



connections newsletter



**JANUARY 2020
UPDATE**

**Serving the NC Life
Sciences Industry**

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NCBIO This Month

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Medical Device Tax Is History



Full repeal of the Medical Device Tax was included in the year-end spending bill approved by Congress and signed into law by President Trump. The industry worked

NCBIO - Media

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

NCBIO Links

- [CED](#)
- [NCBIO](#)
- [NC Biotech Center](#)
- [BRITE](#)
- [BTEC](#)
- [BioNetwork](#)
- [NCBioImpact](#)
- [North Carolina
Pharmaceutical Services
Network](#)
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Biotechnology Workforce](#)

NCBIO Sustaining Members



intensely to repeal the tax, which would have become effective this month.

There was strong bi-partisan support for the repeal. NC BIO worked with AdvaMed, the Medical Device Manufacturers Association (MDMA) and other organizations for the repeal of the tax, which was adopted as part of the Affordable Care Act. "We have talked with many members of Congress about the impact the tax would have had on innovation and growth in the medical device industry since it would have applied to all companies based on sales, even if the companies were not generating a profit. It was making it difficult for companies to plan future activities. We are pleased it is finally repealed," stated NC BIO President Sam Taylor.

The tax was enacted in 2013 and then in 2016 and 2018 Congress authorized two-year suspensions. Scott Whitaker, AdvaMed President and CEO, said, "This is a great day for American patients, American jobs, and American innovation: The medical device tax is officially history. With the end of this burdensome tax, the U.S. medtech industry can do what it does better than anyone else in the world: develop life-changing innovations that save and improve patients' lives, and create high-paying, high-tech jobs to keep the American economy booming."

Mark Leahey, President and CEO of MDMA, stated, "Over ten years ago MDMA and our members engaged Congress to stop the medical device tax from punishing patient care and job creation, and this marks the culmination of this important work."

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Lawmakers Return January 14

Life science proposals are still pending from the 2019 Legislative sessions, and NC BIO will be working with lawmakers to get these issues considered in the January 14th session. An override of Governor Roy Cooper's veto of the main budget bill may resurface in the Senate, if Republicans in the upper chamber can secure the vote of at least one Democratic senator who would support the move. Democrats have indicated they will stick with the Governor's position to include Medicaid expansion in the budget.

Three proposals that NC BIO will push for include:

- \$1M in non-recurring funding in both years of the 2019-21 biennium for the State's SBIR/STTR matching grant program, commonly known as the One North Carolina Small Business Program.
- \$500,000 in additional recurring funding for the North Carolina Biotechnology Center, and \$500,000 in non-recurring funding for the 2020-21 fiscal year.
- \$2M for each year of the biennium for North Carolina's participation in the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).

Other legislation that could be considered includes bills addressing step therapy, PBM transparency, and coverage parity for oral cancer drugs. Following the January session, lawmakers are not expected to return until May.

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NC BIO Luncheon and Forum

Join NC BIO and members on February 19 from 11:30 a.m. to 1:30 p.m. for a Life Science Luncheon and Forum focused on intellectual property strategy. The discussion will highlight IP around drug pricing, product development and protection, and artificial intelligence. The panel will be moderated by **Julie Meigs, Ph.D.**, Partner, Womble Bond Dickinson, and features:

- **Shawn Glidden**, Vice President Legal Affairs & Secretary, Liquidia Technologies
- **Mike Penn**, Principal Counsel, Intellectual Property & Litigation, Amgen
- **Tim Wilson**, Director, Patents, SAS

Additional speakers have been invited. To learn more, [click](#).

Thank you to our current sponsors, [Aon](#) and [Jenkins, Wilson, Taylor & Hunt](#). If you are

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interested in sponsoring this Forum or other 2020 events, please contact [Laura Gunter](#).

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Biotech Manufacturers Forum Discusses Trends in the Industry



[Rich Motruk \(Kymanox\)](#), [Stephen Perry \(Kymanox\)](#), [Keith Fritsky \(Gore PharmBIO Products\)](#) and [Raj Vora \(DPR Construction\)](#)

Data analysis, modular construction applications and continuous processing were just a few of the topics covered at the quarterly NCBIO Biotech Manufacturers Forum meeting. Stephen Perry of [Kymanox](#) told BMF members that industry often fails to assess and capitalize on the availability of increased data generation and collection. He noted a number of data problems such as too much data, data not centralized or linked, no one looking at data and lack of fresh eyes to review data.

Rich Motruk of Kymanox talked with the group about statistical tools that could be used and various opportunities for leveraging data points. Raj Vora of [DPR Construction](#) discussed different types of modular construction and reviewed a case study of a modular construction cGMP project for an NIH National Cancer Institute Tumor Infiltration Lymphocytes Production Facility. Keith Fritsky of [Gore PharmBIO Products](#) reviewed the advantages of single-use systems and of continuous processing. He noted there are challenges to each in adopting these processes and outlined ways the industry can collaborate to solve the challenges.

