July 2023 Update

Serving the NC Life Sciences Industry

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NCBIO This Month

NC shows well at BIO 2023, conference video recap available

North Carolina was front and center at the BIO 2023 convention held in Boston June 5-9. The NC Biotechnology Center and sponsors hosted the North Carolina reception on June 6, and it was a great opportunity for those getting to know North Carolina to mingle with our life sciences community. Read more at NCBiotech.
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If you missed the event, BIO offers these video highlights:

- Rachel King: Welcome to BIO 2023
- Outgoing BIO Board Chair Paul Hastings Farewell Video
- Boston's Mayor Michelle Wu announces Boston's Life Sciences Workforce Initiative
- Katie Couric
- FDA Commissioner Dr. Robert M. Califf on the lessons of COVID
- FDA Commissioner Dr. Robert M. Califf on legal challenges to FDA's authority
- Massachusetts Governor Maura Healey announces reauthorization of Massachusetts Life Science Initiative, new workforce programs
- Rep. Jake Auchincloss (D-Mass) on the biotech industry
- Asha George, Bipartisan Commission on Biodefense
- The BIO Film Festival:Â A series of inspirational short films highlighting patient stories and biotech innovators. Watch the trailer!

NCBIO Sustaining Members

NCBIO Supporting Members

STATE UPDATES

State budget process continues

State budget negotiations continue at a slow pace. Both House Speaker Tim Moore and Senate President Phil Berger have said that a budget compromise will not emerge until at least mid July and possibly well into August.
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Both chambers agreed to break for the week of July 4.

Supreme Court rejects "independent legislature" argument

In a 6-3 ruling in the case of Moore. v. Harper, the U.S. Supreme Court held that state courts have the authority to interpret federal election laws that are carried out by state legislatures.
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The case came about as a result of Republican lawmakers appealing an N.C. Supreme Court ruling that threw out the congressional districts the legislature had drawn the previous year. Legislative leaders relied on a theory known as the “Independent Legislature,” stating that the constitutional authority to draw both congressional and state house and senate district maps lies solely with the state legislature.

NCBIO President Laura Gunter, along with representatives from Lenovo and Research Triangle Institute, presented to the General Assembly's HBCU Caucus on June 21.

State Senate seeks changes to elections

Two bills were filed in the State Senate that would significantly change election procedures for the November 2024 General Election.
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Senate Bill 749 No Partisan Advantage in Elections would restructure the North Carolina State Board of Elections by splitting the appointments between the majority and minority leaders in the General Assembly. The stated purpose of this is to eliminate any chance of a partisan advantage on the board. Currently, the State Board of Elections has two seats for the Republican Party, two seats for the Democratic Party and one member appointed by the Governor. Therefore, the Board is always controlled by the Governor’s party.
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If this legislation passes, it would increase the Board from five members to eight. The President Pro Tempore of the Senate and the Speaker of the House would each have two appointments to the board. The minority leaders in both the House and Senate will also have two appointments each.
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Governor Cooper and Democratic leadership in the Senate have voiced their opposition of the bill.
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The second election bill, Senate Bill 747 Elections Law Changes, proposes to amend the timeframe during which absentee ballots will be accepted, prohibit the State Board of Elections from accepting private monetary donations and remove foreign citizens from voting rolls.

Cooper honored at World Stem Cell Summit

North Carolina Gov. Roy Cooper was recognized June 6 at the 20th annualÂ World Stem Cell SummitÂ in Winston-Salem for his role in developing the life sciences

SummitA in Winston-Salem for his role in developing the life sciences.
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Cooper received the Regenerative Medicine Action Leadership Award from theÂ Regenerative Medicine Foundation, a nonprofit organization that promotes the development of regenerative medicine to improve health and deliver cures.
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After accepting the award at a luncheon ceremony, Cooper praised North Carolina as “the best place in the world” to do medical research, grow a workforce, establish a business and raise a family.Â More at NCBiotech >>

Life Sciences Caucus

On June 28, the NC General Assembly's Life Sciences Caucus heard about the outstanding return the state has received from its investments in the NC Biotechnology Center, the First Flight Venture Center and the One NC Small Business Fund, which support the state's entrepreneurial community.
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Presenters were Krista Covey, president of First Flight; Doug Edgeton, president and CEO of NCBiotech; and Mike McBrierty, a member of the State Board of Science, Technology & Innovation and a member of the NCBIO Board of Directors.Â

Milestone Strategies' Joe Lanier and NCBIO President Laura Gunter with caucus cochairs Rep. Donna White and Sen. Paul Newton

Caucus cochairs Rep. Robert Reives (House Democratic leader) and Sen. Mike Woodard

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NATIONAL UPDATES

If there are any topics or issues that are affecting your business or you want to know more about, please contact Laura Gunter.

