SAVE THE DATE **NCBIO Annual Meeting** Tuesday, Oct. 5



April 2021 Update

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NCBIO This Month

- Taylor honored in Congressional Record
- Governor reveals his budget
- Legislature adjusts tax laws
- Plan to limit coverage for protected drugs canceled
- Federal drug-pricing legislation introduced
- Cancer-screening billed reintroduced
- CSBA releases study of drug-pricing controls
- CED Venture Connect 2021

... and more

- Member news
- Member benefits
- Calendar







Sam Taylor honored in the Congressional Record

A proclamation honoring NCBIO President Sam Taylor was entered into the March 4 Congressional Record by Sen. Thom Tillis and Sen. Richard Burr.

"I rise today with my colleague, the senior Senator from North Carolina, to honor the life and work of Sam Taylor, the president of North Carolina Biosciences Organization. Sam was a giant in our State and a leading voice for our vital and innovative life sciences and biopharmaceutical sector."

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NCBIO Supporting Members



GRAIL





Colleagues remember Sam Taylor

Those who knew and worked with him remember NCBIO President Sam Taylor as a leader, an influencer, an unflagging advocate and friend and remember his kindness, humor and generosity. Taylor died Sunday, Feb. 21, at the age of 64 of pancreatic cancer.

7/10/2024, 6:57 PM

His colleagues, collaborators and friends wrote to share their thoughts and feelings about him. The North Carolina Board of Science, Technology & Innovation said, "As champion of economic development through the life sciences, including small business, Sam Taylor was a tremendous leader, tireless advocate and loyal partner that the North Carolina Board of Science, Technology & Innovation was grateful to work with. Sam's legacy created economic opportunities that benefited the state and improved the livelihood of its citizens. The board wishes to express their deepest condolences to Sam's family, friends and his team at NCBIO."

Read more from Sam's friends and colleagues <u>here</u>. If you would like to share a memory, anecdote or thought about Sam, send it to <u>David Etchison</u>. We'll collect your submissions and share them on our website.

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STATE UPDATES

Gov. Cooper announces his budget

Governor Roy Cooper unveiled his budget proposal, kicking off the budgeting process in the NC General Assembly. Of particular interest to NCBIO and its members is **\$9 million** earmarked for the One NC Small Business Fund, which provides matching grant funding to small businesses that receive federal awards from the SBIR/STTR program.

From his letter introducing the budget, the Gov. Cooper says, "Our state budget availability is strong, with nearly \$5 billion in unreserved cash in the General Fund as we enter the FY 2021-2023 biennium. Our economic forecast anticipates continued economic expansion. And our debt affordability of almost \$15 billion over the next 10 years presents the state with a generational opportunity to make lasting investments at historically low interest rates. This recommendation is a fiscally responsible path forward, structurally balanced and based on recurring state revenue. Some funding that would ordinarily be proposed in this budget will be presented in my forthcoming recommendations for how we should invest funds from the federal American Rescue Plan."

The governor's proposed state budget would give teachers 10% raises over two years, increase education funding and put a \$4.7 billion general obligation bond on the ballot this November. The bond would provide \$2.5 billion for public schools, \$783 million for the UNC System, \$500 million for the community college system, \$430 million for health and safety projects across state government and \$460 million for parks, zoos, museums and state historic sites.

Cooper's budget proposal also includes a 7.5% raise over two years for UNC and state-funded local community college employees. All other employees would see a 5% raise over two years. Additionally, the proposal calls for a \$1,000 bonus each of the next two years for all state-funded employees.

The governor continues to call for Medicaid expansion, but this is a contentious issue with the legislature and is unlikely to be adopted.

The five-year forecast of revenues and expenditures for General Fund net appropriations includes many assumptions. A key assumption is that revenue will grow annually at 4.4%. This figure is based on an average of income growth and historical average tax-law-adjusted General Fund revenue growth encompassing the last two recessions and economic expansions prior to the COVID-19 pandemic.

The following are other highlights of the budget proposal:

 \$11 million over the biennium to market the state as a business destination and to identify new markets for North Carolina's products including \$10 million to the

Economic Development Partnership of North Carolina, which increases awareness of North Carolina and draws prospective businesses and investment to the state, including in the life sciences

- \$40 million to create the NC GROW (Getting Ready for Opportunities in the Workforce)
 Completion Incentive and Aid for Students Seeking Industry Credentials Program. The
 program incentivizes enrollment in high-demand curriculum programs or noncredit,
 short-term workforce training programs leading to industry credentials in fields with
 documented employer demand and competitive wages. Includes funds for staff
 recruitment, development and retention in those programs.
- \$327.8 million toward IT Infrastructure in the state system, including modernizing community college workforce IT systems.
- \$2.5 million in FY21-22 and \$5 million in FY22-23 to provide additional funds to support staff recruitment, development and retention for high demand areas and programs at community colleges, including architecture and construction, health sciences, information technology, and manufacturing.
- \$3.4 million to study emerging compounds in the water supply.

