



STATE OF NORTH CAROLINA
OFFICE OF THE GOVERNOR
20301 MAIL SERVICE CENTER • RALEIGH, NC 27699-0301

BEVERLY EAVES PERDUE
GOVERNOR

December 6, 2011

To the White House Office of Science & Technology Policy:

Twenty-seven years ago, North Carolina made a commitment to invest in the life sciences and, by embracing technology-based economic development, we tapped the best of our considerable wellspring of academic, commercial and workforce-training creativity. Our collective vision helped to establish North Carolina as a consistent leader among America's key life-science states and gave us a solid economic growth sector that actually added jobs during the recent recession. Those of us fortunate enough to be among the "elder states" on America's life-science map can contribute real and useful ideas to what will ultimately be a National Bioeconomy Blueprint.

In this document, we have shared specific solutions in each broad area of President Obama's request for information on the bioeconomy. I believe that, with additional time and money, solutions that have proven worthwhile in North Carolina can lift all boats, creating jobs across the nation. A combination of proven strategies and new ideas will help us tackle unfolding problems, from gaps in capital allocation to corrections in critically short supplies of some therapeutics.

The bioeconomy is broad and deep, and includes agriculture, marine science and energy, as well as therapeutics and diagnostics. It opens doors for this and future generations of Americans to prosper, and promises to help boost the health and well-being of our friends around the world.

Sincerely,

A handwritten signature in black ink, appearing to read "Be Perdue".

Beverly Eaves Perdue

National Bioeconomy Challenge Response

Introduction

Forty years ago, scientists developed techniques that later allowed us to make human insulin. At the time, North Carolina's economy revolved around tobacco, textiles and furniture.

The discovery paralleled another change. Technology made us more efficient. Machines replaced human labor. Unskilled jobs went overseas. In the subsequent decades the South lost a significant number of jobs in its traditional industries. North Carolina was no exception. From 1996 to 2006 employment statewide dropped:

- 10 percent in furniture
- 23.5 percent in tobacco
- 51 percent in traditional textiles

North Carolina leaders looked through the job loss and saw opportunity. The state launched two centers in the early 1980s: the North Carolina Microelectronics Center to develop the information technology industry and the North Carolina Biotechnology Center to develop the life-science industry.

In the last three decades, the Biotechnology Center's work mirrors the intent of the Bioeconomy Challenge – working at all points along the technology development continuum to bridge gaps between research, business and education in order to create jobs. Through deliberate attention to this emerging industry, North Carolina built a **\$64.6 billion** economic engine that supports more than **226,000 jobs**. Nearly 60,000 of those jobs are at life-science companies and pay nearly double the state's average private-sector wage.

These impacts didn't come through short-term investments or luck. North Carolina deliberately assembled the pieces to build its biotechnology cluster. Thousands of respondents to President Obama's request for information on the bioeconomy will offer ideas for initiatives that will work with increased federal funding. We want to share some ideas that proved valuable during the 27 years that North Carolina has nurtured this significant life-science growth engine.



E. Norris Tolson
President and CEO
North Carolina Biotechnology Center



NOVARTIS



FUJIFILM DIOSYNTH BIOTECHNOLOGIES

Research and Development

Life-science research faces major challenges that go beyond the technical: expensive infrastructure; complex research problems that involve multiple fields; and weak connections between research, invention and commercialization.

North Carolina designed programs to address each of these issues. Biotechnology Center grants strengthen infrastructure by putting research equipment in spaces accessible to multiple labs. Our grants fund multidisciplinary research teams to work on complex problems. And, to link academic research to commercialization, the Biotechnology Center funds projects of commercial interest. Junior scientists often work on those projects thereby broadening their future career prospects.

Partners

North Carolina's public and private universities; RTI International and other private research organizations.

Future Challenge

New ideas are required for job growth. In life science, discovery is expensive and proving ideas takes time. To meet this challenge, the federal government can:

- Increase funding to the level needed to stimulate life-science research and innovation long-term.
- Strengthen existing programs that fund proof-of-concept studies and intellectual property creation.
- Develop new funding programs that foster academic-industry collaboration and professional career transitions between academia and industry, such as industry post-doctoral fellowships.

