



March 2022 Update

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NCBIO This Month

- Life Science Caucus visits NC Research Campus
- State voting maps are set
- Sen. Thom Tillis fights against bad policy
- CMS decision on amyloid therapies is just bad
- Rep. Deborah Ross talks with NCBIO members
- BMF talks commissioning facilities in pandemic
- Register now for NCBIO Roadmap to Diversity event

... and more

Life Science Caucus tours NC Reseach Campus in Kannapolis



Members of the NC Life Science Caucus toured the NC Research Campus in Kannapolis on Wednesday, Feb. 23, along with local leaders and representatives of industry, such as Eli Lilly and Company, which is setting up shop in nearby Concord.

The North Carolina Research Campus is a 350-acre research center and scientific community that collaboratively works to empower human health through nutrition and clinical research. Eight North Carolina universities, the David H. Murdock Research Institute, companies and entrepreneurs focus research and development on safer and more nutritious crops, healthier foods, precision nutrition and clinical research. The tour focused on the work of the NC Food Innovation Lab and on the collaborations between the research campus and the broader community.

State legislators attending were Sens. Natasha Marcus, Vickie Sawyer and Mike Woodard (caucus co-chair) and Reps. Kristin Baker, Mary Belk, Jamie Boles, Mike Clampitt, Rachel Hunt, Carolyn Logan, Robert Reives (caucus co-chair), Wayne Sasser and Harry Warren. Caucus co-chairs Sen. Paul Newton and Rep. Donna White were not able to attend but sent staff on their behalf.

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NCBIO Sustaining Members



NCBIO Supporting Members





STATE UPDATES

Court rulings mean NC political maps are official

The judges overseeing the redistricting lawsuit ruled that they would accept the newly redrawn versions of maps for the N.C. House and N.C. Senate districts that lawmakers passed. The three-judge panel did not accept the new U.S. congressional map. The judges had a group of outside experts draw a new congressional map for the state.

The redistricting map adopted by the trial judges appears to give Democrats a good chance to win a sixth seat, with Republicans in a strong position to win seven seats, according to the Associated Press. One district — stretching from parts of Raleigh south into three fast-growing counties — is a likely toss-up.

Both sides appealed different parts of the ruling, but the N.C. Supreme Court declined to hear them. NC Republican lawmakers have appealed the trial court's decision to the U.S. Supreme Court. Candidate filing for the 2022 election can begin as scheduled.

[More @ N&O >>](#)



NATIONAL UPDATES

Tillis opposes use of march-in rights, questions 'patent thicket' report

Sen. Thom Tillis has been active in opposing a Congressional petition asking the NIH to exercise its march-in rights and in fighting against misinformation regarding the effect of patent protection on drug prices.

Sen. Elizabeth Warren, D-Massachusetts; Sen. Angus King, I-Maine; and Rep. Lloyd Doggett, D-Texas, have asked Department of Health and Human Services Secretary Xavier Becerra to move forward with a march-in petition submitted for Xtandi, Astellas and Pfizer's drug for prostate cancer.

"We write you today regarding calls by certain Congressional colleagues to misuse the government's march-in rights," Tillis [wrote to Becerra](#). "It is hard to imagine a policy more toxic to America's biopharmaceutical innovation than the threatened misuse of march-in rights. March-in rights, exercised inappropriately, would destroy the development of new, innovative and life-saving medications."

Tillis also pushed back against a flawed report from the Initiative for Medicines, Access & Knowledge that blamed "patent thickets" for giving brand-name drugs a purported 30 to 48 years of protection from generic competition.

"But according to at least one new analysis that looks more closely at your figures, you do not transparently disclose or explain your underlying data. and the data differs by orders of

magnitude from public sources," he [wrote to the founder of I-MAK](#). "There appears to be no attempt to provide numbers based on issued patents that actually would extend exclusivity. It also appears that many of the drugs alleged to be protected by 'patent thickets' blocking competition for decades to come have already gone generic"

Tillis followed his letter to I-MAK with a [similar missive](#) to acting FDA Commissioner Janet Woodcock and Drew Hirshfeld, acting director of the U.S. Patent and Trademark Office. NCBIO and nine of its NC-headquartered member companies wrote to Tillis to thank him for his support on this issue.