House hearing focuses on PBM transparency

A June 21 House hearing on health care costs put a sharp focus on the need for transparency to prevent pharmacy benefit managers from driving up the price of prescription

transparency to prevent pharmacy benefit managers from driving up the price of prescription drugs.

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Experts at the House Committee on Education and the Workforce Subcommittee on Health, Employment, Labor, and Pensions hearing laid out the ways in which PBMs benefit by raising costs for patients and reducing revenue for drug makers. In response, Congress members from both parties called for legislation to stop the abuses by shining light on the practices of PBMs.

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PBMs determine the formulary of drugs that insurers will cover and demand rebates from drug makers in exchange for this coverage. While PBMs are supposed to pass on the savings from these rebates to insurers and patients, research shows they pocket those savings as profits ? though it's hard to know how much PBMs profit.

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The PBMs "operate in a black box," said Subcommittee Chair Bob Good (R-VA). "Nobody knows the details of the rebate deals they negotiate with drug manufacturers, creating perverse incentives for PBMs to choose more expensive drugs with larger rebates."

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Earlier in the month, a bipartisan group of senators introduced the Patients Before Middlemen Act to delink the compensation of pharmacy benefit managers from drug price and utilization in order to better align incentives that will help lower prescription drugs costs for Medicare Part D beneficiaries. More at BIO >>

Ways and Means takes first step to fix R&D amortization

The House Ways & Means Committee approved the Small Business Jobs Act, a step toward saving investment in research and development.

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The Tax Cuts & Jobs Act of 2017 changed the longstanding deduction for R&D expenditures to a mandatory five-year amortization for domestic R&D and a 15-year amortization for foreign R&D.

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The House Ways & Means Committee approved the Small Business Jobs Act (H.R. 3937), which includes language to delay retroactively through 2025 the mandatory capitalization of R&D expenses.

Cohen named CDC head

President Joe Biden appointed Mandy Cohen, M.D., as director of the Centers for Disease Control and Prevention.

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Cohen served as secretary of the N.C. Department of Health and Human Services during the majority of the COVID-19 pandemic. Before serving in North Carolina, Cohen was chief operating officer and chief of staff at the Centers for Medicare & Medicaid Services where she helped implement Affordable Care Act programs, including expanding insurance coverage and protections. She has also worked in the Department of Veterans Affairs.

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A graduate of Cornell University, Cohen received her medical degree from Yale School of Medicine and a Master's in Public Health from the Harvard School of Public Health. She trained in internal medicine at Massachusetts General Hospital.

Senators seek input on 340B program

The Senate's 340B bipartisan working group sent a letter to stakeholders seeking feedback on ways to improve the 340B program.

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BIO will be responding to this request on behalf of its membership. If you have any questions or you're interested in preparing your own response, please don't hesitate to reach out to Laura Gunter as NCBIO would be happy to support you.Â

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Specifically, the senators are seeking input on bipartisan policy solutions that would provide stability and appropriate transparency to ensure the 340B program can continue to achieve its original intent of supporting entities serving eligible patients.

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Hospitals in the 340B program are exploiting lax eligibility criteria and program guardrails to profit from the substantial 340B discounts that were intended to ensure low-income access to discounted prescription drugs and services. Despite the intent of the program, the 340B statute does not restrict how hospitals and other covered entities can use revenue from the 340B program. Many studies have shown that the actions of hospitals have hurt rather than helped patients by limiting their access to treatment and restricting affordable therapy options.

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In 2022, the 340B program reached $106 billion in sales at list prices and is now the second largest pharmaceutical program in the nation behind Medicare Part D fueled largely by the dramatic growth and abuse of the 340B program by disproportionate-share hospitals. If the program continues growing at this rate, it will soon surpass Part D, which is projected to amount to $119 billion in 2023. This explosive trend has been largely caused by the dramatic growth and abuse of the 340B program by disproportionate-share hospitals, which now