For more information about the Biotech Manufacturers Forum, contact program manager [John Wagner](#).

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BIO World Congress on Industrial Biotechnology, Sept. 21-24 in Raleigh

[The BIO World Congress on Industrial Biotechnology](#) is the largest industrial biotechnology event for business leaders, investors, and policy makers in biofuels, biobased products, and renewable chemicals. By presenting at this conference, you can share your corporate message and present research to 1,000+ attendees. Additionally, presenters receive a discounted registration rate which provides access to networking, sessions, BIO One-on-One Partnering Meetings, and more!

Calls for proposal for breakout sessions opens January 9 and closes February 21. Visit [bioevents.hubb.me](#) to submit a proposal. Submissions for Company and Technical Presentations and Start-Up Stadium will be reviewed on an ongoing basis. [Find out more.](#)

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Prepare for 2020 with Two Small Business Commercialization Webinars in January

[The National Center for Advancing Translational Sciences \(NCATS\)](#) is offering two great opportunities to learn more about the SBIR and STTR programs, as well as skills and resources for taking your SBIR and STTR research to the next step in commercialization. Learn about programs and current funding opportunities available to small business biotech entrepreneurs and researchers under the [Small Business Innovation Research \(SBIR\) and Small Business Technology Transfer \(STTR\)](#) programs.

NCATS Small Business Funding: Early-Stage Support to Commercialize Your Translational Science Innovation, Thursday, January 23 from 2:00 to 3:00 p.m. ET

NCATS SBIR/STTR Presents: Essential IP Advice for Small Business Commercialization, Featuring USPTO Patent Application & Examination Processes on Wednesday, Webinar: January 29 from 1:00 to 3:00 p.m.

[Find out more.](#)

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AgTech Prize Announced

Alexandria LaunchLabs - AgTech, announced its inaugural \$100,000 AgTech Prize. Startup companies who have a passion for transforming the food value chain should apply on the company [website](#) by January 31. Alexandria will host optional prize information/Q&A sessions via Webex on January 9, 2020, at 2 p.m. EST. [RSVP for Webex](#). Agtech is defined broadly, looking for companies working in:

- Crop enhancement & protection
- Digital & data solutions
- Animal health
- Breeding & genetics
- Next gen farming & food
- Supply chain solutions

The \$100,000 prize, which consists of a \$75,000 cash award and a \$25,000 LaunchLabs scholarship, will be awarded at an expense-paid, in-person pitch event to investors and industry experts at the facility in Research Triangle Park, North Carolina. [More](#)

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First Flight's 2020 Fast Cohort

Up to 30 science-focused startup companies will be selected for a cohort who will receive support in submitting a Phase I SBIR/STTR application during the 2020 calendar year. Participants selected for the **2020 FAST Cohort** will receive an extensive grant-readiness **Boot Camp held on Feb. 5-6, 2020** at First Flight Venture Center in Research Triangle Park. Companies will engage in two-days of targeted grant readiness evaluation and mentor engagement.

Companies must meet the following criteria:

- Company must be headquartered in North Carolina
- The company must submit a Phase I SBIR/STTR application during 2020.
- The company should be seeking support for the preparation of a Phase I SBIR or STTR application only. Fast Track and Direct-to-Phase II applicants are not eligible.

January 15 is application deadline on the 2020 Fast Cohort program.

[Learn more.](#)

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Venture Connect March 17-19

Redefining the traditional conference, [Venture Connect](#) is a new three-day experience. Recognizing the innovation potential across the Tech & Life Science communities, CED is focused on creating an environment that supports stronger connections, valuable programming, and learning for all.

You can attend Venture Connect as an Entrepreneurial Company or General Attendee. A ticket will include – three days of nonstop content, a keynote lunch, networking receptions, one-on-one meeting access, and more. Early registration runs through February 14. [Click to register](#).

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At the National Level

NC Senators Co-Introduce Legislation on Drug Pricing



Senator Thom Tillis (R-NC) and Senator Richard Burr (R-NC) co-introduced legislation with Senators Mike Crapo (R-ID), Mike Enzi (R-WY), John Barrasso (R-WY), and Jim Risch (R-ID) to lower prescription drug prices, bring greater transparency to the prescription drug industry and encourage American ingenuity in the development of new treatments and cures.

“I’ve been fighting to make sure that North Carolinians have affordable health care with the choices they want and the protections they deserve, which includes having access to prescription drugs they can afford,” Senator Tillis said. [More](#)

Full text of the Senate bill can be found [here](#), a section-by-section [here](#), and a two-page summary [here](#).

