# SurFACTS in Biomaterials

January-February 2009 Volume 14 Issue 1

#### **BioInterface 2008**

More than 100 surface science professionals and those interested in surface science attended the Surfaces in Biomaterials Foundation annual BioInterface Workshop and Symposium Oct. 27-29 at the Millennium Hotel in downtown Minneapolis, MN.

The conference received high marks from attendees. Evaluations applauded the three days of presentations and sessions for being both relaxed and open to discussion about developments in the field. Attendees also commented on the size as a plus, as it fostered networking that is not found in larger bioscience conferences.

Ken Stokes, renowned scientist and Bakken Society Fellow

from Medtronic (Retired)was this year's Surface Science Award winner. Stoke's luncheon address riveted attendees with a discussion of Implantable Polyether Polyurethanes.

Seven student posters were submitted in the Student Poster Contest. The posters are a method for the Foundation to open its doors to students to interact with professionals in the field. Zeeshan Syedain was this year's Student Poster Award winner and recipient of \$1,000 from the Foundation.

The Foundation thanks this year's sponsors: DePuy Orthopaedics, Diamond level; DSM PTG, Gold; Boston Scientific, Point-Counterpoint session.

### From the Editor

Greetings from the frozen north. Frozen not just in terms of temperature (currently -25 C in Madison, Wisconsin) but also frozen economically, just like the rest of the world. There's not much we can do with the temperature, at least not over a time scale of years, but perhaps there is something we can do with the economy. We are in an excellent position to generate economic growth through our chosen fields of medical technology and healthcare since these are major economic drivers. We also want to keep our own personal economy sound through the current worldwide turmoil. Joe Flannigan, SurFACTS staff editor, addresses this briefly on page 3 through a

powerful opportunity for networking: Surfaces in Biomaterials has created a networking group through <u>LinkedIn</u>.

In the remainder of this editorial, I will provide my assessment of such networking and encourage your participation.

The value of extensive professional networking is tremendous. This is why we attend professional meetings and exchange business cards. For driving economic growth, we use our networks to create value in our current jobs by bringing in new opportunities, new technologies, and improving methods to decrease costs and create sales. And of course, we use networking to find employment and consulting opportunities.

Editor Continued on Page 2

#### What's Inside

FDA chief to step down as Obama is sworn in Pg. 3

C.R. Bard announces vascular stent approved by FDA Pg. 3

## Foundation Networking Opportunities Pg. 3

Medtronic: Device Helps Epilepsy Patients In Study Pg. 4 Massachusetts Releases Proposed Pharmaceutical and Medical Device Manufacturer Code of Conduct Pg. 5

Eye on BioInterface 2008 Pg. 6

Funding a Watchdog at Foundation Pg. 8

W. L. Gore & Associates Receives CE Mark Pg. 8

Boston Scientific Acquires Labcoat Limited Pg. 9 Agion Partners with Stryker Instruments to introduce FDA 510k-Cleared Catheters Pg. 9

Meetings/Upcoming Events Pg. 11

# From the Editor

Web-based Social networking is no longer just the stuff of kids using Facebook and MySpace to discuss who is dating whom. Social networking websites are now in the mainstream of business. About a year ago, even the Wall Street Journal discussed how to effectively utilize webbased social networking.

There are many choices for social networking websites. Some of these are guite specialized such as Sermo.com (for licensed physicians to consult with colleagues), Scispace.net (for scientists), as well as others that connect those with mutual interests in music, art, religion, and other areas. For general business networking sites, the premier site is LinkedIn. com with its 30 million current members. As indicated, Surfaces in Biomaterials has chosen to create a group on this site. The utility of LinkedIn is demonstrated by the readers of BioTechniques, where 43% of their polled membership report utilizing LinkedIn to pursue professional development. I encourage our readership to consider joining our user group on LinkedIn.

I have been a member of LinkedIn for three years and have found it to be a very helpful tool. As I draft this, my personal network consists of <u>97 direct connections</u> to persons I know professionally. Through my direct connections, I have more than 12,400 second-degree connections (persons connected to my direct connections) and 1.2 million third degree connections. Many of them are active in our Foundation, many in various related areas, as well as other professional areas relevant to my work.

