

June 2021 Update

Serving the NC Life Sciences Industry

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## NCBIO This Month

- Medical Device Forum
- State budget and tax cut plans
- Pushing back on IP waiver
- Proposed changes for Emerging Growth Companies
- NC Biotech awards \$1.8 million
- Save money with NCBIO
- NCBIO Lab Space Forum, BIO Digital and more events

... and more



# NCBIO Medical Device Forum covers product development during pandemic

Depending on people, being flexible and agile and remembering the lessons learned during this pandemic were some of the key points shared by the panelists participating in NCBIO's Medical Device Forum held online Wednesday, May 19.

The forum was sponsored by Brex, Jenkins Wilson Taylor & Hunt, and PSC Biotech and moderated by Julie Fife, Ph.D., vice president, program management at Grant Engine. The panelists were

- Kendall Foster, vice president, technical operations for
- Don Gurskis, CEO and co-founder of Arctx Medical;
- Alyssa Schmidt, associate director, global regulatory consulting of Syneos Health; and
- Tony Voiers, chief executive officer of Advanced Chemotherapy Technologies.

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# **NCBIO Sustaining Members**











## **NCBIO Supporting Members**



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From NCBIO: State tax cuts, federal IP waiver and lots of events and ways to save

# STATE UPDATES

If you have questions or concerns on any of these topics, please contact Laura Gunter.

## Senate proposes tax cut, negotiating with House on budget

The NC Senate and House are about \$500 million apart on a spending cap with the House advocating for the larger amount for the first year of the two-year budget.

Senate Republicans announced a tax cut plan that would result in a 21% income tax cut for the median North Carolina household. The proposal reduces the flat income tax rate from 5.25% to 4.99% and increases the standard deduction from \$21,500 to \$25,500 for joint filers. It also increases the child tax deduction by \$500, bringing the total deduction to \$3,000 for families that earn less than \$40,000 per year. Additionally, the proposal phases out the corporate income tax (currently 2.5%) over the next seven years.

The Senate is proposing a change to the franchise tax by using net worth as the sole measure of calculating liability under the franchise tax. Under North Carolina law, taxpayers must currently use the highest of three bases when paying franchise taxes. The two bases that would be eliminated are 1) the book value of North Carolina real and tangible personal property less the debt used to acquire that property and 2) a base method equal to 55% of the appraised value of North Carolina real and tangible personal property.

The Senate Finance Committee discussed the tax proposal as well as their COVID relief proposal called the JOBS Grant Program. The JOBS Grant Program appropriates \$1 billion of federal funds from the American Rescue Plan Act of 2021 to provide grants to NC businesses that received a COVID-related loan from the state or federal government. The maximum grant amount would be \$18,750 or 7.5% of the loan, whichever is less. The Senate passed the package on Thursday and now waits for the House to concur.

### Governor announces unemployment changes

Gov. Roy Cooper signed an executive order restoring many of the prepandemic requirements for receiving unemployment benefits. All existing claimants of unemployment benefits must fulfill work search requirements beginning June 6 and will be required over the next several weeks to register on NCWorks.gov. The order also does the following:

- Claimants must make contact with at least three different employers each week and keep a record of their work search, as is required by state law.
- To continue receiving benefits, all unemployment claimants will be required to register with a jobseeker account on NCWorks.gov, North Carolina's online portal for employment and training services.

The order also directs the N.C. Department of Commerce to explore the use of certain federal funds to establish a re-employment incentive program for jobless workers who find and maintain employment.





## NATIONAL UPDATES

## BIO cautions US officials against IP waiver for vaccines

The Biden Administration's announcement that it would support a waiver of the TRIPS Agreement for COVID-19 vaccines set off a firestorm in Congress. Members of Congress have written to President Biden urging him to reconsider the policy including. Rep. Byron Donalds (R-FL) introduced legislation with 20 cosponsors aimed at preventing the president from proceeding. Other members have filed amendments to the Endless Frontiers Act. When questioning U.S. Trade Ambassador Katherine Tai before the Ways and Means Committee, Rep. Stephanie Murphy (D-FL) called IP the "lifeblood of our innovation sector" and stressed the importance of alternatives to the TRIPS waiver.

BIO continues to educate policymakers on the facts. Most importantly, BIO's Global SHARE Program, as spelled out in <u>a letter from Michelle McMurry-Heath</u>, M.D., Ph.D, to the president, provides concrete steps the United States can take to expedite the production and distribution of vaccines to meet the current crisis. As reflected in comments like those from Rep. Murphy, these proposals are having a positive impact on the debate.

