



# connections newsletter



**February 2017  
UPDATE**

**Serving the NC Life  
Sciences Industry**

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## NCBIO This Month

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- NC Cancer Fairness Act
- Less Than A Month Until NCBIO Legislative Reception
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- BIO CEO Jim Greenwood Speaks at Life Science Conference
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- TRIAD BIO Night March 30th
- Register for Johnson & Johnson Innovation Event, April 12th
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- NCBIO Welcomes New Members

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## **NCBIO Board Approves Legislative Agenda**

## NCBIO - Media

Find the latest news from NCBIO on the website [ncbioscience.net](http://ncbioscience.net), on [LinkedIn](#) and on Twitter at [@ncbio](#).

## NCBIO Links

[CED](#)

[NCBIO](#)

[NC Biotech Center](#)

[BRITE](#)

[BTEC](#)

[BioNetwork](#)

[NCBioImpact](#)

## NCBIO Sustaining Members





The 2017 NCBIO legislative agenda approved by the Board of Directors at its February meeting focuses on three key areas:

- Protect and improve state policies encouraging life science innovation – proposals include support for small companies conducting research and development, full funding for the North Carolina Biotechnology Center and additional funding for the State’s SBIR/STTR matching grant program;
- Protect and improve North Carolina’s business climate as a location for life science manufacturing and service businesses – recommendations include additional funding for NCBioImpact training programs, identifying potential strategies for funding waste water treatment facilities for biomanufacturing companies and expanding the State’s clinical research labor force;
- Protect and improve North Carolina’s climate as a market for life science products – including defeating drug price control legislation and bringing any proposals related to drug price transparency into conformance with BIO transparency principles.

[Click](#) for more details on the agenda.

NCBIO expects to present these recommendations to the Legislative Life Science Caucus at the Caucus’ inaugural meeting later this month.

In addition to the issues outlined above, NCBIO is also working with lawmakers on market-based sourcing (MBS) legislation, which would govern what revenues are assigned to North Carolina for the purposes of determining the company’s taxable income. Draft MBS rules were developed by the Department of Revenue at the request of the 2016 General Assembly. Although the rules deal primarily with sourcing of income for services, there are also provisions addressing income from licensure of intellectual property.

NCBIO is asking all members to review the rules for potentially negative impacts on their business models. [Click](#) for a copy of the rules. Members with concerns should contact [Sam Taylor](#).

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## **NC Cancer Fairness Act**

Proposed legislation has been introduced in the State House ([HB 206](#)) and Senate ([SB 152](#)) that would require insurance companies to treat oral anti-cancer medications in the same way as intravenous therapies. The legislation provides that “coverage for orally administered anticancer drugs shall not be subject to any prior authorization, dollar limit, co-payment, coinsurance, or deductible provision or to any other out-of-pocket expense that does not apply to intravenously administered or injected anticancer drugs.” NCBIO members interested in this legislation should contact [Sam Taylor](#) or [Laura Gunter](#).

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Pfizer



We Work For Health



## **NCBIO Supporting Members**

Cook Medical



Merck



## **Less Than A Month Until NCBIO Legislative Reception**

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**2017** Life Sciences  
Legislative Reception

More than 160 legislators and NCBIO members have signed up for the 2017 Annual Legislative Reception on April 5th. Members have the opportunity to talk with lawmakers about key issues pending in the session and the value of the industry to the state.

The reception will be held at the NC History Museum from 5:30-7:30 PM. For more information about the session or to register, contact [Amber Niebauer](#).

Thanks to [AbbVie](#), [Amgen](#), [Astellas](#), [Bayer](#), [Biogen](#), [Johnson & Johnson](#), [Lilly](#), [Novozymes](#), [PhRMA](#), and [Syngenta](#) for helping make this event possible. If your organization is interested in sponsoring the event, please contact [Laura Gunter](#). Deadline to sponsor is March 10th.

