

Advocate. Advance.

# 2025 Year in Review

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NCLifeSci



# NCLifeSci

*Advocate. Advance.*

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# Highlights

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### State Advocacy

Fiscal year ends with no state budget, legislature's work continues.

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### Federal Advocacy

Rapid-fire changes create challenges for NC life sciences industry.

## 41

### 2024-25 Samuel M. Taylor Scholarships

NCLifeSci awarded four scholarships totaling approximately \$12,000.

## 42

### AgBio 2025

North Carolina and Virginia come together to explore agriculture, and biotech.

# GROWTH + INNOVATION

## LETTER FROM THE PRESIDENT



As we celebrate another remarkable year of growth and innovation in North Carolina's life sciences industry, I am excited to share with you our 2025 Year in Review. This publication chronicles a pivotal year that saw our industry continue its upward trajectory while navigating significant challenges and embracing new opportunities.

The year 2025 brought both celebration and remembrance. We marked NCLifeSci's 30th anniversary at our Annual Meeting in September 2024, reflecting on three decades of remarkable growth that has positioned North Carolina as the fourth largest life sciences hub in the United States. Our industry now comprises more than 840 companies generating over \$20 billion in investment and creating more than 20,000 jobs between 2020 and 2024 alone.

We were deeply saddened by the passing of Dr. Charles Hamner on July 4, 2025. Dr. Hamner was so instrumental in building North Carolina's life sciences industry that he is often referred to as the Father of North Carolina's Life Sciences. His vision and leadership as president of the NC Biotechnology Center from 1988 to 2002 laid the foundation for everything we see today. Dr. Hamner predicted that life sciences would follow an S-shaped growth curve, starting slowly with university-based research before accelerating rapidly — a prediction that has proven remarkably prescient. His legacy lives on in the thriving life sciences ecosystem he left behind.

At the state level, we experienced significant leadership changes in the NC General Assembly's Life Sciences Caucus. I want to extend our heartfelt gratitude to Sen. Paul Newton and Sen. Mike Woodard for their outstanding service to both the General Assembly and our industry. Senator Woodard's thoughtful advocacy and Senator Newton's steady guidance as Senate majority leader were instrumental in advancing key initiatives like securing recurring funding for the One NC Small Business Program and supporting infrastructure improvements critical to our sector's growth. Senator Newton's departure to serve as general counsel at UNC-Chapel Hill represents our industry's loss but higher education's gain.

We warmly welcome their successors: Sen. Jay Chaudhuri (D-15 Wake), who joined as Democratic co-chair early in the year, and Sen. Benton Sawrey (R-10 Johnston), who stepped in to replace Senator Newton. Both senators bring fresh perspectives and continued commitment to bipartisan support for life sciences. They join long-serving House chairs Rep. Donna White (R-26 Johnston) and Rep. Robert Reives (D-54 Chatham).

The caucus maintained an active schedule throughout 2025, addressing everything from workforce development and emerging biotechnology trends to drug development processes and the bioeconomy. These regular legislative briefings continue to provide the foundation for informed policy decisions that shape our industry's future.

The Trump Administration's return brought a complex mix of opportunities and challenges. While we welcomed initiatives like the restoration of domestic R&D expensing provisions in H.R. 1 and fixes to orphan drug exemptions from Medicare price negotiations, we also navigated regulatory uncertainties and operational complexities. The 20% reduction in FDA staffing on April 1 created particular concerns about maintaining efficient drug approval processes, while new restrictions on international collaboration affected companies with global research partnerships.

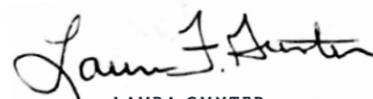
Despite these challenges, North Carolina's life sciences community demonstrated remarkable resilience and innovation. Our state was selected as the first stop for the National Security Commission on Emerging Biotechnology's nationwide tour, highlighting our role in America's biotechnology ecosystem. The commission's visit underscored North Carolina's unique position to capitalize on emerging opportunities in industrial and agricultural biotechnology.

Our advocacy efforts remained robust at both state and federal levels. We maintained strong relationships with our Congressional delegation, participating in multiple fly-ins and working closely with all members of the North Carolina delegation on crucial legislation. The partnership between public and private sectors continues to be a hallmark of North Carolina's approach to life sciences development.

Looking ahead, NCLifeSci remains committed to supporting our industry through continued advocacy, workforce development, networking opportunities and member services. We will pay particular attention to infrastructure needs and work to address challenges in power, transportation, wastewater and communications infrastructure that are essential for continued growth.

The strength of North Carolina's life sciences industry lies not just in our companies and research institutions, but in the collaborative spirit that brings us together. As we face the opportunities and challenges ahead, we do so with the confidence that comes from three decades of sustained growth and the knowledge that our best days lie ahead.

Thank you for your continued support and engagement. Together, we're not just building an industry — we're improving lives and creating a healthier future for North Carolina, the nation and the world.

  
LAURA GUNTER  
NCLifeSci PRESIDENT



# AGENDA

Wednesday, September 17 // 8:30 a.m. – 2:30 p.m.

## REGISTRATION AND NETWORKING



8:30 - 9:00 a.m.

## MORNING SESSION



9:00 a.m.

### Welcome Remarks

- Laura Gunter, president, NCLifeSci
- Susan Lenderts, global head of life sciences, SAS

9:20 a.m.

### The Discovery of Semaglutide and its Impact on Health

Introduction by *Chandler Conley*, senior director of technical operations, East Coast, PSC Biotech

- Jason Brett, M.D., principal medical head, clinical development, medical and regulatory affairs, Novo Nordisk

9:50 a.m.

### Platinum Sponsor Remarks

- Carrie Kleinle, director, product marketing and partner engagement, ALT
- Tina Nuthulaganti, director of strategic alliances, Avantor

9:55 a.m.

### Business Session and Recognition of Scholarship Recipients

10:15 a.m.

### Networking Break

Introduction by *Megan Lambert*, partner, Smith Anderson

10:40 a.m.

### Federal Update

Introduction by *Mark Kuenzi*, interim site head, RTP, FUJIFILM Biotechnologies

- Rebecca Haynie, Ph.D., director, science policy and regulatory affairs, CroLife America
- Joe Lanier, principal, Milestone Strategies (moderator)
- Sophia McLeod, advocacy adviser, ACRO
- Kristin Murphy, vice president, federal government relations, BIO
- Bobby Patrick, senior vice president, government affairs, AdvaMed
- Zach Sentementes, senior director, federal advocacy, PhRMA

11:35 a.m.

### Platinum Sponsor Remarks

- Stephen Perry, chief executive officer and founder, Kymanox
- Melissa Bishop-Murphy, senior director, national government relations, Pfizer

11:40 a.m.

### Networking Lunch

## AFTERNOON SESSION



12:40 p.m.

### Balance of Food and Pharma in Health Care

Introduction by *Brian Stoker*, senior manager, corporate affairs, Grifols

- Tom Croce, vice president, global patient advocacy and engagement, Jazz Pharmaceuticals
- Frannie Nilsen, Ph.D. environmental toxicologist, North Carolina Department of Environmental Quality
- Ron Phillips, senior vice president, policy, Animal Health Institute
- Marlene Sanders-Seye, director, state government affairs and policy, Merck (moderator)
- Northe Saunders, president, American Families for Vaccines

1:30 p.m.

### Technology Landscape in North Carolina

Introduction by *Maeve Gardner*, director, state government affairs, Jazz Pharmaceuticals

- Juliana Blum, Ph.D., chief executive officer, BioAesthetics
- Laura DiMichele, Ph.D., director, clinical development sciences, BioCryst
- Marcel Frenkel, Ph.D., co-founder and chief executive officer, Ten63 Therapeutics
- Tengfang Huang, Ph.D., vice president and head of research, The Traits Company
- Michael Hunter, senior vice president of manufacturing operations, Liquidia
- Susan Lenderts, global head of life sciences, SAS (moderator)

2:20 p.m.

### Closing Remarks

Laura Gunter, president, NCLifeSci

Gold Sponsor Platinum Sponsor



# SPEAKER BIOS

**JULIANA BLUM, PH.D.**



**CHIEF EXECUTIVE OFFICER**  
// BIOAESTHETICS

Blum is a co-founder of Humacyte where she spent 20 years leading the development, management and execution of a commercial scale bioengineering platform, eventually transitioning the start up to a public company in 2021. Currently, she is the CEO of BioAesthetics, an early stage company developing novel tissue grafts that are transformed with various drug eluting polymers to treat and repair multiple types of wounds, surgical injuries and soft tissue reconstructions. Blum is also an executive in residence at the North Carolina Biotechnology Center where she provides entrepreneurial mentoring and coaching for the early stage companies in the center's loan portfolio. She sits on the board of directors of inSoma Bio. Blum received her B.S. from Carthage College and Ph.D. in molecular biology and cardiovascular gene therapy from Loyola University.

**JASON BRETT, M.D.**



**KEYNOTE**

**PRINCIPAL MEDICAL HEAD, CLINICAL DEVELOPMENT, MEDICAL AND REGULATORY AFFAIRS**  
// NOVO NORDISK

Brett provides strategic medical leadership and functions as the medical spokesperson for the U.S. organization. Prior to his current role, he was the executive director leading a team of medical directors for Novo Nordisk's in-line and pipeline products for obesity. During his time at Novo Nordisk, he has served as a leader of medical director teams working in the cardiometabolic disease space, including in obesity, diabetes, cardiovascular diseases, metabolic dysfunction-associated steatohepatitis and neurodegenerative diseases. Prior to joining Novo Nordisk in 2003, Brett was in full-time clinical practice at Mount Sinai Medical Associates. In addition, he was a clinical assistant professor in the department of Medicine at Mount Sinai School of Medicine and was also an attending physician at the Mount Sinai Hospital.

**TOM CROCE**



**VICE PRESIDENT, GLOBAL PATIENT ADVOCACY AND ENGAGEMENT**  
// JAZZ PHARMACEUTICALS

Croce and his team are responsible for the identification and integration of patient perspectives across the entire development and commercial continuum, while ensuring meaningful representation to patient, caregiver and advocate partners around the world. He is also responsible for building and implementing the company's social impact strategy. Prior to joining Jazz, Croce was vice president for global patient advocacy at bluebird bio and delivered actionable patient and caregiver insights across the organization that contributed to the development and approval of two gene therapies. He also saw the company's efforts to educate and activate the advocacy community on the transformative nature of regenerative medicine. Earlier, Croce held senior roles at Amgen, Shire Pharmaceuticals, Boehringer Ingelheim, Pfizer and Wyeth. He is a graduate of the Philadelphia College of Pharmacy, University of Sciences.

