



**DEC 2020
UPDATE**

**Serving the NC Life
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NCBIO This Month

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Wishing safe and healthy holidays to all

The year 2020 has been an interesting time for all of us. We appreciate your support throughout the year as we have worked to deliver you information about state activities on COVID-19, provide ongoing forums and the annual meeting and ensure you had the resources you needed on state and federal policies. We send our best wishes for a safe and healthy holiday season and look forward to working with you in 2021: Sam Taylor, Laura Gunter, Casey Nelson, Amber Niebauer, David Etchison, Brenda Summers and John Wagner.

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NCBIO speaks out against MFN drug-pricing executive order

A new executive order from the Trump administration that slashes Medicare payments to hospitals and physicians for certain medicines will hurt patients' access to care and financially stress already overburdened hospitals and innovation-based pharmaceutical companies, according to NCBIO.

NCBIO - Media

Find the latest news from NCBIO on the website ncbioscience.net, on [LinkedIn](#) and on Twitter at [@ncbio](#).

NCBIO Links

- [CED](#)
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- [North Carolina Pharmaceutical Services Network](#)
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- [National Center for Biotechnology Workforce](#)

NCBIO Sustaining Members



Biogen

"By reducing reimbursement, it's going to be very difficult for smaller hospitals and medical practices, particularly those in rural areas, to provide patients with all the medicines that they need," said NCBCIO President Sam Taylor. "Even as pharmaceutical companies reduce prices, the other parts of the most-favored-nation rule will likely work to limit patient access to both existing and new life-saving medications." [MORE](#)

Dr. Michelle McMurry-Heath, president and CEO of the Biotechnology Innovation Organization, also spoke out against the executive order.

"The president's routine politicization of science has needlessly hurt our nation's response to the pandemic," she said. "Now, in the waning days of his administration, the president is rushing to impose arbitrary foreign price controls on the very researchers trying to develop vaccines and treatments to end this public health crisis." [MORE](#)

Stephen Ubl, president and CEO of the Pharmaceutical Research and Manufacturers of America, also weighed in.

"It defies logic that the administration is blindly proceeding with a policy that gives foreign governments the upper hand in deciding the value of medicines in the United States," Ubl said. "History proves that when governments take unilateral action to set prices, it disrupts patient access to treatments, discourages investment in new medicines and threatens jobs and economic growth." [MORE](#)

On December 4, BIO, the California Life Sciences Association, and BIOCOM California filed a challenge against the attempt by the Department of Health and Human Services to implement the MFN reimbursement policy for certain drugs administered by Medicare Part B providers. The change in policy would drastically alter this system in ways that will harm its ability to serve America's most vulnerable senior citizens. On the same day, PhRMA, the Association of Community Cancer Centers, the Global Colon Cancer Association and National Infusion Center Association filed a lawsuit in the U.S. District Court for the District of Maryland asserting that the Most Favored Nation Interim Final Rule exceeds the statutory authority provided to the Centers for Medicare and Medicaid Services, raises serious constitutional questions and improperly fails to follow required rule-making procedures.

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NCBCIO announced new board chairman, members

Neal Fowler, CEO of Liquidia Technologies, is the new chairman of the NCBCIO Board of Directors, and five new members have joined the board. New officers and the 2020-21 executive committee were elected at the board meeting November 12.

The new board members of NCBCIO are Bekki Brown of Syneos Health, Sinu Bhandaru of Precision Biosciences, Inc., Sholeh Ehdaivand of LMK Clinical Research Consulting and Julie Meigs of Womble Bond Dickinson. They are each starting a new three-year term on the board. Additionally, Daniel Amburn of UCB Biosciences is beginning a new term after filling a vacated seat earlier in the year, and Bennett Love of BioKier, Inc. will step in for two years to fill an open seat on the board. [MORE](#)

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How the election affects the life science industry

Drug pricing will continue to be an issue at the federal level. President Trump has pushed ahead with his executive order on most-favored-nation status. The order adopts international reference pricing for certain prescription pharmaceuticals and could impair innovations and investments in the bio/pharma industry. Democrats in Congress are also expected to push for some type of drug-pricing reform.

