NCBIO This Month · COVID-19 and Flu Vaccines - Topics for Legislative Life Science Caucus Meeting

Recombinant

Protein

Genetic Vaccine

(DNA or RNA)

· Expanding target populations,

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· NCBIO Speaks Out Against Executive Order on International Drug Pricing · Register Now for NCBIO's Virtual Annual Meeting

· BIO Impact Conference Featured Virtual Tour of NC Companies and Research Facilities · BMF Members Hear about Future of the Office · Series on Diversity in Life Science · Census Reminder

· At the National Level · Member News Member Benefits

· Calendar **P**COVID-19 and Flu Vaccines – Topics for Legislative Life Science **Caucus Meeting**

Viral Vector

Vaccine

Types of Vaccines for SARS-COV2

Virus-like or

Nanoparticle

Vaccine Vaccine protein gene to a virus and unloads the gene Because the adenovirus missing one of its own Phyllis Arthur, BIO Members of the NC Legislative Life Science Caucus got international, national and state updates on COVID-19 vaccines and plans for fall campaigns for the flu vaccine during the September virtual

meeting. Phyllis Arthur, VP, Infectious Diseases and Diagnostics Policy for BIO, briefed lawmakers on the types of vaccines under development and in clinical trials for COVID-19. She noted that companies with COVID-19 vaccines are accelerating their potential availability by contracting with manufacturing companies to make large quantities of the products while they are still in clinical trials. She stressed that speed would in no way sacrifice safety and efficacy. She also outlined the process for determining which groups of individuals will get vaccines during the early stages of release. **Key Learnings** · Begin preparations as soon as possible, with consideration to:

· Modifying timing, location, and providers · Communicating clearly and consistently across all stakeholders. Policy changes need to be sustained · maintain vaccine uptake, · protect public health, · reduce the burden on health infrastructure · provide pandemic preparedness. Demand was high and all programs wanted earlier and more · Consistent communication key Segirus Jonathan Anderson, Segirus Jonathan Anderson, Senior Medical Director, Segirus Asia-Pacific, discussed lessons learned in the Southern Hemisphere where governments addressed the annual flu season as the COVID-19

pandemic was developing. The Seqirus vaccine facility in Holly Springs, NC, is a leading producer of flu vaccine. Anderson discussed the importance of expanding the target population for the flu vaccine and communicating the importance of getting the flu vaccine this year, so individuals can avoid getting the flu and COVID-19 at the same time. He also stressed consistent messaging and finding safe places to provide the vaccines, explaining how government officials in Australia came together in a concerted manner. Kelly Kimple, with the Division of Public Health in the North Carolina Department of Health and Human Services, outlined steps the State is taking to promote immunization activities. She said the State is working to make sure children get the childhood vaccines they need, since some parents have delayed child-wellness doctor visits because of the pandemic. Kimple said the Department is using funds from the Centers for Disease Control to help fund a media-based vaccination campaign. She also discussed the State's preparations for the release of a COVID-19 vaccine. "We are pleased we could present this information to lawmakers," said NCBIO President Sam Taylor. "The virtual event actually allowed us to bring in national and international experts that would not have been available for an in-person meeting."

PONCBIO Speaks Out Against Executive Order on International Drug Pricing "The executive order would impair pharmaceutical innovation at the very time that bioscience companies are investing in treatments and vaccines for COVID-19 and other life-threatening diseases. As the number two pharmaceutical manufacturing state in

> the nation, our economy will be impacted disproportionately by the

President's order."

SAM TAYLOR President, NCBIO

NCBIO reacted to President Donald Trump's Executive Order to adopt international reference pricing for certain prescription pharmaceuticals. NCBIO President Sam Taylor stated in a news release that the order "will threaten pharmaceutical, clinical research and related jobs in North Carolina" and that the order "will impair pharmaceutical innovation at the very time that bioscience companies are investing in treatments and vaccines for COVID-19 and other life-threatening diseases." "As the number-two pharmaceutical manufacturing state in the nation, our economy will be impacted disproportionately by the President's order," said Taylor. "The order will also hurt North Carolina's innovative young pharmaceutical companies by discouraging venture investment in drug discovery and development. The pharmaceutical innovation ecosystem that North Carolina has for so long

pharmaceutical innovations." More

Journal, and WRAL Techwire.

nothing less." More

a political issue.