**LAURA DIMICHELE, PH.D.**



**DIRECTOR, CLINICAL DEVELOPMENT SCIENCES**  
// BIOCRYST

DiMichele brings almost two decades of clinical and regulatory development experience to her role BioCryst. She and her team lead the design, execution and oversight of global clinical programs across all phases. Prior to joining BioCryst, DiMichele held various leadership roles at a contract research organization, advancing programs from preclinical through registration across a range of therapeutic areas. She brings deep expertise across a broad range of therapeutic areas, including infectious disease, oncology, nephrology and ophthalmology. DiMichele's product experience spans small molecules, immunotherapies and biologics, and she possesses a thorough command of regulations and protocols governing drug development from early-phase coordination through marketing approval. DiMichele holds a Ph.D. in biomedical sciences and is certified in both regulatory affairs and clinical research.

**MARCEL FRENKEL, PH.D.**



**CO-FOUNDER AND CHIEF EXECUTIVE OFFICER**  
// TEN63 THERAPEUTICS

Frenkel is a biophysicist with over ten years of expertise in computational drug design. He founded Ten63 in 2018 after losing his mother to pancreatic cancer, with the goal of transforming cancer treatment. Ten63 is a venture-backed company at the forefront of AI-driven generative chemistry and quantum simulations and leverages its unique platform to pursue some of the most challenging targets in oncology. Frenkel earned his Ph.D. in biochemistry from Duke University, where he developed novel computational approaches to target undruggable proteins such as KRas and to combat drug resistance in cancer. His research also contributed to the design of a novel HIV vaccine currently in clinical trials, the discovery of new drug-resistance mechanisms and the engineering of potent, broadly neutralizing antibodies in collaboration with the NIH.

**LAURA GUNTER**



**PRESIDENT**  
// NCLIFESCI

Gunter directs the work of the life sciences advocacy association in conjunction with its executive committee and board of directors. NCLifeSci promotes policy initiatives that encourage the growth and success of life science companies doing business in the state by advocating for the industry before the NC General Assembly and the NC Congressional delegation. She works closely with state and federal partners on the advocacy and policy front. Before becoming president, Gunter served as NCLifeSci's membership development and government affairs director. Previously, she served as business development director for NCBiotech and as a technical sales representative for Fisher Scientific. She received a bachelor's degree in chemistry from the University of Virginia and earned a Master's in Business Administration from the University of North Carolina at Chapel Hill.

**REBECCA HAYNIE, PH.D.**



**DIRECTOR, SCIENCE POLICY AND REGULATORY AFFAIRS**  
// CROPLIFE AMERICA

Haynie joined Crop Life America's science and regulatory team in July 2023, bringing years of experience in pesticide regulation and knowledge of current pesticide issues affecting pesticide retailers and end-users. Previously, she acted as senior federal regulatory manager at Syngenta Crop Protection focused on EPA's implementation of ESA across all formulations. Prior to joining Syngenta in 2020, Haynie gained experience in pesticide regulations on the compliance team at Walmart, and she began her career with the SePRO Corporation in Indianapolis. Haynie earned both her B.S. in wildlife biology and Ph.D. in environmental toxicology from Clemson University and completed a postdoc at the University of Georgia.

**TENGFANG HUANG, PH.D.**



**VICE PRESIDENT AND HEAD OF RESEARCH**  
// THE TRAITS COMPANY

Huang joined The Traits Company in 2023, when it was founded as Traitology. He has held a range of positions in agricultural biotechnology at institutions and companies including the Boyce Thompson Institute, KeyGene, Precision BioSciences and Elo Life Systems. Huang's expertise spans plant genomics, gene discovery, genome editing and metabolic engineering. He has a Ph.D. in plant molecular biology and biological sciences from Cornell University and B.S. in biological sciences from Fudan University.



# SPEAKER BIOS

**MICHAEL HUNTER**



**SENIOR VICE PRESIDENT OF MANUFACTURING OPERATIONS // LIQUIDIA**

Hunter joined Liquidia in 2007 and brings more than 20 years of experience across all phases of drug and drug-device combination product development. He manages all aspects of the company's manufacturing operations, which, in part, led to the filing of their first NDA. Prior to joining Liquidia, Hunter worked as a quality engineer and manufacturing engineer with Boston Scientific in the company's Stent Manufacturing Division where he was responsible for the transfer and validation of new products from process development to manufacturing. Here, he also served on the site FDA compliance council for the company's Interventional Cardiology Division. Prior to his role at Boston Scientific, he worked for seven years in process development and scale-up in the telecommunications industry with Sony Ericsson and the semiconductor industry with Cree, Inc. Hunter holds a M.S. in materials engineering from NCSU and a B.S. in applied science-biomaterials from UNC Chapel Hill.

**JOE LANIER**



**MODERATOR**

**PRINCIPAL // MILESTONE STRATEGIES**

Lanier represents clients in state and federal government relations issues with a particular focus on matters coming before the North Carolina state government. He has more than 25 years of federal and state government affairs experience in both the public and private sectors. Prior to founding Milestone Strategies, Lanier served as chief legal and legislative counsel for two U.S. senators and worked in the Washington government relations practices of two leading national law firms. His practice focus added state work in 2008 when he joined a local Raleigh law firm and began to also represent clients before the NC General Assembly and state agencies. Lanier holds undergraduate and law degrees from the University of North Carolina at Chapel Hill.

**SUSAN LENDERTS**



**MODERATOR**

**GLOBAL HEAD OF LIFE SCIENCES // SAS**

Lenderts provides executive leadership and partners with customers to enable meaningful impact in the life sciences industry through analytics, innovation and digital transformation. Lenderts' mission is to bring the full power of SAS to the life sciences industry to unlock business value and drive business strategy and decision making, ultimately helping organizations to develop, market and distribute safe and effective therapeutics to the patients who need them. She has spent nearly two decades in the life sciences industry with roles spanning clinical research through to commercial and strategic operations leadership at Quintiles (now IQVIA), Innoviva, ViiV Healthcare (GSK) and her own advisory firm. She holds a bachelor's degree in economics and political science from the University of Notre Dame and a Masters of Business Administration from the University of North Carolina at Chapel Hill Kenan-Flagler Business School.

**SOPHIA MCLEOD**



**ADVOCACY ADVISER // ACRO**

McLeod leads ACRO's legislative strategy and regularly meets with Congressional offices on Capitol Hill to advance ACRO's profile and policy priorities. Prior to joining ACRO, she was on the government affairs team at the Medical Group Management Association, a membership association for medical practice administrators. Her first experience in legislative affairs was at the U.S. Department of Veterans Affairs' Office of Congressional and Legislative Affairs as a graduate fellow. McLeod earned her B.A. in political science and history from Dalhousie University, and she received her M.A. in American government from Georgetown University.

**KRISTIN MURPHY**



**VICE PRESIDENT, FEDERAL GOVERNMENT RELATIONS // BIO**

Murphy brings nearly 20 years of experience in legislative activities to BIO. She joined BIO in 2021 as senior director of federal government affairs and became vice president this year. Previously, she served as director and senior director of federal affairs at the Association for Accessible Medicines for four years. Prior to joining AAM, Murphy was the assistant director for legislative affairs for four years at the Ambulatory Surgery Center Association. She earned her B.A. in political science from the University of South Dakota and her MBA with a concentration in health care management from Johns Hopkins University.

**FRANNIE NILSEN, PH.D**



**ENVIRONMENTAL TOXICOLOGIST // NORTH CAROLINA DEPARTMENT OF ENVIRONMENTAL QUALITY**

Nilsen is involved with a variety of projects related to environmental contamination and exposure including military, industrial and drinking water facilities. She is the technical liaison to the NC Secretaries' Science Advisory Board and is responsible for coordinating the contaminant review activities to support reference dose development for PFAS and other nonregulated chemicals that are specific to industrial facilities. Nilsen was appointed by the governor of NC to the NC Advisory Committee on Cancer Coordination and Control to serve as an expert on PFAS toxicity. She has worked at several federal agencies throughout her career in toxicology. Nilsen holds a B.S., M.S. and certificate in environmental policy from Hawaii Pacific University. She earned her Ph.D. in marine biomedicine and environmental toxicology from the Medical University of South Carolina.

**BOBBY PATRICK**



**SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS // ADVAMED**

Patrick oversees AdvaMed's state affairs work and partnerships with external stakeholders, including patient advocacy organizations and physician groups. Previously, Patrick served as the vice president of strategic growth and policy at the Medical Alley Association where he led the State and federal advocacy efforts. He also oversaw the membership work at the association, where they experienced growth in membership revenue, engagement and retention under his leadership. Prior to that, Patrick served as a staff member in the Minnesota House of Representatives. He holds a J.D. from William Mitchell College of Law and an undergraduate degree from Syracuse University.

**RON PHILLIPS**



**SENIOR VICE PRESIDENT, POLICY // ANIMAL HEALTH INSTITUTE**

Phillips is a distinguished public affairs and policy executive with more than 35 years of leadership experience across government, trade associations and strategic communications. In his current role, he serves as the chief policy strategist and spokesperson, leading federal and state legislative strategies, media relations and coalition-building efforts for the nation's foremost association representing animal medicine innovators. Prior to joining AHI, Phillips served as vice president of public affairs at the Fertilizer Institute. Earlier roles include communications manager at the U.S. Grains Council and public and government relations representative at Arter & Hadden. His career began in the U.S. Congress as press secretary and professional staff member for the U.S. Senate Committee on Agriculture, Nutrition and Forestry. He has a B.A. in communications from Cedarville University and a M.A. in journalism from Ohio State University.



# SPEAKER BIOS



## MARLENE SANDERS-SEYE



**MODERATOR**

### DIRECTOR, STATE GOVERNMENT AFFAIRS AND POLICY // MERCK

Sanders-Seye's passion for public policy, patient health access and health education has guided her career. She worked for several health care entities as a lobbyist in Tennessee and a patient advocacy liaison for Eli Lilly and Co. prior to joining Merck in 2007. She is recognized as a leader at Merck, winning several awards, including being named a Richard T. Clark Global Health Fellow in 2017. Sanders-Seye currently serves on the boards of the North Carolina Aids Action Network and the North Carolina Life Sciences Organization. She holds a bachelor's degree in political science from Middle Tennessee State University and a MPA from Tennessee State University.

## NORTHE SAUNDERS



### PRESIDENT // AMERICAN FAMILIES FOR VACCINES

Saunders brings 19 years of political leadership, grassroots organizing and fundraising experience to the organization. He has worked on the local, state and national levels for numerous political campaigns, candidates and advocacy organizations. In 2019, he testified in support of strengthening vaccine laws for students in Maine and joined the volunteer organization Maine Families for Vaccines to support the effort. Saunders led the grassroots citizen lobbying effort that saw the bill's successful passage. When the opposition attempted a referendum to use a "People's Veto" and overturn the legislation, he served as volunteer political director for Maine Families. Maine Families celebrated a resounding 72.4 percent victory at the polls, and the legislation was upheld. Saunders loves bringing his passion for grassroots organizing, fundraising and pro-science advocacy to other states nationwide.