Republican U.S. Senator Thom Tillis, a strong supporter of the industry, won re-election. The delegation to the House of Representatives will comprise eight Republicans and five Democrats. New representatives are Deborah Ross (D-2nd), Kathy Manning (D-6th) and Madison Cawthorn (R-11th). Representatives George Holding, Mark Walker and Mark Meadows did not seek re-election.

Gov. Roy Cooper won re-election. North Carolina will again have a Republican lieutenant governor, Mark Robinson. Republicans continue to hold the majority in the N.C. General Assembly. Democrats gained one seat in the Senate (28 Republicans and 22 Democrats). Republicans gained four seats in the House (69 Republicans and 51 Democrats).



Lilly



Pfizer



We Work For Health



NCBCIO Supporting Members

Cook Medical



Grail



Merck



Novartis



VWR



All four co-chairs of the Legislative Life Science Caucus were re-elected:

- Senator Paul Newton, R (Cabarrus, Union)
- Senator Mike Woodard, D (Durham, Granville, Person)
- Representative Donna White, R (Johnston)
- Representative Robert Reives, D (Chatham, Durham)

When lawmakers return in January, they will focus on a budget deficit unless there is additional federal stimulus money. Local governments, education institutions and other areas have seen reductions in revenues because of the economic impact of the pandemic. NCBIO will cover the upcoming General Assembly in the January newsletter.

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NCBIO names new communications director

NCBIO has named David Etchison as its new communications director. Etchison has more than 25 years of experience in communications, public relations and marketing. Brenda Summers, Ed.D., who has served as NCBIO's director of communications since 2004, will continue in a new role. [MORE](#)

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BIO Business Solutions webinar explores imaging with AI, EQMS transitions, single-use supply chains

Single-use supply chain strategy, moving to an electronic quality management system and applying AI and machine learning to microscopy were the topics discussed during the virtual BIO Business Solutions Spotlight webinar presented by NCBIO for its members Wednesday, Oct. 28. [MORE](#)

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CRO Forum explores virtual, decentralized clinical trials

A COVID-resilient environment and clinical trials was the topic of discussion at a virtual forum hosted by NCBIO November 19.

The concept of virtual or decentralized trials has been around for a while, but COVID-19 forced companies and the FDA to act. Biopharma, regulatory and CRO representatives shared their perspectives on decentralized trials, their challenges and limitations, and on COVID-19 as a catalyst for clinical development change.

The session was moderated by Phil Collis, Ph.D., vice president, global development at BioCryst Pharmaceuticals, and featured Amy Cramer, director, global product development strategic partnerships at Pfizer; Tina Papagiannopoulos, associate with Foley Hoag; Kristen Pappas, associate director at bluebird bio, and David Tripi, vice president, innovation and customer engagement lead, at IQVIA. [MORE](#)

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LaunchBio webinar addresses implicit bias and workplace tensions

November's Let's Talk About webinar hosted by LaunchBio explored implicit biases and workplace tension. Panelists shared examples of implicit biases, coached participants in having open discussions about race and negative experiences in the workplace, covered creating an inclusive workplace culture and discussed what companies can do to lead change. Let's Talk About is a LaunchBio webinar series that explores the experiences of People of Color in the life sciences. [MORE](#)

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BMF shares environmentally sustainable best practices

Cutting manufacturing steps to reduce carbon footprint and adopting other environmentally sustainable practices were among the topics shared at the quarterly NCBIO Biotech Manufacturers Forum. [MORE](#)

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Regional Skill Analysis: Job growth to continue

NCBIO members were among those participating in the Regional Job Skills Analysis conducted by the Wake County Economic Development, the City of Raleigh and Capital Area Workforce Development Board with the help of RTI International. Eighty-five percent of the life science companies participating in the survey predicted their companies will be hiring more employees in next three years. [READ THE REPORT](#)

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2020-21 FAST Program open

To increase the success of North Carolina companies with SBIR/STTR grants success, First Flight and scientific consultants from Eva Garland Consulting are offering education seminars in December and January on how to submit and win SBIR/STTR grants. [MORE](#)

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Register now for CED Venture Connect