*("The North Carolina Museum of History does not sponsor or endorse this event.")*

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## **Life Science Industry Continues to Grow in NC**

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"North Carolina's life science industry is on a high-growth trajectory in recent years, led by rapid growth in some of its largest and highest-paying industry subsectors, and acting as a core driver of the state economy," according to information released by TEconomy Partners LLC. "These gains, as one would expect, are translating into broader, steadily rising economic impacts. The total economic impact of the state's life science industry exceeded \$86 billion in 2016, rising an impressive 34 percent during the current economic expansion." [More](#)

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## **BIO CEO Jim Greenwood Speaks at Life Science Conference**

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BIO CEO Jim Greenwood

Market-based sourcing, drug transparency, waste water treatment, SBIR funding and other issues are topics for NCBIO members to discuss with legislators at the 2017 Annual Legislative Reception on April 5th.

BIO CEO Jim Greenwood told participants at the CED Life Science Conference that, "our industry is under attack. It is not the first time." He added, "But this is different. It's more intense and it's coming from more directions. The stakes are higher that short-sighted policy changes could endanger innovation and hope."

Greenwood stated, "We need to tell our story better. We need a consistent narrative – the true story about the miracles we've accomplished, the staggering unmet medical needs we face, and the economic realities that face our businesses." [Click](#) for more information on drug costs facts developed by BIO.

In other activities at the event hosted by CED and co-hosted by NCBIO and the NC Biotechnology Center, Doug Edgeton, CEO of the Center, announced that [Pfizer Inc.](#) has committed to providing funding in the amount of \$4 million which will enable the Center to establish and administer a multi-year academic fellowship program to help advance North Carolina's fast-growing expertise in gene therapy. [More](#)



Art Pappas receives award from Bill Hawkins

[Art Pappas](#), managing partner of Pappas Capital received the Life Science Leadership Award at the Closing Lunch on March 1. Mr. Pappas called the recognition "humbling" and thanked the many life science leaders that have worked with him during his years in the industry. He founded the firm in 1994 and since that time has invested in more than 70 companies and managed more than \$450M in capital.

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## **Dr. Robert Califf Discusses Experiences at FDA**

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John Wagner of NCBio and Robert Califf

Former FDA Commissioner Robert Califf talked about the federal regulatory agency at the CED Life Science Conference and at luncheon hosted by the UNC School of Pharmacy, NCCU's BRITE Program, NCBio and the North Carolina Biotechnology Center.

At the luncheon, Dr. Califf focused on "Ensuring Product Safety through Diversity in Clinical Trials." He stated "our national clinical research system is well-intentioned but flawed," and said, a high percentage of decisions not supported by evidence and health outcomes and disparities are not improving. He added, "The current system is great except it is:

- Too slow, too expensive, and not reliable,
- Doesn't answer questions that matter most to patients,
- Unattractive to clinicians & administrators."

Dr. Califf served as Commissioner at the FDA from February 2016 until January 2017 and was Deputy Commissioner from January 2015 until he became Commissioner. He will return to Duke University Medical Center, where he was previously the founding director of the Duke Clinical Research Institute.

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## **MEDIC Event on Advanced Manufacturing**

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[MEDIC's](#), quarterly Professional Forum, is scheduled for March 21, 3-6 pm, and will focus on Advanced Manufacturing. The event is at The Frontier and is in collaboration with NCBio and the BMES RTP Industry Chapter. Panelists are:

- **Rahima Benhabbour, Ph.D.**, Research Assistant Professor, School of Pharmacy UNC-CH
- **Caroline Webster**, Graduate Student, Industrial and Systems Engineering NCSU
- **Moderator: Ken Gall, Ph.D.**, Department Chair and Professor, Mechanical Engineering and Material Science, Duke University

For tickets and more information about the event, [click here](#). PROMOTIONAL CODE: **MEDIC21 (for 50% off)**

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## [TRIAD BioNight March 30th](#)

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David King, Chairman and CEO of LabCorp, will be the keynote speaker at Triad BioNight. This event attracts several hundred leaders from academia, industry, and government from across the state and features awards to celebrate biotechnology leadership in the region. [Click](#) for more information and registration details.