## ZACH SENTEMENTES



### SENIOR DIRECTOR, FEDERAL ADVOCACY // PHRMA

Sentementes is a seasoned public affairs and government relations professional who has represented a variety of major trade associations, civil rights organizations and Fortune 500 companies at the federal level on key health care, intellectual property, trade and social justice issues. He joined PhRMA in August 2022 as director of federal advocacy. Prior to PhRMA, his most recent role was with Advanced Advocacy as their vice president. Sentementes also held positions at the Washington International Trade Association, Concordia University and Montreal Institute for Genocide and Human Rights Studies. He earned a B.A. in political science and government from Concordia University with a certificate in Mandarin language and culture from Communication University of China.

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**PETER WIRTH**  
VP, Business Development //  
RTI International

## NOT PICTURED:

**TONI LOCKETT**  
Life Science Assurance Partner  
// PricewaterhouseCooper

# SUSTAINING + SUPPORTING MEMBERS



## SUSTAINING MEMBERS



## SUPPORTING MEMBERS



# 2025 Year in Review

# 2024 ANNUAL MEETING



The NC Life Sciences Organization marked a significant milestone at its 2024 Annual Meeting, celebrating its 30th anniversary with events that highlighted both the organization's remarkable journey and the bright future ahead for North Carolina's life sciences industry.



▲ BIO's Laura Srebnik moderated a panel comprising Karin Hoelzer of the National Organization for Rare Disorders (on screen), Melissa Horn of the Arthritis Foundation, Merck's Brian Smith and Rhyoye Taylor of Edwards Lifesciences

## A day of learning and leadership

On Sept. 18, 2024, more than 220 member representatives gathered at the NC Biotechnology Center for NCLifeSci's Annual Meeting followed by an evening dinner celebration. The day began with expert panels exploring cutting-edge topics, including artificial intelligence, patient advocacy and the future of patient experience, all anchored by a keynote presentation from Eli Lilly's Edgardo Hernandez.

Hernandez, executive vice president and president of manufacturing operations at Eli Lilly and Company, delivered a compelling talk titled, "The Future of Pharma Manufacturing is Now: The Role of Strategic Partnerships." He outlined Lilly's impressive \$20 billion investment in new facilities since 2020, including the groundbreaking \$1.7 billion Research Triangle Park site and the massive \$2 billion, 400-acre Concord facility. These highly automated facilities represent Lilly's vision of completely automated manufacturing in the future.

The success of Lilly's North Carolina expansion exemplifies the power of strategic partnerships. Hernandez credited strong collaborations with organizations like NCLifeSci, NCBiotech, BioWork, Wake Tech and Durham Tech as key enablers of the company's rapid growth in the state.

## Governance and recognition



NCLifeSci President Laura Gunter recognized the 2024 recipients of the Samuel M. Taylor Memorial Life Sciences Scholarship. This program, established in honor of NCLifeSci's founding president, has raised over \$250,000 and awarded 18 scholarships to 14 students since its inception. The 2024 recipients included students from Johnston County Community College, Durham Technical College, Central Carolina Community College and Guilford Technical Community College.

The Annual Meeting included important organizational business, with members approving five new board members: Tom Alapaattikoski (chief executive officer, Brinter), Harold Alterson (chief quality officer, Humacyte), Matt Goodrich (corporate real estate adviser, Davis Moore), Nikki Heron (chief financial officer, Tavros Therapeutics) and Paul Lewus (vice president, NC site operations, Amgen).

## Expert insights on industry evolution



▲ A panel of Womble Bond's Jay Silver (moderator), Stanley Ahalt of the UNC School of Data Science and Society, Marinela Profi of SAS and PPD's John Van Hoy discussed the evolution and implications of generative AI.

Three panel discussions provided deep insights into the industry's direction. The first panel, "Working with Patient Advocates," emphasized the critical importance of long-term partnerships, transparency and clear communication between biopharmaceutical companies and patient advocacy groups. Panelists discussed specific policy challenges, including copay accumulator bans, biomarker testing coverage and the Carroll

Act's impact on heart-valve disease research funding.

The second panel, "Best Practices and Lessons Learned from AI," explored the transformative potential of generative AI in life sciences. Experts highlighted rapid advancements while emphasizing the continued need for human oversight, data governance and model transparency. Success stories included PPD's use of AI for quality checks and SAS's synthetic data generation for clinical trials.

The final panel, "Future Technology and the Patient Experience," focused on addressing unmet medical needs through innovation. Discussions covered the challenges of rare disease therapy development, the success of gene therapy for retinal diseases and the potential of natural bioactives in drug development.

## Evening celebration and vision for health care reform



▲ NCLifeSci President Laura Gunter honors Neal Fowler, NCLifeSci board chairman from 2020 to 2023

The celebration continued with the NCLifeSci Annual Dinner, where the organization honored Neal Fowler, the organization's immediate past chairman of the board who led from 2020 to 2023. NCLifeSci President Laura Gunter praised Fowler's steady leadership during a challenging period that included the loss of founding president Sam Taylor to pancreatic cancer, the COVID pandemic, the creation of the organization's strategic plan and the rebranding from NCBIO to NCLifeSci.

"We could not have gotten through all of this and all of the issues without him," Gunter said. "His wise counsel and willingness to participate were key to a steady transition."

The evening featured a forward-looking panel discussion on the North Carolina State Transformation Collaborative, a multistakeholder initiative working to shift from fee-for-service to value-based whole-person care for Medicaid and Medicare patients. The collaborative focuses on aligning quality measures, improving data sharing and enhancing health equity through initiatives like the Healthy Opportunities Pilots and the Making Care Primary model.

# BIO BUSINESS SOLUTIONS PROGRAM



▲ Theresa Welch and David Bauer of BBS partner Avantor

## If you're not working with BBS vendors, you're leaving money on the table.

The BIO Business Solutions program is a comprehensive cost-savings initiative available to NCLifeSci members that is operated by the Biotechnology Innovation Organization. This program leverages the collective purchasing power of life sciences companies nationwide to provide significant discounts on essential products and services.

The program is available to all NCLifeSci member companies at no charge as part of their membership.

The program delivers substantial financial benefits to participating companies. Over 4,700 companies currently use BIO Business Solutions and, together, save over \$705 million annually through the program.

The discounted prices and value-added features available are negotiated based on the pooled buying power of thousands of life sciences companies of all sizes across North America, giving you the same purchasing power as the largest life sciences companies. This levels the playing field for smaller companies that would not otherwise have access to volume-based pricing.

The BIO Business Solutions program represents significant value added for NCLifeSci members, offering substantial cost savings across essential business operations while requiring no additional fees beyond your existing membership.

## The BIO Business Solutions program offers discounted pricing on

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▲ Jim Seymour, regional business development manager for BIO Business Solutions



▲ Dylan Commodore with BBS partner SU Group



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**Lynn M. Cilinski,**  
Vice President,  
Controller & Treasurer  
at MacroGenics, Inc.

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# STATE ADVOCACY

## Fiscal year ends with no state budget, legislature's work continues

At the July 1 end of the state's fiscal year, the NC General Assembly was still considering competing budget proposals for the 2025-27 biennium, with significant implications for the state's life sciences sector and related infrastructure.

The Senate passed its version of the state budget in April. The Senate proposal included \$73 million for Propel NC, the community college system's new funding model designed to better align educational programs with industry workforce needs. However, the NC Community College System requested nearly \$100 million total for Propel NC implementation.

Following the Senate's action, the House of Representatives approved its budget bill in May with a decisive 93-20 vote, taking a different approach to workforce training initiatives.

The House proposal allocates \$4.5 million for the NC Community College System to contract with third-party entities for workforce diploma programs targeting adults aged 21 and older. These programs aim to help participants obtain high school diplomas while developing essential employability skills.

The House budget delayed previously planned income tax cuts to fund state worker raises and increased investments in public safety, child care and workforce training programs.

Both budget proposals provide some resources for wastewater management improvements, which are critical for biotechnology manufacturing facilities and research operations throughout the state.

Both budget proposals fund the One NC Small Business Program at current levels. The program supports entrepreneurship and small business development across the state by providing matching funds for federal SBIR/STTR awards.

Appropriations for the NC Biotechnology Center vary between proposals.

Additionally, the NC Community College System has specifically requested \$68.5 million in recurring funds for workforce sectors experiencing high demand. These investments reflect recognition of critical workforce shortages that affect North Carolina's economic competitiveness.

Following passage of their respective budget bills, the House and Senate entered negotiations to reconcile differences between their proposals.

Gov. Josh Stein specifically commented on the House budget proposal. He noted that "the House budget cuts taxes for working families while recognizing that North Carolina is a growing state and reduces personal income tax rates after this year only when the economy is growing." He was more critical of the Senate proposal.

The legislature returned to session at the end of July. A full budget was still pending, but legislators approved a mini-budget, or continuing operations bill. The bill appropriated funding for a variety of time-sensitive programs, including K-12 and community college enrollment, state employee benefits and Medicaid enrollment.

As of Aug. 1, the Senate budget had moved to the House for consideration. Key differences between the chambers' approaches to revenue and spending levels required reconciliation. Both chambers faced pressure to address workforce development needs in high-demand sectors while managing fiscal constraints and competing priorities. The final budget must be approved by both chambers and signed by the governor before taking effect. North Carolina is operating under the continuing budget while legislative leadership negotiates a comprehensive budget.



▲ A great turnout for the March meeting of the Life Sciences Caucus. The meetings are usually held in the Member's Cafeteria of the NC General Assembly once a month while the legislature is in session. Let Laura Gunter know if you would like to attend one of these meetings.

### NCLifeSci state policy report

North Carolina's life sciences industry continues to thrive as a cornerstone of the state's economy, with approximately 840 companies generating over \$20 billion in investment and creating more than 20,000 jobs between 2020 and 2024. The state government, working through various agencies and legislative initiatives, is actively addressing key policy areas that affect both the industry's growth and public health protection. Here's a look at eight critical policy areas affecting North Carolina's life sciences sector.

#### One NC Small Business Program

The One NC Small Business Program matches federal technology grants from the SBIR or STTR programs with state funds and assists companies preparing to submit initial SBIR or STTR grant proposals.

Created in 2005, the program has a history of uneven support and has gone without funding during some years. NCLifeSci made securing recurring funding for the One NC Small Business Program a priority and achieved that goal in 2021 with a \$2 million appropriation that is part of the baseline state budget each year. NCLifeSci continues to advocate for additional funding for the program each year.

#### Propel NC: Workforce development and community colleges

The North Carolina Community College System plays a pivotal role

in developing the life sciences workforce through targeted training programs and strategic partnerships. The 58 community colleges across the state are integral to supporting the industry's workforce needs, with specialized programs delivered through the Life Science Training Initiative known as NCBioNetwork.

The significant development for the Community Colleges this year was the advancement of Propel NC, the system's new funding model first unveiled in January 2024. The State Board of Community Colleges has been granted permission to revise its funding formula and may increase tuition rates to accommodate the new model. Additionally, all curriculum and continuing education courses within the same workforce sector are being consolidated to improve efficiency and coordination.

