Magee's account of Popper's years at Oxford in Chapter 1.) In *Logik der Forschung* he lays the foundation for the concept of a falsifiable hypothesis and the role of statistics in its disproof. Today, most scientific philosophers consider his abandonment of induction as overkill and propose good science consists of using deductive logic to formulate hypotheses from conclusions (theories or hypotheses) well supported by published work, and they use inductive logic to organize the data gathered into a conclusion stating some statistical level of confidence that a falsified version of the hypothesis has been disproved. There can be little doubt, however, that his approach comforted many thoughtful scientists. Those who were completely ignorant of both the implications of Heisenberg's conclusions and Popper's contribution (and the majority of scientists today fit this category) worked on in pseudoscholarly bliss.

Students and young investigators are encouraged to read this book. Regardless of whether you embrace all of Popper's teachings, an understanding of his approach to the scientific method can enhance your research and have a significant impact on how you justify your own scientific approach. Furthermore, his pragmatic view to the scientific method may be one of the most important things to take away from this text.

Other relevant books:

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McGrew, T., Kelly, M.A., Allhoff, F. (eds) 2009. Philosophy of Science: An Historical Anthology. Wiley-Blackwell. Pp 680.

Popper, K. 1935 (German);1959 (English); 2007. The Logic of Scientific Discovery. New York: Routledge Classics. pp, 513.

And the postscript series to *The Logic of Scientific Discovery*:

- *Realism and the Aim of Science*
- *The Open Universe: an Argument for Interminism*

How Well do you Know Your MATES?

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MATES was established in 2000 under the auspices of the Subcommittee on Biotechnology of the National Science and Technology Council but is now an independently operating organization. In 2007, a strategic plan was developed using contributions from all of the participating agencies. This plan identifies the technological needs which, if supported, will advance the field of TE/RM. From this document, four overarching goals are being pursued:

1. Understanding and controlling the cellular response.
2. Formulating biomaterial scaffolds and the tissue matrix environment.
3. Developing enabling tools
4. Promoting scale-up, translation and commercialization.

To accomplish these goals, eight strategic priorities for Federal Government agencies reflect a broad portfolio of work: from fundamental understanding of cellular machinery and cell/environment interaction, to biomarkers and assays, imaging and computation, tissue scale-up, storage and commercialization. Finally, the plan discusses the various vehicles used to implement the MATES vision.

Since 2007, MATES has concentrated on fulfilling its strategic plan goals. A workshop will be held in May/June 2012 on advanced imaging techniques and methodologies for TE/RM. The goal is to accelerate development and adoption of advanced imaging techniques and methodologies by identifying current needs of tissue engineers. A paper summarizing the meeting and its outcome will be published.

MATES is currently examining agency portfolios in modeling and simulation in TE/RM. It is anticipated that, similar to imaging in TE/RM, there will be a gap to fill in what the federal government currently funds that will help move the field ahead at a quicker pace. A workshop or a funding initiative in the future in this area is a possibility once more information is gathered.

Dr. Christine Kelley from the National Institute of Biomedical Imaging and Bioengineering (NIBIB) at NIH, the current chair of the MATES Working Group, says, "The group is very committed toward achieving all of the strategic plan goals and will provide updates beyond the imaging for TE/RM and modeling and simulation in TE/RM activities in the near future."

Hopefully, now you can say with confidence, "I know my MATES." To learn more about the organization, its members, strategic plan and activities, go to www.tissueengineering.gov.

The TopoChip by Materiomics

Carl Simon, Jr.

Extensive research has demonstrated the role of substrate topography in directing cell function. However, much of this work has tested surface structures using a "one at a time" approach. In order to accelerate discovery of new surface topographies that can direct cell function, Materiomics (www.materiomics.com) has pioneered a high-throughput approach to screening surface topographies called the "TopoChip" [1]. TopoChips are created using lithographic methods where 2000 different surface topographies are represented on a chip in a grid-shaped array. Each topography is mathematically designed using three primitive shapes: a circle, a rectangle and a triangle. TopoChips can be custom-designed and there are a total of 158 million topographies from which to choose. The topography libraries can be constructed from different materials such as degradable polymers, calcium phosphates or titanium. Stem cells can be seeded on the TopoChips and their response assessed using high-throughput microscopy. In a recent example, TopoChips were used to identify optimal surface topographies for driving proliferation or differentiation of mesenchymal stem cells [1]. The TopoChip technology enables systematic screening of topographical parameter space to determine how surface structure can be leveraged to direct stem cell fates.