Venture Connect Online is a digital experience designed to maximize the visibility of your company and help you build relationships with people (investors, peers, customers and partners) who can help you scale. This year CED has expanded their offering to include live interviews with pitch companies, virtual tables with recorded pitches, scheduled or on-demand meetings with attendees and networking opportunities in each session. [MORE](#)

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NCBiotech awards \$600,000 in grants and loans

The North Carolina Biotechnology Center awarded 11 grants and loans totaling \$623,136 to bioscience companies, universities and nonprofit organizations in the first quarter of fiscal year 2021. [MORE](#)

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National News and Events

BIO reveals new strategic vision

The Biotechnology Innovation Organization announced a new, strategic direction that will help guide it to achieving long-term goals while maintaining responsiveness to changing political headwinds.

BIO President and CEO Dr. Michelle McMurry-Heath said, "We need to be the face and the voice of science—speaking up for the millions of families around the globe who depend upon our success. That means being bold, memorable, and—at times—provocative. But if we are as proud of our scientists and as committed to our patients and consumers as I know we are, then it is not only the best tactic, it is our duty." [MORE](#)

BIO Partnering @ JPM

January 11-15, 2021

BIO is once again offering affordable access to BIO One-on-One Partnering during [2021 JPM Week, January 11-15](#). This unique industry service, free for BIO members and only \$150 for nonmembers, allows your company to connect with biotechs, investors, in-licensors, medical device and medtech companies and other life science leaders, regardless of whether you are registered for a specific event during JPM week.

BIO CEO & Investor Digital Conference

February 16-18, 2021

For more than 20 years, the BIO CEO & Investor Conference has fueled biotech industry networking with premier investor and banking communities, focused on established and emerging publicly traded and select private biotech companies. With a

robust landscape of BIO and investor events taking place over the next six months, now is the time to develop a strategic sponsorship platform that allows you access to BIO's global network of biopharma leaders. BIO Members receive the greatest discounts to attend BIO events. Email BIO at biomember@bio.org to request your 20% discount code or join today! [MORE](#)

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New Members

During the November NC BIO Board of Directors meeting, the following six companies joined the organization as members:

- [Elemental Machines](#) offers a sensor-based platform that can be used to gather and assess critical equipment and environmental parameters that can and do affect critical processes, often making them irreproducible.
- [GRAIL](#) is a healthcare company whose mission is to detect cancer early, when it can be cured.
- [Kriya Therapeutics](#) is a next-generation gene therapy company focused on developing transformative treatments for highly prevalent serious diseases.
- [Mycovia Pharmaceuticals](#) is a late stage emerging biopharmaceutical company dedicated to recognizing and empowering those living with unmet medical needs by developing novel therapies.
- [Polsinelli](#) is an Am Law 100 firm with 900 attorneys in 21 offices nationwide with a focus on health care, financial services, real estate, intellectual property, middle-market corporate, labor and employment and business litigation.
- [Precision Biosciences](#) is a clinical stage biotechnology company dedicated to improving life with its novel and proprietary ARCUS genome editing platform.

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Member News

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

Asklepios BioPharmaceutical, Inc., a US-headquartered biopharmaceutical company specialized in the research, development and manufacturing of gene therapies across different therapeutic areas, was acquired by Bayer AG. [MORE](#)

BioCryst Pharmaceuticals, Inc. announced that the United Kingdom's Medicines and Healthcare Products Regulatory Agency has granted oral, once-daily berotralstat a positive scientific opinion through the Early Access to Medicines Scheme. [MORE](#)

Biogen Inc. has been ranked the number one biotechnology company on the Dow Jones Sustainability World Index for the fifth time, more than any other biotechnology company. [MORE](#)

Biogen Inc. and **Sage Therapeutics, Inc.** announced that they have executed a global collaboration and license agreement to jointly develop and commercialize zuranolone (SAGE-217) for major depressive disorder, postpartum depression and other psychiatric disorders and SAGE-324 for essential tremor and other neurological disorders. [MORE](#)

Cambrex is expanding its mid-scale and large-scale API manufacturing capacity in Charles City, Iowa. The \$50+ million investment is designed to meet the continually growing demand for small molecule drug substance development and manufacturing. [MORE](#)