#### Infrastructure and wastewater regionalization

North Carolina's wastewater management operates through a dual structure with both state and local involvement, but the state level has primary regulatory authority.

The NC Department of Environmental Quality maintains centralized control over wastewater regulation through its Division of Water Resources. All wastewater discharges to surface waters in North Carolina must receive a permit to control water pollution from the state.

However, local governments and utilities are responsible for operating many wastewater treatment facilities and collection

systems. Municipalities, counties and local utility authorities own and operate treatment plants under state-issued permits, while private industries operate their own facilities under individual NPDES permits.

North Carolina's water infrastructure development is a consistent focus for NCLifeSci and other industry advocates who continue to work closely with the NC Department of Environmental Quality.

DEQ's Viable Utilities program focuses on creating long-term, self-sufficient business enterprises that establish organizational excellence in water and wastewater management. This initiative supports regionalization efforts by helping smaller utilities develop sustainable operational models or merge with larger, more viable systems.

### Biomarkers and cancer screening

NCLifeSci supports efforts by the American Cancer Society's Cancer Action Network to expand coverage of and access to biomarker testing. Biomarker testing is a laboratory analysis that looks for specific biological markers like proteins, genetic mutations, tumor markers and circulating tumor cells and DNA to help diagnose, monitor and guide treatment decisions for cancer patients.

Biomarker testing can screen for cancer in people without symptoms, help confirm a cancer diagnosis, determine the specific type or subtype of cancer, predict how aggressive a cancer might be, guide treatment selection by identifying which therapies are most likely to work and monitor treatment response or detect cancer recurrence.

ACS CAN has been working state-by-state to pass legislation requiring insurance coverage for biomarker testing. Currently, 15 states mandate biomarker testing coverage for all state-regulated plans, but North Carolina is not among them.

### Copay maximizers and share the savings programs

NCLifeSci is working closely with the Pharmaceutical Research and Manufacturers of America to support PhRMA initiatives at the state level, which currently include banning maximizer programs and implementing share-the-savings models for patients.

- **Copay maximizer programs** are cost management strategies used by health insurers and pharmacy benefit managers to redirect pharmaceutical manufacturer copay assistance away from patients and toward the insurance plan. Copay maximizers exhaust manufacturer copay assistance as quickly as possible by front-loading the assistance early in the benefit year.

North Carolina and at least 20 other states have banned copay accumulator programs, which prevent assistance from a drug's manufacturer from counting toward a patient's copay, but no state laws have yet directly addressed copay maximizer programs. Accumulators spread manufacturer assistance throughout the year but don't count it toward cost-sharing limits. Maximizers deliberately exhaust the assistance early in the benefit year.

- **The share-the-savings model** is designed to ensure that negotiated rebates and discounts flow directly to patients at the pharmacy counter, rather than being retained by insurers

and pharmacy benefit managers. This requirement has been implemented in a few states, but not in North Carolina.

The model requires state legislation that mandates insurers and PBMs pass through a specified percentage of negotiated savings directly to patients as reduced copays or coinsurance at the point of sale.

Several states have enacted share-the-savings laws with different requirements, but North Carolina has not. Some states require a specific percentage (like 85%) of rebates to be passed through. Others require 100% pass-through to employer plan sponsors. The laws typically apply to specific market segments, such as the individual market or fully insured group plans.

### BioMADE: Federal support for biomanufacturing

The Bioindustrial Manufacturing and Design Ecosystem is a federally funded program established in 2020 to build a sustainable, domestic end-to-end bioindustrial manufacturing ecosystem. BioMADE will enable domestic bioindustrial manufacturing at all scales, develop technologies to enhance U.S. bioindustrial competitiveness, de-risk investment in relevant infrastructure and expand the biomanufacturing workforce to realize the economic promise of industrial biotechnology. The program focuses on bioindustrial manufacturing that uses biology to convert agricultural feedstocks and waste streams to high-value chemicals, materials, textiles, fuels, bioplastics and other products.

For North Carolina's robust life sciences industry, BioMADE presents significant opportunities for growth and innovation. NCLifeSci is advocating for North Carolina's access to federal funding for biomanufacturing projects, collaborative research initiatives and further development of our biotech workforce.

### BTEC 2.0 at NC State University

NCLifeSci supports BTEC 2.0, the next evolution of NC State's Biomanufacturing Training and Education Center. It is described as a vision for the future of biopharmaceutical manufacturing, education, training, process development and research in North Carolina and is centered around the creation of the North Carolina Facility for Advanced Biomanufacturing.

BTEC 2.0 will feature a faculty cluster that will lead university-wide, transdisciplinary research and educational efforts related to the discovery, process development and manufacturing of next-generation biologics including protein therapeutics, gene and cell therapies, nucleic-acid-based products and vaccines.

The initiative addresses significant changes in the biopharmaceutical industry over the past two decades, including unprecedented growth in North Carolina, new therapeutic modalities like gene and cell therapies, advances in processing technologies, and the integration of big data, predictive analytics, and artificial intelligence.

Beyond traditional biopharmaceuticals, BTEC 2.0 recognizes the growing need for biomanufacturing in industrial enzymes and precision fermentation for food and animal health applications.

### PFAS regulation and monitoring

PFAS (per- and polyfluoroalkyl substances) play critical roles in the medical device industry due to their unique chemical properties. The characteristics that make fluoropolymers, a type of PFAS material, valuable in a wide range of applications — chemical inertness and durability — are what make them good for multiple uses in health care, too.

Fluoropolymers provide low-friction and clot-resistant coatings for catheters, stents and needles, which improve patient comfort and safety, including in deep needle operations such as drug injections and biopsies. These substances are used extensively in implanted devices, orthopedic components, surgical devices, contact lenses, surgical gloves, catheters, tubing and blood bags, where their biocompatibility and resistance to chemical degradation are essential for patient safety and device functionality.

Given the critical nature of PFAS in life-saving medical applications, discharge regulations should carefully consider the

unique requirements of the medical device industry. Regulators should recognize that medical devices often require materials that meet stringent biocompatibility standards where no suitable alternatives currently exist, and that abrupt restrictions could compromise patient care and medical innovation.

NCLifeSci advocates for a balanced regulatory approach that must include extended compliance timelines for medical applications, provisions for essential use exemptions where patient safety is at stake, and collaboration with the industry to develop and validate suitable alternatives that maintain the same level of performance and safety required for medical applications.

PFAS regulation represents one of the most active and contentious environmental policy areas in North Carolina. The state has not yet enacted comprehensive PFAS regulations, but environmental groups continue advocating for stronger regulatory action, particularly as EPA federal regulations face delays with finalized rules not expected until 2026.



Thanks to the tireless efforts of the NC Life Sciences Organization, the biotech ecosystem in North Carolina is stronger and the future brighter. We are proud of our partnership with NCLifeSci. Together, we help our members make the impossible, possible.

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# NC LIFE SCIENCES CAUCUS



▲ The NC General Assembly's Life Sciences Caucus allows NCLifeSci, member companies and industry advocates to meet regularly with legislators to educate them about the issues important to the life sciences sector in North Carolina.

## NC Life Sciences Caucus drives innovation and workforce development in 2025

The NC General Assembly's Life Sciences Caucus serves as a vital bridge between industry and state government, ensuring that North Carolina remains at the forefront of biotechnology innovation while addressing the practical challenges of workforce development and infrastructure needs. As the state looks toward the next phase of growth, these regular legislative briefings provide the foundation for informed policy decisions that will shape the future of life sciences in North Carolina.

The Life Sciences Caucus maintained an active schedule during the 2025 long legislative session, bringing together bipartisan legislative leadership to address critical issues facing the state's \$27 billion life sciences industry.

Through a series of focused meetings, the caucus has addressed everything from workforce development to emerging biotechnology trends to educate state legislators about the need to maintain and grow North Carolina's position as a national leader in life sciences innovation.

### New leadership, continuing mission

The year began with a leadership change as Sen. Jay Chaudhuri, a Democrat representing District 15 in Wake County, joined the caucus as co-chair alongside Sen. Paul Newton, Rep. Donna White, and Rep. Robert Reives. Chaudhuri's predecessor as co-chair, Sen. Mike Woodard, was not re-elected in 2024. This bipartisan leadership reflects the cross-party support for the life sciences that has characterized North Carolina's approach to the industry.

In March, the Republican Senate caucus co-chair, Sen. Paul Newton, left the legislature to become the general counsel of the University of North Carolina at Chapel Hill. He was replaced by Sen. Benton Sawrey representing District 10 in Johnston County.

### February: Industry growth and strategic positioning

The February 27 meeting highlighted remarkable industry growth, with North Carolina being one of just three states to see more than 20% job growth in the life sciences sector last

year, surpassing the 100,000 life sciences jobs threshold for the first time. The meeting featured presentations from the NC Biotechnology Center, which reported that every dollar loaned by NCBiotech generates a \$132 return on the investment. Likewise, the One NC Small Business Program reported that every dollar awarded generates a 250% return on the state's investment.

### March: Workforce development takes center stage

The March 20 meeting focused on workforce development, addressing one of the industry's most pressing challenges. The caucus learned about two innovative programs run by the NC Biotechnology Center designed to connect different talent pools to the growing life sciences sector.

The NC Grad2Work program targets high school seniors, providing training and guaranteed job interviews with industry partners like Thermo Fisher and Catalent. The program has expanded to multiple counties, helping over 50 students secure jobs in the past two years.

Equally impressive is the MOVE program, which connects veteran talent to the life sciences industry, offering industry-specific job training, internships and on-the-job experience. The program has placed over 40 veterans. The personal impact of these programs was highlighted by veteran Alex Riccardi, who shared how the program helped him make the transition from military service to a career at CSL Seqirus.

### April: Industry insights and drug development

The April 17 meeting provided legislators with a comprehensive overview of the drug development process, courtesy of NovaQuest Capital Management. The presentation covered clinical trial phases and associated costs and success rates, giving lawmakers crucial context for understanding the complex journey from laboratory discovery to patient treatment. Additionally, Joe Lanier of Milestone Strategies reviewed 20 House and Senate bills introduced in the 2025 session that could affect North Carolina's life sciences industry.

### May: North Carolina's opportunity in the bioeconomy

The caucus learned of the National Security Commission on Emerging Biotechnology report that calls on the nation to "support domestic precommercial facilities that integrate expanding state-of-the-art infrastructure to help innovators mature their technologies." This type of dedicated facility here in North Carolina would attract technologies, innovators and companies to come here and grow here thanks to the enormous resources and ecosystem North Carolina can provide.

Participants described how North Carolina has an opportunity to grow and scale up its biotechnology industry by creating a facility that fills a gap that exists in the state. Pharmaceutical startups can count on our state's numerous contract development and manufacturing organization to assist them in scaling up, but such an ecosystem does not exist for bio-agriculture and bio-industrial applications. Currently, this kind of work is done outside the state or the country.