account for more than 80% of 340B sales. More from Sen. John Thune >>

Congress introduces three BIO-backed bills

The Promoting and Respecting Economically Vital American Innovation Leadership Act better balances interests of patent owners and patent challengers by reforming the Patent Trial and Appeals Board at the U.S. Patent and Trademark Office. The PREVAIL bill was introduced by Sen. Chris Coons (D-DE), Sen. Thom Tillis (R-NC), Rep. Ken Buck (R-CO) and Rep. Deborah Ross (D-NC). USPTO is proposing reforms to PTAB patent invalidation proceedings, and PREVAIL would codify important reforms.
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"NCBIO is very pleased to see the support the PREVAIL act is receiving from the North Carolina delegation, and we thank both Senator Tillis and Representative Ross for their primary sponsorship of the bill in the Senate and House," NCBIO President Laura Gunter.
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The Patent Eligibility Restoration Act of 2023, also from Tillis and Coons, would clarify patent eligibility for complex new technologies, such as gene therapy. Courts and stakeholders have long called for clarification in the law on what is eligible for patent protection. Providing clearer guidance will help early-stage innovators. NCBIO wrote to Senator Tillis thanking him for his support.
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"In addition to providing needed and long overdue clarity to this critical area of the law, this legislation would also afford U.S. innovators the same protection now enjoyed by their foreign counterparts," Gunter wrote. "At a time when the American peopled are demanding that critical industries be brought home, this equal treatment will be especially important."
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The Medical Supply Chain Resiliency Act, from Sen. Tom Carper (D-DE) and Tillis, aims to ensure critical medical supplies are delivered safely, swiftly and efficiently by authorizing the president to negotiate with trusted trading partners committed to global health security, rule of law and transparency. The legislation is an important step toward creating robust supply chains to meet global medical needs. More at BIO >>

PhRMA joins lawsuit challenging IRA's drug-price "negotiations"

Pharmaceutical Research and Manufacturers of America, along with Merck and Bristol-Myers Squibb, has filed a lawsuit against the federal government over the price-setting provisions in the Inflation Reduction Act.
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The IRA was signed into law in 2021 and allows Medicare to negotiate prices for certain high-cost prescription drugs. Manufacturers who do not agree to the price set by the goverment would be subject to a 90% tax on their drug's profits.
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The lawsuit alleges that the IRA's Drug Price Negotiation Program violates the Fifth Amendment's due-process clause and the Eighth Amendment's excessive fines clause.
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PhRMA argues that the IRA's negotiation provision infringes upon the Fifth Amendment, which mandates that the government must provide fair compensation when it acquires private property for public use.
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The industry also claims that the excise tax, which would be levied on manufacturers not complying with the negotiated prices, is unconstitutional. More at Biospace >>

CMS releases updated guidance on drug-price negotiations

CMS is releasing its revised guidance for how Medicare intends to use its new authority to directly negotiate with drug companies for lower Medicare prices on selected covered high-expenditure drugs without generic or biosimilar competition.Â
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In the negotiations, CMS says it will consider the selected drug’s clinical benefit, the extent to which it fulfills an unmet medical need and its effect on people who rely on Medicare. Additional considerations include costs associated with research and development and production and distribution for selected drugs.
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The changes to the CMS guidance includes

- clarifications of how CMS will identify selected drugs (for example, CMS will only consider active designations and approvals when evaluating a drug for the orphan drug exclusion),
- revisions to and clarifications of the process applicable for participating drug companies of selected drugs (for example, confidentiality policy revised to state that CMS will release information about the negotiation when the explanation of the maximum fair price is published and that drug companies may choose to publicly discuss the negotiation at their discretion) and
- inclusion of additional opportunities for drug companies and members of the public to engage with CMS during the negotiation process on the selected drugs (such as through patient-focused listening sessions) Â

through patient-focused listening sessions).Â

CMS issued the initial guidance and sought public comment on key elements of the Medicare Drug Price Negotiation Program in March 2023. The agency received more than 7,500 comments on the initial guidance from consumer and patient groups, drug companies, pharmacies, individuals and other interested parties. More at CMS >>

The number of drugs subject to inflation rebates doubles

The Biden administration has identified 43 drugs subject to rebates from manufacturers to Medicare and lower coinsurance rates for beneficiaries starting July 1. This is more than double the current number of drugs subject to rebates.

The named drugs had price hikes outpacing the annual rate of inflation last quarter. The number of drugs could change before next month, though. If the agency gets feedback from drugmakers that requires a change, the list will be updated.

CMS will start to collect rebates from the drugmakers starting no later than fall 2025.

HHS also released a report that showed Medicare Part B drug spending increased at a 9.2 percent annual rate every year from 2008 through 2021.

The annual increase was more than triple the 2.6 percent hike for Part D, Medicare's prescription drug program. Medicare Part B covers drugs administered to patients in doctors' offices or hospitals, such as chemotherapy.

The report, required under last year's Inflation Reduction Act, found that Medicare Part B spending was concentrated in a relatively small number of drugs centered in oncology, rheumatology and ophthalmology.

The agency will identify 10 drugs by Sept. 1 that will be subject to "negotiation" under the Inflation Reduction Act with the prices effective for Medicare Part D in 2026.

