



May 2021 Update
Serving the NC Life Sciences Industry

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NCBIO This Month

- Business NC talks biomanufacturing supply chain
- Gov. Cooper delivers State of the State address
- NCBIO legislative agenda
- H.R. 3, MFN pricing is back
- TRIPS waiver warning issued
- Cut waste, abolish paper labeling for clinicians
- New lobbyists join NCBIO
- CED Venture Connect 2021

... and more

- New NCBIO members
- Member news
- Member benefits
- Calendar

NCBIO Sustaining Members



Business NC panel discusses biotech manufacturing supply chain

Business North Carolina held its life-sciences round table discussion recently, bringing together experts in workforce training, higher education, professional services and life-sciences companies via Zoom to discuss the industry.

The discussion was sponsored by NCBIO and FUJIFILM Diosynth, among others, and will be featured in the May issue of the magazine. Until then, you can tune in to this video featuring **Doug Edgeton** of NC Biotech, **Gary Gilleskie** of BTEC, **Leslie Isenhour** of Wake Technical Community College, **Matthew Roberts** of Nexsen Pruet, **Christine Vannais** of FUJIFILM Diosynth and **John Wagner** of the NCBIO Biotech Manufacturers Forum.



NCBIO Supporting Members





STATE UPDATES

State of the State, budget and NCBIO's legislative priorities

On Monday, April 26, the House and Senate held a joint session and invited Gov. Roy Cooper to give his State of the State address. Much like in his 2019 speech, Governor Cooper called for increases in teacher pay and Medicaid expansion. After the [Apple campus announcement](#) from earlier that morning, Governor Cooper also called for more bipartisan common ground and would like to see a budget passed this year with the three signatures: his, Senate leader Phil Berger's, and House Speaker Tim Moore's.

The General Assembly has begun budget discussions after receiving Cooper's budget proposal at the end of March. This year, the first pass at the legislature's budget will come from the Senate. Talk continues that recurring dollars will be tight, but that nonrecurring funds will be more available.

NCBIO continues to share with our legislature that the life science industry is a transformational and innovative industry, and we are bringing good paying jobs to North Carolina. NCBIO's legislative agenda is progressing as follows:

One NC Small Business Program

This matching state grant program to recipients of SBIR/STTR awards has a filed bill in the Senate and a complimentary one is being filed in the House shortly. It includes some statutory changes that bring the program up to 2020 standards from the original in 2005, as well as \$2 million in recurring funds and \$7 million in nonrecurring funds. We ultimately expect these bills to roll into the budget.

NCBiotech Funding

NCBiotech has received \$13.6 million in recurring funding since 2014. This year, NCBiotech is seeking \$500,000 in additional recurring funds and \$3.5 million in nonrecurring funds to enhance early entrepreneurial company growth, to expand grant and loan programs, to augment programs to bring nontraditional workers to biomanufacturing jobs and to recruit new life science companies to North Carolina.

Workforce

The next Life Science Caucus meeting, scheduled for May 5, will highlight talent and workforce needs. FUJIFILM Diosynth Biotechnologies and BioAgilytix will provide an overview of their growth and job needs to give the General Assembly a good picture of the breadth and depth of opportunities. NCBIO, in conjunction with our partners, NCBiotech, BTEC, BRITE and BioNetwork; have prepared a list of support items that includes funding for the university system and the community college system to continue to fill the pipeline of trained workers.

In addition to these items, NCBIO is tracking a PBM transparency bill (S257), several tort reform bills (including S477 regarding contributory negligence), PFAS bills, a reinstatement of the Qualified Business Venture tax credit (H680) and a possible fund of funds.

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

State government roundup

- Governor Cooper has issued an executive order easing more COVID-19 restrictions for the month of May. With stable trends and continued vaccination success, the state plans to lift mandatory social distancing, capacity and mass gathering restrictions by June 1. The one restriction in question is the indoor mask mandate, which will continue until at least two-thirds of NC adults have received at least one shot of the COVID vaccine.
- After 42 years of service, Director of the N.C. Division of Emergency Management Mike Sprayberry, has announced he will be retiring on August 1st. He has been the director of the Emergency Management Division since 2013.



NATIONAL UPDATES

H.R. 3 is back, putting MFN drug pricing before Congress

On April 22, House Democrats reintroduced H.R. 3, a sweeping drug pricing bill. In a nutshell, H.R. 3 would require drug manufacturers to negotiate prices with the government based on an international price index of prices paid in several other countries. [Here's Speaker Nancy Pelosi's explanation of what's in the bill.](#)

This is the same H.R. 3 that House Democrats passed in 2019 and stalled in the then-Republican-controlled Senate.