Legislators address 2021 tax laws

NCBIO News: pricing controls, cancer screening bill, governor's budget

The finance committee chairs in both houses introduced the 2021 Revenue Laws bill. This bill, which historically contains the main tax changes for the year, dictates what areas of the federal tax code North Carolina will adopt. One issue that will be closely watched is how North Carolina will treat federal Paycheck Protection Program loans that helped struggling businesses during the COVID-19 pandemic. Currently, North Carolina allows companies to exempt forgiven PPP loans from income for tax purposes, but businesses cannot deduct business expenses paid for by these loans. Several bills have been introduced to address this issue. If you received PPP money and have concerns, contact Laura Gunter.

Due to ongoing COVID-19 concerns, the North Carolina Department of Revenue has moved the state tax filing deadline for individual income taxes from April 15 to May 17. This shift mirrors the action the IRS took earlier, shifting the federal tax deadline. While the Revenue Department can move the tax filing deadline and waive penalties, only the legislature can waive interest payments. The General Assembly passed a provision extending interest payments for 2019 tax filings last year and has indicated its intention to pass another extension for 2020 filings.

NC legislators discuss workforce with NCBIO members during BMF meeting

NCBIO manufacturing companies discussed their workforce needs with North Carolina state legislators during the quarterly meeting of the NCBIO Biomanufacturers Forum held online Tuesday, March 2.

Representatives of Biogen, FUJIFILM DioSynth, Grifols, Merck, Novartis, Novozymes and Pfizer were among those who spoke to leaders of the NC General Assembly's Life Sciences Caucus. Caucus co-chairs Sen. Paul Newton (R-Cabarrus, Union) and Sen. Mike Woodard (D-Durham, Granville) were on the call while Rep. Donna McDowell White (R-Johnston) and Rep. Robert Reives (D-Chatham, Durham) were forced to miss the discussion when the House was called into session just before the meeting began.

Newton and Woodard said they would work with the state's life sciences companies on industry concerns.

"We understand that if we can't provide your workforce, you're going to go elsewhere. How can we help?" Newton asked. "We absolutely want to facilitate workforce creation. I would like to understand how in big ways and little ways we can help you be successful."

Woodard said, "In my 15 years as an elected official, I've seen a lot of business recruitment. Workforce is always the No. 1 question." He assured the NCBIO members on the call that workforce development was a top priority and asked them to continue to work with policy makers to prepare the workforce of the future.





NATIONAL UPDATES

Plan to let insurers cover fewer protected drugs canceled

The Centers for Medicare & Medicaid Services announced it will not move forward with a proposed change to the Part D Payment Modernization Model that could have resulted in seniors losing access to critical drugs — a win for the most vulnerable patients.

The outgoing Trump administration <u>announced a new policy</u> that would have allowed insurance plans to cover fewer drugs in their formularies in six protected classes (antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals for treatment of HIV, and antineoplastics).

Medicare Part D sponsors have been required to cover ALL FDA-approved drugs in these six classes — but the proposed change could have resulted in seniors losing access to treatments they rely on.

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Coverage for cancer early detection reintroduced

The Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021 (<u>H.R. 1946</u>) has been re-introduced by Rep. Terri Sewell (D-AL). Immediately following, a letter of support led by the Prevent Cancer Foundation was sent, and NCBIO was a signer of this letter. Rep. Richard Hudson (R-NC) is a cosponsor of the bill. For details on the bill, see this <u>joint press</u> release put out by the sponsoring members of Congress.

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Drug-pricing legislation reintroduced

On March 23, the Senate Health, Education, Labor and Pensions Subcommittee on Primary Health and Retirement Security, chaired by Sen. Bernie Sanders (I-VT), held a two-hour hearing focused on U.S. drug prices and international comparisons.

In addition to drug pricing, the hearing also covered patent thickets, the need for more robust generic and biosimilar markets, and funding for R&D at NIH—and overall, there was considerable criticism of the industry and support for international reference pricing. (Watch the whole thing here.)

The hearing coincided with the <u>reintroduction of three bills</u> to control the prices of drugs: the Prescription Drug Price Relief Act, the Medicare Drug Price Negotiation Act, and the Affordable and Safe Prescription Drug Importation Act.

Notably, The Prescription Drug Price Relief Act would link the prices of prescription drugs in the United States to prices in Canada, the UK, France, Germany, and Japan—similar to what was proposed in H.R. 3 in 2019 and the Trump administration's "Most Favored Nation" proposal.

New study analyzes potential impact of various drug pricing proposals

The Council of State Bioscience Associations released data 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 found that if a bill like the Lower Drug Costs Now Act of 2019 had been in place from 2009 to 2019, it would have had the following consequences:

- A basket of 68 innovative therapies that had been developed by small and emerging biotechs and approved during that timeframe 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 affected.
- 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 Updates



Virtual CED Venture Connects brings together 500 life science executives, investors and others

Like last year, this year's <u>Venture Connect</u> held March 23-25 produced by the <u>Council for Entrepreneurial Development</u> took place entirely online but with many exciting new features.