So how is LinkedIn useful and how do I use these connections? Let's say I am working on a project that requires specific expertise. This might be a technical proj-

By Steven L. Goodman, Ph.D., 10H Technology Corporation

ect such as SIMS analysis, polyurethanes, device pathology, regulatory submission, or perhaps I am working with a start-up business that is seeking investors. To find assistance I can simply type keywords into a search box. For example, if I enter "drug delivery" up pops a list of 7,000 persons. A few of these are direct contacts, while most are two or three degrees away. Since each is linked to their biographical profile, a LinkedIn search is more complete than searching my own contacts list on "Outlook," or rifling through a pile of business cards. And of course, this is much more focused than a Google search. Most importantly, these are persons I know directly or are known by persons we know in common, hence are recommended. Quite often the secondary and tertiary contacts are persons I have previously met at a meeting, or even worked with many years ago but their business card in my possession (somewhere?) may be from two or three jobs or locations ago. It is then easy to make contact, either via direct email or via LinkedIn email. LinkedIn also has a mechanism to enable introductions when there is no direct connection.

The Surfaces in Biomaterials group will enable our membership to share our connections in this way. This is what professional societies are all about – making connections. A second aspect of LinkedIn that has not been discussed is that the groups create very convenient discussion forums. This provides a different route for finding expertise or opportunities. For example, I could post to the Surfaces in Biomaterial group (or to other groups such as "Medical Devices," or "Bionanotechies") a question such as, "I need some expertise in biomaterials based drug delivery, especially relating to release rates...." Or, I can answer

Editor Continued on Page 10

SurFACTS in Biomaterials is the official publication of the foundation and is dedicated to serving industrial engineers, research scientists, and academicians working in the field of biomaterials, biomedical devices, or diagnostic research.

#### Foundation Officers

Joe Chinn, President

J Chinn, LLC. 6428 Oxford Rd S Shakopee, MN 55379 Telephone (952) 496-1159

Carl Turnquist, Past President

Genzyme PO Box 9322

Framingham, MA 01701-9322 Telephone (508) 271-4728 **Dave Sogard, Vice President** 

Boston Scientific, Cardiovascular 5905 Nathan Lane MS-P33 Plymouth, MN 55442 Telephone (763) 694-3009

Facsimile (763) 694-6940

Klaus Wormuth, Secretary SurModics, Inc. 9924 West 74th Street Eden Prairie, MN 55344 Telephone (952) 947-8652

Facsimile (952) 829-2743 Lawrence Salvati, Treasurer

DePuy Orthopaedics 700 Orthopaedic Dr Warsaw, IN 46581-0988 PO Box 30450 Telephone (574) 372-7159

Committee Chairs

Membership Larry Salvati

BioInterface 2008 Program
Carl Turnquist

BioInterface 2008 Workshop Dave Sogard

Awards

Dave Sogard

Foundation Office Staff
Bill Monn, Executive Director

1000 Westgate Drive, Suite 252 St. Paul, MN 55114 Telephone 651-290-6267 Fax 651-290-2266 Fmail: billm@surfaces.org

Andy Shelp, Assistant Executive Director 1000 Westgate Drive, Suite 252

St. Paul, MN 55114 Telephone 847-977-6153 Fax 651-290-2266 Email: andys@surfaces.org

#### SurFACTS in Biomaterials Editors

**Executive Editor** 

Steven Goodman 10H Technology sgoodman@10htech.com

Staff Editor

Joe Flannigan Ewald Consulting joef@ewald.com

Biology Editor

Joe Berglund Medtronic Cardiovascular joseph.berglund@medtronic.com

Characterization & Analysis Editor

Klaus Wormuth SurModics kwormuth@surmodics.com

Surface Modification Editor

Dan Storey Chameleon Scientific dan.storey@chmsci.com

Regulatory Editor

Phil Triolo Phil Triolo & Associates LC philt@philt.com

Advertising Manager

Ewald Consulting advertising@surfaces.org

© 2009 published by the Surfaces in Biomaterials Foundation. All rights reserved.

### **Foundation Networking Opportunities**

With the economy in peril, one of the best things to do is to join together socially and find ways to improve. Learning from one another is the best way to succeed.

With that in mind. The Foundation has created a number of ways for members to come together to "stay warm." The Foundation website (surfaces.org) has a job bank at the disposal of all members who are

looking for work, or looking for a prospective employee. It is free of charge for all members, so we invite you to please résumés and job openings from your company.