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## [Register for Johnson & Johnson Innovation Event, April 12th](#)

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How can Johnson & Johnson Innovation (JJI) help you reach your goals? The company is supporting innovation in major life science clusters through the life science incubator, Johnson & Johnson Innovation, JLABS, with the ultimate aim of enabling commercialization of new healthcare solutions for patients.

On April 12, hear from JJI leaders as they provide an overview of JJI goals and mission, highlighting how JJI interacts with the entrepreneurial community through JLABS, JJDC, and other JJI initiatives. The event is at the NC Biotechnology Center at 10:30 am.

Speakers will also be on hand to meet with a handful of [applicants](#) one-on-one after the presentations. Deadline for one-on-one application is March 14th.

Participating representatives are:

- **Ibraheem Badejo**, Sr Director, New Ventures, Johnson & Johnson Innovation
- **Dana Deardorff**, Sr Director, New Ventures, Johnson & Johnson Innovation
- **Stefanie Dhanda**, Sr Director, Consumer Scientific Innovation, Johnson & Johnson Innovation
- **Nicola La Monica**, Sr Director, Infectious Disease and Vaccines Scientific Innovation, Johnson & Johnson Innovation
- **Kuldeep Neote**, Sr Director, New Ventures, Johnson & Johnson Innovation
- **Bob Radinsky**, VP, Oncology Scientific Innovation, Janssen R&D
- **Eric Schaeffer**, Sr Director, Neuroscience External Innovation, Janssen R&D

The event is free. To register and find out more, [click here](#).

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## [Clinical Trial Supply Southeast Conference 2017](#)

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Clinical Trial Supply Southeast will be returning to North Carolina May 3-4 in Cary. The 3rd annual event brings together industry peers in the Southeast area to discuss and discover potential solutions to the biggest challenges with clinical supply processes,

with speakers from US Customs, GSK, Biogen and many more. Reasons to attend:

1. Excellent networking opportunities: The Clinical Trial Supply Southeast Conference is going into its 3<sup>rd</sup> year in 2017 and has already built up an excellent, high-level client list.
2. Ongoing inefficiencies in the clinical supply chain: The clinical supply chain is a very complex beast with many different balls in the air to constantly juggle. The Clinical Trial Supply Southeast Conference gives you the opportunity to dive deep into each aspect of this supply chain and ensure that your efforts are getting you the best results.
3. Sourcing solutions: With many smaller and start-up companies in the Southeast region the Clinical Trial Supply Southeast Conference gives you the opportunity to meet with well-established and experienced vendors who can help you through the entirety of your supply chain ensuring your resources are spent in the optimal way

Secure your place today by quoting reference **MK-ACEL** and [registering](#). [Email](#) for more information.

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## **Ag Biotech Entrepreneurial Showcase 2017**

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For the fifth year, NCBiotech will convene ag biotech investment firms, global ag biotech companies and other key industry stakeholders for information sharing, networking, and partnering. This year's keynote, Vern Hawkins, will share his perspective on the value innovation provides in support of agribusiness, as seen through his eyes as the president of Syngenta Crop Protection. The event is May 10-11 at the North Carolina Biotechnology Center. [More](#) on the event and to register.

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## **NCBIO Welcomes New Members**

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New and presenting members, First Row Catherine Maher (Greenwich Biosciences), Jessica Brock (Longfellow Real Estate Partners), Lorraine Rusch (High Point Clinical Trials Center), Second Row Rudi Gall (Raumedica), Simon Selwood (SoBran), Greg Kelly (SoBran), Jean-Philippe Therrien (EnDev Laboratories), and Neill Sherron (Longfellows Real Estate Partners)

Six companies were approved for NCBIO membership at the Board of Directors meeting in February. New members are:

- [AbbVie](#) is an innovation-driven, patient-focused speciality biopharmaceutical company capable of achieving sustainable top-tier performance through outstanding execution and a consistent stream of innovative medicines in immunology, oncology, neuroscience, virology and general medicine.