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TopoChips can be custom-designed and there are a total of 158 million topographies from which to choose.

Announcing the SFB Biomaterials and Medical Products Commercialization SIG

Dear Members,

We are excited to announce that the name change of the Biomaterials Availability and Policy (BAP) Special Interest Group to the Biomaterials and Medical Products Commercialization (BMPC) Special Interest Group has been approved by Council. We agree that this new name better reflects the current purpose and mission of this SIG.

The Biomaterials and Medical Products Commercialization (BMPC) SIG would like to make Society members aware of some important legislative initiatives that have been introduced for consideration in the House Energy and Commerce Committee and that are intended to "improve the predictability, consistency, and transparency of FDA's medical device review and approval process." The House Energy and Commerce Committee news release can be found here: www.qmed.com/news/committee-members-introduce-fda-reform-package-protect-american-patients-jobs-and-medical-innov

Here is a summary of the initiatives:

- The Premarket Predictability Act reaffirms the "least burdensome" provisions already included in the law but appear not to have been followed in recent years. These provisions were enacted to streamline the review of new devices. Second, the PPA would require reviewers to provide the scientific or regulatory rationale for major decisions and establish an expedited approval appellate process. Finally, the PPA would establish two Investigational Device Exemption pathways to create more flexibility in conducting trials for clearance/approval.
- Novel Device Regulatory Relief Act of 2011 streamlines the de novo (lower risk devices) classification process by striking the requirement that an applicant submit a 510(k) application before entering the de novo process.
- Keeping America Competitive through Harmonization Act requires FDA to enter into agreements, when feasible, with Tier One countries on methods and approaches to harmonize regulatory requirements for premarket review, inspections, and common labels.
- Humanitarian Device Reform Act of 2011 fosters the increased development of devices for those with rare diseases that affect fewer than 4,000 patients by removing the current profit cap and clarifies the 4,000 patients limit applies per year.
- Patients Come First Act reaffirms the mandates of the Safe Medical Devices Act of 1990 that FDA require Premarket Approvals from the more complex, pre-amendment Class III devices or move them to Class II. The act also codifies GAO's recommendations that Congress reform FDA's current device recall authority.
- Cultivating Scientific Expertise to Foster Innovation Act fixes FDA's conflict of interest policies to ensure the most knowledgeable experts are able to serve on FDA advisory committees.
- Food and Drug Administration Mission Reform Act clarifies that establishing a predictable, consistent, and transparent regulatory environment, facilitating innovation and applying a patient-focused, risk-benefit framework is part of FDA's mission to ensure the agency takes them into account.
- Modernizing Laboratory Test Standards for Patients Act clarifies that the FDA does not have authority over Lab-Developed Tests, which are developed within labs and not sold as medical devices, and Direct-to-Consumer Tests.
- Guidance Accountability and Transparency Act requires public notice and involvement in the development of level 1 guidance documents, which set forth initial interpretations of law or changes in interpretation of regulatory requirements, and if the agency is not able to comply, requires FDA to provide an explanation. The bill also requires FDA to finalize draft guidance documents by a certain date.
- FDA Renewing Efficiency from Outside Review Management Act of 2011 reauthorizes the third party inspection program and reforms the third party review program to foster better participation, decrease approval times and conserve FDA resources.

Industrial News

Steve T. Lin, Industrial News Contributing Editor

The medical device tax, slated to go into effect in 2013, could cost tens of thousands of jobs, almost double the industry's total taxes, raise the effective tax rate to among the highest in the world and harm U.S. competiveness, according to a study, "Employment Effects of the New Excise Tax on the Medical Device Industry," released by the Advanced Medical Technology Association (AdvaMed). The medical device industry directly employs about 400,000 Americans, and the study concludes the device tax puts 43,000 of those jobs at risk, with a corresponding loss in wages of more than $3.5 billion. The new tax would add $2.67 billion a year in new taxes. The study identified the following conclusions as a result of the implementation of the device tax:

- U.S. industry employment and employment compensation could decline. Based on reasonable assumptions, the study estimates the loss of 43,000 jobs or 11% in the medical device industry.
- The economic effects of the tax likely would be seen in every state, especially harming states employing large numbers in the medical device industry.
- Innovation could be stifled, as the new tax must be paid by companies regardless of net income.
- The cost of medical devices would increase for health care providers and consumers.

