

## October 2007 E-Chronicle

### **GaBio, DOE Partner to Infuse Biotech into Science Curriculum**

As part of its education initiative, Georgia Bio (GaBio) is working with the Georgia Department of Education to bring leading-edge biotechnology content and experiences into all Georgia public schools, starting with middle and high school curricula.

GaBio is collaborating with DOE to develop hands-on biotechnology experiments and teaching resources aligned with the state's current seventh, eight and ninth grade science curricula. These experiments, or tasks, will bring real world life science applications and content into the classroom.

A Committee of industry and higher education scientists along with middle and high school educators are developing four tasks for each grade level, and aligning them with Georgia performance standards for the life science, physical science and biology curricula currently taught. The tasks bring together science and math content in a single classroom learning experience based on a practical application of the science.

The Committee is expected to complete the tasks in January 2008. Subsequent to approval by DOE, the biotechnology tasks will be available along with supporting resources on the DOE website for teachers' use statewide.

At the same time, GaBio is participating in the development of a new high school Biotechnology Research and Development career pathway through the Department of Education's Division of Career, Technical and Agricultural Education (CTAE).

Under the Health Science Careers Division, this pathway will prepare students for post-secondary education and careers in life science laboratory settings. Modeled after successful programs already in operation around the country, the career pathway will give students intensive hands-on experience in modern laboratory management and practices while teaching the science behind the techniques.

Envisioned as a curriculum that could provide either science elective or CTAE credit, this career pathway is expected to be launched statewide in the fall of 2009.

### **Federal Legislative Update: SBIR on Mend, But Dangerous Patent Bill Looms**

Several years ago, the Small Business Administration (SBA) changed the definition of "individual" with regards to business ownership for eligibility for SBA programs such as the Small Business Innovation Research (SBIR) grants program. This alteration prohibited small companies with more than fifty percent ownership by venture capital entities from receiving SBIR grants.

In September, the U.S. House of Representatives passed the Small Business Investment Expansion Act (H.R. 3567). One key component allows small biotechnology companies with majority venture capital backing to once again access SBA programs like SBIR. It changed the definition of what it means for a company to be "independently owned and controlled" to more narrowly define what type of venture capital investment a small business can receive to remain eligible for SBA programs. The bill now must win approval by the U.S. Senate and currently has been sent to the Senate Committee on Small Business and Entrepreneurship.

## Patent Legislation Potentially Disastrous for Life Sciences

The U.S. House of Representatives passed the Patent Reform Act of 2007 (H.R.1908) in September by a narrow margin. Currently, the U.S. Senate is discussing its version of the Patent Reform Act (S.1145). There are three provisions that are particularly troubling for the life science industry in these Patent Reform Act bills. [Click here for a draft letter outlining the provisions.](#)

Contact Senator Saxby Chambliss and Senator Johnny Isakson, urge them to oppose S. 1145 until these controversial issues are addressed. Feel free to personalize the draft letter and email or mail to the Senators.

Contact information is:

The Honorable Saxby Chambliss  
United States Senate  
416 Russell Senate Office Building  
Washington, DC 20510  
Email, phone and fax the Senator's assistant, Camila Knowles, at  
[camila\\_knowles@chambliss.senate.gov](mailto:camila_knowles@chambliss.senate.gov); phone, (202) 224-3521 and fax, (202) 224-0103:

The Honorable Johnny Isakson  
United States Senate  
120 Russell Senate Office Building  
Washington, DC 20510  
Email, phone and fax the Senator's assistant, Mike Quiello, at  
[Michael.Quiello@isakson.senate.gov](mailto:Michael.Quiello@isakson.senate.gov); phone, (202) 224-3643 and fax, (202) 228-0724

## PDUFA/Follow-On Biologics

President Bush signed into law in late September the Food and Drug Administration (FDA) Amendments Act of 2007. This legislation enhances and improves drug safety by providing necessary resources to the FDA. It also reauthorized for five years, the Prescription Drug User Act Fee (PDUFA) which collects fees from pharmaceutical and medical device manufacturers to help with FDA's costs in reviewing products.

Throughout the legislative process in both the House and Senate, legislators debated adding an amendment to create a new pathway for the approval of follow-on biologics or biosimilars. Georgia Bio and our members have been active in voicing concern over a hastily approved pathway that does not take into account investment efforts, research and development time, and data exclusivity.

Congress decided not to create a follow-on biologics pathway through the PDUFA reauthorization and FDA drug safety changes. There is a high probability that stand-alone legislation will be introduced to accomplish a follow-on biologics approval pathway. Georgia Bio will continue educating legislators about the industry's concerns.

