



INCREASING PRODUCTION

North Carolina's dedicated effort to the biotechnology industry stretches back almost 40 years, before the idea was even a twinkle in most states' eyes. Since then, it has embraced the industry's many sectors, including biomanufacturing. The industry continues to produce a seemingly continuous supply of announcements, including startups, expansions, investments and jobs. While a solid foundation of support is established, more is needed to sustain the industry and its benefits. *Business North Carolina* magazine and N.C. Biotechnology Center recently gathered a panel of biotech experts and leaders to frame biomanufacturing's past, present and future.

BTEC, Eli Lilly, NCBIO, N.C. Biotechnology Center, Smith Anderson and Seqirus sponsored the discussion at N.C. Biotechnology Center, which was moderated by *Business North Carolina* Publisher Ben Kinney. It was edited for brevity and clarity.

Photography by Bryan Regan

WHAT IS THE CURRENT STATE OF NORTH CAROLINA BIOMANUFACTURING?

EDGE TON: North Carolina welcomed 34 life-sciences companies last year. They invested almost \$4 billion and announced about 4,000 jobs. We currently have about 30 active projects. We've done really well in recent years, and there's no reason why that won't continue. The industry's footprint is spreading. Drugmaker Eli Lilly, for example, recently announced it's building a \$1 billion

factory, which will employ about 600 people, in the Charlotte suburb of Concord. We'll see more investments and innovations in the Charlotte region, which is welcoming two medical schools and has access to plenty of capital. Every community that we talk to is doing something within the industry. Much of that is driven by post-pandemic activities. We have the opportunity for a significant grant through the federal Build Back Better Challenge Grant. We coordinated the application for 28 peers statewide, and we won \$500,000 in Phase I. We

submitted Phase II on March 15, and we hope to hear its result in mid-September. The state will see about \$70 million, if it comes through. Most of that money will be used to diversify the industry's workforce and share its wealth and experience with communities that haven't experienced either. Workforce is the key to unlocking future growth in biomanufacturing. We're excited. It wouldn't happen without great partnerships.

GUNTER: It's an exciting time. We've seen tremendous growth. Supply chain

PICTURED BELOW, FIRST ROW:

DOUG EDGETON

president and CEO, N.C. Biotechnology Center

GARY GILLESKIE

Biomufacturing Training and Education Center executive director, N.C. State University

LAURA GUNTER

president, North Carolina Biosciences Organization

SECOND ROW:

VERN HORNER

head of project management office and operational governance, Seqirus

SHEILA MIKHAIL

co-founder and CEO, AskBio

STEPHENIE ROBERTSON

vice president of operations, Fujifilm Diosynth Biotechnologies

THIRD ROW:

EMILY SISK

BioNetwork executive director, N.C. Community College System

JOHN WAGNER

program manager, Biotech Manufacturers Forum, North Carolina Biosciences Organization

DAN VONDIELINGEN

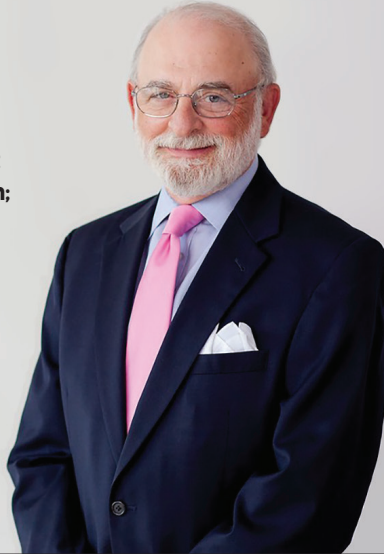
RTP site head, Eli Lilly and Co.

PANELISTS



PROUD PAST AND STRONG FUTURE

Santo Costa is no stranger to the pharmaceutical, health care and life-sciences industries, where he has worked for 40 years. He is an attorney at Smith Anderson; board chair, NC Biotech; board chair, Aquestive Therapeutics; and a former pharmaceutical executive at Quintiles and Glaxo Inc. He shared his thoughts on biotechnology's role in the state's economy.



WHY IS BIOMANUFACTURING IMPORTANT TO NORTH CAROLINA?