CMS decision not to cover Alzheimer's treatment a bad one

NCBIO stands in solidarity with patient advocates and industry leaders in opposing the Centers for Medicare and Medicaid Services' proposal to restrict coverage for current and future Alzheimer's drugs and other drugs that attack amyloid, an abnormal protein produced in bone marrow that can be deposited in any tissue or organ. The CMS decision is bad for many reasons.

The current proposal undermines FDA's Accelerated Approval pathway and would make it untenable for developers of novel therapies to pursue FDA Accelerated Approval. CMS's proposal to limit coverage only to patients enrolled in government-approved trials means that the vast majority of individuals suffering from Alzheimer's will have no meaningful access to an approved medicine simply because of where they live and where they go for care.

A [new study](#) from Vital Transformation found that the CMS decision could add three or more years to the process of approving new Alzheimer's therapies for coverage. This delay would have a profound impact on the financial viability of developing and commercializing those treatments successfully. According to the VT model, a three-year delay has the potential to reduce the number of therapies that will provide a return-on-investment by more than 80%.

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Rep. Ross discusses immigration, IP, workforce and more with NCBIO members



Immigration reform, protection of intellectual property, the threat of antimicrobial resistance, workforce training and more were topics covered by [Rep. Deborah Ross](#) at an NCBIO legislative roundtable held Monday, Feb. 14, at the NC Biotechnology Center.

Ross is a Democrat representing the 2nd NC Congressional District comprising Raleigh and southern and central Wake County. She was elected in 2020. She is a member of the House Rules Committee, Judiciary Committee and Committee on Science, Space and Technology.

"In the wake of the pandemic, the scientific community has found itself at the center of the world stage, and we know how much you are needed and how much you are appreciated," Ross said.

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Senate confirms Robert Califf as FDA commissioner

The U.S. Senate confirmed Robert Califf, M.D. by a narrow margin, 50-46, to run the FDA, a post he held in the last year of former President Barack Obama's administration. The Duke-trained cardiologist fills the country's top health regulator post as many leaders have called for a permanent chief. Janet Woodcock, M.D., filled the interim post for 391 days.

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NC BIO Updates

NC BIO welcomes new members

At the Feb. 17 meeting of the NC BIO Board of Directors, board members unanimously voted to accept the following new members:

[Enzyvant](#), based in Durham, is an accelerator for transformative regenerative medicines with a focus on tissue-based therapies for rare conditions.

[Epigenos Biosciences](#), based in Morrisville, is a precision epigenetic gene therapy company that develops personalized epigenome-based therapeutics that leverage Cas9 technology to treat disease at the root of gene misregulation.

[ICON](#), based in Raleigh, is a global provider of outsourced development and commercialization services to the pharmaceutical, biotechnology and medical device industries.

[Medical Moving Solutions](#), with offices in Durham, provides storage, cold storage, inventory management, white glove delivery and lab relocation services.

[Medix Life Sciences](#) is a staffing agency with offices in Durham involved in health care, life sciences, technology and engineering and construction.

[Oblon, McClelland, Maier & Neustadt, LLP](#), based in Alexandria, Virginia, is one of the largest law firms in the United States focusing exclusively on intellectual property law. [Learn more \(PDF\)](#).

[Opus Genetics](#) is a patient-first, science-driven gene therapy company based in Raleigh tackling manufacturing obstacles standing in the way of treatments for ultra-rare blinding conditions.

