



June 2022 Update
Serving the NC Life Sciences Industry

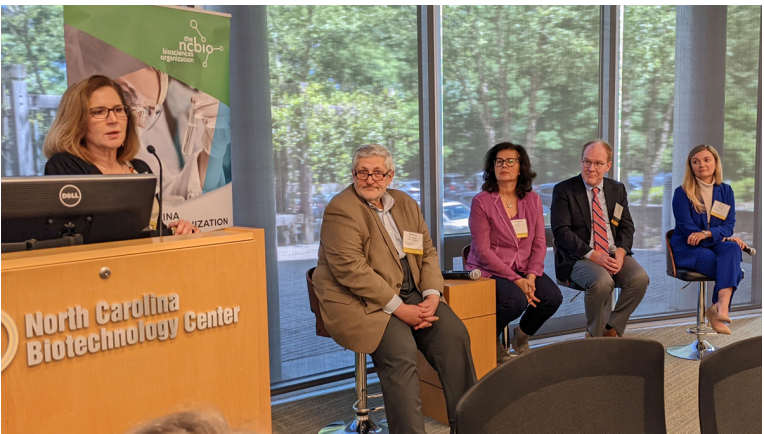
ncbioscience.net
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NCBIO This Month

- Forum covers current regulatory situation at FDA
- NC Senate considers Medicaid expansion
- Register for June 22 NCBIO Legislative Reception
- Save the date for Oct 12 Annual Meeting

... and more

Medical Device Forum discusses current FDA regulatory environment



NCBIO President Laura Gunter introduces the panelists at the May 11 NCBIO Medical Device Forum.

NCBIO members got an overview of the Food and Drug Administration's regulatory environment for medical devices both during the pandemic and now at the NCBIO Medical Device Forum held May 11 at the NC Biotechnology Center.

Robert Rosenthal, a partner with MED1 Ventures, moderated a panel comprising

- **Roxy Kozyckyj**, director of state government and regional affairs at AdvaMed;
- **Karl Nobert**, senior counsel at Michael Best; and
- **Alessandra Pavesio**, senior vice president and chief scientific officer at Bioventus.

The event was made possible by sponsor [Michael Best](#), a full-service law and consulting firm with offices in Raleigh and around the country and world.

FDA was understaffed before the COVID-19 pandemic, panelists said, and the added stress of the pandemic has not helped matters.

[More >>](#)

NCBIO Sustaining Members



NCBIO Supporting Members





STATE UPDATES

Senate approves Medicaid expansion, House passage in doubt

On June 2, the North Carolina Senate passed legislation 35-10 expanding Medicaid coverage to hundreds of thousands of additional low-income adults. The legislation marks a turnabout by Republicans in the chamber who have been dead set against expansion for a decade.

The bill includes several other medical, health care coverage and insurance reforms. Many of these proposals, including expansion, have been discussed in a House-Senate health care study committee that's met several times since February.

The bill and its components face an uncertain fate in the House, where leaders have expressed skepticism about both the timing and substance of the proposal. House Speaker Tim Moore said on [PBS NC's FRONT ROW](#), "I do not see Medicaid expansion having much legs in the House at this point."

In addition to expanding Medicaid eligibility for individuals making up to 135 percent of the Federal Poverty Level, the bill includes the following provisions:

1. Changes to the Hospital Assessment program taxing hospitals to cover the 10% state share of Medicaid.
2. Establishment of the Healthcare Access and Stabilization Program, an hospital industry proposal to require DHHS to apply for a waiver to increase hospital assessments to achieve the maximum Medicaid reimbursement for hospitals allowed by CMS.
3. Significant changes to the Certificate of Need program that would, among other things, no longer require applications for construction of acute care beds to be consistent with need requirements identified by DHHS
4. Expansion of the scope of practice for nurse practitioners (previously introduced as the SAVE Act);
5. So-called "surprise billing" requirements for out-of-network referrals (previously introduced as Senate Bill 550)
6. Insurance coverage for certain telehealth services.