BIO Has New Website

The Biotechnology Innovation Organization has a new website. The new site has information to keep you updated on a variety of activities. [Click to check out site](#).

Upcoming Events – National Partners

BIO CEO & Investor Forum February 10-11

The BIO CEO & Investor Conference held in New York is one of the largest investor conferences focused on established and emerging publicly traded and select private biotech companies.

- Experience two-days of partnering meetings with investors, industry analysts, and senior biotech executives.
- Hear Washington’s perspective on policy and other timely developments affecting the industry.
- Evaluate fresh investment opportunities including compatible, complementary, and competitive companies.

View the [schedule of events](#) and proposed educational topics. To learn more

visit bio.org/ceo or download the [conference brochure](#). [Register](#) now. NC BIO members can save up to \$200 off the biotech/pharma rate. Contact [Amber Niebauer](#) for the discount code.

BIO 2020

It's never too early to start planning for the [2020 BIO International Convention](#) in San Diego, June 8-11, 2020. Secure your accommodations through the only office housing provider of the BIO International Convention. [Book](#) early for the best selection and price.

Explore the new registration packages available in January 2020! [View](#) your options and select the packages that work for you and your team.

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Member News

To be included in Member News, send information about your organization to [Brenda Summers](#).

[Baebies](#) announced that FINDER, a near-patient testing platform, now has CE Mark as an In Vitro Diagnostic device (IVD) and is commercially available in Europe and other countries that recognize CE Mark. [More](#) Baebies has shipped a total of 6 million newborn screening (NBS) tests – which translates to 6 million chances to save a life. [More](#)

[Biogen Inc.](#) announced topline results from the Phase 2 PASSPORT study of gosuranemab (BIIB092) for progressive supranuclear palsy (PSP). [More](#) Biogen will present at the 38th Annual J.P. Morgan Healthcare Conference. The webcast will be live on Monday, January 13, 2020 at 6:30 p.m. ET. [More](#)



Scott Sewell of [Cook Medical](#) was honored by the Winston-Salem City Council for his 4.5-year effort to start the Winston-Salem Police Foundation. Congresswoman Virginia Foxx recognized Sewell's work as President of the Foundation during a [speech](#) on floor of U.S. House of Representatives.

[Eva Garland Consulting](#) (EGC) has announced that Sue Reyer, CPA, will be directing the Company's Accounting and Compliance division. Ms. Reyer has over 25 years of public and private company financial and operations experience. [More](#)

[IQVIA](#) announced that AstraZeneca has selected IQVIA Technologies' Orchestrated Customer Engagement (OCE) platform to further its digital agenda and establish its "Field of the Future." [More](#)

[Merck](#) will invest \$57 million and create 55 jobs in Wilson, Governor Roy Cooper announced. The expansion will establish a filling and packaging line for the company's RotaTeq® vaccine. [More](#)

[Novan, Inc.](#) announced that Paula Brown Stafford, currently President and Chief Operating Officer ("COO") of Novan, will succeed G. Kelly Martin as its Chief Executive Officer ("CEO"), effective February 2, and she will remain a member of the Novan Board of Directors. [More](#)

[PPD, Inc.](#) has been selected by Medidata, part of Dassault Systèmes, to receive its Patient First Award. The award recognizes a company that is trailblazing ways to improve lives by demonstrating a commitment to decreasing patient burden in clinical trials through technology. [More](#) PPD announced that its SiteCoach training program for new clinical trial investigators has been named one of 2019's most innovative services in the life sciences industry. [More](#)

[Syneos Health](#) has released its *2020 Health Trends* report. The report outlines 15 critical shifts that are changing how life sciences leaders will develop and commercialize novel new therapies and innovations in the year ahead. [More](#)

[TCG](#) has released a [White Paper](#) on the medtech reimbursement landscape and potential pathways to coverage. [More](#)



Christof Jensen of [UCB Biosciences](#) was appointed as Honorary Consul of Belgium at a reception for the opening of the Honorary Consulate of Belgium in North Carolina. The Consul General of Belgium William de Baets and the Ambassador of Belgium Dirk Wouters were present for the event.

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BIO Business Solutions



In 2019 BIO saved 4,300 companies nearly \$430 million through BIO Business Solutions® with volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases, and more.

NCBIO members, you are eligible! This is a benefit of your NCBIO membership. Review the cost-savings offered by clicking [here](#) and choose the programs you're interested in. Email biobusinesssolutions@bio.org with your choices and they will get you started. For all the latest news, promos, and event information, follow [BIO Business Solutions® on LinkedIn!](#)

For other questions or help, NCBIO members also have access to a dedicated BIO Business Solution's representative. Bob Dearth can be reached via bdearth@bio.org or 718-716-7555. He's available to help you maximize your savings!