On September 16, 2011, President Obama signed into law the 2011 America Invents Act (i.e., Patent Reform law). The 2011 America Invents Act is the most comprehensive patent reform since the 1952 Patent Act. Many of the proposed changes would harmonize U.S. patent laws with those of Europe, China and other nations.

Some key highlights of the Patent Reform law include:

- The switch from a first-to-invent system to a "first-inventor-to-file" system.
- False Patent Marking cases would be limited to only those filed by persons who have actually been harmed by the alleged misconduct.
- A revamped post-grant procedure consisting of (a) post-grant review request that may be filed with the PTO within nine months of a patent's issuance; and (b) inter partes reexamination request that may be filed with the PTO after this timeframe.
- Permitting third parties to submit prior art patents or publications, PTO or court statements by the patent applicant to the patent examiner during pendency of a patent application.
- Transitional post-grant review proceeding for review of the validity of covered business method patents of a "financial product or service."
- Prior Commercial Use Defense — prior user rights would apply to any technology, with a showing of prior commercial activity.
- Study of Patent Litigation by GAO regarding Non-Practicing Entities.

Surgical products company Ethicon Endo-Surgery, a division of Johnson & Johnson, is entering the medical device reprocessing and remanufacturing business with a planned acquisition of SterilMed. With the cost of healthcare in the U.S. continuing to skyrocket, medical device reprocessing could become a service in high demand, and SterilMed appears well-positioned to capitalize on the stronger emphasis on cost containment by private firms and the federal government in the coming years. Reprocessed devices typically cost about half the amount of new devices. SterilMed has some big-name customers, including Cleveland Clinic, Duke University and Massachusetts General Hospital. Along with Ascent Healthcare Solutions, the two companies perform about 95 percent of device reprocessing in the U.S.

Medtronic Inc. (Minneapolis, Minn.) launched a pivotal trial in support of a European regulatory win for its Engager transcatheter aortic valve implantation system. The trial will include 150 people with severe aortic stenosis, a condition where the aortic valve doesn't open fully and blood isn't properly pumped out of the heart. The Engager system delivers a replacement valve via catheter, rather than through open-heart surgery. The trial will enroll 150 patients at centers across Germany, Israel, France, Belgium and Switzerland to assess the safety and clinical performance of the Engager system, which Medtronic obtained through its acquisition of Ventor Technologies Ltd. in February 2009.

Sony, a consumer electronics giant, had acquired Micronics, based in Redmond, Wash., and plans to enter the market for portable medical testing. Micronics specializes in developing portable devices that can be used to perform tests on body fluids such as blood and saliva. Sony said it will look to accelerate a move into producing "point of care" medical testing devices that can be easily performed on patients without having to move them. The company already sells items such as printers, cameras and data recorders for medical use, but this would mark a new venture. Last year, Sony acquired iCyt Mission Technology, which produces devices that can sort cells for use in stem cell and disease research.

The U.S. Food and Drug Administration issued draft guidance for manufacturers that updates and streamlines the de novo review process used for certain innovative, low- to moderate-risk medical devices that do not meet the requirements for clearance under the better-known 510(k) review process. Currently, devices are only considered for the de novo program after the agency rejects a 510(k), establishing that the device is not substantially equivalent to another legally

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Member News

Alan Litsky,
Society Business & Membership Contributing Editor

Bingyun Li, Associate Professor at West Virginia University Medical School, has been awarded the Berton Rahn Prize from the AO Foundation for his research project entitled "A Pilot Study of Interleukin-12 local Delivery for Infection Prevention after a Traumatic Open Fracture." Dr. Li received the award in July, 2011, at the Foundation Trustee's meeting in Berlin, Germany. Bingyun is currently vice-chair of the Orthopaedic Biomaterials SIG.