Burr believes partisans will come together on PAHPA reauthorization

The Pandemic and All-Hazards Preparedness Act is up for reauthorization, and there are concerns that partisan bickering could derail the process. However, former Sen. Richard Burr, the bill's original co-author, said he believes that the two lead negotiators, Reps. Anna Eshoo (D-CA) and Richard Hudson (R-NC), will be able to find consensus.
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Eshoo and Hudson are at odds over some provisions, including those meant to avert drug shortages. Burr disagrees with Democrats who want to include these provisions in the bill, arguing that it would turn it into a "Christmas tree bill." He believes that lawmakers should focus on the areas of agreement and create a foundation from which other policies can be evaluated based on their relevance.
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Sen. Bill Cassidy (R-LA), the ranking member on the Senate HELP Committee, said that negotiations in the Senate are being held up because of drug policy demands from Chair Bernie Sanders (I-VT) that are "completely outside the purview of PAHPA." Sanders wants to include policies that would let the government retain intellectual property rights over treatments and vaccines developed by pharmaceutical companies that received government funds to do so. The HELP Committee is seeking feedback on PAHPA through Monday, July 10.
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BIO testified before the committee in support of removing the so-called "reasonable-pricing clause" from the legislation.
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“The inclusion of a reasonable pricing clause in the PAHPA reauthorization will effectively shut down private sector investment and the type of public-private partnerships that are vital to the development of life-saving medical countermeasures," Phyllis Arthur, senior vice president for infectious disease and emerging science policy at BIO . "This is especially true for many MCMs that have a limited or no commercial market and rely on these partnerships."
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Burr, who retired from the Senate last year and now works at a law and lobbying firm, said he believes that both sides will eventually reach an agreement, but he said doesn't think it will happen quickly.

Senate committee approves 1% increase to FDA budget

The Senate Appropriations Committee has approved a spending bill that would increase the FDA's budget by 1% in fiscal 2024.
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The increase, to $6.63 billion, is in line with the amount approved by House appropriators earlier in June. The relatively small increase in funding would go toward cosmetics oversight, food safety programs and device and drug shortages, neuroscience research, and ALS research. User fees would make up $3.07 billion of the total, compared with $3.55 billion in

appropriation. The FDA's budget has not kept pace with inflation in recent years.
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Lawmakers on both sides lamented restrictions on spending from the debt ceiling deal negotiated by President Joe Biden and House Speaker Kevin McCarthy. House and Senate appropriators have until Sept. 30 to pass a bill or extend current funding levels in order to avoid a partial government shutdown. In addition, under the debt limit deal, federal funding will automatically fall by 1% in January if Congress resorts to a stopgap spending bill.
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The House Appropriations Committee advanced its fiscal 2024 FDA spending bill earlier this month despite strong Democratic opposition to language tied to abortion pills and curbing tobacco regulation. House appropriators capped Agriculture-FDA spending at $17.8 billion, with the biggest reductions coming in the Agriculture Department budget.

FDA releases first draft guidance on psychedelic research

The Food and Drug Administration on Friday released its first draft guidance for researchers designing clinical trials using psychedelic drugs.
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The bulk of the new guidance details basic considerations for researchers during the drug development process, including:

- Trial conduct
- Data collection
- Study participant safety
- New drug application requirements

"The goal is to help researchers design studies that will yield interpretable results that will be capable of supporting future drug applications," Tiffany Farchione, director of the division of psychiatry at the FDA's Center for Drug Evaluation and Research, said in a statement.
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The guidance also highlights the potential for safety issues and abuse, given that psychedelic substances can produce mood and cognitive changes, or hallucinations.
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Many psychedelics are Schedule I controlled substances that are also regulated by the Drug Enforcement Administration to prevent misuse. Researchers should collect data about the drugs' abuse potential during development, according to the guidance. More at FDA >>

NCBIO Updates

BMF explores resiliency, honors WagnerÂ

NCBIO Chairman Neal Fowler thanks John Wagner for his service to the BMF.