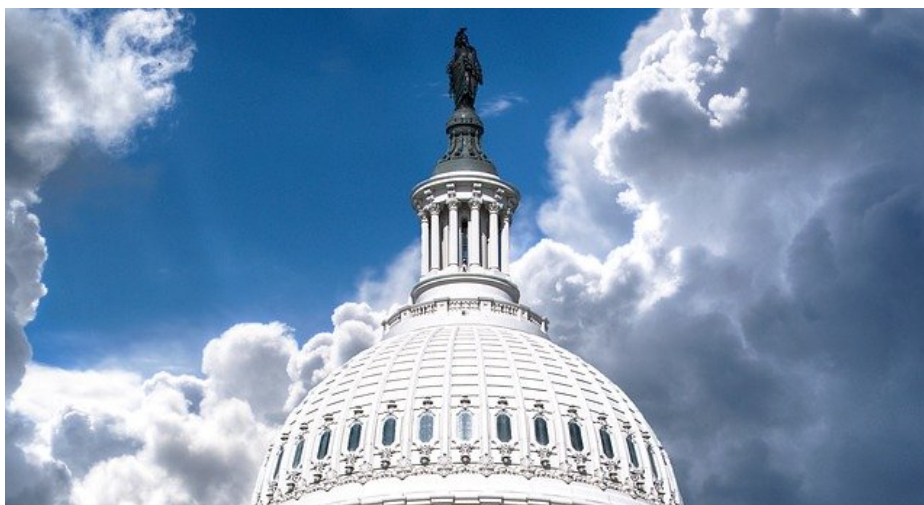
NC Republicans considering state employee and teacher raises, tax cuts this session

As legislators begin the short session of their two-year cycle, Republicans are looking at both money for state employees and some sort of possible tax relief, House Speaker Tim Moore said.

The state will have \$6.2 billion more in projected revenue this and next year, according to the bipartisan revenue forecast. Gov. Roy Cooper called for Medicaid expansion and more money for state employees and teachers this year in his budget proposal ahead of the legislature's session.

The 2021 budget that Cooper signed into law in November already included 2.5% raises last year and again this year for state employees. And teachers also received an average 5% raise over the two years. The budget also included individual and corporate income tax reductions in phases. So any new legislation would be on top of that.

[More @ News & Observer >>](#)





NATIONAL UPDATES

Medtech groups want more time to implement FDA's QMSR rule

Medical device lobby groups say they support the US Food and Drug Administration's plan to align its Quality System Regulations with the international quality system standard, but they want more than a year to make the transition.

In February, FDA published a long-awaited proposed Quality Management System Regulation rule to harmonize its regulatory requirements for medical device quality systems contained in 21 CFR part 820 with the international standard ISO 13485:2016. The agency said the move would help reduce the regulatory burden on manufacturers and save around a half billion dollars over 10 years.

[More @ RAPS >>](#)

AdvaMed exec joins Biden administration's supply chain group

Abby Pratt, AdvaMed's senior vice president for its global policy department, has joined the executive committee of the Biden administration's Joint Supply Chain Resilience Working Group.

Pratt, along with other government and industry members, will help implement the National Strategy for a Resilient Public Health Supply Chain.

[More @ Medical Design & Outsourcing >>](#)

Brand-name drug prices declined – or grew slowly – in 2021

Drug Channels' annual analysis of prices of drugs at 10 large pharmaceutical manufacturers declined or grew slowly in 2021.

"When rebates and discounts were factored in, brand-name drug prices declined—or grew slowly—in 2021," writes Drug Channels' Adam Fein. "Consistent with our previous analyses, rebates and discounts reduced the selling prices of brand-name drugs to less than half of their list prices."

"For 2021, brand-name drug list prices grew by less than 5% at all 10 companies," Fein said. "The unweighted average discount off list was 52%, i.e. less than half price. The weighted average brand-name portfolio had list-price discounts of -42% to -75%."

[More @ Drug Channels >>](#)

NCPIO Updates

NCPIO Member News

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

Azzur Group celebrated the opening of its latest Azzur Cleanrooms on Demand facility in Morrisville May 25. [MORE >>](#)

BioAgilytix has appointed top health care executive David King to its Board of Directors. King is the former executive chairman and CEO of Labcorp and led its transformation from a pure-play U.S. testing laboratory into a leading global life sciences company. [MORE >>](#)

Biogen Inc. and **Sage Therapeutics, Inc.** announced that the Phase 3 SKYLARK Study of zuranolone, an investigational oral drug being evaluated in women with postpartum depression, met its primary and all key secondary endpoints. [MORE >>](#)

Biogen Inc. and MedRhythms have entered into a license agreement to develop and commercialize MR-004, an investigational prescription digital therapeutic for the potential treatment of gait deficits in multiple sclerosis. [MORE >>](#)

