



September 2021 Update
Serving the NC Life Sciences Industry

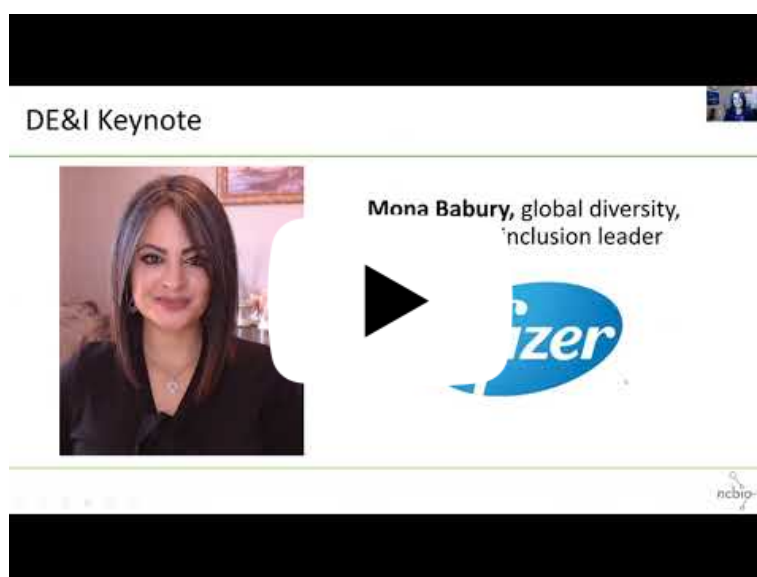
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NCBIO This Month

- Insights on diversity, equity and inclusion
- State budget goes to conference, drug licensing improvements, accumulator ban update
- From DC: budget, price controls, TRIPS update
- Sam Taylor scholarship fund hits halfway mark
- Grant for aseptic training at Durham Tech
- Member news

... and more

NCBIO Roadmap to Diversity event offers strategies for building diverse and inclusive organizations



NCBIO hosted its first event in the Roadmap to Diversity in Life Sciences series on Tuesday, Aug. 24, featuring experts in diversity, equity and inclusion from a number of North Carolina life sciences companies who shared their experience in recruiting and retaining a diverse workforce.

Event co-chairs **Shaylah Nunn Jones**, J.D., principal, government and public affairs at Novo Nordisk, and **Neil Jones**, vice president, corporate strategic partnerships at Lindy Biosciences, opened the event. **Mona Babury**, M.B.A., global diversity, equity and inclusion leader at Pfizer, was the keynote speaker.

Babury kicked things off talking about the difference between equality, which she defined as giving everyone the same thing, and equity, which is understanding what each person actually needs to succeed.

"Equity is hard," she said. "It takes more time, it takes more investment, it takes more work. But it's the right thing to do."

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NCBIO Sustaining Members



NCBIO Supporting Members





STATE UPDATES

If you have questions or concerns on any of these topics, please contact [Laura Gunter](#).

General Assembly seeks to finalize budget

As expected, the NC Senate rejected the House's version of its two-year North Carolina government budget, kicking off formal talks between the two chambers on forming a final spending plan for approximately \$26 billion a year, which will likely take a few more weeks to hammer out.

The NC Senate voted in June to approve its proposed state budget (SB 105) with four Democrats joining the Republicans. The House passed its version Aug. 12, 72-41. Here are some of the key differences in the two budget proposals.

- The Senate plan offers a 3% across the board raise for almost all state employees, including teachers. The House budget proposes an average of 5.5% over the next two years for teachers. Most other state employees would get a raise of 5% over two years.
- The House's budget wants the individual income tax rate to be reduced from the current rate of 5.25% to 4.99%. The Senate wants the rate to go down to 3.99%.
- Both the House and Senate want to lower the corporate tax rate. The House tax plan reduces it from 2.5% to 1.99% over two years. The Senate proposal phases the corporate tax out completely over five years.
- Senate lawmakers have allocated a nonrecurring \$2 million in the state budget for the One North Carolina Small Business Program to increase state grants to businesses that win federal SBIR/STTR grants. The House is offering a \$2 million recurring and \$7 million nonrecurring appropriation.