The Foundation has also created a LinkedIn group for everyone to join to exchange ideas professionally. We will post information there as well as creating discussion topics, and we invite you to contribute your thoughts and opinions. By Joe Flannigan, Staff Editor

You can view or post jobs at www. surfaces.org. To join the Linkedln group, go to linkedin.com/ groups?gid=1769017&trk=hb side g.

Click here to Join the Foundation LinkedIn Group

Linked in 8



## C.R. Bard announces vascular stent approved by FDA

Regulators have approved C. R. Bard Inc.'s E.Luminexx vascular stent to treat blockages in a large pelvic artery, the company said in December.

The Food and Drug Administration approved marketing of the flexible, self-expanding stent for common or external iliac artery occlusive disease. Marketing will be done by Bard Peripheral Vascular Division, the company said in a statement.

The patient population for the Bard stent is expected to grow more than 10 percent annually due in part to the increasing number of diabetic patients who have a higher risk of developing the blockages, the company said.

In October, Bard said the FDA also approved its Flair endovascular stent graft as a treatment for stenosis in dialysis bypass grafts.

Company officials said the latest approval makes Bard the only medical device maker offering both a stent and a stent graft with peripheral vascular indications in the U.S.

### FDA chief to step down as Obama is sworn in

By Tracy Staton

It's official: FDA Commissioner Andrew von Eschenbach will step down on inauguration day. The commish announced his plans to FDA staff in December, saying that he expects the agency's senior management team to change — at least somewhat — as well. Of course, von Eschenbach pledged to work with President-elect Obama's transition team to ensure a "seamless change in political leadership" at the FDA.

In anticipation of von Eschenbach's resignation, pharma observers have been speculating on his successor. Politicians have weighed in with their opinions, too. Industry and FDA critic Rep. Bart

Stupak, for instance, wrote Obama to plead for a complete overhaul in agency management. "Current senior FDA employees are too close with the industries they regulate," Stupak wrote.

Whoever takes over at the FDA will be tackling a tough task. Last fall, the agency's own Science Board said it is ill-equipped to supervise the pharma business, lacking scientific talent, adequate funding, adequate staffing and up-to-date computer systems. And critics have lined up to offer their own critiques, including Congressional reps and committees who've taken issue with FDA's activities on everything from drug safety to advertising to off-label marketing to industry-doctor/ industry-regulator relationships.

Then there are a myriad of safety problems that have arisen over the last couple of years. Take the big heparin recall early this year, which exposed major holes in the agency's oversight of foreign drugmakers and overseas active ingredient manufacturers. The agency has taken some steps toward fixing those problems — including opening new offices in China, where many APIs are made these days — but the new commissioner will still have plenty to do on that score.

### Medtronic: Device Helps Epilepsy Patients In Study

By Jon Kamp

A Medtronic Inc. device that delivers electrical pulses to the brain helped some patients in a study who were stricken with hard-to-treat cases of epilepsy, paving the way for a U.S. regulatory filing, the company said recently.

The deep brain-stimulation technology could make Medtronic a competitor to Cyberonics Inc., which thus far has a monopoly in the market for treating severe epilepsy cases with stimulation devices.

Having the marketing muscle from much-larger Medtronic behind device-based epilepsy treatment may help more than it hurts. Also, Medtronic's entry into this market could put Cyberonics in the medical device giant's crosshairs, Lazard Capital Markets analyst Sean Lavin suggested in a note to investors.

"We believe that Cyberonics likely becomes a potential Medtronic acquisition target as Medtronic could sell both products with one sales force," he said. He called Cyberonics "the real beneficiary" of Medtronic's data release.

Data from the 110-patient, Medtronic-sponsored study on that company's device were presented at the American Epilepsy Society's annual meeting in Seattle. The company plans to submit a filing with the Food and Drug Administration in mid- 2009 for epilepsy, suggesting approval could come in mid-2010.

With the Medtronic system, a power generator similar to a pacemaker is implanted in the chest and wires con-

nected to the device are buried deep in the brain to deliver energy to very specific areas. All patients received devices but only half were set to deliver power for the first three months; the study determined whether patients with the devices switched on saw fewer seizures.