At its June 14 meeting at the NC Biotechnology Center, the NCBIO Biomanufacturers Forum learned lessons of resiliency presented by McKinsey & Co., Novozymes and SAS and recognized John Wagner's eight years of service to the group as BMF program manager. Wagner plans to retire from the role this summer.Â
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Wagner updated members on recentÂ issues the organization is focusing on, including a proposed revamp of the Biomanufacturing Training and Education Center at NCSU called BTEC 2.0, a new logo and website for NCBioImpact and the 2023 Life Sciences Workforce Trends Report released at the recent BIO convention in Boston.Â
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NCBIO President Laura Gunter, BMF Chairman Jon Tucker and NCBIO Chairman Neal Fowler also recognized the contributions and work of BMF Program Director John Wagner, who is retiring. Gunter and Tucker are seeking a successor, and Wagner said he will continue to assist with BMF programming until one is found.Â

The presentations focused on building resiliency within organization, and the featured speakers wereÂ

- Alex Maiersperger, global health care principal, SAS Institute;Â
- Tacy Foster, partner, McKinsey & Co.; andÂ Â
- Jeff Stine, senior manager supply chain operations, Novozymes.Â

More at NCBIO >>

Study projects extensive damage to drug development, jobs, from drug-pricing policies

A new study estimates that there would be 237 fewer FDA approvals of new medicines over the next decade and 1.1 million lost jobs if proposals to expand government-mandated drug pricing policies are implemented.
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The policies include allowing Medicare to set prices for specific drugs five years after FDA approval, which would lead to a significant number of lost therapies, innovation and jobs in the biopharma ecosystem. These proposals are included in the White House's FY 2024 budget as well as the Senate's SMART Prices Act.
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Research firm Vital Transformation modeled the impacts of expanded government-mandated drug pricing policies at five years following FDA approval. The study analyzed the reduction of new drug approvals and loss of jobs if these policies or others similar to them were enacted into law.
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The study found that, if proposed expansions of government-mandated drug pricing policies are implemented, there are serious consequences around the development of and investment in new medicines, and significant job losses in major innovation hubs across a number of states.

- Lost therapies: More than 80 currently available therapies of 121 identified for price setting ? approximately 70% ? would likely not have been developed had the pricing provisions been in place prior to their development.
- Lost innovation: There would be 237 fewer FDA approvals of new medicines or new uses over a 10-year period. Impacts of the proposed policies will be felt most heavily in many areas of unmet need, particularly in oncology, neurology, and rare and infectious diseases.
- Lost jobs and investment: This would result in a loss of 146,000-223,000 direct biopharmaceutical industry jobs and a total loss of 730,000-1,100,000 U.S. jobs across the economy. There would be loss of ecosystem investments into 50 different therapeutic indications.

More at We Work for Health >>

NCBIO Member News

To be included in member news, send information about your organization to David Etchison.

Sen. Mike Woodard talks with United Therapeutics Corporation CEO Martine Rothblatt, Ph.D., at the June 14 unveiling of UT's new net zero energy distribution center located on the company's co-headquarters campus in Research Triangle Park. More >>

AgBiome and Ginkgo Bioworks announced a partnership to optimize the performance of products in AgBiome's pipeline of agricultural biologicals. More >>
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Alcami Corporation appointed Bill Humphries as its new CEO following the retirement of Patrick Walsh. Humphries also joined the company's board of directors. More >>
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Chiesi USA, Inc., in partnership with **Smith Anderson**, will host Cecilia Poston, the Chiesi's 2023 1L Excellence in Diversity Fellow for three weeks this month. While at Chiesi, Cecilia will work alongside the in-house legal team. More >>
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Chimerix, Inc. promoted Mike Andriole, chief business officer and CFO, to president and CEO of the company. He was also appointed to the Board of Directors. More >>
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Cushman & Wakefield's Kathryn Lawn was recognized with a 40 under 40 award by the Triangle Business Journal. Lawn is the firm's executive managing director. More >>
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Eisai Co., Ltd. and **Biogen Inc.** announced that an FDA advisory committee voted unanimously that the data from Eisai's Phase 3 Clarity AD clinical trial confirms the clinical benefit of LEQEMBI (lecanemab-irmb) 100 mg/mL injection for the treatment of Alzheimer's disease. More >>
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The **NC Biotechnology Center** awarded 87 grants and loans totaling $2,283,930 to universities, bioscience companies and non-profit organizations in the third quarter of its fiscal year. More >>
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The **NC Biotechnology Center's** Katie Stember, Ph.D., was recognized with a 40 under 40 award by the Triangle Business Journal. Stember is the center's director of life science economic development. More >>
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Novartis received European Commission approval of Cosentyx (secukinumab) for use in adults with active moderate to severe hidradenitis suppurativa. More >>
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ProKidney Corp. will purchase a 210,000 square foot facility and approximately 22 acres of land in Greensboro to support the company's future commercial manufacturing needs. More >>
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RTI International's James Hunter was recognized with a 40 under 40 award by the Triangle Business Journal. Hunter is the institute's vice president of government relations. More >>
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Sarepta Therapeutics, Inc. received FDA accelerated approval of ELEVIDYS, an adeno-associated virus-based gene therapy for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy. More >>
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SAS and the Texas Department of State Health Services are teaming up to develop new public health dashboards for tracking influenza data across the state, unifying multiple flu surveillance sources into a central visualization platform. More >>