Group, and UCB

Research Facilities

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nurtured would lose the financial backing it needs to create new companies and commercialize new

Dr. Michelle McMurry-Heath, President and CEO of BIO, issued a statement saying, "With scientists and researchers at America's biopharmaceutical companies working around the clock to fight a deadly pandemic, it is simply dumbfounding that the Trump administration would move forward with its threat to import foreign price controls and the inevitable delays to innovation that will follow. This

Taylor was interviewed by several media outlets including Spectrum News, Triangle Business

reckless scheme will eliminate hope for vulnerable seniors and other patients waiting for new treatments by drastically reducing investment in cutting-edge scientific research and development. That is why we will use every tool available – including legal action if necessary – to fight this risky foreign price control scheme. America's patients, families, scientists and researchers deserve

PhRMA President and CEO Steve Ubl also criticized the Order. "The Administration has chosen to pursue the most favored nation policy – an irresponsible and unworkable policy that will give foreign governments a say in how America provides access to treatments and cures for seniors and people

struggling with devastating diseases. What's worse is that they are now expanding the policy to include medicines in both Medicare Part B and Part D, an overreach that further threatens America's innovation leadership and puts access to medicines for tens of millions of seniors at risk. Rather than emulating countries that allow politicians to arbitrarily decide what medicines are worth and what diseases are worth investing in, we should use existing trade enforcement tools to prevent them from freeloading off American innovation." More Back to top. Register Now for NCBIO's Virtual Annual Meeting TWENTY SIXTH

ANNUAL MEETING

VIRTUAL

SEPTEMBER 29 - OCTOBER 2

. National Policy Outlook and Ramifications looks at what this means in terms of policy agendas for 2021 and how various issues from the pandemic to the election will impact our members. • Value of Life Sciences: The Future of Health for Our People focuses on the technology landscape in NC in a fireside chat with respected observers of North Carolina's life science landscape and three TED talks from some of North Carolina's most innovative life science companies. • Biotechnology's Promise: Feeding, Fueling and Healing the World wraps up the week's program of election, policy and promising technologies, and discusses the impact on all of our member companies in terms of job growth and innovation. To learn more about each topic and session speakers, please check the event page. Members can register online. If you have any questions regarding your registration, please contact Amber Niebauer. Thank you to our Annual Meeting sponsors:

• Platinum: BIO, Bioventus, Cook Medical, and VWR, Part of Avantor

• Gold: FUJIFILM Diosynth Biotechnologies, Grifols, Merz, and PSC Biotech Silver: AdvaMed, G1 Therapeutics, GSK, IQVIA Biotech, Liquidia, Mispro Biotech, Nikon, Novo Nordisk, Novozymes, Sage Therapeutics, The Conafay

BIO Impact Conference Featured Virtual Tour of NC Companies and

NCBIO's 26th Annual Meeting is being held virtually beginning Tuesday, September 29 to Friday,

• Local Election Outlook with Democratic and Republican campaign consultants discussing the issues that are driving political debate and campaign promises, including an examination of the allure of drug price control and healthcare costs as

October 2 from noon to 1:30 p.m. Each day, we will host a program session including:

Sonny Perdue Brian Brazeau North Carolina's bioeconomy was featured during the new, one-of-a-kind Bioeconomy Virtual Tour Program at BIOIMPACT Digital, September 21-22. One session explored BASF and Syngenta's leading North Carolina research facilities and how these sites are conducting the critical research on seeds, traits and plant biotech that fuel and feed our world in a more sustainable fashion. A second tour looked inside the North Carolina based facilities of Novozymes and the Food Innovation Lab at NC State University. The sessions focused on harnessing solutions to address the future of nutrition. Participants also heard from Pairwise leaders on how they are ensuring enough quality food for our communities. Brian Brazeau, President of Novozymes NA & VP of Bioenergy, hosted a fireside chat with USDA Secretary Sonny Perdue on "USDA Leadership in Driving Innovation in Agriculture." In addition to the impact of biotechnology on the food innovation, Perdue discussed the resilience of the food

supply during the COVID-19 pandemic. Other leaders focused on the bioeconomy—in agriculture, sustainable fuels, and biobased manufacturing along with discussions on the role of biotechnology

The conference was originally scheduled to be held at the Raleigh Convention Center but due to the

in protecting our planet's resources, driving a strong economy and improving people's lives.

COVID-19 pandemic, BIO Impact became a virtual event.

BMF Members Hear about Future of the Office

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NUMBER OF DESKS IN OPEN OFFICES

employees and businesses."

Series on Diversity in Life Science

offices.