At Smith Anderson, we work with many life-sciences industry leaders and have seen firsthand how bio-manufacturing puts our state at the forefront of an industry that generates innovation on a global scale. The greatest positive effect of our state's strength in biomanufacturing are the thousands of jobs that have been created in biomanufacturing and other sectors of the life sciences. As this highly technical industry grows and flourishes, it provides a great incentive for individuals to get technical degrees and training through our universities and community colleges, further cementing the state's ability to attract world-class talent.

HOW HAS THE STATE POSITIONED ITSELF AS A BIOMANUFACTURING HUB?

In large measure, the state positioned itself decades ago to grow biomanufacturing through the efforts of organizations such as N.C. Biotechnology Center and North Carolina Biosciences Organization. These organizations and others have developed and implemented effective outreach programs to target companies in the life sciences, including biomanufacturing.

WHAT ARE THE INDUSTRY'S CHALLENGES?

One of the greatest challenges we have is attracting young people to pursue careers in the life sciences. The demand for technically educated and trained individuals will only increase and is one of the lynchpins to a flourishing life-sciences community. Fortunately, we have world-class universities and other institutions that will help meet this challenge.

and talent are NC BIO's manufacturing members' biggest concerns. They want to ensure there is an adequate supply of skilled workers as they expand in North Carolina. We want to help innovative companies, too. NC BIO represents the industry when it comes to legislative policies that make North Carolina a good place for companies to form and grow. We've had recent success at the General Assembly. The Life-Sciences Caucus is interested in what it can do to help the industry. Its members helped adjust some regulatory items last year. We also had an appropriations win when the General Assembly added recurring dollars to the One North Carolina Small Business Program, which will match federal funding awarded to companies for innovative research. We're always looking for ways to bring more capital to the state. We have biomanufacturers moving to North Carolina. Companies are working from product inception through the start of manufacturing. A large group of companies are moving into the commercialization stage, bringing products to the market. In the past, those companies may have sold that technology to a larger company.

ROBERTSON: Fujifilm Diosynth Biotechnologies is growing tremendously. It has acquired several sites since I joined the company four years ago. It is building a large facility for mammalian cell culture in Holly Springs that will create about 475 jobs over the next five years. A nearly 32,000-square-foot expansion was recently completed at our Research Triangle Park facility. It expands downstream capability and adds a receiving warehouse, which was something missing from the site for some time. And soon we'll break ground on an 83,000-square-foot expansion to our BioProcess Innovation Center, which is at RTP, too. It will almost double capacity and add about 150 jobs by 2024. Growing demand for process characterization, quality control services, and analytical and process development put us in a place

where we need to expand. The company also recently acquired a cell therapy facility in California and is establishing a new process development and manufacturing facility for viral vectors and advanced therapies in Boston.

HORNER: It has been a busy time for Seqirus. We're improving our process and yield, expanding capacity to match growing demand, especially for influenza vaccines, which is an effect of the COVID-19 pandemic. CDC requested more flu vaccines during the pandemic in hopes of keeping more people out of hospitals. We're developing an sa-mRNA flu vaccine, which is similar to the approach used to create the COVID-19 vaccines, in parallel with extending the use of our cell-based flu vaccine. The supply chain has been a challenge over the past 12 to 18 months,

as it has been for many companies and individuals. There's not enough of some things that we need. So, it's constant conversations with suppliers, making sure they know when we need materials and confirming that they can deliver them.

MIKHAIL: COVID-19 did not impact us negatively. We doubled our size in the United States and tripled our size overseas in one year. We have about 700 employees, and we're expecting to grow to 1,000 during the first quarter of next year. Our contract development and manufacturing business has seen growing demand. Gene-therapy manufacturing is in demand. We recently opened a more than 380,000-square-foot commercial factory overseas, where most of our manufacturing is located. Our process development is in North Carolina. We

plan to open a U.S.-based origin facility and companion CDMO factory. We're pushing many gene-therapy programs through the clinic, including ones for Parkinson's disease, heart failure and Pompe disease. We're excited about it.

VONDIELINGEN: We're seeing tremendous growth in our company and others in North Carolina's biomanufacturing industry. We purchased more than 200 acres of land in RTP in the last two years. We're nearing construction completion of our manufacturing factory on that site, and we'll do our first-process validation there during the second half of this year. We'll be manufacturing medicine very soon. We announced our Concord expansion, which includes a state-of-the-art factory on about 400 acres of land, in January. Those two announcements will create about 1,200 jobs.