Patients continued to receive epilepsy medication as well as electrical stimulation. At the end of the blinded period of the study, patients with the devices switched on saw a 38% average reduction in seizures, compared with 14.5% average reduction for patients in the control group. The result was considered a statistically significant difference.

Devices were set to deliver power for all patients after three months and results suggested benefits from treatment can accrue over time. Among longer- term findings, 40% of patients who completed diaries of their progress through 13 months experienced a 50% or greater reduction in their baseline rate of seizures, Medtronic said.

The company's system does not cure epilepsy but may offer an option for patients who have tried several drugs and even corrective brain surgery without relief.

"They have significant improvement, enough that it can notably benefit their quality of life," said Robert Fisher, a neurology professor who directs the Stanford Epilepsy Center in California and is the main investigator for the Medtronic study.

"But they still have seizures with this," he said.

Among adverse events associated with the Medtronic device, there was a nearly 11% rate of infection in the study, all of which were treated with antibiotics and none of which were severe, Fisher said. A few patients did have wires pulled due to infections, however.

Infections were generally in the chest pocket where the power generator was implanted, along the course of the wires, or at the scalp, Fisher said. Analyst Lavin said the infection rate was "a bit concerning" and noted it was significantly higher than the infection rate with Cyberonics' device.

There was also a 1.3% rate of asymptomatic intracranial hemorrhage per implanted wire — each patient had two wires — in the Medtronic study. These are hemorrhages that show up on brain scans but heal on their own. There were no cases of serious hemorrhages that entailed major bleeding on the brain, Fisher said.

The Cyberonics device hooks up to a major nerve in the neck, and therefore is less invasive than the Medtronic device. This suggests Medtronic's device, if approved, could become the next step in a line of treatment options for patients with epilepsy. Analyst Lavin expects it to be positioned that way.

Fisher said it was too soon to tell. The Medtronic device did help patients in the new study who had previously tried the Cyberonics device, he noted. In fact, nearly half of studied patients had the Cyberonics device "and didn't think it worked well," he said.

Speaking during a financial conference,

# Massachusetts Releases Proposed Pharmaceutical and Medical Device Manufacturer Code of Conduct

By Karen F. Green, Scott M. Lassman, Michelle D. Miller, Felicia H. Ellsworth

n December 10, 2008, the Massachusetts Public Health Council released proposed regulations to implement M.G.L. c. 111N, the recently-enacted state statute governing marketing activities by pharmaceutical and medical device manufacturers operating in Massachusetts.

The proposed regulations establish a Marketing Code of Conduct (Code) that will, when effective, prohibit certain payments to health care practitioners in the Commonwealth of Massachusetts, require disclosure of the nature, amount, and recipient of payments over \$50 made to health care practitioners, and impose auditing and reporting requirements on pharmaceutical and medical device manufacturers to ensure compliance with the Code. The regulations apply to pharmaceutical and medical device manufacturers that employ a person to sell or market prescription drugs or medical devices in the Commonwealth. In a press release and presentation accompanying the release of the proposed regulations, Massachusetts described the proposed Code as the most "stringent" and "comprehensive" regulation of pharmaceutical and medical device manufacturer conduct to date. The proposed regulations are "intended to benefit patients, enhance the practice of medicine, and ensure that the relationship between pharmaceutical or medical device manufacturers and health care practitioners not interfere with the independent judgment of

health care practitioners." 105 CMR 970.001.

#### **Prohibited Activities**

The proposed regulations would, among other things, prohibit a pharmaceutical or medical device manufacturer, or its agent, from providing to a health care practitioner in the Commonwealth:

- grants, scholarships, subsidies, consulting contracts, or educational items in exchange for prescribing or disbursing prescription drugs or medical devices;
- entertainment or recreational items of any value;
- payments in cash or cash equivalents either directly or indirectly except as compensation for bona fide services;
- complimentary items such as pens, coffee mugs, gift cards, or flowers;
- meals that are part of an entertainment or recreational event, offered
  without an informational presentation, offered outside of a health
  care provider's office, or provided to
  a health care provider's spouse or
  other guest; and
- financial support for the cost of travel, lodging, attendance, or other personal expenses of a non-faculty health care provider in connection with continuing medical education events, conferences, or meetings.