### June: Emerging technologies and environmental solutions

The final meeting of the 2025 long session on June 25 showcased cutting-edge companies addressing global challenges. Hoofprint Biome presented their innovative feed supplement aimed at reducing methane emissions from cattle, which are responsible for 30% of the world's methane emissions. Their first product, targeting more than 80% methane reduction, is expected to launch in 2027.

BioMérieux demonstrated their WATCHFIRE platform, a cloud-based solution that monitors wastewater for pathogens to provide early warnings of public health threats. This technology represents the growing intersection of life sciences and public health infrastructure.

NCLifeSci President Laura Gunter used the June meeting to highlight findings from the National Security Commission on Emerging Biotechnology report, which outlines strategic recommendations for advancing U.S. biotechnology capabilities. The discussion emphasized North Carolina's unique position to capitalize on emerging opportunities in industrial and agricultural biotechnology.

The caucus learned that North Carolina has an opportunity to fill a critical gap in the biotechnology ecosystem by creating facilities that would help bio-agriculture and bio-industrial applications scale up, similar to how the state's contract development and manufacturing organizations support pharmaceutical startups.

## Caucus Presentations

- **June 2025**  
*Presenters:* bioMérieux and Hoofprint Biome  
Diagnostics and cutting carbon emissions
- **MAY 2025**  
*Presenters:* Biomason and Novonesis  
The bioeconomy and using biology to solve problems
- **APRIL 2025**  
*Presenters:* NovaQuest Capital Management  
Pharmaceutical and vaccine development
- **MARCH 2025**  
*Presenters:* NCBiotech  
Workforce training programs, Grads2Work and MOVE Boots to Biotech
- **FEBRUARY 2025**  
*Presenters:* NCBiotech and NC Office of Science, Technology and Innovation  
TEconomy report and the One NC Small Business Program

# Legislative Reception

NCLifeSci brought together nearly 200 NC policymakers and members of the state's life sciences industry for food, drinks and conversation at the organization's annual Legislative Reception held March 11 at Marbles in Raleigh.



▲ Judy Jenkins with Johnson & Johnson, Laura Gunter of NCLifeSci, Melanie Newton, Life Sciences Caucus Co-chair Sen. Paul Newton and Maeve Gardner of Jazz Pharmaceuticals



▲ Life Sciences Caucus Co-Chairs Rep. Robert Reives, Rep. Donna White and Sen. Jay Chaudhuri with NCLifeSci President Laura Gunter



▲ Life Sciences Co-chairs Senators Chaudhuri and Newton and Representative Reives. Newton stepped down from the Senate to serve as general counsel at UNC-Chapel Hill. He was succeeded by Sen. Benton Sawrey.



▲ Rep. Timothy Reeder, M.D.; NCLifeSci's Laura Gunter; and Travis Manasco of Solas Bioventures



▲ Life Sciences Caucus Co-chair Rep. Donna White with Shayla Jones of Novo Nordisk



▲ Sen. Lisa Grafstein with Attorney General Jeff Jackson



▲ Rep. Amber Baker, Rep. Ray Jeffers and Rep. Mike Colvin



▲ Rep. Dante Pittman and Rep. Ray Jeffers with NCLifeSci lobbyist Joe Lanier of Milestone Strategies



▲ NCLifeSci BMF Program Manager Bill Monteith, Matt Foster with Eli Lilly and Sen. Lisa Grafstein

# NCLIFESCI LEGISLATIVE FORUM



▲ Rep. Robert Reives, Rep. Donna White, Sen. Mike Woodard and Sen. Paul Newton at the Nov. 14 NCLifeSci Legislative Forum

## NC legislators outline priorities for life sciences industry

North Carolina's thriving life sciences industry engaged directly with state legislative leaders at the annual NCLifeSci Legislative Luncheon and Forum held November 14, at the NC Biotechnology Center. All four co-chairs of the NC General Assembly's Life Sciences Caucus attended: Sen. Paul Newton, Sen. Mike Woodard, Rep. Donna White and Rep. Robert Reives.

Senate Majority Leader Paul Newton emphasized North Carolina's strong fiscal position, noting the state has billions in reserves to weather Hurricane Helene recovery costs.

All speakers highlighted infrastructure as critical for life sciences growth. Newton pointed to regulatory reform successes, such as unlocking wastewater capacity through rule adjustments. White, representing rapidly growing western Johnston County, emphasized the ongoing challenge of modernizing outdated roads, water and sewer systems in her district. Woodard stressed the importance of engaging local officials and transportation planning organizations to prioritize industry needs in NCDOT's multibillion-dollar spending.

Legislators emphasized building talent pipelines through community colleges and K-12 engagement. Woodard encouraged

industry leaders to share personal stories about their life-saving work to inspire the next generation. White called for breaking out of "individual cages" to collaborate on workforce development, noting that population growth should eliminate workforce shortages if properly directed into appropriate education.

House Democratic Leader Reives emphasized bipartisan cooperation following the recent election that broke the House supermajority. He encouraged direct engagement between industry leaders and legislators, sharing personal stories to demonstrate real-world impact.

Newton strongly defended intellectual property rights, emphasizing that companies earned their patents through investment and research, and expressing clear state-level support for pharmaceutical innovation.

The forum demonstrated the strong partnership between North Carolina's life sciences industry and state legislators, with shared commitment to supporting continued sector growth through infrastructure investment, workforce development and regulatory reform.



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Breakthroughs that change patients' lives 

# FEDERAL ADVOCACY



## Rapid-fire changes create challenges for NC life sciences industry

The Trump administration has introduced significant regulatory and operational challenges for life sciences companies throughout 2025. One of the most immediate impacts was the substantial reduction in force at the FDA, with a 20% staff reduction on April 1, which created widespread concern across the pharmaceutical industry. This downsizing has raised questions about the agency's capacity to maintain efficient drug approval processes and regulatory oversight.

The Trump administration's sweeping cuts to National Institutes of Health funding have delivered a significant blow to North Carolina's research corridor, forcing major universities to implement layoffs and freeze construction projects while threatening thousands of jobs across the state.

The cuts, orchestrated through the administration's Department of Government Efficiency, reduced NIH contract spending by roughly 35% across the agency's 27 institutes and centers, resulting in a roughly 28% contraction in overall funding that has rippled through North Carolina's academic and research institutions. The state faces a total of \$668 million in NIH funding cuts, according to one analysis.

Regulatory uncertainty has become a major challenge as the Supreme Court's landmark *Loper Bright* decision fundamentally altered how federal agencies can interpret and implement legislation. This has forced companies to navigate an evolving regulatory landscape while adapting to new restrictions on international collaboration, creating obstacles for companies that rely on global research partnerships and supply chains.

The administration has also implemented policies that create operational complexities for companies. New executive orders direct the FDA to increase fees for and inspections of foreign manufacturing plants while simultaneously pushing for faster approval of domestic facilities. This dual approach creates cost pressures and supply chain challenges for companies with international manufacturing operations. Additionally, pressures on domestic manufacturing and ESG compliance could complicate operations, forcing companies to restructure their manufacturing strategies and compliance frameworks.

Financial pressures have intensified as well, with USPTO fees increasing in January 2025, raising many patent-related fees by approximately 7%. These increases particularly affect smaller biotech companies with limited patent budgets. The broader policy environment reflects pharmaceutical industry pressure along three different channels — taxes, trade and drug pricing. This created a challenging operating environment where companies must balance compliance costs with profitability while adapting to rapidly changing regulatory expectations.

### Federal commission launches biotechnology tour in North Carolina

The National Security Commission on Emerging Biotechnology launched its nationwide "Biotech Across America" roadshow in North Carolina in June, highlighting the state's role in the nation's biotechnology ecosystem.

NSCEB Vice Chair Michelle Rozo kicked off the three-month tour on June 5, meeting with biotechnology leaders in the Research Triangle Park region. The commission selected North Carolina as its first stop to emphasize public-private collaboration in securing America's biotechnology future.

The tour follows the commission's comprehensive report published in April 2025, which warned that the United States risks losing its position as the global leader in biotechnology. The bipartisan commission issued policy recommendations to Congress and the federal government.

The trip started in Raleigh where she discussed the state of the North Carolina biotechnology industry with leaders from the NC Biotechnology Center before meeting with the co-chairs of the NC General Assembly's Life Sciences Caucus Sen. Benton Sawrey, Sen. Jay Chaudhuri, Rep. Donna White and Rep. Robert Reives. Rozo also joined leaders from industry and academia for a roundtable discussion on the ways North Carolina's leadership in biopharma manufacturing and workforce development is powering national progress across the biotech industry.

Rozo and NSCEB staff then traveled to Franklinton to tour the Novonesis enzyme manufacturing facility with representatives of the offices of U.S. Sen. Ted Budd, Sen. Thom Tillis and Rep. David Rouzer. There they discussed recent agricultural biotechnology innovations that can serve as a cornerstone for national security, economic independence and agricultural resilience. The group then closed the day by meeting with members of the North Carolina agricultural and industrial biotechnology community at a showcase of local biotech innovations.



▲ NCLifeSci joined the Council of State Bioscience Associations and the Biotechnology Innovation Organization in D.C. in early April to meet with Reps. Richard Hudson; Greg Murphy, M.D.; and Deborah Ross along with staff from the offices of Sen. Thom Tillis and Sen. Ted Budd and Reps. Don Davis, Chuck Edwards, Valerie Foushee and David Rouzer about the vital importance of continuing support for research that leads to new treatments for patients. Attending on behalf of NCLifeSci were President Laura Gunter, Neil Jones of Lindy Biosciences, Patrick Jordan of Mycovia and NovaQuest Capital Management, Heidi Kay of Jericho Sciences and lobbyist Joe Lanier of Milestone Strategies.

The commission's April report led to the introduction of the National Biotechnology Initiative Act on April 9, legislation to create a National Biotechnology Coordination Office at the White House.

North Carolina is home to 840 life sciences companies that directly employ 75,000 people, making it a significant biotechnology hub. The roadshow went on to visit additional states as the commission works to promote implementation of its national security recommendations.

### Reversing 2022 R&D deduction change: From amortization back to immediate expensing

H.R. 1 (the One Big Beautiful Bill Act) restored most of the R&D expensing provisions passed by Congress in 2017, but which expired in 2022.

Prior to Jan. 1, 2022, companies could immediately deduct their research and development costs in the year they were incurred, providing immediate tax benefits and improved cash flow. This favorable treatment encouraged R&D investment by allowing companies to reduce their tax burden dollar-for-dollar with their innovation spending.

The Tax Cuts and Jobs Act of 2017 included a provision that took effect in 2022. Under that provision — Section 174 of the tax code — companies had to capitalize and amortize R&D expenses over extended periods.

- **Domestic R&D expenses** were spread over five years.
- **Foreign R&D expenses** require fifteen years of amortization.

While H.R. 1 restored the domestic R&D tax deduction, the

requirement to amortize foreign R&D expenses remains. Smaller companies who were forced to amortize R&D costs in 2022 and 2023 may amend those returns to claim the full deduction.