Moving Life Sciences Breakthroughs from Lab to Market

Early-stage funding is the greatest challenge facing companies and universities commercializing technologies, according to a 2010 survey of North Carolina's life-science industry¹. In the past decade, venture capital funding has declined substantially and life-science VC investments are now mostly focused on later-stage companies.

The Biotechnology Center created several funding programs to address this gap. The Technology Enhancement Grant helps universities strengthen a technology's ability to be licensed. Low-interest loans spur start-up, product development and growth for promising companies with few funding options. Finally, North Carolina allocated part of the state's pension fund to create the N.C. Innovation Fund that invests in innovative North Carolina companies and in other life-science investment funds.

Partners

State of North Carolina, Council for Entrepreneurial Development, Small Business and Technology Development Center, North Carolina's public and private universities, North Carolina angel and venture capital funds.

Future Challenge

Too little seed-stage risk capital is available for advancing promising technologies. To meet this challenge, the federal government can:

¹ Bridging the Gaps. <http://www.ncbiotech.org/business-commercialization/business-loans-support>

Areas of Future Promise

The techniques of biotechnology are widely applicable to a number of industries.

Agriculture

From food to fuel, or medicine to clothing, nearly anything that's not metal or glass can be produced in or by plants. Research, production and distribution jobs will abound.

More on the web at ncbiotech.org/agbio

Regenerative Medicine

Science fiction has become life-saving reality, as human organs grown from a patient's own cells are being produced in the laboratory and implanted in the patient.

More on the web at wakehealth.edu/WFIRM

Industrial and Environmental Applications

From engineering more efficient processes for industry to mitigating pollution, biotechnology is making a positive impact for the environment.

More on the web at bio.org/content/new-biotech-tools-cleaner-environment

BACKGROUND IMAGE COURTESY OF RTI



NCSU/BTEC



GRIFOLS

- Reduce uncertainty within the regulatory environment, a primary cause of diminishing venture investment in early-stage companies.
- Fill the gap by developing or expanding bridge funding programs that stimulate translational activities or refine a technology to make it more attractive to investors. Two excellent existing models are the National Cancer Institute's SBIR Phase II Bridge Award and the Department of Defense Commercialization Pilot Program.

Workforce Development

To compete in today's global economy, bioscience companies need employees with scientific competence and professional skills. Potential workers don't know where to get these skills.

North Carolina developed NCBioImpact², a public-private partnership of industry, universities, community colleges, and government, to educate employees for the biomanufacturing sector. This consortium has earned international recognition and enhanced the state's ability to recruit new manufacturing facilities. The resulting community of highly trained graduates and industry veterans enables North Carolina's biomanufacturing companies to fill more than 90 percent of job openings with local candidates.

Partners

Bio- and pharmaceutical manufacturers, North Carolina Biosciences Organization, University of North Carolina System, North Carolina Community College System, state and local governments.

Future Challenge

Success in other sectors and high-tech industries requires systemic changes to create a knowledgeable and "work-ready" employment base. To achieve this, classrooms from community college to graduate school must be more like the workplace. To meet these challenges, the federal government can:

- Engage students' imagination in K-12 Science, Technology, Engineering and Math (STEM) subjects through web-based technologies, including video games.

- Implement programs for high schools that enable students to earn a high school diploma and an associate's degree in five years.
- Involve industry advisory boards to develop and fund science education grant programs that use job-related success measures.
- Support professional science master's and doctoral programs that combine post-graduate work in science with industry sector-focused basic business education.

Regulatory

We live in a world replete with regulations. Consumers, companies and investors rely on clear, dependable and evenly enforced rules. In recent years the approval of medicines and medical devices has become increasingly unpredictable. N.C. life-science companies reinforce the message that the regulatory pathway is a significant challenge because it is not clear when a product might be approved. This ambiguity further limits companies from recruiting investors to fund product development. An uncertain regulatory environment is undermining the innovation process and will lead to lost jobs if not handled well and soon.