Merck, NC A&T to establish biotech training center at Gateway Research Park

North Carolina Agricultural and Technical State University and Merck announced a collaboration agreement today for Merck to build a biotechnology training center at Gateway Research Park's South Campus in East Greensboro.
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Merck will outfit the facility with the equipment and classroom spaces necessary to provide and enhance academic programming and training for biotechnology careers for North Carolina A&T students. A process laboratory will allow opportunities for students to put knowledge into practice in an advanced discovery setting.
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The 4,025-square-foot facility, expected to be completed in 2024, will include manufacturing and research components with vaccine manufacturing process training for new and existing Merck employees. More at NCBiotech >>

Merck employees. More at NCBiotech >>

BIO's Bob Dearth and NCBIO's Natacha Janvier

The Beckman Coulter table

ADP's Shannon Barnett and Nicole Corrigan

Twisted Ladder

Drinks and deals with Avantor, BIO Business Solutions

NCBIO and Avantor (delivered by VWR) hosted a happy hour June 21 where guests could learn more about the savings delivered by BIO Business Solutions. The event was held at Twisted Ladder, who provided the food and beverages.

Help inform the future of our workforce

The quality of our current and future workforce is increasingly seen as the most important factor in our region’s economic growth and vitality. To address this and improve the employment pipeline, NCBIO is partnering with regional workforce and economic development groups to better understand skills gaps and employer needs.
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We are seeking business owners and HR professionals to participate in the 2023 iteration of the Regional Skills Analysis, which covers both the greater Triangle and Cape Fear regions of North Carolina. The study was previously conducted in both 2020 and 2017. The survey is being conducted by RTI International, an independent nonprofit research institute.

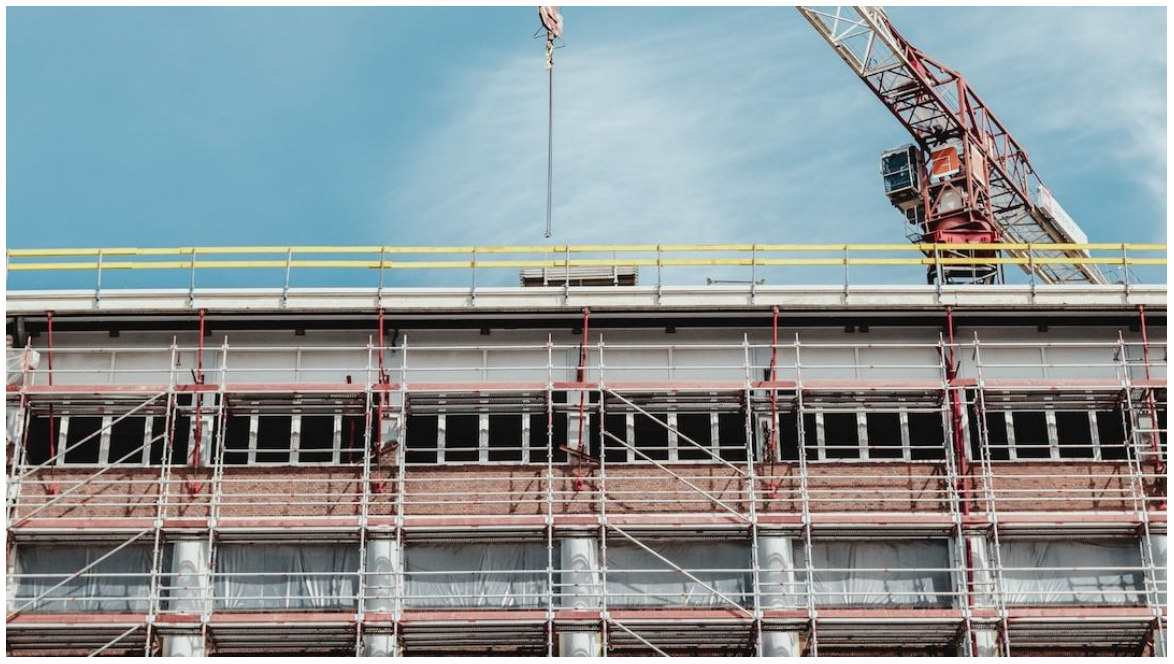
The survey will take approximately 20 minutes to complete. As a thank you for your participation, there are weekly prize drawings for gift cards to local favorites. You will also be entered to win a grand prize of $1,000 to the Umstead Hotel and Spa.