NCLifeSci and other groups consistently criticized the amortization requirement as harmful to American innovation and competitiveness in global markets, where companies in other jurisdictions can immediately deduct R&D expenses while American companies face extended amortization periods.

For life sciences companies, the inability to immediately expense R&D costs created cash flow constraints that limit their ability to pursue aggressive innovation strategies. Startups and growth-stage companies have been particularly affected, as they often rely on immediate tax benefits to manage their financial resources during critical development phases.

### Orphan drugs and Medicare price negotiations: The multiple indication problem fixed

H.R. 1, the One Big Beautiful Bill Act, included Medicare negotiation exemptions for orphan drugs approved to treat more than one rare disease, addressing a core issue that has concerned the rare disease community since the Inflation Reduction Act's implementation.

The IRA included an exemption for orphan drugs from Medicare's drug price negotiation program, but this protection came with a significant limitation. The exemption applied only to orphan drugs with a single approved indication for a rare disease. Once an orphan drug received FDA approval for multiple indications — whether for

additional rare diseases or common conditions — it became eligible for Medicare price negotiations.

Multiple indications are common in orphan drug development, with many treatments initially approved for one rare disease later receiving additional approvals. NCLifeSci, along with patient advocacy groups and rare disease organizations, consistently argued that the single-indication limitation undermined the policy goals of both the Orphan Drug Act and the broader rare disease treatment ecosystem. Pharmaceutical companies should be encouraged, not penalized, for discovering additional therapeutic uses for orphan drugs.

In the 119th Congress, Rep. Don Davis (NC-01) introduced the bipartisan Orphan Cures Act in the House alongside Rep. John Joyce, M.D. (PA-13) in February 2025. The Orphan Cures Act was included in H.R. 1, allowing drugs with multiple rare disease indications to remain exempt from Medicare's drug price negotiations under the IRA. The fix maintains incentives for pharmaceutical companies to develop treatments for multiple rare diseases without facing regulatory penalties for successful drug development.

### North Carolina leaders champion fix for pill penalty

The controversial "pill penalty" embedded in the Inflation Reduction Act remained intact following the passage of the One Big Beautiful Bill Act, despite earlier signals from the administration that the policy would be addressed.

The OBBBA includes modifications to Medicare drug pricing but notably omits changes to the differential treatment of small-molecule drugs versus biologics in price negotiations.

North Carolina's congressional delegation had emerged as a driving force behind the Ensuring Pathways to Innovative Cures Act, a bipartisan effort to eliminate what critics call the "pill penalty" from the Inflation Reduction Act.

Representatives Greg Murphy, M.D. (R-NC), Don Davis (D-NC), and Richard Hudson (R-NC) reintroduced the EPIC Act as H.R. 1492 in the 119th Congress, building on their previous work in the 118th Congress. The bipartisan collaboration demonstrated the issue's importance to North Carolina. Senators Thom Tillis and Ted Budd introduced the bill in the Senate.

Murphy, a physician-turned-congressman, has been a primary champion of the legislation since its original introduction. Murphy first introduced the EPIC Act alongside Davis and Energy and Commerce Health Subcommittee Chairman Brett Guthrie (R-KY) in February 2024.

Under the current system, small-molecule drugs face Medicare price negotiations after nine years on the market, while biologics receive 13 years of protection. This disparity, dubbed the "pill penalty" by critics, has drawn opposition from pharmaceutical companies who argue it unfairly penalizes traditional chemical drugs.

The absence of reforms was particularly striking given Trump's previous support for addressing the issue. A month before the passage of the budget bill, the president had signaled his backing for removing the penalty through executive action.

### SBIR/STTR programs face uncertain future amid foreign-risk screening controversies

The federal government's flagship SBIR/STTR small business innovation programs are approaching a critical juncture as their

authorization expires in September 2025, while mounting concerns over inscrutable foreign risk assessments threaten to undermine their effectiveness.

The statutory authority for the SBIR/STTR programs is set to expire on Sept. 30, 2025, creating uncertainty for thousands of small companies that depend on these federal grants for research and development funding. The Small Business Innovation Research and Small Business Technology Transfer programs distribute billions annually across 11 federal agencies like the NIH that are required to spend a certain percentage of their budgets to support commercialization of cutting-edge technologies.

While Congress considers reauthorization legislation, a parallel crisis is unfolding over foreign influence screening that has left many small businesses shut out of the programs entirely. A recent investigation found that 303 proposals — or 36% — were denied due to foreign risk concerns.

According to a Senate Small Business Committee investigation report, NIH flagged 144 proposals for foreign risk in fiscal years 2023-24 and denied them all, creating what industry advocates describe as a 100% denial rate that lacks transparency or appeal processes.

Companies are not provided information about their specific "risk" and are not provided with any opportunity to appeal the decision or cure the risk. The denials are happening inconsistently across federal agencies, creating additional confusion for small businesses trying to navigate the system.

The foreign risk assessments were implemented in recent years to protect against potential foreign influence and technology transfer and to evaluate factors including cybersecurity posture, patent ownership, employee backgrounds and foreign ownership stakes.

NCLifeSci and other industry groups are mobilizing to address both the reauthorization timeline and the foreign risk screening concerns and advocating for legislative language that would create more transparency in the foreign risk assessment process and provide denied companies with appeal opportunities.

The timing is particularly critical given expectations that Congress may pass a continuing resolution in September rather than a full budget, potentially delaying SBIR reauthorization until December or later in the fiscal year.

For North Carolina alone, the stakes are significant. The state's biotechnology and life sciences sectors have historically relied heavily on SBIR/STTR funding to support early-stage innovation and company formation. Industry advocates are encouraging companies to contact their congressional representatives to emphasize the programs' importance for technology-based economic development.

NCLifeSci coordinated various responses including op-eds and letters to Congress in partnership with other state associations around the country facing similar threats to their states' economic engines. University research is a critical early step in life sciences innovation and offers a training ground for future scientists and entrepreneurs. Concerns about overall funding for the NIH are being addressed, as well. NIH funding directly connects to the SBIR/STTR program and its reauthorization as an agency's SBIR/STTR contributions are a percentage of its overall budget.

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## NIH cuts leave North Carolina research organizations reeling

The Trump administration's sweeping cuts to National Institutes of Health funding delivered a significant blow to North Carolina's innovation infrastructure, forcing major universities to implement layoffs and freeze construction projects while threatening tens of thousands of jobs across the state.

The cuts, orchestrated through the administration's Department of Government Efficiency, reduced NIH contract spending by about 35% across the agency's 27 institutes and centers, resulting in a roughly 28% contraction in overall funding that has rippled through North Carolina's academic and research institutions like the Research Triangle Institute.

Duke University estimates that over 25,000 jobs in North Carolina could be at risk, potentially resulting in at least \$5 billion in lost economic activity for the state if the funding cuts continue.

North Carolina faces a total of \$668 million in NIH funding cuts, according to one analysis. The state's major research universities have historically been among the nation's top NIH grant recipients. The cuts particularly target what are known as "indirect costs" – overhead expenses that help institutions maintain research infrastructure. At UNC Chapel Hill, the negotiated rate for indirect costs is 55.5%, while at Duke University it's 61.5%. The Trump administration is seeking to cap the maximum rate at 15%.

North Carolina joined a multistate lawsuit to challenge the cuts, which are debilitating to the institutions that are a crucial source of innovation and future scientists. A federal judge issued a temporary restraining order to halt some of the reductions. However, internal records showed the Trump administration continued to axe research grants even after the judicial intervention.

The funding cuts represent a significant challenge to North Carolina's position as a leading research hub, potentially undermining decades of investment in building the state's biotechnology and pharmaceutical sectors. As legal battles continue in federal court, research institutions across the Triangle are bracing for additional reductions and planning for a fundamentally altered funding landscape.

## Federal efforts to regulate pharmacy benefit managers heat up

Federal regulators and lawmakers have intensified their scrutiny of pharmacy benefit managers over the past year, with the Federal Trade Commission releasing damning reports and Congress advancing multiple reform bills targeting an industry accused of inflating prescription drug prices while squeezing independent pharmacies.

Pharmacy benefit managers serve as intermediaries between health insurance plans and pharmacies, originally designed to reduce administrative costs and negotiate lower drug prices for insurers. When PBMs emerged decades ago, their stated purpose was to leverage collective bargaining power to secure discounts from drug manufacturers and pass those savings to patients and insurance plans. However, the industry has evolved far from its original mission.

The six largest PBMs control almost 95% of the prescriptions filed in the U.S., allowing them to influence which drugs are available and at what price, according to the FTC's investigation. This concentration

has given a handful of companies enormous leverage over the entire prescription drug ecosystem. Rather than consistently lowering costs as originally intended, PBMs employ several practices that drive up prescription drug prices for patients.

Multiple bills targeting PBM practices have been introduced in both chambers of Congress, reflecting bipartisan support in the House and Senate and indicating a strong desire to further regulate PBMs at the federal level.

Key legislation included the Pharmacy Benefit Manager Reform Act and the Pharmacy Benefit Manager Transparency Act, both aimed at increasing transparency in PBM operations and ensuring that negotiated savings reach patients rather than being retained by intermediaries.

However, despite years of hearings and bill introductions, pharmacy benefit manager reform has failed to make the cut in federal legislation.

## Trump Administration revives Most Favored Nations drug pricing policy

The Trump administration renewed its push to lower prescription drug costs through a revived Most Favored Nations pricing policy, issuing a new executive order in May 2025 to end what officials call "global freeloading" on American pharmaceutical innovation.

MFN pricing pegs U.S. prescription drug prices to the lowest prices paid by economically comparable countries. Under this approach, Americans would pay no more for medications than patients in other developed nations, targeting price disparities where the same drugs often cost three to five times more in the United States.

Prescription drugs cost less in other countries than in the United States primarily due to different health care systems and government pricing policies. Most developed nations employ some form of centralized price regulation, where government agencies negotiate directly with pharmaceutical companies or set maximum allowable prices for medications.

Countries like Germany, France and the United Kingdom use health technology assessment bodies that evaluate a drug's clinical effectiveness and cost-effectiveness before determining reimbursement prices. Additionally, many countries operate single-payer or heavily regulated health care systems that pool purchasing power, allowing them to negotiate volume discounts that individual American insurers cannot match. The U.S. health care system is largely market-based with multiple private insurers, hospitals and pharmacy benefit managers, creating a fragmented purchasing environment.

On May 12, President Trump signed an executive order directing the administration to bring American drug prices in line with those paid by similar nations. HHS expects manufacturers to align U.S. pricing for brand products without generic competition with the lowest price in OECD countries with GDP per capita of at least 60 percent of U.S. levels.

The policy targets brand-name drugs where price disparities are most pronounced. The administration plans to use international pricing as the starting point for Medicare drug price negotiations rather than current U.S. market prices.