Biopharmaceutical manufacturers have pledged 1.3 billion vaccine doses at low cost/no profit to low- and middle-income countries by the end of 2021. These include 1 billion of Pfizer-BioNTech, 200 million of Johnson & Johnson and 100 million of Moderna with an additional 1 billion total pledged for 2022.

NCBIO is in touch with the members of the North Carolina Congressional delegation on this issue.

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## New bill would help Emerging Growth Companies grow

The Helping Startups Continue to Grow Act (<u>H.R. 3448</u>) streamlines reporting requirements for Emerging Growth Companies so they can invest in innovation, which is especially helpful for biotech startups.

Reintroduced by Rep. Bryan Steil (R-WI), H.R. 3448 gives Emerging Growth Companies more time to continue expanding and developing their product under streamlined disclosure and filing procedures — which is helpful for all startups but especially for companies developing lifesaving drugs and medical devices.

The legislation would provide a five-year extension of certain exemptions and reduced disclosure requirements. Currently, EGCs can maintain EGC status for up to five years after they go public.

Many EGCs are not generating enough revenue five years after becoming public to support the compliance costs that come with a loss of EGC status. With this five-year extension, startups would not have to spend time and money on bureaucratic regulations and burdensome compliance procedures meant for larger and more mature firms.

## Tillis co-sponsors IDEA Act

<u>S.632</u>, introduced by Senators Mazie Hirono (D-HI) and Thom Tillis (R-NC), was adopted by the Senate as an amendment to the Endless Frontier Act with a strong bipartisan vote. The Inventor Diversity for Economic Advancement Act of 2021 is an effort to close the gap that women, minorities and others face when procuring patent rights in the United States. The IDEA Act works to close those gaps by directing the U.S. Patent and Trademark Office to collect demographic data – including gender, race, and military or veteran status – from patent applicants on a voluntary basis. BIO has endorsed this legislation.

## Brooks-LaSure to head CMS

The Senate confirmed Chiquita Brooks-LaSure as the first Black woman to lead the Centers for Medicare and Medicaid Services. She was approved by 55-44, with five Republicans joining all Democrats in support.

One of the architects of the Affordable Care Act under President Obama, Brooks-LaSure is expected to work to roll back Trump-era efforts to weaken the ACA.

She could also play a role in the Biden administration's efforts to control drug prices as she may be asked to use the agency's rule-making power to try to negotiate lower prices for drugs purchased with Medicare or Medicaid.

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#### Lander nomination moves forward

The Senate Commerce Committee advanced President Biden's nominee, Eric Lander, Ph.D., to head the Office of Science and Technology Policy with a bipartisan voice vote. Lander is widely expected to receive strong, bipartisan support from the full Senate.

#### **USMCA Free Trade Commission authorized**

Due to the advocacy of BIO and support from members of Congress, USTR Ambassador Katherine Tai called on the Mexican government to immediately resume authorizations of ag biotech products during the first Free Trade Commission meeting of the United States – Mexico – Canada Agreement.

# **NCBIO Updates**

#### **Member News**

#### NCBiotech Awards \$1.8M in Grants, Loans in Latest Quarter

The North Carolina Biotechnology Center awarded 48 grants and loans totaling nearly \$1.8 million to universities, bioscience companies and other entities in the third quarter of its fiscal year.

The awards, made in January, February and March, support life sciences research, technology commercialization and entrepreneurship throughout North Carolina. The funding also helps universities and companies attract follow-on funding from other sources.

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#### NCBIO Members receive TBJ Life Sciences Awards

AskBio, BioAesthetics, Chiesi USA, Humacyte, Mycovia Pharmaceuticals, Pairwise, PPD, Precision BioSciences and Ribometrix were among the 16 recipients honored as winners of 2021 Triangle Business Journal Life Science Awards.

The Life Sciences Awards recognize both individuals and research organizations that are blazing trails and breaking ground in this field. The broad spectrum of the life sciences arena represents a number of focus areas, including biotechnology, pharmaceuticals, clinical research, human health, medical devices and diagnostics, and many others.

- AskBio Company of the Year (Private)
- BioAesthetics Best Medical Device Company
- Chiesi Company of the Year (Private)
- Humacyte Best Medical Device Company
- Mycovia Best Late Stage Product Development Company
- Pairwise Best AgBio Company
- PPD Most Innovative Clinical Research Organization
- Precision BioSciences Company of the Year (Public)
- Ribometrix Best Early Stage Product Development Company

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## Member News Briefs

To be included in Member News, send information about your organization to <u>David Etchison</u>.