Gov. Roy Cooper has said that he favors the House's budget proposal, and budget talks continue between the two chambers.

General Assembly moves swiftly to address drug licensing concerns raised by NCBIO members

The NC General Assembly are taking action to modernize North Carolina's rules for wholesale drug distribution licensing after the Life Sciences Caucus heard from G1 Therapeutics, Inc. CEO Jack Bailey.

During the July 21 meeting of the caucus, Bailey explained that North Carolina will not grant a license to manufacture a new drug until the drug is FDA approved. Other states will grant a license that is contingent on FDA approval. North Carolina's policy significantly increases the time to market for new drugs developed in the state. At least one other NCBIO member is having a similar issue, and we hope we'll hear from any others affected by this issue.

After the caucus meeting, co-chairs Sen. Paul Newton and Sen. Mike Woodard drafted legislation to allow the NC Department of Agriculture to make the necessary changes to improve the licensing process. Their proposal also ensures that out of state companies are treated similarly during the registration process.

The corrective legislation was offered as an amendment to [H95](#), which passed the Senate unanimously on Aug. 25 and returns to the House. NCBIO will continue to advocate for approval of the bill by the House and the governor.

House passes accumulator ban to help patients

An accumulator ban provision was added to [S257](#), the Medication Cost Transparency Act, while the bill was being considered in the House as part of a House rework of the bill. This

provision prevents insurance companies from excluding manufacturer coupons from patient copays and deductibles. The new version passed the House and returned to the Senate where it failed in concurrence. It now goes to conference committee to work out the differences.

While the accumulator ban provision received little pushback, some other added provisions are getting opposition from insurers and pharmacy benefit managers. NCPIO and PhRMA member companies are in support and have brought patient advocate groups in to share the patient perspective with lawmakers.

No state-level COVID restrictions in effect, local rules apply

There are no statewide restrictions due to COVID or measures imposed by executive order for the general public for more than a month. Local governments can and have imposed their own restrictions.

Unvaccinated employees of state cabinet agency must wear face coverings in any indoor area of a state government office, building or facility that is controlled by an agency that is part of the Governor's Office or is headed by a member of the governor's cabinet. Employees of state cabinet agencies who are not vaccinated are required to wear a mask and be tested at least once a week for COVID-19. Gov. Roy Cooper encourages other state agencies to do the same.

COVID-19 and variants of the virus, however, remain a threat as North Carolina experiences a rapid increase in cases among those who are unvaccinated. NCPIO will continue to monitor COVID-related issues and keep you updated as needed.

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Elizabeth Biser Confirmed as DEQ Secretary

North Carolina Senate voted to confirm Gov. Roy Cooper's appointment of Elizabeth S. Biser as Secretary of the Department of Environmental Quality. She is the first woman to be confirmed for the role of DEQ Secretary.

Biser previously served as the director of legislative and intergovernmental affairs at DEQ's predecessor agency, the N.C. Department of Environment and Natural Resources. Her private sector experience included serving as the president of Biser Strategies, LLC; senior policy adviser of the Recycling Partnership; vice president of policy and public affairs of the Recycling Partnership; and the government relations and policy adviser of Brooks, Pierce, McLendon, Humphrey & Leonard, LLP. She holds a bachelor's degree and a Master of Public Administration from the University of North Carolina at Chapel Hill.

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NATIONAL UPDATES

Senate passes infrastructure package, approves FY22 budget resolution

The U.S. Senate was busy in August. First, the Senate passed the infrastructure package. The \$1 trillion Infrastructure Investment and Jobs Act (H.R. 3684) passed in a bipartisan vote of 69-30, with every Democrat and 19 Republicans voting for it.