BMF.

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LB

Click to see video of the event.

Dec. 9)

Census Reminder

for Eradicating Covid-19

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Other topics and dates for series:

Register here for upcoming webinars.

likely to gain another seat;

Make sure you participate in the 2020 Census, which will:

According to 15 years of data analytics from Herman Millor's good utilization services. "The workplace needs to evolve from a singular space into a dynamic network of places from which employees can choose to work," Ryan Anderson, VP of Digital Innovation, at Herman Miller told members of the Biotech Manufacturers Forum (BMF) at the September meeting. Anderson stated, "During COVID-19, working from home has become an extended experiment. Many organizations no longer view the office as a requirement for enabling productivity." He said people are seeking the following types of offices: Areas that encourage people to interact with their extended networks • Reservable on-site workstations that give people the focus they can't get at home

Anderson added, "To thrive, organizations need to help people learn new skills and experiment with

preparations for onboarding remote workers, mentorships for new workers and assistance for home

Contact Ryan Anderson for more about the presentation, and John Wagner for information about

LB

new ways of working. The workplace should be an on-demand resource that brings value to

During discussion, members talked about virtual teambuilding activities for remote workers,

• Interactive settings that facilitate immersive teamwork

UTILIZATION

OF DESKS

NCBIO is one of five community partners working with LaunchBio in hosting "Let's Talk About" a webinar series that explores the experiences of People of Color in the Life Sciences. These sessions uncover the issues of race and awareness and provide actionable takeaways to help make the industry more inclusive. The first session September 9th was "A Seat at the Table - Learning from Black Entrepreneurs, Investors and Executives." The panelists were: Michael Penn, MD, PhD, Founder & Managing Director, Health Equity Ventures (Moderator) • Ibraheem Badejo, PhD, Senior Director - New Ventures, Johnson & Johnson **Innovation Center** • Nick Davis, SCD, Founding Partner & CEO, Epitoire • Roslyn Rawlins, Co-Founder & CEO, Bleuberi

The panelists shared their experiences in seeking jobs, mentors and investments. Several noted that even with high academic grades and experience they had difficulty getting into the industry.

• Let's talk about strategies on improving workplace culture. (Wednesday, Nov. 11) • Let's talk about how life science is addressing race and inclusivity. (Wednesday,

Let's talk about increasing diversity in clinical trials. (Wednesday, Oct. 14)

Former Biogen Executive Machelle Sanders is now Secretary of the State Department of Administration and Chair of the North Carolina Complete Count Commission. To learn how Census data impacts you and your community and to participate, visit 2020census.gov and census.nc.gov. Back to top. $^{\circ}$ At the National Level

Biotech Leaders Outline Principles to Ensure the "Public's Trust" in New Medical Products

Merck, Moderna, Novavax, Pfizer, and Sanofi announced a historic pledge, outlining a united commitment to uphold the integrity of the scientific process as they work towards potential global

CMS Proposed Rule to Improve Coverage For Innovative, "Breakthrough" Technologies

Organizations representing a broad cross-section of health care stakeholders support efforts to modernize access to prescribing information through digital platforms (electronic labeling) to improve patient safety and reduce waste. Electronic labeling of prescribing information will help ensure that providers have access to the most up-to-date information available almost instantaneously, instead

of the average 8-12 months that it often takes to develop, print, and deliver a paper label for prescribers. However, this will only be possible if the Food and Drug Administration (FDA) can

Recognizing the need to keep pace with the information needs of modern health care providers and consumers, FDA published a proposed rule in 2014 (79 Fed. Reg. 75506) that would provide for electronic distribution of prescribing information for human prescription drugs and biological products. Unfortunately, Congress has used the appropriations process to block FDA from

AdvaMed commends the Centers for Medicare and Medicaid Services (CMS) for issuing a proposed rule on Medicare coverage of innovative technologies. "In order to incentivize innovative medical breakthroughs, the federal government must ensure those breakthrough technologies are covered

The CEOs of AstraZeneca, BioNTech, GlaxoSmithKline, Johnson & Johnson,

regulatory filings and approvals of the first COVID-19 vaccines. More

by Medicare," said Scott Whitaker, AdvaMed president and CEO. More

advance its proposed rule for electronic labeling of prescribing information.