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We recently hired our 150th Lilly RTP employee. The economic incentives that North Carolina offers are good, without doubt. But what differentiates it from other states is forums such as NCBio and the Biotech Center. They rally industry, educational institutions, government and community behind biomanufacturing and grow its workforce. They're where we heard state legislators talk about the importance of partnering with community colleges. As we've come into North Carolina, we see our peers and colleagues investing in educational and workforce development partnerships. That spurred us to partner with Wake Technical Community College, where we recently cut the ribbon on the Lilly Science and Technology Center at its RTP campus. The Center was conceived about a year and a half ago as a means to train more information-technology and biotechnology workers. The only way to fill jobs is through growing

the workforce. We all have employees who have worked for other companies within the industry. A larger workforce is the only way that we'll minimize trading talent among ourselves. We recognize our role in that, and we're doubling down on our efforts. I expect the Center to be the first of many opportunities to partner and grow North Carolina's workforce.

HOW DOES HIGHER EDUCATION SUPPORT THE INDUSTRY?

EDGETON: We need skilled workers, but the skill set changes constantly. So, curriculum has to change, and the equipment has to change. We're always trying to focus North Carolina on where demand and technology is headed not where it currently resides.

GILLESKIE: N.C. State University is preparing students for the life-sciences industry. BTEC, in particular, is focused on biopharmaceutical manufacturing. It attracts students from all over the university. We help them apply their skills in engineering or science to biopharmaceutical manufacturing. BTEC needs to keep pace with the industry to ensure students are prepared when they graduate. We want them to be trained in gene therapy, for example, which has been a busy sector in North Carolina. Automation and process control are advancing, so we need to make sure they are trained in those areas, too. There is high demand for BTEC's professional training and its graduates. About 35 companies participated in BTEC's most recent career fair. That's a significant number; there were only about 20 at past fairs. We are fortunate that BTEC students always have found jobs — the placement rate after six months is nearly 100%.

ON THE FRONT LINE™

EVERY PERSON PROTECTED HELPS REDUCE THE FLU BURDEN

Vaccinating against influenza helps slow its spread. With an estimated 1 billion flu cases each year globally,¹ we've got our work cut out — but as one of the world's largest flu vaccine companies, we're in the process of transforming flu protection on a global scale.

Reference: 1. WHO News Release, 11 March 2019. Found at: <https://www.who.int/news/item/11-03-2019-who-launches-new-global-influenza-strategy> (Accessed August 20).



WAGNER: I was helping Merck select a factory site in the early 2000s, when the decision was made to invest in BTEC and BioNetwork, a workforce-development program. They were the reasons Merck put that factory in North Carolina. They were a differentiator. Other states may have had better incentives, but North Carolina had the strongest commitment to long-term development and support of workforce. We came here on the promise that workforce development was going to be there. If you start and continue those type of programs, you become an attractive location. You can't wait until after companies arrive. Other states are trying to mimic them, but they're 25 years behind. The people running North Carolina's workforce programs have held true to those efforts. But the industry's growth is pressuring them. We're always training engineers, biologists and scientists. The

community college programs have done a great job training shopfloor workers. BioNetwork's program for technicians was recently reviewed, and we probably will start that process again in a year or so. It was done with biomanufacturing experts. It wasn't an educational exercise. They gave their input as to what's needed from shopfloor workers. They usually are recruited locally, and scientists are recruited regionally, sometimes nationally. You can have a central BTEC, but training programs need to be distributed. The industry's geography will expand naturally beyond RTP.

SISK: BioWork, a process technician training program, was developed in the early 2000s. It started with the Biotechnology Center, then it made its way to the community college system. It's a short-term program, 130 to 150 hours over eight to

10 weeks, depending on the college. It provides individuals with the foundational principles of biomanufacturing, so its curriculum must be current. It's reviewed, with help from industry representatives, every couple of years. That was last done just before the pandemic in 2020, so it's time to review it again. We're actively recruiting for gene therapy, a hot sector. Lilly's Concord announcement has opened the eyes of community colleges outside of RTP and surrounding counties, where most of the state's biotechnology business has historically been done, to biomanufacturing's opportunities. We offer biotech training and studies from Caldwell Community College and Technical Institute in the west to Pitt Community College in the east. We can offer it in more locations. BioNetwork supports all of the state's community colleges, so wherever a company is located, it can be there.