The Council of State Bioscience Associations released a report analyzing the potential impact of various drug pricing proposals on patient access to lifesaving medicines, future biomedical innovation, and the economic health of the life sciences industry.

The study, which was conducted by Vital Transformation, an international health economics firm, examines the negative effects of bills like “Lower Drug Costs Now Act of 2019” and other foreign reference pricing models had they been enacted. The research finds that, had a bill like the “Lower Drug Costs Now Act of 2019” been in place from 2009-2019:

- A group of 68 innovative therapies that had been developed by small and emerging biotechs and approved during that time frame would have been reduced to only 7, leaving critical health care gaps for millions of Americans.
- New medicines for some of the most difficult conditions to treat, including in rare diseases, oncology, and neurology, would be disproportionately impacted.
- Biopharmaceutical industry job losses alone would total nearly 191,000, with total job losses across the economy of more than 950,000 when indirect effects are included.
- Triggering these losses would be the sharp drop in U.S. biopharmaceutical industry earnings (a 62% reduction, or \$125 billion in 2024 alone) caused by the bill, leading to large reductions in established companies' ability to invest in small and emerging biotechs, chilling drug development.

NCBIO worked with CSBA to create a full page ad that appeared in the Raleigh News & Observer on Thursday, April 8; Sunday, April 11; and Monday, April 12. NCBIO also put out a press release outlining some of the problems with H.R. 3, which was picked up by [WRAL TechWire](#).

You can read the NCBIO press release and access the Vital Transformation report [on our website](#).

[MORE >>](#)

BIO cautions US officials against IP waiver for vaccines

India, South Africa and [some U.S. senators](#) claim that a waiver of the WTO Trade-Related Aspects of Intellectual Property Rights agreement would facilitate COVID-19 vaccine development. But as Hans Sauer, BIO's deputy general counsel for intellectual property, explained in [an article published by IP Watchdog](#), IP rights enable development.

BIO President and CEO Dr. Michelle McMurry-Heath sent a letter to U.S. Trade Representative Ambassador Katherine Tai to explain why the World Trade Organization's proposed TRIPS waiver would have global health and economic consequences as the pandemic rages on.

BIO agrees on the need for access, calling for the U.S. and other countries to prioritize the distribution of medicines to the most at-risk patients around the globe. However, federal agencies

distribution of vaccines to the most at-risk patients around the globe. However, forced transfer of vaccine technology by WTO members will only impel countries to try to go it alone in terms of supplying vaccines, resulting in supply and capacity problems.

BIO is urging the United States to devote significantly more resources to multilateral and unilateral efforts to procure vaccines for low-and middle-income countries.

You can read the full letter [here](#).

[MORE >>](#)

Paper prescribing info for clinicians is a waste

Providing outdated and wasteful paper prescribing information to pharmacists and prescribers when they can — and do — obtain the most up-to-date prescribing information online is an obsolete and harmful practice.

FDA-approved information for prescribers includes detailed technical information about a drug's molecular structure, along with its approved uses, dosing, expected side effects, warnings, contraindications and precautions. The prescribing information is different than patient labeling for the patient. The FDA requires prescribing information to be provided on or within each package of prescription medication from which the drug is to be dispensed.

These labels have been available online for 15 years, which is how the majority of practitioners have been accessing the most up-to-date prescribing information. The labeling can range from a few pages to more than 100 and is often out of date. It may lack the most recent warnings or contraindications necessary for safe use of the drug. Prescribing labels have been available on the National Library of Medicine's [DailyMed website](#) since 2005.

DailyMed should have made the practice of printing paper labels obsolete. At the behest of the paper industry and companies that specialize in printing and folding label inserts, Congress has perennially blocked the FDA from following through with a proposed 2014 rule to eliminate the paper requirement and require electronic distribution of prescribing information.

Opponents of eliminating paper labeling argue that paper must be available for pharmacists and physicians who practice in rural areas and who may lack online access. This issue is easily resolved by providing paper prescribing information to practitioners who request it.

NCBIO is signing on to a letter spearheaded by the [Alliance to Modernize Prescribing Information](#) encouraging Congress to step aside and let the FDA take the actions necessary to best serve practitioners, patients and the environment.

[MORE >>](#)

NCBIO Updates

New lobbyists join NCBIO team

NCBIO has retained two lobbyists to advocate for its members before the N.C. General Assembly.