Partners

North Carolina Biosciences Organization, state and local governments, industry, consumer groups, general public.

Future Challenge

The Biotechnology Industry Organization (BIO) drafted a five-year plan that suggests creating a 21st Century FDA. We support BIO's recommendations on the FDA. The federal government can also:

- Create a task force that includes the FDA, industry and consumer group representatives to develop recommendations for streamlining FDA approval processes while maintaining reasonable safety standards.
- Keep the 12 years of data exclusivity included in the biosimilars legislation passed under the Affordable Care Act. The protection is critical to continued innovation in investments in researching and developing new treatments for patients.

² ncbioimpact.org

Grand Challenge

Tackle the Issue of Abandoned Drugs and Critical Drug Shortages

From 2005 to 2010, we saw drug shortages triple. Currently, 178 drugs are difficult or impossible to obtain. Factors that contribute to this situation include issues in the supply chain, problems at the manufacturing plant, lack of production capacity, an increase in demand and lower profitability for manufacturers. Of the drugs in short supply, four out of five are delivered by sterile injection, which means that they require specialized manufacturing processes.

The keystone of this grand challenge solution is to remedy critical drug shortages while eliminating the limits that costs and profit place on drug production. We suggest a national Critical Drug Manufacturing Initiative, which would:

- Provide a reliable production schedule for the manufacture of drugs that are in short supply.
- Establish a centralized Manufacturing Training Center for pharmaceutical manufacturing workers.
- Create a public-private forum to develop and improve best practices.

To fund this new initiative, we propose a federal subsidy equivalent to \$1 in new money to manufacture abandoned drugs or drugs in critically short supply for every \$100 spent on researching new treatments and cures. This \$1-for-\$100 approach would alleviate the worst of the drug shortages. This funding would be deployed:

- To existing drug producers, including contract manufacturers, or
- To a Critical Drug Manufacturing Center, a physical location with state-of-the-art facilities, subject-matter expertise in production methods, and world-class training in manufacturing. A non-profit CDMC could produce drugs at a modest premium above cost that would provide a shared revenue stream for the industry partner and the CDMC.

As an example of the impact, using the current NIH budget of \$34 billion, a \$1 for \$100 match would generate \$340 million toward the production of abandoned or short-supplied drugs



DSM

Public-Private Partnerships

When North Carolina's leaders began building a biotech industry for the state, they drew on broad talents across the state. Experts and leaders in research, public policy, business development and worker training created initiatives that drove the new industry. Collaboration continues today, as demonstrated in this document.

The North Carolina Research Campus³ in Kannapolis is a striking example of partnership. Where an old textile mill once stood is now home to state-of-the-art research facilities. Scientists from eight companies including LabCorp, Monsanto, and Dole as well as from seven public North Carolina universities and Duke University work side-by-side to better understand links between agriculture, nutrition and health.

Another example of partnership is the Centers of Innovation⁴ program created by the Biotechnology Center. Here, broadly based public-private partnerships are established through industry-sector-focused commercialization centers. Current Centers of Innovation have been established to smooth the path from university lab to market in the areas of nanobiotechnology, advanced medical technologies, drug discovery and marine biotechnology.

Future Challenge

Limited funding for new discoveries and the rising costs of product development make public-private partnerships crucial. Future problems will require this critical mass of attention and broad range of expertise. To meet this challenge, the federal government can:

- Incentivize public-private partnerships focused on technology commercialization by initially targeting three to five high-priority problems for federal funding.
- Create councils of science and business leaders to address current industry challenges.

³ NCResearchCampus.net

⁴ ncbiotech.org/COI



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Vice Provost for Research, Wake Forest University

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North Carolina Board of Science & Technology

DEPARTMENT OF COMMERCE, STATE OF NORTH CAROLINA

December 5, 2011

Ted Wackler
Deputy Chief of Staff
Office of Science and Technology Policy
Executive Office of the President
725 17th Street, Room 5228
Washington, DC 20502

Dear Mr. Wackler,

On behalf of the Board of Science & Technology, a state-level Board administered by the North Carolina Department of Commerce, I am pleased to endorse the NC Biotechnology Center's Response to the following Request for Information (RFI): *Building A 21st Century Bioeconomy*.