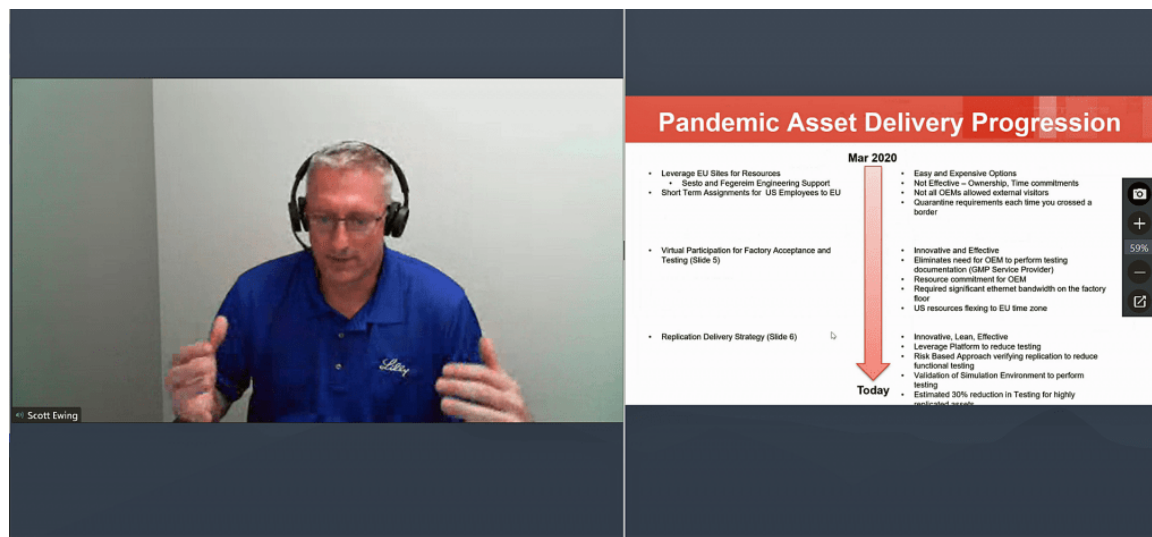
[Sobi](#) (Swedish Orphan Biovitrum AB) is an international biopharmaceutical company dedicated to treatments in the areas of haematology, immunology and specialty care based in Stockholm, Sweden.

[Tanner Pharma Group](#), based in Charlotte, provides specialized pharmaceutical services to pharmaceutical and biotech companies to license and commercialize their products in challenging international markets, develop and manage their Global Access Programs and source comparator drugs for clinical trials and bioanalysis.



Gunter joins NC Women in Science Roundtable

[Business North Carolina](#) magazine, with the help of NC BIO member [Merz Aesthetics](#), recently gathered a panel of experts that included NC BIO President Laura Gunter and panelists from FUJIFILM, Hatteras Ventures, Merck and Merz to discuss the state of women in science, why it's important, how it's changing and what needs to be done to expand it. Business NC released this teaser video with the full version coming out soon.



BMF presenters share lessons learned commissioning facilities during pandemic

At the NCBio Biomanufacturers Forum held online Feb. 23, representatives from FUJIFILM Diosynth Biotechnologies, Eli Lilly and Company and Project Farma shared what they had learned about commissioning new facilities and equipment during the during the COVID-19 pandemic.

Presenting at the meeting were Scott Ewing, an engineering adviser for Lilly; Chris Cassada, a staff engineer with FUJIFILM and Christian Hermanas, Southeast lead for Project Farma.

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New BIO report examines state of antibacterial innovation

BIO released the [State of Innovation in Antibacterial Therapeutics](#) on Feb. 14, a new report examining antibacterial innovation and the current pipeline for new antibacterial medicines, .

The report analyzes the pipeline for new antibacterial medicines, the market's unique investment challenges and potential policy solutions to support the development of new treatments. Key takeaways include:

- Although there have been 164 FDA-approved direct-acting antibacterial new chemical entities since the early 1900s, only one new molecular target NCE has been approved over the last 35 years.
- The breadth and novelty of the antibacterial clinical-stage pipeline is insufficient to meet the ongoing threat of wide-spread infection from drug-resistant strains.
- Small companies discovered 81% of the antibacterial therapeutics being tested in the clinic.
- The calculated success rate from Phase I to FDA approval during the period 2011-2020 was 16.3% for an antibacterial NCE.