[Joe Lanier](#) is the founder and principal of [Milestone Strategies](#), a leading boutique government relations firm based in Raleigh. He represents clients in state and federal government relations issues with a particular focus on matters coming before the North Carolina state government. Lanier has more than 25 years of federal and state government affairs experience in both the public and private sectors

[Lindsey Dowling](#) is the founder and president of Dowling Strategies, a lobbying firm in Raleigh. Lindsey has several years of state and local government relations experience. She serves clients on a variety of government affairs matters, including in the areas of healthcare, insurance, tax policy, appropriations, transportation, and government procurement before the North Carolina General Assembly and executive branch.

New NCBIO Members

- [9 Meters Biopharma, Inc.](#) is focused on developing therapies for gastrointestinal disorders that are rare, orphan, and have high unmet need.
- [Alexion Pharmaceuticals, Inc.](#) is a Connecticut-based pharmaceutical company best known for its development of Soliris, a drug used to treat the rare disorders atypical hemolytic uremic syndrome and paroxysmal nocturnal hemoglobinuria. The company is also involved in immune system research related to autoimmune diseases.
- [Athem, LLC](#)'s goal is to provide innovative solutions to solve medical and bioprocessing challenges. They strive to provide unmatched quality and support to

their customers through automated immunoglobulin isolation from donors and downstream purification of mAbs.

- [BioAgilytix Labs](#) is a leading bioanalytical CRO specializing in biomarkers, cell-based assays, immunogenicity and pharmacokinetics.
- [Ci Design, Inc.](#) is an international architectural design firm offering award-winning planning, architecture, interior design, landscape architecture and graphic design services over a diverse range of projects, spanning from mixed-use complexes incorporating retail, office, and residential to the complexities of life sciences and technology facilities.
- [Curie Co., Inc.](#) is a synthetic biology company that's creating solutions to replace preservatives and biocides with sustainably derived ingredients that increase product shelf life.
- [Keystone Compliance](#) is a full-service regulatory compliance laboratory offering solutions for nearly all EMC/EMI, environmental, ISTA-certified package and ingress protection testing requirements. Keystone prides itself on being the engineer's laboratory due to our focus on the four main points of a lab; staff, facility, equipment and location.
- [Mallinckrodt Specialty Generics](#) is a manufacturer of active pharmaceutical ingredients and finished-dose generic drugs based in Missouri.
- [North Carolina Ports Authority](#)'s mission is to enhance the economy of the State of North Carolina. The Ports Authority will be managed like a business, focused on the requirements of its customers. North Carolina's Ports are recognized for self-sustaining operations, environmental stewardship, highly efficient workforce, satisfied customers, and modern, well-maintained facilities and equipment.
- [Ribometrix](#) is a biotechnology company pioneering a completely new class of small molecule therapeutics that directly target and modulate the function of RNA to treat human diseases.

Member News

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

Baebies' diagnostic platform FINDER has been named a Medical Design Excellence Awards finalist. [MORE >>](#)

Baebies will receive up to \$11.6 million in funding from CARB-X to develop a near-patient and rapid diagnostic platform for sepsis specially focused on addressing the unique needs of neonatal and pediatric populations. [MORE >>](#)

Biocryst Pharmaceuticals, Inc. received approval from the Japanese National Health Insurance System to add oral, once-daily ORLADEYO™ (berotralstat) to the NHI drug price list. [MORE >>](#)

Biogen Inc. will offer compassionate-use access to toferson, the company's potential treatment for SOD1-ALS currently in Phase 3 trials, for a subset of the ALS population with the most rapidly progressive disease starting in mid-July, [MORE >>](#)

Biogen Inc. announced new data from the SPINRAZA (nusinersen) clinical development program aimed at optimizing outcomes for people with spinal muscular atrophy and advancing understanding of the disease. [MORE >>](#)

Biogen Inc.'s TECFIDERA® (dimethyl fumarate) has been approved by China's National Medical Products Administration for the treatment of relapsing multiple sclerosis. [MORE >>](#)

Biogen Inc. has been granted marketing authorization for a subcutaneous injection of TYSABRI® (natalizumab) by the European Commission to treat relapsing-remitting multiple sclerosis. [MORE >>](#)

G1 Therapeutics, Inc. announced that Clinical Lung Cancer has published the final pooled results from three clinical trials of COSELA (trilaciclib) in extensive-stage small cell lung cancer. [MORE >>](#)

Humacyte announced the execution of a definitive business combination agreement along with a fully committed PIPE financing with Alpha Healthcare Acquisition Corp. The new company will keep the Humacyte name. [MORE >>](#)

Inivata entered a commercialization agreement with Agendia, Inc. giving Agendia co-exclusive rights to distribute Inivata's RaDaR® liquid biopsy assay for breast cancer. [MORE >>](#)

Mayne Pharma announced that the FDA has approved NEXTSTELLIS, its contraceptive pill containing E4, a naturally occurring estrogen, now produced from a plant source. [MORE >>](#)