Created in 1963, and composed of industry, academic, and nonprofit leaders from throughout the state, the Board is statutorily charged with identifying, supporting, and fostering research and development needs of both public and private institutions and organizations in North Carolina that relate to the state's economic growth and development. The Board has been responsible for numerous internationally recognized initiatives to catalyze the transformation of North Carolina's economy by leveraging research, science, entrepreneurship, and innovation. Examples include recommending organizations such as the NC Biotechnology Center (NCBC), the NC School of Science and Mathematics (NCSSM), and the Microelectronics Center of NC (MCNC), and leading strategic planning efforts such *Vision 2030, A Roadmap for Nanotechnology in North Carolina's 21st Century Economy*, and *Advancing Innovation in North Carolina*.

Several members of the Board of Science & Technology provided input to the Biotechnology Center's response, which addresses each of the RFI's major subject areas. It does so in two ways: first by describing each subject area and then articulating what North Carolina has done to address challenges in that area, and second by identifying a future challenge and proposing one to three actions the federal government can undertake to meet it. This approach draws on the nearly 30-year experience of the Biotechnology Center in supporting biotechnology research and development, business, education, and strategic policy.

We appreciate to opportunity to provide input on this important initiative, we hope you find the responses useful, and we welcome further dialogue on this topic.

Sincerely,

A. Blanton Godfrey
Dean, North Carolina State University College of Textiles
Chair, North Carolina Board of Science & Technology

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Creating Success

NC Community Colleges

Hope • Opportunity • Jobs

Growing the Life Science and Biotechnology Workforce in North Carolina *Connection, Entry, Progress, and Completion*

Introduction

The over-arching challenge for the life science industry in North Carolina is to recruit, train, graduate, and place more students into the critical jobs that will help companies compete in the global marketplace. Over the last decade, North Carolina has felt the effects of the new world economy. In 1999, North Carolina had the 12th lowest unemployment rate in the nation. Today, the Department of Labor shows North Carolina declining to the 44th lowest rate. This is due in large part to the recession of 2008 and the migration of traditional manufacturing (textiles, furniture) in North Carolina to developing countries. Nearly every industry sector in North Carolina has been impacted negatively by the recession except for the biotechnology sector. This sector in North Carolina posted minimal growth between 2008 and 2010 but did not decline like other sectors. To continue to strengthen the sector it is imperative that the pipeline of workers for the life science industry be more highly trained than their counterparts in other countries in order to ensure that the companies in North Carolina maintain and grow their competitive edge in the global economy.

In response to this challenge, the NC Community College System recommends an approach based upon our experience with the since 2004 BioNetwork Initiative. This approach includes using a newly developed world-class talent management and economic development web 2.0 solution coupled with the on-going activities of BioNetwork's seven centers, NC Community College's SuccessNC initiative, and the outreach capabilities of the System's *STEM Bus*.

Background and Significance to North Carolina

In the early part of the 21st century, North Carolina took the mantle of biotechnology and, with targeted investments in workforce development, university research, education and facilities, North Carolina attained the number 3 spot in the country in that growing field. But how do we ensure that North Carolina doesn't fall behind in the coming years? One way is to make use of the foundation put in place through our biotechnology investment at our state's leading workforce training network, the NC Community Colleges, to expand its reach, streamline its resources and develop the education programs that will train the post-recession workers in North Carolina.

The recommended approach will help connect lower socio-economic, minorities, at-risk students, and the general populations to the education opportunities and careers available to them in the life science sector in North Carolina. The process follows a framework that has been the guiding foundation for NC Community College's SuccessNC initiative. This framework focuses on: a) how students obtain information and *connect* to education and careers, b) how they gain *entry* into training and education programs, c) how they *progress* towards attainment of credentials and degrees, d) how they *complete* programs of study and are placed into careers.