Alliance to Modernize Prescribing Information Formed

implementing its proposed rule. More

Biotech Votes 2020

• Determine the size of North Carolina's representation in Congress - and our state is

• Determine how federal programs will distribute more than \$600 billion in funding to

 Bring tax dollars back to our North Carolina communities – more than \$16 billion per year in federal funding – or approximately \$1,623 per person, per year to our state

(source: George Washington University "Counting for Dollars 2020" report).

Science is the way out of this pandemic—and scientific breakthroughs are on the ballot on November 3. To help you get ready for Election Day, BIO's initiative Biotech Votes has resources to help you get registered and get informed. Check out the North Carolina page to verify your voter information and find out about state in-depth analysis of the races that matter the most, from the top of the ticket down the ballot to Senate, House, and state races. Register Now for The Virtual MedTech Conference October 5-7 The world's top medtech executives will gather virtually this year to lead the advancements in

Biogen Inc. announced Healthy Climate, Healthy Lives, a groundbreaking \$250 million, 20-year initiative to eliminate fossil fuels across its operations and collaborate with renowned institutions with the aim to improve health, especially for the world's most vulnerable populations. More bluebird bio, Inc. announced updated results from the clinical development program for its investigational elivaldogene autotemcel (eli-cel, Lenti-D) gene therapy in patients with cerebral adrenoleukodystrophy (CALD). "CALD is a fatal neurodegenerative disease primarily affecting young boys. Currently, the only treatment available is allogeneic hematopoietic stem cell transplantation (allo-HSCT), which comes with associated, significant risks, including transplant-related mortality, graft failure or rejection, and graft-versus-host disease (GVHD)," said David Davidson, M.D., chief medical officer, bluebird bio. More

CureDuchenne celebrated World Duchene Day September 9 and has held a variety of awareness activities throughout the month. Check out the video. Join Dr. Paolo Bettica for an update about the Italfarmaco Givinostat development program. Dr. Bettica will review progress in the Italfarmaco

CureDuchenne webinar to learn the latest updates and to ask your questions about the program.

G1 Therapeutics, Inc. announced that the FDA has accepted the New Drug Application (NDA) for trilaciclib for small cell lung cancer (SCLC) patients being treated with chemotherapy and granted Priority Review with a Prescription Drug User Fee Act (PDUFA) action date of February 15, 2021.

studies about Givinostat in Duchenne and Becker Muscular Dystrophy. Sign up for the

In 2019, BIO saved 4,300 companies nearly \$430 million through BIO Business Solutions® with volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases, and more. 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!**

Thursday Sep 24, 2020 ... read more **2020 Medical Technology Executive Forum** Friday Sep 25, 2020 ... read more **NCBIO Annual Meeting 2020** Tuesday Sep 29, 2020 - Friday Oct 2, 2020

Feedback and Reflection to Drive Engagement in Remote Learning

Optimizing Commercial Pharma Channels During COVID-19

The Virtual MedTech Conference Monday Oct 5, 2020 - Wednesday Oct 7, 2020 ... read more FDA - PDS Symposium IX Rare Cancer Registries Wednesday Oct 7, 2020 ... read more **Compensation Confidential: M&A Edition** Wednesday Oct 7, 2020

Precision Medicine Leaders' Summit Tuesday Oct 20, 2020 ... read more **Going Green: The Lab of the Future** Wednesday Oct 21, 2020 ... read more

Whole-Virus

Find the latest news from NCBIO on the website ncbioscience.net, on LinkedIn and on Twitter at @ncbio. **NCBIO Links**

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OCT 2020

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http://ncbioscience.net

UPDATE

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NCBioImpact

North Carolina

Network

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We Work For Health

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GRAIL Merck MERCK

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candidates. Then, get informed. BIO released the Biotech Votes 2020 Election Preview Report, an medical technology that will make you better prepared for future challenges. Discover the newest advancements in medical technology that will make us better prepared for future challenges during The MedTech Conference. Register now. **BIO Investor Forum October 13-15** BIO Investor Forum Digital, October 13-15, provides three days of enhanced BIO One-on-One Partnering, interactive educational sessions and fireside chats and 160 on-demand company presentations showcasing their drug development programs ready for partnering or venture funding. There is no better virtual event for biotech innovators looking for investors and strategic partners to advance their company to the next stage in their business life cycle. Register now. Back to top. Member News **Going Beyond Carbon Neutrality Healthy Climate, Healthy Lives** Biogen.