Then the Senate narrowly approved the \$3.5 trillion budget resolution for FY22, "setting the stage in the weeks and months to come for the party to craft and attempt to pass a sweeping economic package expanding the social safety net that President Joe Biden has made a signature agenda item without the threat of a filibuster from Republicans who oppose it."

signature agenda item without the threat of a filibuster from Republicans who oppose it, [reports CNN](#).

The budget focuses on four key buckets: families, climate, health care, and infrastructure and jobs. The budget reconciliation is likely to have a massive drug pricing package with drug price controls — [Axios Health has more on that](#). This will be a major priority for BIO.

President Biden calls for drug price controls

President Joe Biden announced a slew of drug pricing reforms including changes that would radically alter Medicare program for seniors and people with disabilities. Here are the details and what BIO says about it.

The White House [supports drug price controls](#), President Biden said. Specifically, the White House is calling for allowing Medicare to negotiate drug prices, “for a subset of expensive drugs that don’t face any competition in the market,” [says the fact sheet](#). “Medicare negotiators would be provided a framework for what constitutes a fair price for each drug, and there should be powerful incentives to make sure drug companies agree to a reasonable price.”

In other words, price controls, which, as we’ve explained [again](#) and [again](#) and [again](#), won’t work.

He also repeated myths about the high costs of prescription drugs in the U.S., [which we’ve refuted](#).

He did acknowledge “the groundbreaking and lifesaving work that many pharmaceutical companies are doing,” especially during the pandemic, and called for an out-of-pocket cap for Medicare beneficiaries ([which BIO supports](#)).

But price controls will impede this lifesaving work in the future, by creating massive barriers to medical innovation and making it more difficult for small, innovative biotech companies to attract the investment they need to discover future vaccines, treatments, and cures.

BIO has made clear its desire to advocate for policy reforms that lower patient spending at the pharmacy counter without compromising scientific advancement and the support needed to usher in the next generation of cures and breakthrough medicines. Unfortunately, the president’s plan is no such reform. BIO hopes the White House reconsiders this plan and looks forward to working with the president and members of Congress on both sides of the aisle to find bipartisan solutions that benefit patients today **and** tomorrow.

BIO: Where things stand on TRIPS

The World Trade Organization is still considering a proposal backed by India and South Africa (and supported by the U.S.) to waive the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights for vaccine technology. This is the TRIPS waiver. The WTO is on a six-week summer holiday until Sept. 6.

The waiver would make vaccines **more** expensive. The average cost of a new vaccine manufacturing facility is \$700 million, said BIO President Michelle McMurry-Heath, M.D., Ph.D. Additionally, a waiver could cause competition for raw materials, leading to price increases of materials and, ultimately, vaccines.

Vaccines are already low-cost or free. India and South Africa are currently paying \$8 and \$5.25 per dose, respectively—lower than the annual flu shot in the U.S. (\$14), for perspective. And COVAX is set to deliver 2 billion doses to countries that cannot afford to purchase them, with the U.S. set to donate 500 million more doses by the end of the summer.

TRIPS would set a bad precedent with regards to IP protection, causing a ripple effect throughout the biotech sector in the U.S. NCBIO continues to work with our national partners and to talk directly with the NC Congressional delegation in opposition of this measure.

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NCBIO Updates





Sam Taylor scholarship fund passes halfway mark

Pledges and gifts to the [Samuel M. Taylor Memorial Life Sciences Scholarship](#) in the North Carolina Community Colleges Foundation have topped \$135,000. Our goal is to raise \$250,000 to endow scholarships for NC Community College students pursuing training and careers in the life sciences.

We will cover the tuition of three students in the fall of 2021 and then work to create an endowed fund that will support up to four students a year in 2022 and beyond. The scholarships are for students enrolled in agricultural biotechnology, biopharmaceutical technology, biotechnology, bioprocess technology, clinical trials research associate, facility maintenance technology and medical laboratory technology programs.