- [Greenwich Biosciences Inc.](#) is the US subsidiary of GW Pharmaceuticals plc, which is the global leader in developing cannabinoid-based medicines. The lead product, Epidiolex® (cannabidiol or CBD) is in development to treat rare and catastrophic forms of childhood-onset epilepsy, potentially offering relief to children and adults for conditions that previously had few treatment options.
- [Longfellow Real Estate Partners](#) collaborates with leading universities, institutions and companies to deliver holistic real estate solutions for life science and technology organizations. The company also provides leasing, facilities and property management services for tenant partners.
- [PharmaDirections](#) provides CMC, preclinical, and regulatory expertise coupled with project leadership and management to help you find the fastest, surest, and most cost-effective path from late discovery to clinical proof-of-concept to approval.
- [SoBran, Inc.](#) includes experts in bioscience, engineering, supply chain, and security. Whether supporting scientists developing vaccines, managing complex supply chain operations, or protecting critical infrastructure and workplaces, the company works hand-in-hand with you toward a common goal.
- [TCG Life Sciences](#) (formerly "Chembiotek Research International") is a contract research services company in the area of early drug discovery and development. Operations started in India and currently the company has a presence in United States, Europe, Japan and Australia.

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## At the National Level

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### Repeal of Medical Device Tax Moving Forward

AdvaMed issued the following statement from President and CEO Scott Whitaker after introduction of reconciliation legislation in the U.S. House of Representatives:

"AdvaMed commends the House Ways and Means Committee for moving forward with legislation that will permanently repeal the medical device excise tax. Bipartisan majorities in both the House and Senate are on record in support of repeal of this onerous tax, which has been associated with a significant loss of American jobs. Recent data from the U.S. Commerce Department showed that the medical technology industry experienced a decline of nearly 29,000 U.S. jobs while the tax was in effect."

"Conversely, an analysis by the American Action Forum demonstrated that permanent repeal of the tax could result in excess of 53,000 additional industry jobs, compared to what would occur if the tax remains in effect. Repealing the tax will provide medical technology innovators with the long-term certainty necessary to support future job growth and sustainable, cutting-edge R&D that will ultimately lead to the next generation of breakthroughs in patient care and treatment. We urge the House and Senate to act expeditiously to pass this important legislation."

### AdvaMed Announces New Name for Annual Conference

The annual conference of the Advanced Medical Technology Association (AdvaMed) – the premiere gathering of medtech officials in North America – has been renamed "[The MedTech Conference](#)," the association announced.

"Our new name reinforces our annual conference's role as the global summit for medical technology industry leaders," said Scott Whitaker, president and CEO of AdvaMed. "The MedTech Conference will still be powered by AdvaMed, but we are open to the entire medtech community beyond our membership, and we will continue to draw the trailblazers in our industry from around the world." [Read more.](#)

### Recalls from A to Z: Regulations, Decisions, Procedures, and Best Practices

Join AdvaMed on March 29-30 in Washington, D.C. where FDA and industry experts will come together to help you establish a clear understanding of how the regulatory affairs function is pivotal to every recall and team decision, and how to build an effective strategy for successfully handling a recall. [More details and to register.](#)

### BIO Has New Senior Executive Vice President

BIO announced that long-time Majority Staff Director of the House Energy and Commerce Committee, Dr. Gary Andres, will be joining BIO as Senior Executive Vice President of Public Affairs. "I am delighted to have Gary join the BIO team. He brings a wealth of experiences and skills to this critical advocacy position. Gary has a deep understanding of Washington, Congress, the White House and our industry. BIO's executive leadership team and the BIO Board of Directors look forward to Gary helping us improve the public policy environment for continued innovation," said Jim Greenwood, President & CEO of BIO. [More](#)

## **BIO 2017 - San Diego Convention Center, June 19-22**

There's no better place to connect with biotech's top people and most innovative technologies than at BIO 2017. The ideas shared here go beyond professional development. Experience powerful business partnering, benefit from invaluable education sessions and network with 16,000+ of the industry's brightest.