The proposed regulations do not prevent pharmaceutical and medical device manufacturers from providing

modest and occasional meals in conjunction with informational sessions in specified clinical training settings, reasonable compensation for substantial professional and consulting services of health care practitioners for a genuine research project or clinical trial, the provision of prescription drug or medical device demonstration and evaluation units, and payments for bona fide services, which are defined to include consulting services such as research and participation on advisory boards.

#### **Disclosure Requirement**

The proposed regulations require annual disclosure to the Department of Public Health (Department), by July 1 each year, of "the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50" provided by a pharmaceutical or medical device manufacturer to any health care practitioner in connection with the company's sales and marketing activities (105 CMR 970.009). The definition of sales and marketing activities included in the proposed regulations excludes payments made as reasonable compensation in connection with a genuine research project or clinical trial (105 CMR 970.004). Each annual disclosure must be accompanied by a fee of \$2,000 and a certification of accuracy by the disclosing company. The proposed regulations also prohibit a pharmaceutical or medical device manufacturer from knowingly structuring fees or payments to health care practitioners to circumvent the reporting requirements.

# BIO INTERFACE OIS



Keynote speaker Art Coury, Genzyme, addresses a packed crowd at BioInterface.

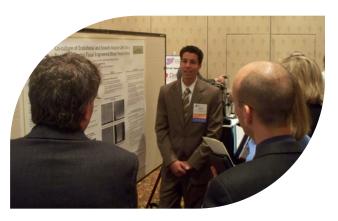
#### **Diamond Sponsor**



Gold Sponsor

Point Counterpoint Session Sponsor





There were many student poster submissions this year. Each student had his or her poster reviewed by a group of industry-leading judges.



Immediate Past President Carl Turnquist presents student poster award winner Zeeshan Syedain with a check for \$1,000.



BioInterface attendees network and enjoy the downtown Minneapolis skyline during the evening reception.



2006 Excellence in Surface Science Award winner Robert Ward, DSM PTG, presents Ken Stokes, Metronic (Retired), with the 2008 Excellence in Surface Science Award.



A frank discussion between attendees at the point-counterpoint session, on the topic, "Nanoengineering: Enabling Technology or Marketing Slogan?"



A packed crowd listens to Excellence in Surface Science Award winner Ken Stokes discuss, "Implantable Polyether Polyurethanes: Finding the Unknown."



The Symposium and Workshop offered more than 30 sessions that ran the gamut of surface-science-related topics.



### **Funding a Watchdog at Foundation**

By Janet Moore

# A \$1 million grant from lawyers who won a settlement against Medtronic will help track the performance of heart devices.

Lawyers who won a \$114 million settlement last year on behalf of thousands of patients who had potentially faulty heart defibrillators made by Medtronic Inc. have given \$1 million to a Minneapolis foundation that has done groundbreaking work tracking the safety of cardiac devices.

A check was presented to the Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital. The funds will be used to further develop the foundation's Multi-Center Registry, which collects safety data about defibrillators and pacemakers from six hospitals across the country.

The registry is the brainchild of Dr. Robert Hauser, a prominent cardiologist at the foundation who, along with a colleague, Dr. Barry Maron, went public in 2005 after the death of a patient who had a defibrillator made by Guidant Corp.

The ensuing furor led to the recall of thousands of heart devices made by Guidant, now part of Boston Scientific Corp., and raised questions about how federal regulators track faulty devices.

It also led to a massive legal case in U.S. District Court in Minneapolis filed by aggrieved patients against Fridley-based Medtronic, which resulted in the \$114 million settlement.

The settlement included \$18.5 million in attorneys' fees.

The plaintiffs' litigation team was led by Daniel Gustafson, of Gustafson Gluek, and Charles Zimmerman, of Zimmerman Reed, both of which are based in the Twin Cities.

"The work of Dr. Hauser, along with Dr. Maron, was so heroic, and it took so much courage for them to come forward and take the heat," said Randy Hopper, an attorney with Zimmerman Reed.

James Toscano, president of the foundation's board, said the court-approved grant will support independent research that "is not influenced by the support we receive from donors."

The foundation also receives grant money from heart device makers Medtronic, Boston Scientific and St. Jude Medical Inc.