Chiesi USA, the U.S. affiliate of Chiesi Farmaceutici S.p.A., an international research-focused health care group (Chiesi Group), has announced the appointment of Jon Zwinski as general manager and chief executive officer of Chiesi USA to advance the company's global therapeutic efforts. [MORE](#)

CureDuchenne Ventures announced an investment in Mesentech, a company based in Vancouver, Canada, that has a novel therapeutic approach for improving bone density and strength. CureDuchenne will be hosting a webinar with Mesentech on December 10, entitled, "Mesentech and The Importance of Bone Health." [MORE](#)

Humacyte appointed Laura Niklason M.D., Ph.D. as president and CEO. Jeffrey Lawson M.D., Ph.D. has been appointed to the newly established role of chief surgical officer and vice chairman. [MORE](#)

Locus Biosciences has signed an agreement with a global nonprofit to help fund a new CRISPR Cas3 antibacterial therapy to treat recurrent urinary tract infections. Locus also intends to advance the product for lung, intra-abdominal and bloodstream infections. [MORE](#)

Mycovia Pharmaceuticals, Inc., an emerging biopharmaceutical company dedicated to recognizing and empowering those living with unmet medical needs by developing novel therapies, announced positive topline results from its two pivotal Phase 3 VIOLET clinical trials for oteseconazole, its drug candidate for treating patients with recurrent vulvovaginal candidiasis¹, commonly known as chronic yeast infection. [MORE](#)

Pappas Capital, a leading venture capital firm focused on advancing life sciences, today announced that its portfolio company, VelosBio Inc. has entered into a definitive agreement to be acquired by a subsidiary of **Merck** (for \$2.75 billion in cash, subject to customary adjustments. The exit is amongst Pappas Capital's most successful in its 25-plus-year history. [MORE](#)

Precision BioSciences, Inc. and **Eli Lilly and Company** announced a research collaboration and exclusive license agreement to use Precision's proprietary ARCUS genome editing platform for the research and development of potential in vivo therapies for genetic disorders, with an initial focus on Duchenne muscular dystrophy and two other undisclosed gene targets. [MORE](#)

Rare Disease Innovations Institute President and Founder Tara Britt is nominated for state advocacy as part of the Ninth Annual RareVoice Awards. [MORE](#)

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BIO Business Solutions



NCBIO members, you are eligible for BIO Business Solutions volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases and more. This is a benefit of your NCBIO membership. Review the cost-savings offered by clicking [here](#), and choose the programs you're interested in. Email [Bob Dearth](#) or call 781-716-7555 with your choices, and they will get you started. For all the latest news, promos and event information, follow [BIO Business Solutions on LinkedIn](#).

Health care plans for small companies

Your NCBIO membership unlocks access to NEW small group health plans from Mercer available through the Biotechnology Innovation Organization. This valuable NCBIO benefit gives small life sciences companies with 5 to 50 employees the same flexibility, choice and reduced administrative costs typically available only to large corporations. [LEARN MORE](#)

NEW! UniFirst offers alternative solutions for workwear needs

If your company is experiencing supply chain challenges with your workwear and cleanroom apparel needs, consider UniFirst, BIO's preferred partner for workwear rental and facility services. A leading supplier for companies of all sizes since 1936, UniFirst provides a range of apparel from traditional uniforms, protective clothing, cleanroom gowning and corporate casual attire. UniFirst offers BIO members exclusive savings (30-50%) and favorable contractual terms. [LEARN MORE](#)

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Calendar

To view full calendar, [click](#).

[SBIR/STTR Education Seminar](#)

Wednesday Dec 9, 2020

[Beyond Elemental Impurities: New Applications of ICP-MS](#)

Wednesday Dec 9, 2020

[Let's Talk About Series - Race and Inclusivity in the Life Sciences](#)

Wednesday Dec 9, 2020

[Becoming an Investor-Ready Entrepreneur](#)

Wednesday Dec 9, 2020

[Genesis Digital](#)

Thursday Dec 10, 2020

[Mesentech and The Importance of Bone Health](#)

Thursday Dec 10, 2020

[19th Annual Economic Forecast Forum](#)

Thursday Jan 7, 2021

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