[More @ BIO >>](#)

NCBio Member News

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

AgBiome announced a joint development agreement with Lamberti to develop biological crop protection solutions that will provide farmers with tools that maximize the utility of agricultural inputs and minimize the consumption of natural resources. [More >>](#)

AskBio and Touchlight have announced a revised structure to their former joint venture, Touchlight AAV, where both parties benefit from co-exclusive rights to independently supply the adeno-associated virus market with doggybone DNA. [More >>](#)

BD ranked No. 1 in the Health Care Equipment & Services industry in America's Best Large Employers List by Forbes. [More >>](#)

BD completed the acquisition of Cytognos, a privately held company headquartered in Salamanca, Spain, specializing in flow cytometry solutions for blood cancer diagnosis, minimal residual disease detection and immune monitoring research for blood diseases. [More >>](#)

Biogen exercised its option to participate in the development and commercialization of mosunetuzumab. Biogen will pay a \$30 million one-time option fee to Genentech as part of the companies' long-standing collaboration on antibodies targeting CD20. [More >>](#)

Bioventus announced that the FDA has awarded 510(k) clearance to the next generation StimRouter Neuromodulation System for the treatment of chronic pain of peripheral nerve origin, excluding craniofacial pain. [More >>](#)

Cambrex received awards in categories of quality and service from the CMO Leadership Awards, marking the eighth consecutive year Cambrex has received an award. [More >>](#)

Chiesi USA earned the Great Place to Work Certification for 2021 in the U.S., following its first recognition in 2019. The accreditation is awarded by Great Place to Work. [More >>](#)

Cook Medical signed a letter of intent to sell the entirety of Cook's Reproductive Health business within the MedSurg division to CooperCompanies. [More >>](#)

EpiCypher will partner with New England Biolabs to codevelop a first-in-class library prep kit specifically optimized for best performance with their CUTANA CUT&RUN epigenomic assays. [More >>](#)

The **North Carolina Biotechnology Center** awarded 17 grants and loans totaling \$1.3 million to universities, bioscience companies and nonprofit organizations in the second quarter of its fiscal year. [More >>](#)

Pairwise and Tropic Biosciences, a U.K. agricultural technology company focused on tropical crops, announced a deal that will grant access to base editing technologies in order to extend its game-changing potential to critically important crops with major global economic impact. [More >>](#)

Pfizer and BioNTech SE extended their rolling submission to the U.S. FDA seeking to amend the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 vaccine to include children 6 months through 4 years of age, which had been requested by FDA. [More >>](#)

Sage Therapeutics and **Biogen** announced the CORAL Study in people with major depressive disorder met the trial objectives, demonstrating a rapid and statistically significant reduction in depressive symptoms, achieving the primary and key secondary endpoints. [More >>](#)

Smith Anderson will be recognized as a Chambers Global Market Leader for the third year in a row in the Agribusiness chapter of the Chambers Global 2022 guide. [More >>](#)

Thermo Fisher Scientific announced a multiyear partnership with Medidata Acorn AI to develop PPD TrueCast, a comprehensive enterprise application combining extensive patient recruitment and site performance data with predictive models and advanced analytics. [More >>](#)

Thermo Fisher Scientific's PPD clinical research business has been named a winner in Training magazine's 2022 Training APEX Awards, recognizing its robust enterprise learning programs designed to grow employees' skills and drive customers' success. [More >>](#)

Events

NCBIO Roadmap to Diversity in Life Sciences March 9

NCBIO is committed to prioritizing diversity, equity and inclusion and supporting its members on their DEI journeys. In early 2021, NCBIO established a DEI committee and subcommittees to assist with this effort. In August 2021, we held our first DEI Roadmap event with nearly 200 attendees.

NCBIO and its DEI committee members are planning a second hybrid DEI event on March 9 in Research Triangle Park and hope you will join us in person or virtually. The program features a keynote address by Celeste Warren, vice president, Global Diversity and Inclusion Center of Excellence, Merck, along with two panel sessions.