Cambrex acquired Q1 Scientific, a leading provider of environmentally-controlled cGMP stability storage services for the pharmaceutical, medical device and life science industries, strategically located in Waterford, Ireland. [MORE >>](#)

Cook Medical's Winston-Salem manufacturing facility received an ISO 14001 certification, the global standard for environmental management system practices. The Winston-Salem facility is the third Cook Medical location to receive the certification, following their Denmark

and Ireland locations. [MORE >>](#)

G1 Therapeutics announced results of a post-hoc study analysis showing that ES-SCLC patients who received trilaciclib prior to chemotherapy had a lower incidence of single- and multilineage myelosuppressive events — fewer cases of severe neutropenia, anemia and thrombocytopenia — compared to patients receiving placebo. [MORE >>](#)

IQVIA launched OCE+, the first of several new advancements to its life science customer engagement platform. OCE+ adds IQVIA's Next Best recommendation engine – a daily workflow tool providing AI-driven recommendations for engaging health care professionals – to its Orchestrated Customer Engagement platform. [MORE >>](#)

The **PPD** clinical research business of **Thermo Fisher Scientific** has been recognized for excellence in the 2022 CRO Leadership Awards for the 11th consecutive year. [MORE >>](#)

The **PPD** clinical research business of **Thermo Fisher Scientific** has been distinguished for industry leadership in digital and decentralized clinical trial solutions by Information Services Group, a leading global technology research and advisory firm, for the second consecutive year. [MORE >>](#)

United Therapeutics announced that the FDA has approved Tyvaso DPI (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease to improve exercise ability. [MORE >>](#)

The following NCBIO members were recognized with 2022 Life Sciences Awards by the Triangle Business Journal:

- **BioCryst Pharmaceuticals**, Public Company of the Year
- **G1 Therapeutics**, Public Company of the Year
- **IQVIA**, Most Innovative CRO
- **Kriya Therapeutics**, Shankar Ramaswamy, CEO of the Year
- **Kymanox**, Private Company of the Year
- **Medicago**, Best Late-Stage Development Company
- **Syneos Health**, Most Innovative CRO

Events

NCBIO Legislative Reception June 22

Join NCBIO members and legislators for an evening reception Wednesday, June 22, from 5:30 to 7:30 p.m. at the NC Museum of History highlighting North Carolina’s life sciences industry. You will have the opportunity to discuss workforce training, life science program funding, innovation and tax policy and other topics of interest with legislators and policy makers. Registration is open to all NCBIO member companies and their representatives.

NCBIO thanks premier sponsors **Amgen**, **IQVIA**, **Lilly**, **Pfizer** and **We Work for Health NC** and sponsors **BIO**, **Biogen**, **Bristol Myers Squibb**, **FUJIFILM Diosynth Biotechnologies**, **Mallinckrodt Pharmaceuticals** and **Seqirus** for supporting this event. If you are interested in sponsoring, please contact Membership Director [Natacha Janvier](#).

REGISTER NOW

Save the date: NCBIO Annual Meeting Oct. 12

NCBIO is hosting our Annual Meeting on Wednesday, Oct. 12, at the NC Biotechnology Center in Research Triangle Park. Please mark your calendars now and plan to join us. The Annual Meeting program features a keynote address and three panels.

- Success Stories: Talent Recruitment and Retention
- Financial Trends and Outlook
- Health Equity and Disparity

You do not want to miss this year’s programming and networking opportunities. Thank you to our current sponsors.

- Platinum: [Bioventus](#), [Cook Medical](#), [Kymanox](#) and [VWR](#)
- Gold: [Azzur Group](#), [FUJIFILM Diosynth Biotechnologies](#), [Grifols](#) and [Novo Nordisk](#)
- Silver: [AdvaMed](#)
- Bronze: [Novozymes](#)

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NCBIO is a 501(c)(3) non-profit organization.