LILLY FOR BETTER

At Lilly, we are constantly evolving the way we discover, develop and manufacture medicines to bring new treatments to the people who need them even faster – and expand access to these medicines for even more people around the world.

Lilly

WHY DOES NORTH CAROLINA CONTINUE TO ATTRACT BIOMANUFACTURERS?

MIKHAIL: It's because of innovation at local universities. Our company is based on work done at UNC Chapel Hill, but we also have technology that was developed at Duke University. N.C. State University is doing a lot of work with gene therapy. When you have great innovation that's accessible locally, there's no reason to go anywhere else. Professors want to remain affiliated with their academic institutions, so the brain trust is here.

GUNTER: The state played a role in the industry's development, starting with the early funding of the Biotechnology Center in the late 1980s. Somebody called RTP a natural resource. There's nothing natural about it. It was intentionally created, as was the Biotechnology Center. The vision of some North Carolinians to engage government has been instrumental. We're doing things today that down the road, 25 to 30 years in the future, we'll point to and say those are the things that we lined up.

HOW DID COVID AFFECT THE INDUSTRY?

ROBERTSON: Supply chain challenges have been intense the past 18 to 24 months. Lead times for some consumables have jumped to 30, 40, 50 or more weeks from eight to 12 weeks. Demand for those materials has increased tremendously. We're running our supply chain operations differently. We onboarded more planners. They spend several hours on the phone every day, working out delivery details with vendors. If they can't get enough for four batches, for example, they'll ask if there is enough for two batches. We're looking at alternative suppliers of critical materials. Some vendors say we'll be beyond these issues in six months. But they're as intense right now as they were 12 months ago.

GUNTER: While we never discuss specific technologies between members, we hosted many calls with them during the pandemic to share information, bring experts in to discuss employment issues, vaccine distribution and other pertinent issues. We surveyed members about their COVID response to masks, distancing, curfews, work-at-home options and more. We shared that information in a noncompetitive anonymized format. It allowed other companies to benchmark their response to COVID-19 and ensured everyone was updated on the latest changes.

HORNER: We really appreciated that NC-BIO stepped up. The pandemic-response benchmarks were very helpful, especially during COVID-19's peak. Our employees would share that they heard this company is doing that or that company is doing this. We gauged our efforts, letting us know where we needed to be, while everyone remained somewhat confidential. Beyond supply chain issues, the biggest challenge is ensuring that we're doing the right thing for our patients and our employees. The environment around COVID, including rules and guidance, continues to change constantly. A large part of our emergency management is protecting our manufacturing team. We reduced our plant's population as much as possible, for example, allowing our most critical people and processes to keep pushing product out the door.

VONDIELINGEN: Supply chain issues and COVID-19 have been challenging enough, but demand for our products is at a level that we have never seen before. It takes a network of companies, many outside biomanufacturing, to make medicine right now. On an average day, we have 500 people onsite in RTP. They're construction workers, general contractors and from specific trades. While recapitalization efforts and expansions will create a continued need for them down the road, we will see a transition to more than

500 people making medicine in the next few years. But Lilly employees will be just the tip of the iceberg. North Carolina companies will comprise our supply chain for making medicine, which include many components such as autoinjector parts and printed packaging materials. Other companies are helping us write procedures, commission, qualify, and validate our equipment, ensuring good manufacturing practices. You can no longer rely on a single-source supply chain. You need multiple supply chains. You have to call your suppliers. They need to understand what is critical to you, and you need to appreciate their costs and constraints.

WAGNER: At its onset, some experts predicted the pandemic would last only six months. So, many biomanufacturers decided to weather the storm and fight their way through it. Our industry has a bit larger buffer inventories of supplies than many commodity industries, where goods are turned daily. But that original approach cost us six months. While hindsight is 20/20, we should've implemented changes immediately. The pandemic has caused businesses, especially large multinational ones that leverage buying power from a single global source, to rethink their operations. An interruption in that approach affects their entire operation, whereas a local interruption only affects a portion of their network.