Description of Key Components

Connect:

- This process begins in K-12 where students are introduced to critical careers and plugged into one of the *online interactive* portals using the *STEM Bus*. These students and any student enrolling into a community college course will gain access to virtual career explorations and highly interactive and engaging 3-D immersive learning systems (www.launchingbrightfutures.com). Industry and businesses will be able to promote their companies by partnering and become a 3-D immersive world for students to explore and learn about the life science industry.
- An essential part of the recruitment of students will be appeal of the video game-like technology available on www.launchingbrightfutures.com and access via internet connections at public schools and community centers State-wide.

Entry:

- North Carolina will implement in January 2012 structured dual enrollment opportunities for high school students. Qualified juniors and seniors may enroll in college transfer and career technical education certificate programs in life science and engineering tracks. Qualified ninth grade students may enroll in Cooperative Innovative High School Programs that provide the opportunity to complete a high school diploma and an associate's degree in five years.
- Opportunities also exist for incumbent workers and career changers who complete BioWork to obtain credit in biotechnology associate degree programs at NC Community Colleges. Additionally, workers who have completed various third party industry-recognized credentials will be able to earn credit in appropriate associate degree programs.

Progress:

- BioNetwork's seven centers focus on creating and enhancing the training and education programs delivered through the 58 NC Community Colleges. BioNetwork was created through a grant from the Golden LEAF Foundation in 2004 and has grown and matured to account for over 200 new courses and course enhancements, over 10,000 trainees and students, over 50 life science customized training projects, and over 20,000 outreach/visitors to BioNetwork STEM bus. BioNetwork's centers and staff of subject matter experts is a vital part of supporting and growing the life science cluster in North Carolina.
- Mobile training provides increased flexibility to companies and students by taking portable high tech equipment and expert instructors on the road. Through BioNetwork, a mobile training trailer can be transported to an industry site. The trailer expands to accommodate 12 to 14 students and a wide variety of industry specific equipment.
- BioNetwork's BioEducation Center is a leader in developing advanced learning technologies for the life science and biotechnology programs at NC Community Colleges. These in-

clude simulation and gaming, multimedia learning tools, flash-based web tools, and virtual learning objects. Advanced learning tools are designed to enhance classroom learning and assist an instructor so that more time can be spent on hands-on training.

- A statewide comprehensive agreement between the NC Community College System, the University of North Carolina and selected NC Independent Colleges and Universities, the CAA ensures seamless transfer of up to 64 semester hours of credit and fulfillment of the undergraduate general education core for students who complete the 44-hour core or the associate's degree.

Complete:

- Through a partnership with the National Association of Manufacturers and Futures, Inc., a web-based portal (www.usmanufacturingpipeline.com) will be available to community college students through which they will be able to connect directly with employers, share online portfolios, learn about careers and companies, and identify opportunities for further education. Unlike job boards and other online career sites, this portal provides more functionality and security for students as they prepare their education and work portfolios.
- The NC Community College System and National Center for Biotechnology Workforce at Forsyth Technical Community College have also partnered with the National Association of Manufactures (NAM) to identify or create appropriate biotechnology industry certifications. Following NAM's Endorsed Skill Certification System for advanced manufacturing, the certifications will stackable with other lower level and higher certifications such as the National Career Readiness Certification or the North Carolina Processing Technician Certification.

Biotechnology in the Piedmont Triad

A PARTNERSHIP OF PIEDMONT TRIAD CITIZENS AND THE NORTH CAROLINA BIOTECHNOLOGY CENTER

To the U.S. Office of Science and Technology Policy,

The Piedmont Triad region of North Carolina for a long time was known for tobacco, textiles and furniture. RJ Reynolds, Lorillard, Burlington Industries and others employed a large portion of our residents. We saw our economy change, and we lost good-paying jobs as the knowledge-based economy grew.

Over the last decade, this 12-county region that includes Greensboro, Winston-Salem and High Point has pulled together to develop the research and business infrastructure to support a high-tech economy. It began with the Winston-Salem Chamber of commerce and their blueprint to move toward a biotech and life-science economy.