Cato Laurencin has been named to the advisory council of the National Institute of Biomedical Imaging and Bioengineering (NIBIB), a board advising the secretary and assistant secretary of the Department of Health and Human Services, the director of the National Institutes of Health and the director of the NIBIB on matters concerning research, training and health information dissemination. Laurencin is the director of the Institute for Regenerative Engineering at UConn and the chief executive officer of the Connecticut Institute for Clinical and Translational Research.

Anthony J. Atala, M.D has been chosen as a member of the Institute of Medicine (IOM). Election to the IOM is considered one of the highest honors in the fields of health and medicine. New members are elected by current active members through a highly selective process that recognizes individuals who have made major contributions to the advancement of the medical sciences, health care and public health.

Arthur J. Coury (Genzyme, retired), **Robert S. Langer** (Massachusetts Institute of Technology), **Alan Litsky** (Society Business & Membership News Contributing Editor), **Nicholas A. Peppas** (University of Texas, Austin) and **Buddy Ratner** (University of Washington) were inducted as 2011 Fellows of the American Chemical Society. The ACS Fellows Program was created in December 2008 "…to recognize members of ACS for outstanding achievements in and contributions to Science, the Profession, and the Society."

Recent news of three academic promotions earned by SFB members: **Liisa T. Kuhn** has been promoted to Associate Professor and tenured in the School of Dental Medicine at the University of Connecticut Health Center. **Johnna S. Temenoff** has been promoted to Associate Professor and awarded tenure in the Wallace H. Coulter Dept. of Biomedical Engineering at Georgia Institute of Technology. **Horst von Recum** has been promoted to Associate Professor and is Associate Chair and Director of Graduate Education in the Department of Biomedical Engineering at Case Western Reserve University

Industrial News *continued from previous page*

marketed device. The draft guidance outlines a pathway for a concurrent 510(k) and de novo petition without duplicative data requirements, trimming up to 90 days from the process and fostering more efficient, early interaction between manufacturers and the FDA. It also provides clarity for manufacturers on the suitability of a device for the de novo process.

Carticept Medical, Inc., (Alpharetta, Ga.) a developer of innovative products for the treatment of cartilage injuries and osteoarthritis, announced it has received 510(k) clearance from the Food and Drug Administration to market its Navigator Delivery System (Navigator DS) in the United States. The Navigator DS is a computer-controlled drug delivery system with integrated ultrasound guidance designed to increase the efficiency, accuracy and safety of administering pain-relieving medications for joint pain. The current standard of practice depends on the expertise of the clinician and the accuracy of the medications injected into the affected joint space. Recent studies have demonstrated greater accuracy with improved function and decreased pain in patients receiving ultrasound-guided injections. The Navigator DS automatically prepares the medication dose, guides accurate needle positioning prior to drug delivery and simplifies record-keeping.

The Food and Drug Administration said it is seeking public input on a plan to create a network of outside experts who would help understand new technology in medical devices, potentially speeding up device approval. The agency formed a pilot committee of such experts, which will run through December 30. Although the agency's devices center already has a staff of scientists, engineers and clinicians, the FDA often draws on external expertise in reviewing products, especially in areas where knowledge can change rapidly. The experts in the pilot program will not provide policy advice or opinion but will help center staff form their own conclusions. The program is part of the FDA's efforts to reform its fast-track approval process for medical devices, called 510(k). In recent years the agency's devices unit has been dogged by high staff turnover, funding woes and major recalls. Earlier this year, the Institute of Medicine, in a report to the FDA, said 510(k) did not adequately protect patients and recommended a more thorough process that would likely raise the costs for device makers. For their part, device makers say agency reviewers lack adequate training and are too slow at approving devices.