# W. L. Gore & Associates Receives CE Mark for GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface

W. L. Gore & Associates (Gore) announced that it has received approval to apply the CE Mark and commence commercial distribution of its GORE VIABAHNEndoprosthesis with PRO-PATEN Bioactive Surface in the European Union. The GORE VIABAHN Endoprosthesis with PROPATEN Bioactive Surface combines Gore's propriety heparin surface with the proven performance of the GORE VIABAHN Endoprosthesis for the treatment of arterial vascular disease. The GORE VIABAHNEndoprosthesis with PROPATEN Bioactive Surface is indicated for the endovascular grafting of peripheral arteries.

The GORE VIABAHNEndoprosthesis with PROPATEN Bioactive Surface uses end-point covalent bonding to keep the heparin anchored to the endoprosthesis surface over time. The proprietary end-point surface attachment technology preserves the heparin bioactive sites such that they remain free to interact with the blood without being consumed.

"Gore is excited to provide the clinical community in Europe with the same proven heparin bonded surface technology for patients suffering from peripheral arterial vascular disease that clinicians in the US have been using to treat occlusive disease in the Superficial Femoral Artery for the past 18 months," said Ben Beckstead, PhD, Product Specialist with the Gore Peripheral Vascular Business.

GORE VIABAHNEndoprosthesis with PROPATEN Bioactive Surface (5 to 8 mm devices) is available with a low-profile delivery system that gives interventionalists a more streamlined approach to re-line the peripheral arteries. The GORE VIABAHNEndoprosthesis is constructed with a durable, reinforced, biocompatible, ePTFE liner attached to an external nitinol stent structure. The excellent flexibility of the GORE VIABAHN Endoprosthesis enables it to better traverse tortuous areas of the Superficial Femoral Artery and conform more closely to the complex anatomy of the artery.

#### **Boston Scientific Acquires Labcoat Limited**

Boston Scientific Corporation announced that it has acquired Labcoat Limited, a privately held, development-stage drug-eluting stent technology company located in Galway, Ireland. Terms of the acquisition were not disclosed.

Labcoat has developed a novel technology for coating drug-eluting stents that uses precisely metered droplets of a biodegradable polymer and drug formulation to create a thin (< 1 micron) coating confined to the outer surface of a coronary stent. This proprietary technology is designed to significantly reduce the amount of polymer and drug to which the vessel wall is exposed, while minimizing polymer and drug on the inner surface of the stent where endothelial cell growth is required for healing. Once the drug has been delivered, the biodegradable coating resorbs, leaving behind only the bare-metal stent. This approach is intended to provide the same degree of restenosis reduction as a conventional drug-eluting stent, but faster and more complete vessel healing after stent implantation.

"Boston Scientific has enjoyed an ongoing, productive relationship with Labcoat, and we look forward to building on our shared commitment to developing new drug-eluting stent technologies that improve patient outcomes," said Jim Tobin, President and Chief Executive Officer of Boston

Scientific. "This technology represents a major advance for drug-eluting stents and should help us maintain our strong position in this market."

Labcoat has successfully completed a clinical trial with its JACTAX<sup>TM</sup> Stent, which consists of a Boston Scientific bare-metal Liberte(R) Stent coated on its outer surface with a biodegradable polymer containing the drug paclitaxel. Clinical data presented at TCT 2008 showed promising results for both restenosis and strut coverage nine months after implantation. These data will be used to support CE Mark submission, which is expected to occur in the first half of this year. European launch of a new drug-eluting stent incorporating this technology is planned following regulatory approval.

Boston Scientific plans to evaluate the Labcoat technology for use on both its paclitaxel and everolimus families of drug-eluting stents.

Paclitaxel is employed on the TAXUS(R) family of stents, which have been studied in thousands of patients in clinical trials and implanted in approximately four million patients worldwide.

# Agion Partners with Stryker Instruments to introduce FDA 510k-Cleared Catheters

Nature's Antimocrobial™ Continues to be a popular choice for the medical industry

Agion Technologies, Inc. announced recently that is has signed an agreement with Stryker Coproration's Instruments Division to incorporate Agion's natural antimicrobial technology into a new pain management catheter. The product, Silver ExFen Catheter, has achieved FDA 510K clearande and will be marketed in the US.

"Since medicare and Medicaid will no longer pay for preventable Surgical Site Infections (SSI), products like the Stryker antimicrobial catheter will become a critical tool for the medical profession," said Paul Ford, chief executive officer of Agion technologies. "This partnership is another innovative application of our powerful, natural technology, and sets a standard for the industry to follow."