To be included in Member News, send information about your organization to **Brenda Summers**. Baebies is celebrating Newborn Screening Awareness month. Baebies is proud to be part of the newborn screening (NBS) community by developing tests to support NBS programs around the world. More BioCryst Pharmaceuticals, Inc. announced that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has awarded BioCryst a new contract totaling \$44 million, and has added approximately \$3 million to its existing contract to support the development of galidesivir. Part of the funding will be used to support clinical trials of galidesirvir in non-hospitalized COVID-19 patients at high risk for developing severe disease and complications of COVID-19. More Photo Credit: CDC/Dr. Flyn sciencehumanity meets

Trilaciclib is a first-in-class investigational therapy designed to preserve bone marrow and immune system function during chemotherapy and improve patient outcomes. More GRAIL, Inc., a healthcare company whose mission is to detect cancer early, when it can be cured, announced that it has filed a registration statement on Form S-1 with the Securities and Exchange Commission (SEC) for a proposed initial public offering of its common stock in the United States. More Heat Biologics, Inc. announced it has been issued a patent (US Patent No. 10,758,611) by the U.S. Patent and Trademark Office (USPTO) covering compositions of matter that are part of Heat's gp96 platform in combination with a T cell costimulatory agonist in a single therapy. Jeff Wolf, Chief Executive Officer of Heat, commented, "This newly issued patent represents a potential breakthrough in combination drug development." More Hughes Pittman & Gupton made the 2020 list of Inside Public Accounting, "The Best of the Best." <u>More</u>

Novartis has renamed the previously acquired AveXis to Novartis Gene Therapies. The change signifies the growing importance of gene therapy to building a leading, focused medicines company

Pairwise gets approval from USDA to go ahead with commercialization of leafy greens. More

trial to up to approximately 44,000 participants which also allows for the enrollment of new

PPD, Inc. has earned recognition for its global employee learning and development

screening programs for SARS-CoV-2 — the virus that causes COVID-19. More

Pfizer Inc. and BioNTech SE announced that they have submitted an amended protocol to the U.S. Food and Drug Administration to expand the enrollment of their Phase 3 pivotal COVID-19 vaccine

program in the Brandon Hall Group Human Capital Management (HCM) Excellence in Learning

UCB has recently created the UCB Community Health Fund and has launched its first Call for Projects. Initially the focus will be on contributing to understand and reduce the medium- and longterm impacts of the COVID-19 pandemic on vulnerable populations' physical, mental, and social

RTI International researchers released findings as part of a special collection of systematic and rapid reviews by Cochrane, a global network of researchers, evaluating the effectiveness and accuracy of

with advanced therapy platforms. More

well-being. The first deadline is on 9/30/20. More

BIO Business Solutions

Bio Business Solutions

industry. Find out more.

partner since 1997.

by. Click for more.

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^⁰Calendar

To view full calendar, click.

Thursday Sep 24, 2020

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Tuesday Sep 29, 2020

Wednesday Sep 30, 2020

Tech Transfer During Critical Times

Value Through Cost-Savings

populations. More

Awards. More

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Nikon Nikon is a world-renowned brand, firmly established as a market leader in optics instrumentation

and the only microscope company to manufacture its own glass, ensuring the very finest quality assurance throughout production. Nikon's broad portfolio of microscope systems includes products for the educational, clinical, materials science, and research market as well as the biotech/pharma

Acquired by Avantor in 2017 as a wholly-owned subsidiary, VWR serves as a leading global provider

Need masks? Contact Jason Kempton with VWR (1-843-743-6648) for reduced pricing on the nonsterile masks and now check the inventory on the sterile masks which have been very hard to come

of product and service solutions to laboratory and production customers. VWR offers a diverse portfolio that includes over four million products and enables customer success through innovation,

cGMP manufacturing and a comprehensive service offerings. VWR has been BIO's preferred

CureDuchenne Webinar: Italfarmaco Givinostat Program Update Thursday Sep 24, 2020 ... read more **The Fundamentals of Disinfectant Efficacy Testing**

Extractables Screening of Single Use Components for Qualification Wednesday Sep 30, 2020 ... read more **Opportunities for COVID Response Funding** Friday Oct 2, 2020 ... read more

... read more **BIO Investor Forum Digital** Tuesday Oct 13, 2020 - Thursday Oct 15, 2020 ... read more **Let's Talk About Series - Increasing Diversity in Clinical Trials** Wednesday Oct 14, 2020 ... read more

BIO Patient & Health Advocacy Summit Wednesday Oct 28, 2020 - Thursday Oct 29, 2020

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Tech Transfer During Critical Times

Wednesday Oct 28, 2020