To contribute, make checks payable to the North Carolina Community Colleges Foundation and **write Samuel M. Taylor Memorial Life Sciences Scholarship Fund in the memo field**. Mail them to

North Carolina Community Colleges System
ATTN Bryan W. Jenkins
200 West Jones Street
Raleigh, NC 27603-1379

U.S. Rep. David Price, Durham Tech announce new biotechnology aseptic training

U.S. Rep. David Price joined Durham County leaders to announce a new grant-funded aseptic training program at Durham Tech to help meet the talent demands for a booming life sciences industry in the Research Triangle.

Elected representatives, business and industry leaders, and workforce developers gathered together at the North Carolina Biotechnology Center for the announcement Thursday morning.

At the news conference, Price, Chair of the Durham County Commissioners Brenda Howerton, and Durham Tech President J.B. Buxton announced that the college received \$300,000 to fund the purchase of equipment for aseptic processing training, which is vital in preventing contamination while manufacturing sterile products. The funding included a \$240,000 Economic Adjustment Assistance grant from the U.S. Economic Development Administration and \$60,000 in matching funding from the Durham County Board of Commissioners.

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Biomanufacturing Training and Education Center

BTEC successfully delivers the first of eight new AIM-Bio professional development courses

From Aug. 3-6, BTEC presented the initial offering of Biopharmaceutical Lyophilization and Spray Drying. It is the first of eight new professional development courses that are being offered in 2021 as part of NC State's five-year Accelerated Innovation in Manufacturing Biologics program, which is funded by the Novo Nordisk Foundation.

[MORE >>](#)

Member news briefs

To be included in member news, send information about your organization to [David Etchison](#).

9 Meters Biopharma, Inc. is collaborating with the European Biomedical Research Institute of Salerno, Italy to study larazotide for the treatment of multisystem inflammatory syndrome in children. [More >>](#)

Alcami announced that its Board of Directors appointed Timothy Compton as chief business officer. Compton will be responsible for driving the continued growth of Alcam's extensive

officer. Compton will be responsible for driving the continued growth of Alcamis's extensive service offerings. [More >>](#)

BioAgilytix Labs, LLC signed definitive agreements to purchase [360biolabs](#), the most comprehensive contract research organization in Australia, and [MicroConstants](#), a provider of method development, validation and sample analysis for small and large molecule therapeutics and biomarkers.

Bioventus Inc. and Misonix, Inc., a provider of minimally invasive therapeutic ultrasonic technologies and regenerative medicine that enhance clinical outcomes, entered into a definitive agreement by which Bioventus will acquire Misonix in a cash-and-stock transaction. [More >>](#)

Duke Energy has awarded \$615,000 in grants to 19 workforce development and education programs in North Carolina to help job seekers and students prepare for employment, particularly in the energy sector. [More >>](#)

Eva Garland Consulting, LLC has been named as one of Inc.'s Best Workplaces for 2021. EGC joins an elite group of 11 North Carolina companies and 429 companies throughout the United States who are featured in Inc.'s 2021 Best Workplaces list. [More >>](#)

Eva Garland Consulting, LLC, was included as one of the fastest growing privately-owned companies in the United States on the Inc. 5000 list for the fourth consecutive year. [More >>](#)

G1 Therapeutics, Inc. announced that the Centers for Medicare & Medicaid Services has granted a new technology add-on payment for COSELA (trilaciclib) when administered to Medicare beneficiaries in the hospital inpatient setting. [More >>](#)

Heat Biologics, Inc. added Mark Pryor, former U.S. senator from Arkansas, to the company's Biothreat Advisory Board. [More >>](#)

Heat Biologics, Inc. launched a wholly owned subsidiary, Skunkworx Bio, Inc., focused on the development of a drug discovery paradigm to enable rapid drug development. [More >>](#)

Humacyte's business combination with Alpha Healthcare Acquisition Corp., a special purpose acquisition company, was approved by AHAC stockholders. [More >>](#)