TAKE THE SURVEY

NCBIO attended the June 27 grand opening of the new Azzur Cleanrooms on Demand facility in Morrisville featuring 24 new cleanrooms, storage space with both ambient and controlled temperatures and 24 new office spaces for client use.

On June 21, NCBIO sampled the Purple Tomato bioengineered by Norfolk Healthy Produce to produce high levels of anthocyanins, the powerful antioxidants found in blueberries. These tomatoes were grown by Taylor Garden in Williamston, N.C., one of four trial sites around the country raising this produce. Delicious!

Events



NCBIO Lab Space Luncheon and Forum July 13

The panel will look at the market dynamics, provide an overview of what space looks like (shell space, build to suit or turnkey), who is driving it and what does it mean for a company.
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We will talk about the evolution of RTP and what the next iteration may look like.

- **Carolyn Coia**, vice president, real estate, Research Triangle Foundation
- **Chase Kerley**, managing director, Crescent Communities
- **Alvaro Quintana**, associate principal and designer, Flad Architects
- **Ashley Ingram**, vice president, Jones Lang LaSalle
- **Nathan Swiggett**, project director, McDonald York Building CompanyÂ

Thank you to our sponsors, Clancy & Theys Construction Company, CSC Leasing, Facility Logix, Medical Moving Solutions and PSC Biotech.

REGISTER NOW

Register now for Innovations in Ag: A Regional Perspective, July 19, in Danville, Virginia

In order to foster collaboration, Virginia Bio and NCBIO are bringing together researchers, industry partners, farmers, policy-makers, agribusiness stakeholders, universities and public health representatives under one roof for a half-day conference on Wednesday, July 19, in Danville, Virginia. Come see how your industry peers are growing and working together on the challenges we all face.
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If you register today, July 5, with the code **SUMMER25**, you can save $25.
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The program features four panels on various topics and lightning rounds with companies focused on controlled environment agriculture. The program will highlight leaders from both states. Confirmed speakers are noted below, and additional speakers will be added.
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Regulatory Policy

- **Mitch Peele,** NC Farm Bureau Federation
- **Ben Rowe,** VA Farm Bureau Federation
- **Lisa Zannoni,**Â Zannoni & Associates Consulting

Bio Controls

- **Sajeewa Amaradasa,** IALR
- **Brook Bissinger,** AgBiome
- **Joseph Frank,**Â Agrospheres
- **David Hubert,** Indigo Ag

Bio Stimulants

- **Chuansheng Mei,** IALR
- **Kristi Woods,** Novozymes
- **Brian Miller**, Syngenta
- **Mark Williams**, Virginia Tech

Financing Focus

- **Michelle Bridges,** VDACAS
- **Karen LeVert,** Pappas Capital
- **Melanie Pontier,** CSC Leasing
- **John Reich,** FFAR PIP
- **Paul Ulanch,** NCBiotech (moderator)

CEA Lightning Rounds

- **Nick Genty,** AGEYE Technologies
- **Carl Gubton,** Greenswell Growers
- **John Jackson,** Phlora
- **John Koniski,** AeroFarms

Thank you to the current sponsors: AgroSpheres, Avantor, CSC Leasing, DPR Construction, Hoffman & Baron, SCIEXÂ andÂ Virginia Innovation Partnership CorporationÂ . If you are interested in sponsoring the joint event, please contact NCBIO Events Director Amber Niebauer for more information.Â

REGISTER NOW

Applications due by 7/21/23. Cohort begins in August. Visit CEDNC.ORG to learn more.

Applications open for CED GRO Incubator

Looking for programming and coaching as you kick start your venture? Curious about conducting effective customer discovery to validate your solution? Apply to GRO Incubator by July 21.

If selected, you will attend weekly classes led by subject matter experts and seasoned entrepreneurs, where you will learn how to build a scalable business. Your company will be assigned a coach, and you will receive one-to-one support, collaborate and receive feedback as you progress.

APPLY NOW

Hurry! NCBIO Legislative Forum filling up fast

Hear from the NC Legislative Life Sciences Caucus co-chairs. This is an outstanding opportunity to visit with caucus leadership and discuss the state of our industry.

- Sen. Paul Newton
- Sen. Mike Woodard
- Rep. Donna White
- Rep. Robert Reives

The caucus co-chairs will provide a wrap-up of recent legislative activity with a focus on ongoing economic development initiatives. Additional topics may include discussion of regulatory issues, the One NC Small Business Fund, workforce development, science and technology education and more. The session will be moderated by Laura Gunter, president of NCBIO, and Joe Lanier, principal of Milestone Strategies.Â
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This is your time to help educate and create champions for the life sciences industry. Please bring your questions to the forum and be prepared to interact with caucus leadership.