Agion's innovative antimicrobial technology is based on naturally-occurring silver, a powerful antimicrobial element. Silver is integrated into the polymer blend of the catheter and is not affected by abrasions to the surface. Agion's antimicrobial protection lasts for the life of the product.

#### Code of Conduct Continued from Page 5

#### **Compliance Requirement**

The proposed regulations require pharmaceutical or medical device manufacturers to:

- adopt and comply with the most recent Code as adopted by the Department;
- adopt and submit to the Department a description of a training program to provide regular training to appropriate employees on the Code, which must ensure that all representatives who are employed by, or acting on behalf of, the company and who visit health care practitioners have sufficient knowledge of the Code, general science and product-specific information;
- certify to the Department that it is in compliance with the Code;
- adopt, and submit to the Department, policies and procedures for investigating and taking corrective action in response to instances of non-compliance with the Code; and
- submit to the Department the name, title, address, telephone number, and electronic mail address of the compli-

ance officer it has identified as responsible for operating, monitoring, and enforcing the Code.

The proposed regulations suggest July 1, 2009, as the deadline for initial compliance with the Code, and July 1, 2010, as the date for submission of the first required disclosure report by pharmaceutical and medical device manufacturers.

Although certain consumer and industry groups submitted written and oral comments in advance of the issuance of the proposed regulations, the release of these proposed regulations begins the formal notice and comment period. The Department has set two public hearings on the proposed regulations. The hearings were scheduled to occur on January 9, 2009, in Boston and on January 12, 2009, at UMASS Medical School, in Worcester, MA.

The proposed Code would impose stringent and comprehensive restrictions on the marketing activities of pharmaceutical and medical device companies.

#### Epilepsy Continued from Page 4

Daniel J. Moore, Cyberonics' president and chief executive, said the company was fully prepared for competition.

Treating epilepsy patients with a stimulation device is basically all Cyberonics does. "If we can't defeat anyone that comes into this business, than shame on us," Moore said.

#### Editor Continued from Page 2

other questions posted to the group. I should also mention that there is no cost for a base-level LinkedIn membership.

In summary, LinkedIn provides considerable value, it:

- Provides visibility for my firm's services. This visibility
  extends beyond the LinkedIn network since public member
  profiles are spidered by Google and other search engines.
- Enables searches for information and people within and outside my immediate networks.
- Provides a means to connect with groups with similar and complementary interests and needs.
- Routinely enables reconnection with professionals with whom I have lost touch.



• For job seekers, many search firms now routinely use Linked-In, and jobs are routinely posted on LinkedIn as well.

For more information on maximizing your use of LinkedIn, the WSJ article is valuable, as is *Let's Connect: Using LinkedIn to get ahead at work*, by Ajay Jain (TCP Media). However, here is some general and often repeated advice: Connect to people you already know well. This is where the Surfaces group will provide an excellent start. Use this as a springboard to enable further contacts. One final piece of advice is to manage your time with LinkedIn, since it is easy to spend too much time on the discussion groups, newsfeeds and working with your connections.

Happy networking for our mutual economic development.