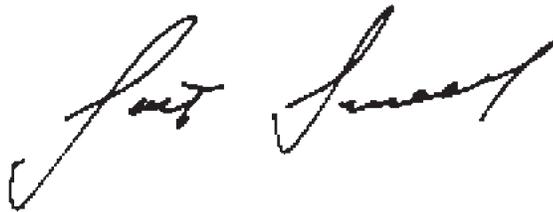
Since then, we've developed two research parks, a joint school specializing in nanoscience and a wet-lab facility designed to serve as a launch pad for small companies. We've helped major companies like Targacept and Cook Medical grow. Our community colleges, particularly Forsyth Tech and Guilford Tech, have developed workforce training programs recognized internationally. And at the Wake Forest Institute for Regenerative Medicine, researchers are revolutionizing the way we think about organ transplantation.

Based on our experience and vision for the future, the Advisory Committee for Biotechnology in the Piedmont Triad has assembled a list of ideas. They include direct responses to the questions posed in the Bioeconomy Challenge as well as some ideas for the National Bioeconomy Blueprint. We also support the response of the North Carolina Biotechnology Center, included.

On behalf of the committee, we thank you for your attention,



Russ Read, Chair
*Advisory Committee for Biotechnology in the
Piedmont Triad and
Executive Director
National Center for the Biotechnology Work
Force
Forsyth Technical Community College*



Scott Sewell, Vice Chair
*Advisory Committee for Biotechnology in the
Piedmont Triad and
Vice President, Technology Acquisition &
Development, Cook Medical*

The Piedmont Triad is pleased to provide this information in response to the BioEconomy Challenge request for information. The input is based on North Carolina's success with building a life-science cluster.

The items listed below are not in order of importance and have been formatted as bullet points.

- Establish an FDA committee of academic and corporate leaders, including those from medical device, diagnostics and theranostics companies, to collaborate on the development and refining of predictive modeling programs for drug safety and efficacy. This could help reduce untoward side effects, costs and time from discovery to the marketplace.
- The FDA should:
 - (a) review list of FDA-approved indications for which INDs, clinical trials, and NDAs can be filed/conducted,
 - (b) review FDA-approved primary and secondary endpoint/outcome metrics. Researchers at prominent academic institutions are developing methodologies for measuring clinical trial results, but the FDA may not be coordinating with them.
- Establish an FDA subcommittee involving FDA clinicians/statisticians, academic researchers and life-science company chief medical officers to address unmet medical needs.
- To spur workforce development and economic growth, the federal government should establish a grant program to enable academic institutions to fund scientific/engineering internships at life science companies. This will broaden opportunities and stimulate interest in STEM education and provide win-win outcomes for students and life-science companies. The North Carolina Biotechnology Center's undergraduate and industrial (postdoctoral) fellowship programs are examples of successful models.
- With the assumption that life sciences companies prefer to hire locally, an obvious source for talent (i.e. laboratory technicians) is the community college system. The Associate of Applied Science degree programs at community colleges can be taken to the next level, particularly in nationally certified/credentialed programs, through federal reimbursement of tuition and related expenses directly to community colleges (subject to certain restrictions) for displaced workers receiving unemployment compensation who are seeking career changes into life sciences. This would help create jobs and provide a workforce-ready pool of talent.
- Encourage commercialization of new technologies through loan programs in the \$100,000 to \$250,000 range that don't require personal collateral such as the family home of an academic scientist or entrepreneur in loan guarantees, and simplify application forms.
- Advance the NIH initiative to establish a national translational research center/institute that can spur commercialization of basic university research discoveries via grants and other funding.
- Repeal that portion of the Patient Protection and Affordable Care Act which will institute a 2.3 percent federal tax on medical device company revenues in 2013.
- Support certification programs in development: Certification of specialized skill-sets affirms a knowledge and experience base for practitioners in a particular field, their employers, and the public at large. Working with partners at the national and state level, we aim to advance a process of adapting existing, or if necessary, creating the required certification for the biosciences technical workforce. (National Center for the Biotechnology Workforce, a NC BioNetwork Center, and the National Association of Manufacturers)