NALA Systems was awarded \$1,000,000 in nondilutive phase II SBIR funding from the NSF for unique chlorine tolerant membranes for industrial and municipal users of reverse osmosis. The technology will provide more efficient and sustainable desalination and water purification

operations using RO. [MORE >>](#)

Novozymes has signed a new food ingredients agreement with Univar Solutions to expand its reach across multiple markets in North America. [MORE >>](#)

Pappas Capital saw the fifth company in its portfolio go public in April as Reneo Pharmaceuticals debuted at \$15 a share. [MORE >>](#)

Pappas Capital also saw **Pfizer Inc.** acquire Amplyx Pharmaceuticals from Pappas' portfolio. Amplyx's lead compound is under development for the treatment of invasive fungal infections. [MORE >>](#)

StrideBio, Inc. signed a multitechnology collaboration with Duke University that will enable novel next-generation gene therapies against a broad range of disorders. [MORE >>](#)

Thermo Fisher will acquire **PPD, Inc.** for \$17.4 billion or \$47.50 per share. The transaction is expected to be completed by the end of the year. [MORE >>](#)

vTv Therapeutics announced that the FDA has granted breakthrough therapy designation for TTP399 as an adjunctive therapy to insulin for the treatment of type 1 diabetes. TTP399 is a novel, oral, investigational once-daily glucokinase activator. [MORE >>](#)



Four Steps to Saving with Your NCBIO Membership

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

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

For all the latest news, promos and event information, follow [BIO Business Solutions on LinkedIn](#).

BIO Business Solutions Highlights

GET STARTED



Avantor adds PROchievA to J.T. Baker family of resins

Avantor announces the new J.T.Baker BAKERBOND PROchievA resin that uses a novel, proprietary ligand to provide best-in-class purification in critical protein A affinity chromatography process. Used with Avantor's proven J.T.Baker family of process chromatography buffers and additives, the BAKERBOND PROchievA resin can provide biopharma operations with great efficiencies and higher purity profiles within the downstream chromatography step.

Features include:

- Proprietary ligand developed exclusively by Avantor with demonstrated first-class dynamic binding capacity for mAbs and improved protein purification capability in other emerging molecules while providing an independent supply chain with global distribution
- Bound to a standard agarose backbone for ease-of-use and supply reliability

- Delivered in a nonhazardous and nonflammable buffer solution as a standard offering to eliminate burdensome handling requirements
- Enables purification process efficiencies when used with other Avantor J.T. Baker BAKERBOND resins

Avantor's J.T.Baker brand chromatography resins and cGMP chemicals allow biopharma manufacturers to realize higher production efficiencies, meet stringent regulatory requirements and accelerate regulatory approval in bringing new mAbs to market.

[LEARN MORE](#)



Humboldt leverages experience and nationwide reach of United Van Lines

Humboldt Storage and Moving, a long-time program partner of BIO, provides preferred discounts on moving, storage and logistics services for members. As a United Van Lines agent, Humboldt is proud to inform you that BIO members also have access to the nationwide reach of United — America's #1 Mover.

What this means that for NCBIO members is that United Van Lines will take the lead, working in collaboration with the Humboldt team to ensure a high level of service and seamless move management for all your relocation needs. With services from movers at more than 300 locations across the country, United Van Lines offers all the benefits you would expect from an industry leader.

- Laboratory, office, and employee relocations
- Coordination of regulatory compliant, climate-controlled specimen relocation for laboratory moves
- A strong nationwide network providing comprehensive household goods moving solutions
- Guaranteed pickup and delivery to minimize downtime on all relocations

When it's time for you to make a move, contact us at Bio@UnitedVanLines.com or 1-800-537-8684 to get a quote.