NCBIO calendar

- [Tech Job Expo hosted by NC TECH \(6/8/2022\)](#)
- [Meet the Investor: Social Impact of DEI & The Investing World hosted by LaunchBioÂ \(6/8/2022\)](#)
- [BIO International Convention 2022 \(6/13/2022 to 6/16/2022\)](#)
- [Summer Institute 2022 hosted by Duke University Department of Population Health Sciences \(6/13/2022 to 6/17/2022\)](#)
- [Informa Markets Engineering South \(6/14/2022 to 6/16/2022\)](#)
- [How to Maintain and Improve your Resume hosted by WIB RTP Chapter \(6/16/2022\)](#)
- [Summer Institute 2022 hosted by Duke University Department of Population Health Sciences \(6/20/2022 to 6/24/2022\)](#)
- [Fundamentals of Mammalian Cell Line Development hosted by BTEC \(6/21/2022 to 6/23/2022\)](#)
- [NCBIO Legislative Reception \(6/22/2022\)](#)
- [Leverage SBIR/STTR Funding and Other Resources to Create a Diverse Workforce in Science and Technology hosted by NCATS \(6/23/2022\)](#)
- [Triad BioNight hosted by NCBiotech \(6/23/2022\)](#)
- [Hands-On cGMP Biomanufacturing of Vectors for Gene Therapy hosted by BTEC \(6/27/2022 to 6/30/2022\)](#)
- [NCBIO Roadmap to Diversity in Life Sciences: Mentoring Programs \(6/28/2022\)](#)
- [Hands-On cGMP Biomanufacturing Operations hosted by BTEC \(7/12/2022 to 7/15/2022\)](#)
- [Hands-On Essentials of Automation for Biomanufacturing hosted by BTEC \(7/13/2022 to 7/14/2022\)](#)

Avantor releases sustainability report

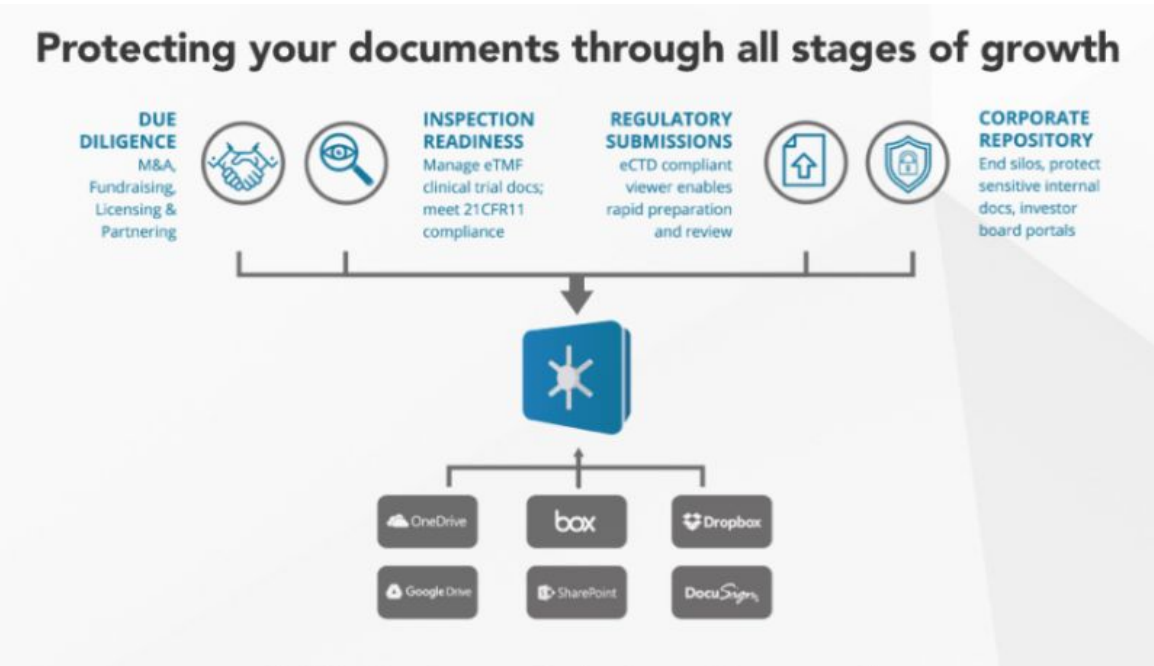


BIO's partner supplier Avantor, released their [2022 Sustainability Report](#), and we applaud their efforts to drive Science for Goodness by building a more sustainable future with smart solutions.

Avantor's portfolio is used in virtually every stage of research, development, and production. Their global footprint enables them to serve more than 225,000 customer locations and gives them access to research laboratories and scientists in more than 180 countries.

GET THE REPORT

ShareVault provides secure cloud solution for documents



BIO’s Business Solutions Partner for
secure document sharing and collaboration since 2013

Whether you are a life science company pitching to investors, engaging in clinical trials, or creating a repository of internal documents, it’s important to utilize a cloud solution that manages time-sensitive and document-centric processes quickly and safely.

BIO partner, ShareVault protects life sciences documents through all stages of growth.

LEARN MORE




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