GILLESKIE: BTEC is proud of its efforts to effectively train students, so they can get jobs and hit the ground running. But the pandemic has proven challenging to that mission. There was a point during the past two years when most universities, including N.C. State, were effectively shut down. We didn't have access to buildings or labs. BTEC, like community colleges, offers hands-on training and education. So, when COVID 'shut us down,' we were forced to re-evaluate our approach, finding creative ways to teach labs in a non-hands-on manner. There's no doubt that



TALENT IS EVERYWHERE

NCBIO works with public leaders, research institutions and life science companies on policies that accelerate innovation for improved health and quality of life.

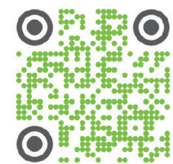
North Carolina's life sciences economy is growing by leaps and bounds, creating exceptional jobs in research and manufacturing. In 2021, the industry announced 4,800 new jobs and almost \$4 billion in new investment.

The challenge now is ensuring that everyone can take advantage of these opportunities and that our skilled workforce is sufficient to support our growth.

TALENT IS EVERYWHERE. We can engage people and communities who have been previously overlooked or excluded.

NCBIO is proud to support and guide our members as they commit to diversity, equity and inclusion efforts that will strengthen their businesses and their communities. It's not just the right thing to do; it's absolutely necessary in order for companies to grow, innovate and succeed.

Learn more about inclusive hiring practices and DEI initiatives at ncbiosciences.net/dei



NCBIO's Roadmap to Diversity events provide inspiration and guidance for member companies in pursuing their diversity, equity and inclusion goals.



North Carolina



BTEC will always offer hands-on instruction, but we see more opportunities for online training, too. Teleconferencing, for example, has made it easier to introduce experts, wherever they are in the world, to our students. The pandemic pushed us in that direction, and that's a good thing. Supply chain issues also have a large impact on training and education. BTEC conducts labs in all areas of bioprocessing such as cell culture and microbial fermentation. The processes we execute in lab require filters and other components, the same ones used by biomanufacturers. But educational institutions are a low priority for vendors. However, because BTEC's activities are not conducted in a regulated environment, we can easily switch vendors in hopes of finding what we need. But technical challenges remain; I can't switch from one type of filter, for exam-

ple, to another without data showing that the new filter is suitable for the application. BTEC's biggest pandemic-induced challenge is loss of subject-matter experts, which is probably a challenge faced by all training and educational institutions. We have lost a large number of staff — highly skilled Ph.D.s — to industry, where salaries are higher. BTEC gave them excellent experience, seeing and experiencing all facets of biopharmaceutical manufacturing, making them much more valuable. It's a serious problem. If it continues, the quality instruction that we want to deploy won't happen.

SISK: Even procuring personal protective equipment for the few courses we needed to deliver in person was a struggle. Some training was delayed, especially six months to a year

ago, because we couldn't obtain required materials.

MIKHAIL: Challenges aren't bad things. We always will encounter difficulties, but they can lead to opportunities. We have to look at them in a positive light and ask how we can innovate over the long term. That's where we'll find competitive advantages. Biomanufacturers can't make big changes in the short term because of regulatory constraints. But they can innovate over the long term. Our drugs, for example, have to be stored at -90 degrees Celsius. We examined how COVID was affecting that. We thought about how we could avoid that constraint all together. So, we started working with thin-film technology, which allows us to store our drugs at room temperature and ship them via the U.S. Postal Service.

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WHAT IS THE INDUSTRY'S ROLE IN ECONOMIC DEVELOPMENT?

EDGETON: We're blessed because North Carolinians collaborate, and that makes it different than other states. The Biotech Center and other groups have long histories of keeping the community connected. That has been important. The Build Back Better Challenge Grant, for example, is bringing together industry, academia and government. We're in the middle, trying to coordinate. A silver lining to the pandemic has been greater acceptance of technology such as teleconferencing. It's easy to get people from different companies, governments, economic development agencies and educational institutions on one call. It has been very helpful in moving projects forward.

GUNTER: Collaboration is part of NC-BioImpact's beauty. It was established years ago, creating partnerships between industry and academia. That allows us to evolve together.

WAGNER: Economic development and expansions lead to a stronger industry. We need to support the health of the industry, because we all win when we do. But that doesn't mean there aren't stresses. It can be a double-edged sword. When you see 600 jobs announced, for example, you know some of your employees will end up filling some of them. That stresses your current workforce.