Save up to \$200 when you register by April 27th! [Find out more and register.](#)

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## **Member News**

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*Please have your organization's media/marketing coordinator send news about your company to Brenda Summers - [bsummers@ncbioscience.net](mailto:bsummers@ncbioscience.net)*

[Baebies, Inc.](#), a company focused on advancing newborn screening and pediatric testing, reported it has completed a \$5 million first close on its Series B financing. The company plans to raise an additional \$5 million in the coming months. Baebies received clearance from the U.S. Food and Drug Administration (FDA) for its SEEKER newborn screening system earlier this month. [More](#)

[BioCryst Pharmaceuticals, Inc.](#), a pharmaceutical company focused on the development and commercialization of treatments for rare and infectious diseases, announced that it is offering to sell \$45.0 million of its common stock in an underwritten public offering. [More](#)

[Novan, Inc.](#) announced that, after further analysis of the results from the NI-AC301 and NI-AC302 pivotal clinical trials for the Company's topical nitric oxide-releasing product candidate, SB204, it intends to proceed with the SB204 development program. [More](#)

Great Place to Work<sup>®</sup> and *Fortune* have recognized [Novo Nordisk](#) in the United States as one of the country's "Best Workplaces for Giving Back." Novo Nordisk, a world leader in diabetes care, ranked #16 out of 50 companies on the list. [More](#)

[QuintilesIMS](#) has again been named to *FORTUNE* magazine's "World's Most Admired Companies" list. The 2017 listing marks the third consecutive year the company has been recognized by *FORTUNE* as a most admired company. QuintilesIMS received the distinction in *FORTUNE*'s Healthcare: Pharmacy and Other Services category with high marks in quality of management, value as a long-term investment, effectiveness in conducting business globally and wise use of corporate assets. [More](#)

[PPD](#) has been honored for employee development and business process programs delivering service excellence for biopharmaceutical clients. [More](#) PPD has secured the fifth renewal of its long-standing contract with the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The original NIAID/DAIDS contract was awarded in 1990, and with the latest renewal, the relationship will extend until 2024. [More](#) PPD has established a [Rare Disease and Pediatric Center of Excellence](#) to oversee all rare disease and pediatric-related drug development activities. [More](#)

[Tryton Medical, Inc.](#), the leading developer of stents designed to treat coronary bifurcation lesions, announced the U.S. Food and Drug Administration (FDA) has approved the company's Premarket Approval (PMA) application for the Tryton Side Branch Stent for the treatment of coronary bifurcation lesions involving large side branches (appropriate for a  $\geq 2.5$ mm stent). The Tryton Side Branch Stent is the first dedicated bifurcation device to receive regulatory approval in the U.S. [More](#)

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## Member Benefits

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[BIO Business Solutions](#)<sup>®</sup> offers NCBio members special discounts. Find out more about [NCBio discounts](#).

Nearly 3,000 companies currently use BIO Business Solutions<sup>®</sup>, spending more than \$400 million through the program annually. The discounted prices and value added features available to you are based on the total volume of the program. BIO Business Solutions<sup>®</sup> gives you the purchasing power of the largest companies in your industry.

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## Calendar

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### [Fish 2.0 South Atlantic and Gulf Coast Shellfish Workshop](#)

Wednesday Mar 15, 2017 - Friday Mar 17, 2017

... [read more](#)

- [Register Now](#)

### [Triad BioNight](#)

Thursday Mar 30, 2017

... [read more](#)

### [NCBio Legislative Reception 2017](#)

Wednesday Apr 5, 2017

... [read more](#)

- [Register Now](#)

### [Meet with Johnson & Johnson Innovation](#)

Wednesday Apr 12, 2017

... [read more](#)

### [Applied Principles & Techniques of Depth Flow Filtration](#)

Tuesday Apr 25, 2017 - Friday Apr 28, 2017

... [read more](#)

### [Clinical Trial Supply Southeast Conference 2017](#)

Wednesday May 3, 2017 - Thursday May 4, 2017

... [read more](#)

### [Ag Biotech Entrepreneurial Showcase 2017](#)

Wednesday May 10, 2017 - Thursday May 11, 2017

... [read more](#)

### [Chromatography Column Packing: Foundation & Applications](#)

Tuesday May 23, 2017 - Thursday May 25, 2017

... [read more](#)

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