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Special Interest Group Application

Please note: You must be a member of SFB to join a SIG

First Name: _____ Last Name: _____ Suffix: _____

Highest Degree: _____ Title: _____

Company/Affiliation: _____

Department: _____

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Special Interest Groups (Optional)

*Each Special Interest Group is $10 per year (**free for Student Members**)*

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- ☐ Biomaterials Education
- ☐ Cardiovascular Biomaterials
- ☐ Dental/Craniofacial Biomaterials
- ☐ Drug Delivery
- ☐ Engineering Cells & Their Microenvironments
- ☐ Implant Pathology
- ☐ Ophthalmic Biomaterials
- ☐ Orthopedic Biomaterials
- ☐ Protein & Cells at Interfaces
- ☐ Surface Characterization & Modifications
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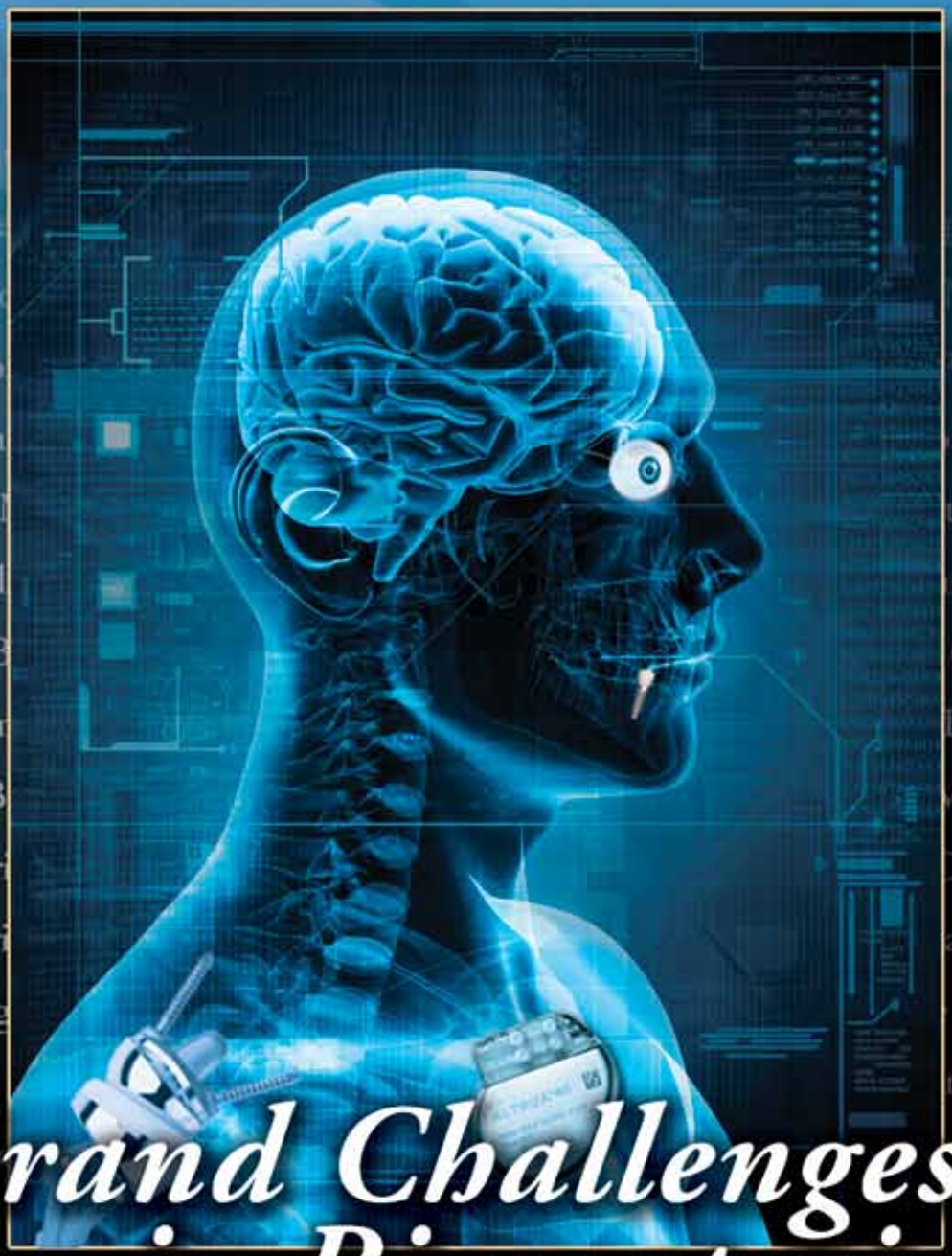

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ABSTRACT DEADLINE: MARCH 25, 2012

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