American Laboratory Trading

Monetize Your Assets and Maximize Your ROI

American Laboratory Trading (ALT) is BIO's preferred partner for surplus strategy services. Whether it be the need to dispose of a single item or liquidate thousands of instruments across multiple labs, ALT purchases, consigns, trades, or auctions your surplus equipment to monetize your assets and maximize your ROI, enabling you to move your research forward more efficiently from ideas to promising treatments. NC BIO members receive a 20% discount on surplus services, a 10% bonus on standard consignment split, and a 5% bonus on seller's premium in auctions.

- Surplus asset disposition through outright purchase, consignment, or auction
- Turnkey move management including decontamination, decommissioning, packing & shipping
- Deinstallation, benchmarking, and reinstallation
- Chemical and waste management
- Inventory management with quarterly or semi-annual equipment audits
- Asset assessment and valuation

[Learn More](#)



Brex

BIO Business Solutions is proud to announce the addition of an exciting new program to our cost-savings portfolio:

- Brex, the Corporate Credit Card for the Life Sciences

Brex is an innovator in the corporate credit card industry and has provided special rewards for NC BIO members.

MEMBER BENEFITS:

BIO has pre-negotiated rewards and favorable terms from Brex:

- 60,000-point signup bonus (\$600 value)
- Waived card fees for life (value equal to \$60 per/card per/year)
- Tailored rewards and points with 3x on lab supplies, 7x on conference registrations, and 4x on travel
- 5-minute application process (completely online) with instant access to virtual cards
- No personal guarantee or collateral requirements

[Find](#) out more on the program and its benefits.

ABOUT BIO BUSINESS SOLUTIONS

BIO Business Solutions is the largest cost savings purchasing program for the biotech industry, operated by the Biotechnology Innovation Organization (BIO). BIO leverages the purchasing power of the industry to negotiate with top suppliers to secure exceptional savings, favorable terms, and superior service for members. NC BIO Members can participate for no charge as a benefit of their membership and to save on items they need to run a successful biotechnology enterprise.

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To view full calendar, [click](#).

[**Raleigh Chamber Launch 2020 Economic Forecast**](#)

Thursday Jan 9, 2020

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[**LaunchBio: Larger than Life Science Looking Back, Looking Ahead**](#)

Thursday Jan 9, 2020

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[**J.P. Morgan Healthcare Conference**](#)

Monday Jan 13, 2020 - Thursday Jan 16, 2020

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[**First Flight's How to Win SBIR/STTR Grants Seminar \(Asheville\)**](#)

Tuesday Jan 14, 2020

... [read more](#)

[**NCRAF Webinar: Limited Population Pathway for Antibacterial and Antifungal Drugs \(LPAD\)**](#)

Thursday Jan 16, 2020

... [read more](#)

[**BTEC Short Courses: Hands-On cGMP Biomanufacturing Operations**](#)

Tuesday Jan 21, 2020 - Friday Jan 24, 2020

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[**NCATS Small Business Funding: Early-Stage Support to Commercialize Your Translational Science Innovation**](#)

Thursday Jan 23, 2020

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[**2020 SciTech Lecture Series: Convergence in the Era of Intelligent and Cognitive Assistants**](#)

Thursday Jan 23, 2020

... [read more](#)

[**NCATS SBIR/STTR Presents: Essential IP Advice for Small Business Commercialization, Featuring USPTO Patent Application & Examination Processes**](#)

Wednesday Jan 29, 2020

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[**Learn How to Write a Competitive Proposal to Access Hundreds of Thousands of Dollars through SBIR/STTR Grants!**](#)

Wednesday Feb 5, 2020 - Friday Feb 7, 2020

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[**LaunchBio: Larger than Life Science**](#)

Thursday Feb 6, 2020

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[Triangle Global Health Career Day](#)

Friday Feb 7, 2020

... [read more](#)

[BIO CEO & Investor Conference](#)

Monday Feb 10, 2020 - Tuesday Feb 11, 2020

... [read more](#)

[Life Science Women's Conference](#)

Wednesday Feb 19, 2020 - Thursday Feb 20, 2020

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[NCBIO Life Science Forum: Intellectual Property Strategy](#)

Wednesday Feb 19, 2020

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[NCBiotech Ag Tech Professional Forum](#)

Wednesday Feb 19, 2020

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[LaunchBio: Larger than Life Science](#)

Thursday Mar 5, 2020

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[BTEC Short Courses: Hands-On cGMP Biomanufacturing Operations](#)

Monday Mar 9, 2020 - Thursday Mar 12, 2020

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[ISPE-CaSA 27th Annual Life Sciences Technology Conference](#)

Tuesday Mar 10, 2020

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[CED Venture Connect 2020 Summit](#)

Tuesday Mar 17, 2020 - Thursday Mar 19, 2020

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