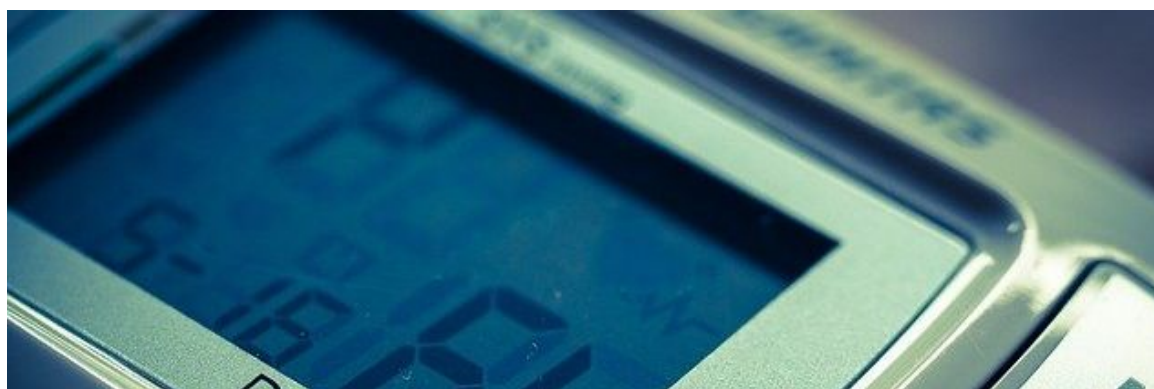


Office Depot offers Aera Max professional air purifiers for virus defense

The rapid spread of viruses has forced us to re-imagine the meaning of a safe facility. A complete hygiene solution should combine air, surface and hand cleaning to help protect against person-to-person virus transmission. AeraMax Professional commercial grade air purifiers provide maximum protection and ultimate peace of mind with true HEPA filters that can capture 99.97% of all airborne contaminants, including airborne viruses. Clean the air you share with Fellowes AeraMax Professional air purifiers.

Learn more at business.officedepot.com or call 888-263-3423.

Upcoming Events





NCBIO Medical Device Forum

Wednesday, May 19
12 - 1:30 p.m.

Although we are in a pandemic, patient needs continue unabated and often are made more dire by the intense focus on COVID that investments, regulatory bodies and government are taking. There are important life-saving technologies, still in various stages of development, that companies are attempting to guide through a process fraught with barriers in the best of times and now struggling against the immediacy of COVID.

Our panelists will share their insights on staying the course, getting funding, regulatory approval and a product to market when the product is not COVID related.

- **Julie Fife**, vice president, program management, [Grant Engine](#) (moderator)
- **Don Gurskis**, chief executive officer and cofounder, [Arctx Medical](#)
- **Kendall Foster**, vice president, technical operations, [ApiJect](#)
- **Alyssa Schmidt**, associate director, global regulatory consulting, [Syneos Health](#)
- **Tony Voiers**, chief executive officer, [Advanced Chemotherapy Technologies](#)

Sponsored by
[Brex](#), [Jenkins Wilson Taylor & Hunt](#) and [PSC Biotech](#)

[REGISTER NOW](#)



BIO Digital

June 10-11 & 14-18

BIO Digital is the world's largest virtual biotech partnering and education event, convening thousands of global biotech leaders and innovators. Join us in our efforts to accelerate a BIO-Revolution through global partnerships, collaboration, and thought leadership. A discounted rate is still available if you register by May 16.

[REGISTER NOW](#)





Digital Medtech Conference May 6

Renowned experts and thought leaders will gather virtually on May 6, 2021 to take a hard look at the state of digital medtech in the wake of COVID-19 and beyond. Join us online for this interactive, one-day conference and meet the minds pushing our industry forward. Reserve your spot today using code **SPO10** for 10% off standard registration pricing!

[REGISTER NOW](#)

NCBIO Calendar

- [MedTech Conference hosted by AdvaMed \(5/6/2021\)](#)
- [A Conversation About Corticosteroids hosted by CureDuchenne \(5/6/2021\)](#)
- [Larger than Life Science: Compensation Confidential - Life Science 2021 Update hosted by LaunchBio \(5/6/2021\)](#)
- [Alcami Lab Open House \(5/11/2021\)](#)
- [State of Technology hosted by NC TECH \(5/12/2021 to 5/13/2021\)](#)
- [Using Existing Data to Compete in the Age of Digital Transformation hosted by EDPNC \(5/12/2021\)](#)
- [BTEC Biopharmaceutical Assay Essentials Course \(5/18/2021 to 5/21/2021\)](#)
- [SAS Global Forum \(5/18/2021 to 5/20/2021\)](#)
- [Larger than Life Science: Funding Fundamentals Part 1 - Early Stage Strategies hosted by LaunchBio \(5/18/2021\)](#)
- [The Magic of IoT in Healthcare and Medical Devices hosted by Hangar6 \(5/19/2021\)](#)
- [NCBIO Medical Device Forum \(5/19/2021\)](#)
- [Application Tips & Resources to Help Secure SBIR & STTR Funding hosted by NCATS \(5/19/2021\)](#)
- [Regulatory Strategies in Global Pediatric Drug Development hosted by NCRAF \(5/20/2021\)](#)
- [Duke Population Health Summer Institute \(6/7/2021 to 6/11/2021\)](#)
- [BTEC Biopharmaceutical Lyophilization and Spray Drying Course \(6/8/2021 to 6/11/2021\)](#)

Partners

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