Istari Oncology, Inc. is proceeding with the expansion of its LUMINOS-103 trial, with a new sub-study evaluating PVSRIPO in adult patients with head and neck squamous cell carcinoma. [More >>](#)

Kymanox Corporation acquired Neuma LLC, an engineering services provider specializing in product development of drug delivery devices and combination products. [More >>](#)

Kymanox Corporation received a growth recapitalization investment from WestView Capital Partners, a Boston-based private equity firm focused on middle market growth companies. [More >>](#)

Sanesco Health offers a CLIA/COLA certified high-complexity clinical laboratory running COVID-19 testing for a wide array of stakeholders including businesses and the general public. [More >>](#)

Seqirus plans to accelerate the development of its next generation of messenger RNA vaccine technology, self-amplifying messenger RNA, with the creation of a dedicated sa-mRNA program and senior leadership appointment. [More >>](#)

Thermo Fisher Scientific's Greenville, N.C., plant is a recipient of a 2021 IndustryWeek Best Plants Award, which recognizes North American manufacturing facilities for excellence across a range of factors, including productivity, customer care and employee engagement. [More >>](#)

Upcoming Events

Register for NCBIO 27th Annual Meeting Oct. 5

Join us for NCBIO's Annual Meeting on Tuesday, Oct. 5. This year's Annual Meeting is a hybrid event that can be attended virtually or in person and is scheduled from 8:15 a.m. to 3:30 p.m.

Our keynote speaker is **Jude Samulski**, Ph.D., president, chief scientific officer and co-founder of AskBio.

Tales from the trenches

North Carolina features a critical mass of life science companies. Join us to hear from four homegrown companies from various sectors as they share their stories on navigating the stages of success.

- **Juliana Blum**, Ph.D., co-founder and executive vice president, corporate development, Humacyte
- **Gil Golden**, M.D., Ph.D., executive vice president and chief medical officer, United Therapeutics
- **Ken Reali**, chief executive officer, Bioventus
- **Eric Ward**, Ph.D., co-chief executive officer, AgBiome

The P-Factor working together

Learn how companies, patient groups and other stakeholders are working together to keep the focus on the patient. Our panelists will have a direct conversation around the sequence of events and patient involvement, and lay out the challenge of access and payment. They will highlight the patient role and experience, and how they are looking to treat disease more holistically.

- **David Cameron**, M.P.H., senior director and global head, novel trial design, IQVIA
- **Tom Croce**, vice president, advocacy, bluebird bio
- **Jenny Klein**, Mucopolidosis type III patient
- **Justina Williams**, M.S.W., Sickle Cell patient, patient engagement coordinator, Piedmont Health Services and Sickle Cell Agency

Issues in play at the federal level

Panelists will discuss various topics including MDUFA and PDUFA reauthorization, drug pricing, decentralized trials and more.

- **Manthan Bhatt**, director, state government and regional affairs, AdvaMed
- **Christine Harhaj**, director, advocacy and strategic alliances, PhRMA
- **Mike Mattoon**, vice president, federal government affairs, BIO
- **Sophia McLeod**, director, government relations, Association of Clinical Research Organizations

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Government Relations Scientific Perspectives

Accelerating Health Care Innovation in North Carolina: Charting the Course Sept. 23-24

NCBiotech and FastTraCS at UNC-Chapel Hill are collaborating with health systems across North Carolina to provide a foundation for clinician innovation.

The two-day virtual event will put an emphasis on action and connect attendees with the people, insights, and strategies needed to systematically tackle the clinical innovation process from ideation through execution.

This event is perfect for health care providers including physicians, nurses, nurse practitioners, physician assistants, allied health professionals (e.g., physical therapy, respiratory therapy), EMTs and paramedics.

We highly encourage anyone interested in the event to register. All registrants will be given access to session recordings after the event, even if you are unable to join on Sept. 23 or 24.

REGISTER NOW



Register today for the leading and most comprehensive global event in the medical device and diagnostics industry on Sept. 27-30 and be part of the community that's defining the path to better health care.