## Farm Bill Includes Biofuels Support

On Thursday, October 25<sup>th</sup>, the Senate Agriculture Committee approved a new five-year Farm Bill that would provide nearly \$283 billion in assistance to farmers, ranchers and participants of federal food and nutrition programs. Included in the bill are incentives for growing biomass crops (i.e. switch grass), support for the construction of biorefineries for cellulosic ethanol production, as well as incentives to spur the biobased products market and speed the progress of the BioPreferred and biobased labeling programs. The full Senate is expected to consider this legislation in early November.

## Med Device Innovation Featured at Nov. 15 House Bioeconomic Study Committee Hearing

The fourth of four hearings organized by the Georgia House Study Committee on Bioeconomic Development will feature medical device company executives, university leaders, and government officials discussing state policies and funding to accelerate commercialization of technologies in Georgia.

The hearing, November 15, will be held in Room 132 of the Georgia State Capitol from 8 am to 3 pm. GaBrio members are encouraged to attend.

The study committee, chaired by Rep. Charlice Byrd, was formed in accordance with House Resolution 662, which was passed during the 2007 legislative session. [Click here is a link to HR 662.](#)

Its objective is to design a comprehensive life sciences economic development strategy for supporting growth in the biomedical, medical device, agriculture and biofuels industries. The committee's final report will identify existing strengths and weaknesses and will suggest how to utilize current resources and expertise within state government more efficiently. It will suggest legislation that will serve as a road map for moving Georgia into a 21st century bioeconomy.

The first three hearings focused on agricultural biotech (August 21), biofuels (September 24) and biomedicine and drug manufacturing (October 16). Following the fourth hearing November 15, the committee will hold a Summit December 4 for all participants to review and endorse the major elements of a master plan and enabling legislation for the 2008 General Assembly.

In addition to Rep. Byrd, the House members on the committee are: Reps. Karla Drenner, Ph.D.; Larry O'Neal; and Carl Rogers. Three industry experts also were appointed: Clifton A. Baile, Ph.D., Georgia Research Alliance Eminent Scholar in Agricultural Biotechnology and Distinguished Professor in Animal Science and Foods & Nutrition at the University of Georgia; Fabrice Egros, Ph.D., MBA, President of UCB, Inc., in Smyrna; and Russell M. Medford, M.D., Ph. D., President and CEO of AtheroGenics, Inc. in Alpharetta.

## GaBio Members Reach Record 320 Organizations Following Successful Summit

Following a record-setting 7th Annual Georgia Life Sciences Summit early this month, Georgia Bio (GaBio) membership also achieved a milestone, topping 320 organizations.

The October 3 Summit, whose theme was Growing Georgia's Bioeconomy, set several records at the Georgia World Congress Center: more than 40 speakers, 750 attendees, 60 exhibitors, more than 100 contestants in the scientific poster competition, and a first-ever expanded focus that included agriculture biotechnology, food nutrition and biofuels in addition to biomedicine, medical devices and global health.

The success of the Summit and the reinvention of GaBio have combined to fuel a surge in new members; more than 70 this year. As of the end of October, GaBio's membership reached 326 life sciences companies, universities, research institutes, government groups, and other business organizations.

The Summit's keynote speakers reflected the expanded focus beyond biomedicine. They included Rhona Applebaum, Ph.D., Chief Regulatory Officer at The Coca-Cola Company; David Mott, President and CEO of MedImmune; Howard Palefsky, Managing Partner of Montreux Equity Partners; and Gerald Steiner, Executive Vice President, Commercial Acceptance, Monsanto.

Russell M. Medford, M.D., Ph.D., President and CEO of AtheroGenics and GaBio chair, gave the State of the Life Sciences Industry address that featured release of data from [Shaping Infinity, The Georgia Life Sciences Industry Analysis 2007](#). Dr. Medford also outlined GaBio's advocacy and education outreach priorities for 2008. [Click here to see Dr. Medford's presentation](#). An electronic copy of Shaping Infinity is available on the GaBio website, [www.gabio.org](http://www.gabio.org).

The 2008 Summit will continue the broader focus incorporated this year. It will also be the last Summit before the 2009 Biotechnology Industry Organization International Convention in Atlanta. GaBio expects to set another attendance record in 2008 as a prelude to BIO 2009, the largest biotech conference in the world.

## **Upcoming Events**

[Ga Bioscience Community: Building on the Foundation](#)

11/14/2007

The Loudermilk Center, Atlanta, GA