Meeting/Conference/Trade Show Calendar			
Meeting/Conference/Trade Show	Dates	Place	Web Address
BioBasics Briefing	Jan 29	Palo Alto, CA	baybio.org/wt/home/BioBasics_0109
International Congress on Endovascular Interventions	Feb 8-12	Scottsdale, AZ	endovascularcongress.org
Medical Design & Manufacturing West (MD&M West)	Feb 9-12	Anaheim, CA	devicelink.com/expo/west09/
Medical Device Breakfast Series   Accelerated Clinical Trials	Feb 10	Palo Alto, CA	baybio.org/wt/home/ MedicalDeviceBreakfasts
(AIMBE) American Institute for Biomedical Engineering	Feb 11-13	Washington, DC	aimbe.org/annualevent
Venture Spotlight   Investments in BioPlastics & BioMaterials	Feb 12	Palo Alto, CA	baybio.org/institute/wt/page/Venture_ Spotlight_Series_February2009
Joint Interventional Meeting (JIM) 2009	Feb 12-14	Rome, Italy	jim-vascular.com
Recent Advances in Drug Delivery Systems	Feb 15-18	Salt Lake City, Utah	drugdeliverysymposium.utah.edu/
BayBioNEST Tech Showcase and Networking Reception   Children's Hospital & Research Institute in Oakland	Feb 19	Palo Alto, CA	baybio.org/institute/wt/page/Nest_Tech_ Showcase_2_19_09
Orthopaedic Research Society (ORS) - 55th Annual Meeting	Feb 22-25	Las Vegas, NV	ors.org/web/meetings/55thAnnualMeeting/ AnnualMeeting.asp
American Academy of Orthopedic Surgeons (AAOS)	Feb 25-28	Las Vegas, NV	aaos.org/education/anmeet/anmeet.asp
MEDTEC Europe	Mar 3-5	Stuttgart, Germany	devicelink.com/expo/medtec09
(CRT) Cardiovascular Research Technologies	Mar 4-6	Washington D.C.	crtonline.org
Medical Device Breakfast Series   Emerging Surgical Techniques	Mar 10	Palo Alto, CA	baybio.org/wt/home/MedicalDeviceBreakfasts
Pharma MedDevice	Mar 17-19	New York, NY	pharmameddevice.com/App/homepage.cfm ?moduleid=3155&appname=100485
American College of Cardiology (ACC) - 58th Annual Scientific Session	Apr 14-16	Orlando, FL	acc09.acc.org/
Design of Medical Devices Conference	Apr 14-16	Minneapolis, MN	dmdconf.org/
BayBio2009   Life Sciences — Branching Out	Apr 16	Palo Alto, CA	baybio.org/wt/home/BayBio2009
BIOMEDevice Boston	Apr 22-23	Boston, MA	devicelink.com/expo/bioboston09/
Society for Biomaterials Annual Meeting	Apr 22-25	San Anonio, TX	biomaterials.org/ Meetings/09AnnualMeeting/
American Academy of Neurology (AAN) - Annual Meeting	Apr 25 - May 2	Seattle, WA	am.aan.com/
Advanced Wound Care & Wound Healing Society (SAWC & WHS) - Annual Symposium	Apr 26-29	Dallas, TX	sawc.net
American Pain Society (APS) - Annual Scientific Meeting	May 7-9	San Diego, CA	ampainsoc.org/meeting/
Heart Rhythm Society (HRS, formerly NASPE)	May 13-16	Boston, MA	hrsonline.org/Sessions
American Society for Microbiology (ASM) - 109th General Meeting	May 17-21	Philadelphia, PA	gm.asm.org
BIO International Convention	May 18-21	Atlanta, GA	bio2009.org
European Association of Percutaneous Cardiovascular Interventions (Euro PCR)	May 19-22	Barcelona, Spain	europcr.com/
American Society for Artificial Internal Organs (ASAIO)	May 28-30	Dallas, TX	asaio.com
Medical Design & Manufacturing East (MD&M)	Jun 9-11	New York, NY	devicelink.com/expo/east08/index.html
American Orthopaedic Assoc.(AOA) - Annual Meeting	Jun 10-13	Bonita Springs, FL	aoassn.org/AnnualMeetings.asp
AAPS National Biotechnology Conference	Jun 21-24	Seattle, WA	aapspharmaceutica.com/meetings/biotec/bt09/index.asp
BioInterface 2009	Oct 26-28	San Mateo, CA	surfaces.org

# **Thank You to Our Members!**











COVIDIEN















# Wanted: Members

# To be leaders in the surface science community

- Join a forum that fosters discussion and sharing of surface and interfacial information
  - Have your voice heard and your interests represented within the surface science and biomedical community
    - Help shape workshops and symposia that further the world-wide education of surface science
      - Promote understanding of interfacial issues common to researchers, bio-medical engineers and material scientists.

Join the Foundation that connects the academic, industrial, and regulatory committees within the surface science/biomedical communities!

Visit the Foundation at www.surfaces.org for a membership application or call 651-290-6267.



## **Benefits of Membership:**

- Discounted registration at BioInterface, the annual symposium of the Surfaces in Biomaterials Foundation.
- Your logo and a link to your Web site in the member directory on the official Web site of the Foundation, www.surfaces.org.
- Complimentary full page ad in surFACTS, the Foundation's newsletter and discounts on all advertising.