Thank you to Clancy & Theys Construction Company, North Carolina Research CampusÂ andÂ Ultragenyx for sponsoring this forum.

REGISTER NOW

Bio Events Impact
September 19-20
Raleigh, NC

Apply to present at Raleigh BIO Impact

Looking for an opportunity to showcase your company's achievements in front of an audience

of C-suite level executives in the ag and environment industry? Company presentations at the Raleigh BIO Ag & Environment Conference are an great way to advance your business development goals.

Increase your visibility at BIO Impact 2023 **and attract 2x the amount of meeting requests** in the BIO One-on-One Partnering System by applying for a company presentation.

APPLY TO PRESENT

Ready. Set. Start-Up Stadium.

Start-Up Stadium is a competition for early-stage, emerging biobased companies. Applications are judged by public and private sector experts in early stage investing, entrepreneurship, and the biobased tech landscape.

Finalists present live at BIO Impact to a panel of distinguished investors and event attendees.

If you're a start up in one of these categories, we encourage you to apply.Â

- Food and farm innovation
- Sustainable fuels
- Biobased manufacturing

The deadline to submit your application is July 10, 2023, 5 p.m.

APPLY FOR START-UP STADIUM

Register for Raleigh BIO Impact Ag & Environment

The BIO Impact Ag & Environment Conference will be held Sept. 19-20 in Raleigh This premier event brings together biotech innovators, investors and policy makers focused on strengthening the bioeconomy to meet societal challenges.

REGISTER NOW

Register by July 20 for NCBIO Annual Meeting discount

Register now for this year's Annual Meeting on Oct. 4. Members who register before July 20 will receive a 20% discount off the $50 registration fee (implemented due to rising costs).
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The program features a keynote presentation by **Emily Chee**, U.S. general manager, Novartis Gene Therapies, and three panel sessions.Â

- **Federal Update** featuring ACRO, AdvaMed, BIO, IQVIA and PhRMA
- **Navigating Regulatory Hurdles in Pharma and Food** with Azzur Group, Duke University School of Medicine, Novozymes, Pairwise and Syneos Health
- **The Customer's Journey** moderated by Care4Carolina and features patients impacted by spinal muscular atrophy, sickle cell, cardiovascular disease and diabetes

See the complete list of speakers here. You will have a number of opportunities to connect with attendees during the day. We hope you will join us on Oct. 4.

REGISTER NOW

Thank you to our 2023 Annual Meeting sponsors.

NCBIO calendar

- Deep Tech Innovation Workshop hosted by Hangar6 (7/5/2023)
- Microbial Contamination Control in Bioprocessing Operations hosted by BTEC (7/10/2023 to 7/12/2023)
- Hands-On cGMP Biomanufacturing Operations hosted by BTEC (7/11/2023 to 7/14/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (7/12/2023)
- NCBIO Lab Space Luncheon and Forum (7/13/2023)
- Hands-On cGMP Biomanufacturing of Vectors for Gene Therapy hosted by BTEC (7/17/2023 to 7/20/2023)
- Protein Precipitation and Crystallization hosted by BTEC (7/18/2023 to 7/19/2023)
- Innovations in Ag: A Regional Perspective hosted by NCBIO and VA Bio (7/19/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (7/19/2023)
- Fermentation Engineering hosted by BTEC (7/24/2023 to 7/26/2023)
- Automation, Process Control, and Real-time Monitoring of Yeast Culture hosted by BTEC (7/25/2023 to 7/27/2023)
- PAT for Real-time Culture Monitoring and Closed-Loop Process Control hosted by BTEC (7/25/2023 to 7/27/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (7/26/2023)
- Hands-On cGMP Biomanufacturing Operations hosted by BTEC (7/31/2023 to 8/3/2023)
- Introduction to Design of Experiments (DoE) for Bioprocess Analysis and Optimization hosted by BTEC (8/1/2023 to 8/3/2023)
- NCBIO Legislative Luncheon and Forum (8/1/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (8/2/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (8/9/2023)
- Hands-On cGMP Biomanufacturing of Vectors for Gene Therapy hosted by BTEC (8/14/2023 to 8/17/2023)

Biocair offers free CRO supply-chain report

Contract Research Organizations have become vital partners in the drug development process, enabling biotech and pharmaceutical companies to develop and market life-saving drugs. To further understand the supply chain complexities for CROs, Biocair recently conducted a qualitative research study with CRO supply chain professionals.
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The study involved 45-minute business interviews with supply chain professionals working for CROs. The results of the study have proved instrumental for Biocair in furthering its understanding of the intricacies facing CROs and how logistics play a vital role in the drug development supply chain.

GET THE REPORT

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