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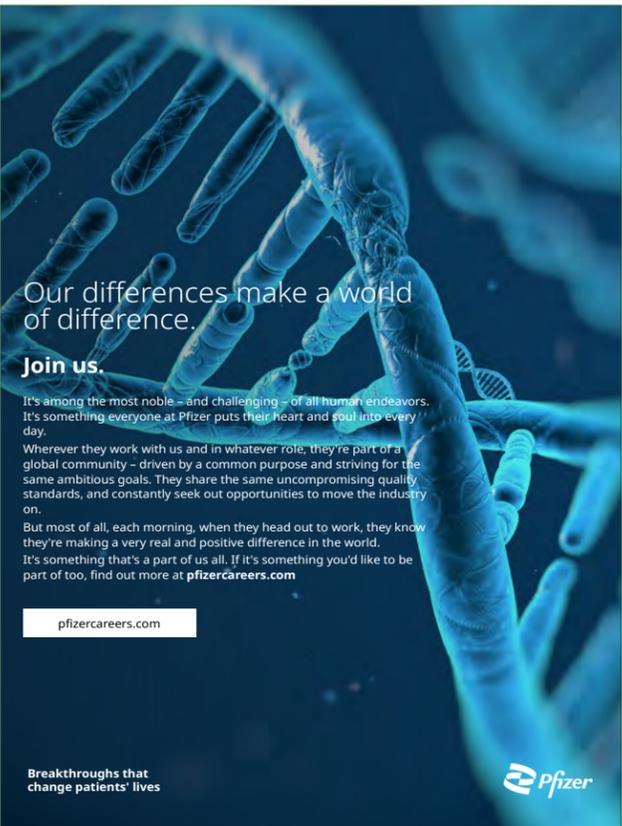
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# Forums & Networking Events



▲ July 17 Lab Space Forum panelists Deb Boucher of Cushman & Wakefield, Lakshmi Ethirajan, Ph.D, of SmaBio, Travis McCready of JLL and Chase Jenkins of HIPP Design & Consulting

**Lab Space:** At the July 17 forum, panelists from Cushman & Wakefield, HIPP Design + Consulting, JLL and SmaBio Labs discussed how the life sciences real estate market is grappling with a perfect storm of reduced venture capital funding, oversupply and evolving technological demands. However, North Carolina remains positioned relatively well compared to other major markets, they said.



▲ Megan Robertson of Epstein Becker Green, Juliana Blum of BioAesthetics, Anna Abram from Akin, Charity Schuller of the PPD clinical research business of Thermo Fisher Scientific and Cartier Esham of Esham Strategies and the Alliance for a Stronger FDA were the Medical Device Forum panelists.

**Medical Device:** The May 15 forum addressed significant changes and challenges at the FDA. Key discussion points included the FDA's workforce issues, such as turnover and the need for clear communication. The impact of the administration's deregulatory efforts on innovation and regulatory processes was a major concern. The forum also noted a trend of companies conducting early-stage clinical trials overseas, underscoring the need to maintain U.S. leadership in medical research. Panelists advised companies to be adaptable and engage proactively to navigate the evolving regulatory landscape.



▲ Drew Cutshaw, M.D., with Pappas Capital; Ned Sharpless, M.D., of Jupiter BioVentures; David Adair, M.D., with Solas BioVentures; John Landers of 2ndF; Kseniya Simpson, Ph.D., with Hatteras Venture Partners and Jimmy Melton of Cape Fear BioCapital comprised the panel at the Feb. 27 Emerging Companies Forum.

**Emerging Companies:** On Feb. 27, panelists from 2ndF, Cape Fear BioCapital, Hatteras Venture Partners, Jupiter BioVentures and Solas BioVentures tackled the challenges of navigating the current difficult investment landscape. Panelists noted that raising early-stage funding has become significantly harder, as venture groups are focusing more on their existing portfolios. The expert panelists said that, for new companies to attract investment, they must demonstrate clear commercial viability and a well-defined lead program. They stressed the critical importance of leveraging nondilutive funding sources, like SBIR grants, to support growth. The forum also highlighted that building a strong team and a positive corporate culture is essential for success.



▲ Nick Pajewski, Ph.D. with the WFU School of Medicine, Univo IRB's Julie Blasingim, Verily's Erich Huang, M.D., Ph.D.; Avery Miles of MyData-TRUST and Patrick Daly of IQVIA were the panelists at the Nov. 19 NCLifeSci Clinical Trials Forum.

**Clinical Research:** A panel of industry leaders from IQVIA, MyData-TRUST, Univo IRB, Verily and the Wake Forest University School of Medicine delved into the complex landscape of data usage and patient engagement in the life sciences and health care sectors at the NCLifeSci Clinical Trials Forum Nov. 19, 2024. The conversation highlighted the need for a more holistic and patient-centric approach to navigating the evolving regulatory environment and unlocking the full potential of data-driven innovation.

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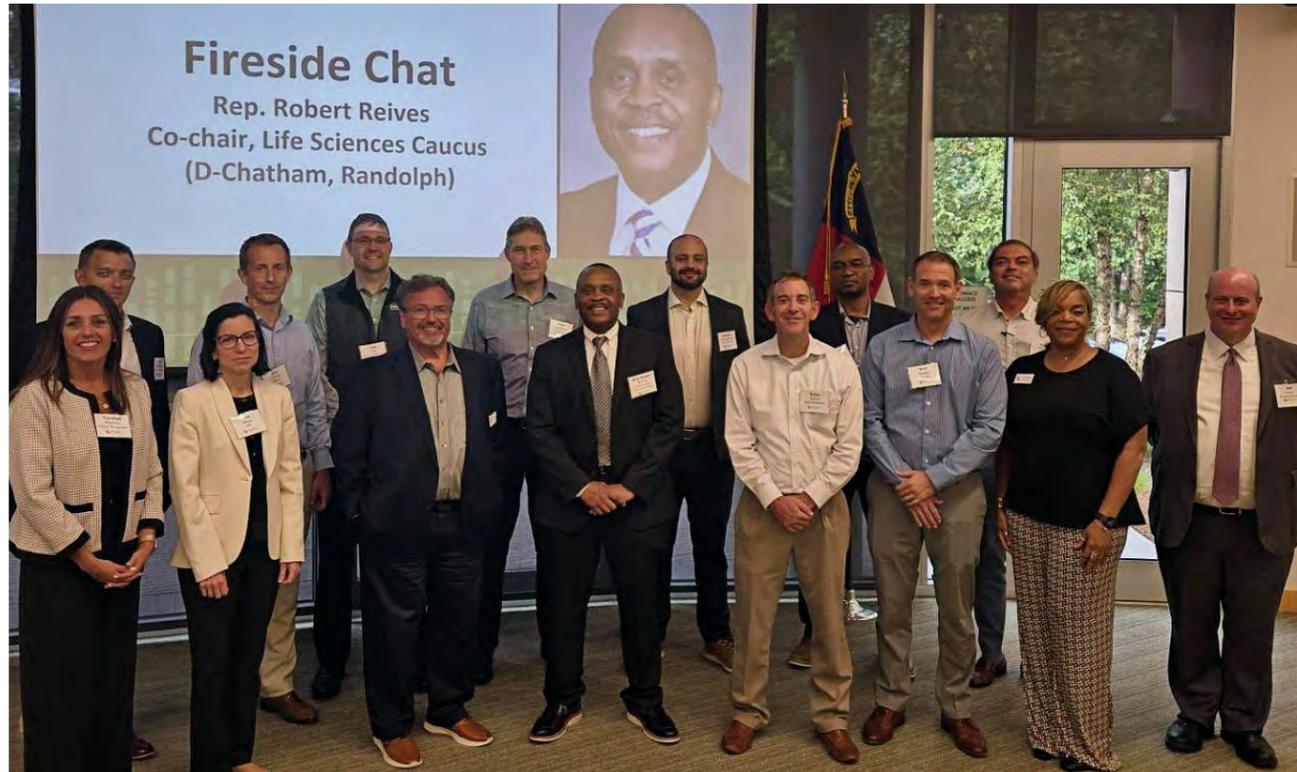
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## Biotech Manufacturers Forum



▲ NCLifeSci hosted the BMF site leaders for a dinner and fireside chat Aug. 20 with Life Sciences Caucus Co-chair Rep. Robert Reives. Attending were (front row) Carolina Martinez of Grifols Therapeutics, Rosa Manso of Lilly, Bill Monteith of NCLifeSci, Rep. Robert Reives, Brian Ridout of KBI Biopharma, Brad Mickey of Astellas Gene Therapies, Jenae Williams of NCLifeSci and Joe Lanier of Milestone Strategies (back row) Pete Goodridge of Johnson & Johnson, Alex Murray of Biogen, Tom Jede of Beam Therapeutics, Neils Laurbjorb of Novo Nordisk, Leonardo Costa Siqueira of Novo Nordisk, Kevin Hatchell of Novo Nordisk and David Posehn of Pfizer.

**July 2025:** Workforce training, the skilled trades and opportunities for veterans were the focus of the second-quarter meeting of the NCLifeSci BMF held July 9. Attendees heard from two maintenance technicians and veterans working at Amgen and CSL Seqirus who talked about their career paths after leaving military service. Their presentations were followed by a panel discussion with representatives from Amgen, Central Carolina Community College, CSL Seqirus and NCBiotech that covered strategies for recruiting and training maintenance technicians, automation specialists and other skilled trade workers essential to modern biomanufacturing operations. Several vendors and presenters provided information on resources and apprenticeship programs that provide potential employees with relevant skills.

**March 2025:** The BMF kicked off 2025 with a first quarter meeting on March 18 focusing on sustainability. The highlight of the evening was presentations by sustainability expert Marguerite Murray of the Samasta Group, who shared insights on global and local sustainability trends, and David Auge of Grifols Therapeutics, who shared the company's approach to sustainability at its Clayton manufacturing site.

**December 2024:** Current automation trends in the life sciences was the topic of discussion at the fourth quarter meeting of the NCLifeSci BMF held Dec. 2. The meeting featured presentations by experts from the Advanced Technology Group, GXP-Storage and Kymanox that covered choosing the right automation partners, embracing digital automation and the integration of artificial intelligence to drive efficiency and compliance and a case study of automating a sterile gene and cell therapy production line.

**September 2024:** The NC Life Sciences BMF Q3 meeting on Sept. 24, focused on employee recruitment and retention. Made in Durham's BULLS Life Sciences Academy presented its training offerings for Durham residents pursuing biotech careers. The program has achieved a 69% hiring rate across 14 partner companies. Amgen's Tracy Schomer outlined three key retention strategies: building strong teams through collaboration and communication, developing individuals through recognition and continuous learning, and creating inclusive leaders who promote psychological safety. She emphasized regular feedback, clear responsibilities and preventing burnout to retain talent. Participants worked collectively to create a list of best practices for retaining employees.

## Diversity, Equity and Inclusion



▲ The "Can You Hear Me Now: Multigenerational Conversations" panel was moderated by Trier Bryant and comprised Larry Diener from CSL Seqirus, David Posehn of Pfizer, Amanda Adams from Biogen and Rashaad Galloway of Clinispan.