GILLESKIE: NCBioImpact is a consortium that includes educational institutions, the Biotech Center and NC BIO. It's impact on the industry has been huge. It allows

BTEC to coordinate with the community college system, so we're not duplicating instruction but making complementary efforts. It also is a great collaboration from an economic development standpoint. That's reflected in current growth.

HOW IS THE INDUSTRY APPROACHING DIVERSITY AND INCLUSION?

VONDIELINGEN: Diversity, equity and inclusion are key for Lilly. Our factories will represent the population of the locations where we operate. One thing that attracted us to North Carolina is access to a diverse, talented and capable workforce. So, as we go through the interviewing process, we make sure that we have a diverse candidate pool. We also employ a diverse interview team. Then

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Over 85% of our graduates start their careers in North Carolina, quickly applying their hands-on biomanufacturing experience in numerous industry roles, including process engineering and development, manufacturing sciences, and quality assurance.

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we select the best candidates. That's proved to be successful for us. When you talk about diversity, there are dimensions you can see and ones you can't. We support that with employee resource groups, which are aimed at making sure employees can bring their entire self to work. It takes an entire team to make medicine. We also look at our partners, starting with our suppliers and vendors, ensuring they also support our diversity. Our partnership with Terrence Holt and Holt Brothers Construction at our RTP site is an excellent example. They're building and fitting out the interior of our administration, laboratory and multiple support buildings. Terrence and I have a two-way mentorship. We learn from each other. We're peeling back the curtain at Lilly in terms of how we do things. And he has been valuable in finding meaningful ways for us to engage the community. It's absolutely a benefit and core to what we do.

MIKHAIL: As a Mexican-American and founder of the company, AskBio takes big strides to ensure its workforce is diverse. Women and individuals of color are well represented in the company. Women are 64% of our manufacturing professionals. African-Americans are 12% of our workforce, and 17% is Asian. If a company's leadership is diverse, then it tends to be diverse. People are attracted to companies that have diverse leadership.

SISK: The community college system is a public institution. It's open enrollment. Anyone who wants to enroll at a commu-

nity college can. Only select programs, such as nursing, have enrollment requirements. But that doesn't mean everyone does. Through the Build Back Better Challenge Grant, we identified a few colleges — the ones closest to RTP — that were working together, identifying diversity, equity and inclusion needs within their programs. Their demographics showed a diverse population, but enrollment from the Hispanic-Latino community was lacking in comparison. The Build Back Better Grant process asked us to name our historically excluded population. That was a new term for us. We're familiar with underrepresented. It caused us to look inward at our programs and enrollment. We identified that the Hispanic-Latino population, for example, has been historically missing from life-sciences industry training. A portion of our proposal — and funding if we're supported — is working with the Hispanic Latino Action Coalition, a collection of nonprofits throughout North Carolina, to speak to and recruit from that community. There is an access gap of Hispanic males to higher education and the community college system as a whole. It was important for us to identify that. Even if we don't receive the federal funding, we know we need to embrace this population and find ways to bring them into our life-sciences industry programs. It has been a great experience to look more in depth then make changes. That's what we're doing.

GILLESKIE: It's important to have a diverse talent pool, whose members are trained and ready to work in the bioman-

ufacturing industry. BTEC recruits mostly N.C. State students into its academic programs. Even though we're part of the College of Engineering, we widened our focus several years ago, recruiting more heavily from the sciences. One of the benefits of that was a flip in the male-to-female ratio. We're recruiting a higher percentage of female students. Hopefully that helps produce a more diverse pool of talent.

GUNTER: We serve our membership. We've been approached by biomanufacturers that want assistance meeting their diversity goals. NCBIO's robust Diversity Committee brings together resources. We've organized a couple events, a virtual one during the pandemic and a hybrid one — a combination of in-person and virtual offerings — more recently. We brought together a diverse group of people. There's a lot of energy around it, and that's exciting. If we're not recruiting and retaining a diverse workforce, then we won't be able to fill all these jobs. The numbers are too high. We're not bringing everyone to the table currently. Other initiatives, such as the Build Back Better Challenge Grant, will help jumpstart activity, too, if North Carolina's proposal is successful. If there's not a way to get that recognition and understanding out to the community, so individuals can avail themselves of these programs, then we've missed the boat. ■

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