**Biogen Inc**. and Capsigen Inc. entered into a strategic research collaboration to engineer novel adeno-associated virus capsids that could deliver transformative gene therapies that address the underlying genetic causes of various CNS and neuromuscular disorders. MORE

**Biogen Inc.** and Envisagenics will collaborate to advance RNA splicing research within CNS diseases. Biogen will leverage Envisagenics' proprietary Al-driven RNA splicing platform, SpliceCore, to define and understand the regulation of different RNA isoforms in CNS cell types. MORE >>

**Cambrex** is expanding its cGMP analytical testing capabilities at its site in Longmont, Colorado. Existing space at the site has been repurposed with cutting-edge technologies and doubles the footprint of the laboratory operations. MORE >>

**Cambrex** completed an investment project at its facility in Tallinn, Estonia, to upgrade its kilogram-scale laboratory to undertake the manufacture of pharmaceutical intermediates under current good manufacturing practice conditions. **MORE** >>

**Chiesi USA** plans to become carbon neutral by 2030 on direct greenhouse gas emissions and indirect GHG emissions from purchased electricity and heat and by 2035 on all the other indirect GHG emissions as defined by <u>actionoverwords.org</u>. <u>MORE >></u>

**Eva Garland Consulting** has been named as one of Inc.'s Best Workplaces for 2021. EGC joins a group of 11 North Carolina companies and 429 companies throughout the United States who are featured in Inc.'s 2021 Best Workplaces list. MORE >>

**Mycovia Pharmaceuticals** submitted its New Drug Application for oteseconazole, an oral antifungal product for the treatment of recurrent vulvovaginal candidiasis. There are currently no FDA-approved treatments fro RVVC. MORE >>

**Pfizer** has launched a Breakthrough Fellowship Program, a nine-year commitment to increase minority representation at Pfizer to enhance its pipeline of diverse leaders with a goal of developing 100 fellows by 2025. <u>MORE >></u>

**PPD**, **Inc**. has been recognized for excellence in the CRO Leadership Awards for the 10th consecutive year in a survey of pharmaceutical and biotech professionals conducted for Clinical Leader and Life Science Leader magazines. **MORE** >>

**PPD, Inc.** was named Best Contract Research Organization at the 14th annual Vaccine Industry Excellence Awards during the 2021 World Vaccine Congress. Accelerated Enrollment Solutions, a business of PPD, received the honor of "highly commended" in the category of Best Clinical Trial Network. MORE >>

## **BIO Business Solutions Highlights**



# Four Steps to Saving with Your NCBIO Membership

NCBIO members are eligible for BIO Business Solutions volume-based discounts and favorable contract terms to help you save on products and services you already use. How does it work? Here it is in four simple steps!

- <u>Browse our cost-savings programs</u> from lab supplies and equipment, research-grade microscopes, office supplies, shipping, insurance, research services and more.
- <u>Contact us</u> Fill out a short inquiry form to let us know which cost-saving options you're interested in hearing more about.
- Sign up Depending on the program, you can enroll yourself, talk to the partner for more information, and/or start a free trial.
- Enjoy the benefits Once your account is set up, your savings will be in place. If you have questions or need support, our team is always here to help!

For all the latest news, promos and event information, follow <u>BIO Business Solutions on LinkedIn</u>.

**GET STARTED** 



# Accelerate and enhance your research — from discovery to analysis

If you haven't taken advantage of your <u>free trial</u> of Article Galaxy Enterprise yet, we recommend you do so now! It's an end-to-end literature management platform that covers discovery, access and management of scientific content. Highlights include:

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- In vitro/in vivo experimentations and data analysis

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# Top health program trends will shift in the COVID-19 business environment

According to Mercer's National Survey of Employer-Sponsored Health Plans, with the pandemic disrupting health care utilization and adding stress to employees' lives, employers are offering more flexible working conditions and focusing on these three trends:

- Telemedicine will play a larger role Nearly all employers anticipated a larger role for virtual care in their health programs in the future.
- Behavioral Health is a top priority for employee well-being Employers are recognizing the need for mental health coverage as part of their health care offering.
- Engaging remote employees Employers are seeking new, creative ways to engage and motivate their remote workforces.

Do you need help adjusting your benefits package and health care offering to your employees? BIO Health Small Group Health Plans can assist you in quoting your health care benefits.

GET A QUOTE NOW



# Navigating idle assets and the surplus equipment marketplace

June 2 | 12PM EDT

Whether your lab has a few idle instruments or you need to liquidate an entire facility, understanding the surplus lab equipment marketplace is the first step in developing a surplus equipment strategy.