**On March 7, 2025**, NCLifeSci held a program that aimed to bridge the communication gap between different generations in the workplace. The event featured a panel of professionals from various age groups representing Biogen, Clinispan, CSL Seqirus and Pfizer who shared their experiences and insights, with a focus on navigating workplace dynamics that have evolved since the COVID-19 pandemic.

Moderated by Trier Bryant, the discussion emphasized the critical need for adaptability, mentorship, and cross-generational



▲ Trier Bryant shared insights on the importance of adapting communication styles to connect with diverse audiences. Her message emphasized the need to move beyond generational stereotypes and instead focus on understanding individual preferences and work styles.

collaboration to create a more equitable and productive work environment. The panelists stressed the importance of addressing biases, fostering inclusion, and valuing the diverse perspectives that each generation brings to the table.

Bryant followed the discussion with a presentation on adapting communication styles by understanding four main social profiles: drivers, expressives, amiables and analytics. By identifying and adjusting to a colleague's preferred style, professionals can improve the effectiveness of their interactions.

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# NCBIO IMPACT



▲ The NCBioImpact Team

## NCBioImpact 2.0 launches ambitious workforce development initiative

NCBioImpact has unveiled an energized "2.0" version of its workforce development program, bringing together universities, community colleges and industry partners to address critical training needs in North Carolina's rapidly expanding life sciences sector.

The reinvigorated initiative represents a collaborative effort involving 24 organizations and dozens of education resources and workforce development partners across the state. NCBioImpact was created to enhance the trained workforce for biotechnology and other life sciences employers by educating students and retraining incumbent workers.

### Addressing industry growth

The timing is critical for North Carolina's booming biotechnology sector. North Carolina's life sciences sector creates more than 225,000 jobs, and major companies like Biogen, CSL Seqirus, FUJIFILM Biotechnologies, Grifols, GSK, Merck, Novo Nordisk, Novozymes, Pfizer and others benefit from NCBioImpact training programs.

NCBioImpact 2.0 has identified five key initiative areas for 2025-2026:

- Industry resource fair to connect employers with workforce development programs
- Comprehensive marketing materials development
- Member asset mapping to catalog training resources

- Enhanced meetings and events programming
- Centralized metrics system to track student careers and outcomes

### Major infrastructure investments

Supporting the workforce development efforts are significant facility expansions across the state. Wilson Community College is constructing the Biomanufacturing Education & Skills Training Center of Eastern NC, a major new facility expected to be completed by December 2026. The project will focus on biomanufacturing education and skills training with input from industry leaders.

Meanwhile, Central Carolina Community College is developing the E. Eugene Moore Manufacturing & Biotech Solutions Center, a 220,000 square foot facility dedicated to advanced manufacturing and life sciences training. The college's biotechnology building construction began in 2025, with occupancy planned for 2026.

### Collaborative structure

The NCBioImpact 2.0 model emphasizes collaboration across educational sectors, bringing together representatives from universities with dedicated life sciences facilities and programs including North Carolina State University, North Carolina Central University, East Carolina University and NC A&T University. All NC Community College System partners that offer the Bioworks program are part of the NCBioImpact model, as well.

# NCLIFESCI AWARDS

## 2024-25 Samuel M. Taylor Scholarships



▲ The recipients of the 2024 Samuel M. Taylor Memorial Life Sciences Scholarships were Lila Bradshaw, Frankie Nobles, Kiera Darden and A.J. Johnson. Hesbam Gamaan is not pictured.



▲ Sam Taylor

NCLifeSci awarded four scholarships totaling approximately \$12,000 for the 2024-25 academic year through the Samuel M. Taylor Memorial Life Sciences Scholarship program, continuing its mission to develop the next generation of skilled workers for the state's booming biotechnology sector. The scholarship recipients were selected on July 18. The funding comes from multiple sources including \$5,600 from the scholarship foundation's managed funds, \$5,400 raised through a venture capital poker fundraiser hosted by Alexandria Real Estate Equities, and \$1,000 from investment earnings.

The Samuel M. Taylor Scholarship was established in memory of Sam Taylor, a founder and president of NCBIO (now NCLifeSci), the trade association for life science companies in North Carolina.

Taylor was passionate about North Carolina's life sciences industry and served at NCBIO's helm for more than 25 years.

The scholarship program has gained significant momentum since its inception. More than 50 donors pledged more than \$250,000 to a fund established at the NC Community Colleges Foundation, Inc. to provide scholarships for students taking life sciences courses in an associate degree program. In the last four years, 18 Taylor scholarships have been awarded to 14 students.

Awards include up to \$3,000 per year to cover tuition, fees and books for students pursuing associate degree programs in life sciences fields including bioprocess manufacturing technology, clinical trials research, bioanalytical laboratory technology and facility maintenance technology.

Leadership gifts for the Taylor Scholarship fund came from Alexandria Real Estate Equities, Amgen, Biogen and Hatteras Venture Partners. Grifols, Novo Nordisk, Frankel Staffing Partners, FUJIFILM Biotechnologies, Thermo Fisher and Smith Anderson also made significant contributions to the scholarship fund.

# AGBIO 2025

## North Carolina and Virginia come together to explore agriculture, and biotech



▲ Paul Ulanich of NCBiotech, Amber Niebauer of NCLifeSci, Caron Trumbo of Virginia Bio, Scott Lowman with the Institute for Advanced Learning and Research, Laura Gunter with NCLifeSci, Tina Nuthulagant with Avantor, Natacha Janvier of NCLifeSci, Jim Seymour with BIO Business Solutions and Frank Wilton and John Newby of Virginia Bio

## Life sciences organizations in North Carolina and Virginia came together at AgBio 2025 to explore the intersection between agriculture and biotechnology at the NC Biotechnology Center on April 9.

Hosted by NCLifeSci, Virginia Bio, the Institute for Advanced Learning and Research and NCBiotech, the event brought together more than 100 stakeholders to discuss the bioeconomy, public policy, intellectual property, support for start-ups and more. Participants also attended a reception at the NC State Plant Sciences Building and toured the facility.

Avantor was the event's Premier Sponsor with the Virginia Innovation Partnership Corporation contributing as the Platinum Sponsor and CSC Leasing as the Gold Sponsor. Finnegan, the Institute for Advanced Learning and Research, Safety Partners, Smith Anderson, SU Group and the Virginia Department of Agriculture and Consumer Affairs all contributed as Silver Sponsors.

The day kicked off with a policy panel discussing the complex challenges and innovative solutions facing agricultural

biotechnology, with panelists offering candid insights into transforming the agricultural landscape.

The discussion centered on the critical need for collaborative approaches to support farmers and advance agricultural technologies.

The discussion underscored a critical point: agricultural innovation is not just about technology but about supporting farmers, rural communities and the broader ecosystem of agricultural production.

The second session of the day brought together experts from across the innovation ecosystem to discuss supporting early-stage startups. The key theme was the critical importance of collaboration, customer discovery and strategic derisking.



▲ Panel 1: Karen Carr (moderator), Laura Kilian, Bryan David and Beth Ellikidis.



▲ Panel 3: Eric Ward (moderator), Ryan O'Quinn and David Saravitz

The panelists unanimously agreed on several key points for startup:

- The importance of understanding real customer needs
- The critical nature of derisking both technical and commercial aspects
- The need for collaborative support across organizations
- The value of creating opportunities for startup interactions

The day's third panel provided an in-depth exploration of intellectual property protection in agricultural biotechnology covering the three primary forms of IP protection in agriculture: utility patents, plant patents and plant varietal protection certificates.

The discussion highlighted significant international variations in patent law with different countries having unique restrictions.

The discussion provided a comprehensive overview of the challenges and strategies in protecting agricultural biotechnology innovations, demonstrating the nuanced and evolving nature of intellectual property law in this critical field.

The day's fourth panel explored the intersection of biotechnology and the bioeconomy, highlighting innovative approaches such as transforming waste into valuable products across agriculture, food and industrial sectors.

The panelists identified several key challenges in advancing the



▲ Panel 2: Krista Covey (moderator), Braden Croy, Phil Taylor, Frank Klemens and Greg Fisher,



▲ Panel 4: Zhiwu "Drew" Wang (moderator), Andrew Magyar, Heather Smith, Edwin Rogers and Toni Bucci.

bioeconomy. Regulatory hurdles emerged as a significant barrier, with members critiquing the FDA, which often doesn't understand new technologies.

The critical gap between fundamental and applied research was noted, and panelists emphasized the need for universities to better understand industrial needs and mobilize resources accordingly.

The panel concluded by calling for more collaboration, ecosystem building and a focus on creating value through innovative biological technologies.

The final session explored the past, present and future of controlled environment agriculture, challenging the notion that CEA is a new technology. CEA is a modern farming approach that uses technology to manage all aspects of the growing process, including temperature, humidity, light and nutrient delivery.

The panel presented CEA not as a revolutionary replacement for traditional agriculture, but as a complementary tool with significant potential to address global food security challenges. The panelists agreed that CEA won't replace traditional agriculture but emphasized CEA's potential for helping with food security, particularly in regions with limited agricultural resources.

Closing remarks highlighted the collaborative potential between universities and industry and on talent development and the unique skills required in CEA.

# BIO 2025 BOSTON



▲ The North Carolina pavilion at BIO International 2025 created by NCBiotech



▲ Sr. Director State Government Affairs Erin Frey and CEO Emil Kakkis, M.D., Ph.D. of Ultragenyx and BIO's VP of Membership Liz Gaskins Civils with Laura Gunter



▲ BIO's Liz Gaskins Civils with John Stanford and John Guy of Incubate Coalition with Laura Gunter at BIO 2025

# LOOKING FORWARD



▲ Your NCLifeSci staff is Membership Director Natacha Janvier, Workforce and Partnerships Director Jenae Williams, Events Director Amber Niebauer, BMF Program Manager Bill Monteith, President Laura Gunter, Communications Director David Etchison and Executive Assistant Alex Caruso.

## As NCLifeSci entered its fourth decade, the organization continued to demonstrate its vital role in North Carolina's life sciences ecosystem.

The 30th anniversary celebration showcased not only the tremendous growth and innovation within the industry but also the collaborative spirit that has made North Carolina a national leader in life sciences.

With strong industry partnerships, commitment to education and workforce development, and a focus on addressing real-world health care challenges, NCLifeSci is well-positioned to continue its mission of serving the industry, the state, and most importantly, the patients who benefit from the life-changing work being done

across North Carolina.

The organization's evolution from NCBio to NCLifeSci reflects its broader mission and the industry's expansion beyond traditional biotechnology into the full spectrum of life sciences. As artificial intelligence, gene therapy, and value-based care reshape health care delivery, NCLifeSci remains at the forefront, fostering the partnerships and innovations that will define the next 30 years of life sciences advancement in North Carolina.

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**Welcome New Members:** NCLifeSci has welcomed the following new or returning members since the 2024 Annual Meeting:

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