There is no cost to attend for NCBIO members, but you do need to register for the event.

REGISTER NOW

Event Partners



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NCBIO Emerging Company and Technology Forum March 16

Hear from investors at all stages on how to move your technology through the funding phases. Join the conversation to understand what venture capital firms are looking for and what makes a company attractive for financing. Hear from

- Jackie Grant, principal, Abingworth;
- Patrick Jordan, chief executive officer, Mycovia Pharmaceuticals (moderator);
- Randy Myer, managing director, Carolina Angel Network; and
- Christy Shaffer, Ph.D., partner, Hatteras Venture Partners.

Thank you to [Marsh & McLennan Agency](#), [Nikon](#) and [Wyrick Robbins](#) for sponsoring this event.

REGISTER NOW

NCBIO calendar

- [Outlook for Tech hosted by NC TECH \(3/4/2022\)](#)
- [Export Education: How to file an Electronic Export Information \(EEI\) hosted by EDPNC \(3/8/2022\)](#)
- [Innovation in LabOps: The Ultimate Guide to Biotech Incubator Partnerships With LabCentral hosted by Elemental Machines \(3/8/2022\)](#)
- [FDA Forum hosted by MDMA \(3/9/2022 to 3/10/2022\)](#)
- [NCBIO Roadmap to Diversity in Life Sciences \(3/9/2022\)](#)
- [Clinical Supervision Workshop Series hosted by UNC-Wilmington \(3/12/2022\)](#)
- [BTEC Protein Precipitation and Crystallization Course \(3/16/2022 to 3/17/2022\)](#)
- [NCBIO Emerging Company and Technology Forum \(3/16/2022\)](#)
- [Automation, Process Control, and Real-time Monitoring of Yeast Culture \(3/22/2022 to 3/24/2022\)](#)
- [Life Sciences Academic Engagement Night hosted by NCBIO and NC Biotechnology Center \(3/23/2022\)](#)
- [Diversity + Inclusion in Tech Summit hosted by NC TECH \(3/24/2022\)](#)
- [Venture Connect hosted by CED \(4/6/2022 to 4/7/2022\)](#)
- [Clinical Supervision Workshop Series hosted by UNC-Wilmington \(4/9/2022\)](#)
- [BPD Cell and Gene Therapy Symposium & Vendor Show hosted by NCBiotech \(4/14/2022\)](#)

MedTech Conference session proposals due March 4

AdvaMed is seeking session proposals for The MedTech Conference 2022 that are relevant, timely and practical to the medical device, diagnostic and digital health industries. Organizations from or affiliated with the medtech industry are welcome to submit session ideas dealing with the latest trends, advancements and critical issues in the field. The deadline for submissions is Friday, March 4. [Learn More >>](#)

NCBIO members save on MDMA FDA Forum March 9-10

NCBIO is partnering with the Medical Device Manufacturers Association to offer our members a discount on registration for the upcoming FDA Forum being held virtually March 9-10. NCBIO members should use the promotional code "STATE" during registration to save \$100. [Learn More >>](#)

2022 Venture Connect Summit | Thursday, April 6-7 | Cisco Systems Campus RTP

Venture Connect is in-person again! Recognizing the collaboration potential across high growth industries like tech, life sciences, agtech and food innovation, CED is creating an environment that fosters connections through valuable programming and open networking. [Learn More >>](#)



LET'S TALK HEALTH INSURANCE



The new and improved BIO Health Small Group Health Plans available to NCBIO members may be a great fit for your business. Even if you have gotten a quote before, you'll want to see their expanded offerings from multiple carriers.

- Multiple-Carrier Quoting – BIO will shop several well-known local and national health carriers, discuss your needs and find you the best plan options to select from.
- Low Minimums – Enroll for as few as two employees.
- Easy Online Enrollment – Paperless enrollment for you and your employees.
- HR Administrative Portal – Helps you easily manage multiple carriers and plans.

GET A QUOTE



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