In this informative session, learn from ALT, BIO Business Solutions' preferred provider of premium refurbished lab equipment and surplus strategy services for the life sciences, how to implement a few easy steps to design a program to maximize your space, resources, and ROI, while also being a good corporate citizen and recycling assets for the next generation of great labs.

REGISTER NOW



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# Office Depot and Fellowes offer seminar on air purifcation

BIO Business Solutions strategic partner, Office Depot, is partnering with Fellowes Brands to offer the Innovation Is in the Air webinar on Thursday, June 3, at 12:30 p.m. EST. It's a guide to establishing a cleaner and healthier environment with air purification solutions.

Join indoor air quality solutions specialist Mike Booth and Wayne Lajoie, the VP of facility supplies sales and strategy at Office Depot, as they demonstrate why commercial air purifiers are not only a smart solution for helping your audience experience a cleaner environment but also how the pandemic brought the importance of air cleaning and filtration to light..

**REGISTER NOW** 

# **Upcoming Events**



# **BIO** Digital

### June 10-11 & 14-18

BIO Digital is the world's largest virtual biotech partnering and education event, convening thousands of global biotech leaders and innovators. Join us in our efforts to accelerate a BIO-Revolution through global partnerships, collaboration, and thought leadership.

## **REGISTER NOW**



NCBIO Lab Space Forum: Converting Office Space to Lab and

# Flex Space

## July 13 | 12 PM

Join NCBIO members and guests virtually on Tuesday, July 13, from 12 to 1:30 p.m. for our Lab Space Forum as we discuss the changing landscape of office and lab space.

The pandemic has caused employers to pause and rethink their return to work and office space need for employees. Many of these employees will return to work on site, but for others the remote environment may continue. For office space that is no longer needed, employers are repurposing those spaces for expanded lab and/or flex space. And perhaps, landlords are more willing to repurpose space to fit laboratory needs.

Hear from our panel of experts as they help companies, like yours, navigate this journey:

- Pat Chisholm, senior vice president, BE&K Building Group
- Blake Stevens, Ph.D., vice president, science and technology, Alexandria Real Estate Equities
- Sue Back, life sciences practice group lead, Davis Moore Advisors

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#### **REGISTER NOW**



# BIO Building a Sustainable and Equitable Clinical Development Ecosystem

Free Virtual Conference Afternoons, June 24-25, 2021

Join BIO's first-ever summit on clinical trial diversity!

At the summit, stakeholders from across the clinical development spectrum will engage in meaningful discussion on advancing health equity in clinical trials. Because ensuring clinical trial diversity is not just at the heart of BIO's Equality Agenda — it's driving the future development and availability of innovative medical products.

Summit participants will connect with renowned industry leaders, esteemed academics, and top-notch experts in health equity over two afternoons of roundtable discussion. Day 1 of the summit will culminate in the creation of a comprehensive vision for an equitable drug development ecosystem, while Day 2 will focus on transforming that vision into an actionable strategy to execute real change. Each day will wrap up with a networking session, designed to provide participants with optimized opportunity to create valuable, new connections while fostering existing relationships.

Please note that the event is FREE, but preregistration is required

### LEARN MORE

## **NCBIO** Calendar

- Duke Population Health Summer Institute (6/7/2021 to 6/11/2021)
- BIO International Convention Digital 2021 (6/10/2021 to 6/11/2021)
- Balancing Cost Efficiencies in the Drug Development Process hosted by

Cambrex (6/10/2021)

- BIO International Convention Digital 2021 (6/14/2021 to 6/18/2021)
- Duke Population Health Summer Institute (6/14/2021 to 6/18/2021)
- Precision Medicine in the Era of a Pandemic Recovery hosted by Precision Medicine World Conference (6/14/2021 to 6/18/2021)
- BTEC Downstream Biopharmaceutical Processes: Fundamentals and Design (6/15/2021 to 6/17/2021)
- Let's Talk About Series: Modeling Behavior Examining DEI in Life Sciences hosted by LaunchBio (6/16/2021)
- C-Suite Fireside Chat hosted by WIB-RTP (6/16/2021)
- BTEC Hands-On Essentials of Automation for Biomanufacturing Course (6/23/2021 to 6/24/2021)
- BTEC Hands-On cGMP Biomanufacturing Operations Course (6/29/2021 to 7/2/2021)
- BTEC Analytical Methods for Raw Materials Testing Course (7/7/2021 to 7/9/2021)
- NCBIO Lab Space Forum (7/13/2021)

### **NCBIO Partners**

CED BRITE BTEC BioNetwork NCBioImpact NC Biotech NCABR NC Pharmaceutical Services Network National Center for the Biotechnology Workforce



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