NCBIO is a sponsor of Venture Connect, which connects life science and technology companies in the Southeast with investors, sponsors and fellow entrepreneurs to network, discuss innovative technologies and foster collaboration.

This year, CED designed a virtual experience that focused on connecting participants to the people at other innovative life science and technology companies. The conference included live streaming content, interactive breakout sessions with live networking opportunities, provocative speakers and panelists covering emerging topics and trends and 120 innovative companies that are growing.

The keynote discussion included prominent Bay Area investor Jeff Ubben, former Fortune magazine journalist Polina Marinova and former Medtronic CEO Bill Hawkins.

The agenda for the conference can be viewed here.

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Member News

To be included in Member News, send information about your organization to <u>David Etchison</u>.

Baebies reached a significant milestone by delivering 10 million tests to newborn screening labs around the world since the company was founded. MORE >>

Biogen Inc. plans to build a new gene therapy manufacturing facility at its Research Triangle Park manufacturing campuses in North Carolina to support its growing gene therapy pipeline across multiple therapeutic areas. MORE >>

The FDA approved Abecma (idecabtagene vicleucel; ide-cel) from **Bristol Myers Squibb** and **bluebird bio** as the first B-cell maturation antigen-directed chimeric antigen receptor T cell immunotherapy for adult patients with relapsed or refractory multiple myeloma. MORE >>

Chiesi USA launched its FDA-approved Bronchitol (mannitol) inhalation powder, an add-on maintenance therapy to improve pulmonary function in cystic fibrosis patients 18 years of age and older. Bronchitol is the first and only dry-powder inhaled mucoactive agent providing a compact, portable option for patients. MORE >>

Chiesi USA contributed more than \$800,000 in 2020 through its Chiesi in the Community employee-led corporate social responsibility program. Chiesi employees supported 215 unique charitable organizations with 1,100 hours of time or donations in 2020. MORE >>

FUJIFILM Diosynth selected Holly Springs for its new U.S. large-scale cell culture production site, the largest end-to-end cell culture biopharmaceutical CDMO facility in North America. The \$2 billion investment will create 725 jobs by the end of 2028. MORE >>

G1 Therapeutics, Inc. and **Boehringer Ingelheim** announced that COSELA (trilaciclib) for injection is now available in the U.S. to decrease the incidence of chemotherapy-induced myelosuppression in adult extensive-stage small-cell lung-cancer patients. MORE >>

GRAIL named Andrew Crenshaw, a North Carolinian with more than 20 years of experience in the clinical and biomedical research industry, vice president of operations and RTP site director. MORE >>

PPD and Clinical Ink have jointly developed a systemic lupus erythematosus assessment review process to simplify operationalizing clinical trials for this chronic autoimmune disease.

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American Laboratory Trading is offering up to 30% off refurbished centrifugal evaporators and sample concentrators for NCBIO members.

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A guide to successful de-SPAC transactions 3 p.m., April 7

2020 was the year of the SPAC, the special purpose acquisition company, with more than 200 entities going public via SPAC last year alone. While the SPAC IPO boom continues, 2021 is also expected to be the year of the "de-SPAC", with many sponsors looking to execute merger transactions.

Join BIO's strategic partner, Aon, and their esteemed panelists representing investment banking, legal and accounting firms, as well as highly successful SPAC sponsors, as they dive into the SPAC target approach, share insights with real-world case studies, and demystify the de-SPACing process.

REGISTER NOW



EVENTS



7/10/2024, 6:57 PM

MDMA 2021 Annual Meeting: "Rising to the Needs of Patients"

The Medical Device Manufacturers Association's flagship event, the MDMA Annual Meeting, will be held virtually in April. MDMA is the leading voice for innovative and entrepreneurial medical device companies, and this year's Annual Meeting will deliver key insights facing our industry.

Topics will include:

- COVID-19 conversations,
- FDA & MDUFA V update,
- Ongoing efforts to accelerate reimbursement and more.

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NCBIO Calendar

- Leading From the Boardroom: The Diversity Imperative hosted by National Association of Corporate Directors (Triangle Chapter) (4/6/2021 to 4/7/2021)
- Finding your Unique Latino Voice in Corporate America: The Nomadic Existence of a Latino Far from Home hosted by Prospanica NC (4/7/2021)
- A Roadmap to De-SPACing hosted by Aon (4/7/2021)
- Larger than Life Science: Making Your Exit Strategic Trends to Consider hosted by LaunchBio (4/8/2021)
- National AgTech Forum: Agricultural Biologicals Going Mainstream (4/20/2021)
- Targeting Stromal Cells in Cancer and Inflammatory Diseases hosted by Cambridge Healthtech Institute (4/21/2021 to 4/22/2021)
- GRAIL Unveils New Durham Facility Open House (4/27/2021)
- MDMA Annual Meeting: Rising to the Needs of Patients (4/29/2021)
- State of Technology hosted by NC TECH (5/12/2021 to 5/13/2021)

Partners

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7/10/2024, 6:57 PM 8 of 9