The MedTech Conference will be held virtually with optional in-person opportunities in Washington and Minneapolis. The hybrid structure combines the benefits of in-person and virtual events, with manageable face-to-face gatherings that tap into the unique opportunities presented by two host cities, and a digital component that facilitates global participation. No matter how you participate, you are guaranteed to experience the same quality programming and networking that you've come to expect from the MedTech Conference.

After being apart for more than a year, we're all eager to get back to business. However, it is important that we do so safely and responsibly. As such, the MedTech Conference is implementing enhanced safety measures designed to protect its conference attendees and staff.

Rest assured, the show will go on! For up-to-date safety information, [visit the MedTech website](#).

NCBIO members can contact [Amber Niebauer](#) for a discount code for 10% offer registration for the Medtech Conference.

REGISTER NOW

NCBIO calendar

- [BTEC Introduction to Chemical Modification of Protein Therapeutics \(9/7/2021 to 9/10/2021\)](#)
- [Focus On Biomanufacturing: Panel Discussion and Networking hosted by WIB-RTP \(9/8/2021\)](#)
- [Larger than Life Science: Putting Your Best Foot Forward - Connecting with Pharma Partners and VCs hosted by LaunchBio \(9/9/2021\)](#)
- [Clinical Supervision Workshop Series hosted by UNC-Wilmington \(9/11/2021\)](#)
- [Ag Innovation Showcase hosted by NCBiotech and Larta Institute \(9/13/2021 to 9/14/2021\)](#)

- NIH-BIO Summer Series: Improving Diversity in Biotech by Leveraging SBIR/STTR Opportunities hosted by NIA, NIAAA and NCATS (9/14/2021)
- New Company Welcome Event hosted by NCBiotech BPD (9/16/2021)
- NC SBIR Funding Celebration Summit hosted by First Flight Venture Center (9/22/2021)
- Summit for Women in Tech – Ignite Change hosted by NC TECH Association (9/23/2021)
- Accelerating Health Care Innovation in NC hosted by NCBiotech and FastTraCS (9/23/2021)
- Let's Talk About: Inclusive Foundation - Diversity Recruiting (9/23/2021)
- Summit for Women in Tech – Ignite Change hosted by NC TECH Association (9/24/2021)
- Accelerating Health Care Innovation in NC hosted by NCBiotech and FastTraCS (9/24/2021)
- The MedTech Conference powered by AdvaMed (9/27/2021 to 9/30/2021)
- BIO Oncology Virtual Partnering (9/28/2021 to 10/1/2021)
- NCBIO 27th Annual Meeting (10/5/2021)
- CureDuchenne 2021 FUTURES National Conference (10/8/2021 to 10/10/2021)
- Clinical Supervision Workshop Series hosted by UNC-Wilmington (10/9/2021)
- BTEC Upstream Production Process Development for Biopharmaceuticals (10/11/2021 to 10/22/2021)

BIO Business Solutions Highlights



Four steps to saving with your NCBIO membership

GET STARTED



Heritage Global Partners acquires American Laboratory Trading

Heritage Global Partners, a worldwide leader in asset advisory and auction services, and a subsidiary of Heritage Global Inc. acquired substantially all of the assets of American Laboratory Trading through an affiliate. ALT is one of the largest suppliers of premium refurbished lab equipment in North America and a key provider of surplus asset services for the life sciences.



- [PerkinElmer Optima 8000 ICP-OES With S10 Autosampler & PolyScience Chiller](#)
- [Baker Company EdgeGARD HF Clean Bench](#)
- [BioTek 405 TS Microplate Washer CAT No. 405TSHTV](#)
- [Panasonic MDF-U700VXC Ultra-Low Temperature Laboratory Freezer](#)
- [Agilent Technologies SureScan G2600D Microarray Scanner](#)
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NCBIO
P.O. Box 14354
Research Triangle Park
North Carolina 27709

detchison@ncbioscience.net
919.281.8960
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