BIOTECHNOLOGY and HUMANITY

at the CROSSROADS of a NEW ERA

A Report from the Institute for Emerging Issues

Emerging Issues Forum 2002

North Carolina State University

Raleigh, North Carolina

THE INSTITUTE FOR EMERGING ISSUES

James B. Hunt, Jr., Chairman
Noah M. J. Pickus, Director

The Institute for Emerging Issues is an initiative of the Kenan Institute for Engineering, Science and Technology. Located on Centennial Campus at North Carolina State University, the Institute for Emerging Issues sponsors interdisciplinary studies and public affairs projects that increase understanding of scientific and social research, generate innovative policies, and spur multisectoral collaborations.

Public Affairs Programs

- **Public Affairs Meetings** that educate leaders and the public about important issues in science and technology, including the Emerging Issues Forum which, for 17 years, has attracted internationally known speakers and experts, as well as hundreds of leaders and citizens from across North Carolina and the south.
- **Working Groups** consisting of academic experts, government decision-makers, non-profit and private-industry leaders, journalists, and grant makers who develop policy recommendations and seek to implement them.
- **Policy Reports** that crystallize the key choices leaders face and identify the best scenarios for forging coalitions that can promote innovative and workable solutions.
- **Leadership Consultations** held across the state to brief small gatherings of civic leaders on important issues in science, technology, and economic development and engage them in seeking solutions.

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- **Multidisciplinary Research Projects and Publications** that emphasize knowledge that is grounded in the public problems of society.
- **Fellowships in Innovation** for journalists, entrepreneurs, civic leaders, scholars and others to shape state and national debate by analyzing critical issues for a broad audience.
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- **Course Development Projects** enabling area faculty to link courses to Institute programs.

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PREFACE

The promise and the peril of biotechnology were examined at the 2002 Emerging Issues Forum held February 11–12 at North Carolina State University. Speakers included a U.S. cabinet secretary, a U.S. senator, the current and immediate past state governors, two U.S. representatives, biotech CEOs and leading scientists, scholars, policy experts, and ethicists.

Numerous speakers extolled the promise of biotechnology to transform the medical care we receive, revolutionize industries ranging from agriculture to mining and reshape our economic future. Several cautioned that North Carolina has far to go if it hopes to compete effectively for the economic benefits biotech offers. Others issued stark warnings: the threat of bioterrorism, the lack of adequate government oversight and the potential for public misunderstanding, opposition and even panic.

The Forum was directed by Noah Pickus, Director of the Institute for Emerging Issues and Research Associate Professor of Political Science and Public Administration at NCSU. We would like to express special appreciation for the fine work of Michael Roth, Susan Rogers, and Brandi Creasman. Garnet Bass, Pam Chastain, and Maura High all made significant contributions to this report. We are also thankful for the gracious assistance of Cindy Malecha, Ena Meng, and Ann Craddock.

For advice and counsel, we are grateful to Steven Burke, Phil Carter, Darren Clark, Stephen Goodman, Patrick Hamlett, Charles Hamner, Tom Hoban, Elizabeth Kiss, Robert Kelly, Russ Lea, Raj Narayan, Gary Pearce, Christy Russell, James Siedow, Barbara Sherry, Sam Taylor, and Ken Tindall.

We gratefully acknowledge the support of Progress Energy, the Office of the Provost, and the Board of the Kenan Institute for Engineering, Technology and Science.

Ruben Carbonell
Director, Kenan Institute for Engineering, Technology and Science
KoSa Professor of Chemical Engineering

FROM THE CHANCELLOR

While plant and animal breeding have been around for hundreds of years, new biotechnology techniques now enable scientists to move genes in ways they could not before. At North Carolina State University we are proud of our efforts to stay in the forefront of biotechnology initiatives, developing programs and initiating research in this rapidly advancing technology. For this reason we think that NCSU is exactly the right place to engage a range of participants in a continuing dialogue about this technology and all the potential it holds as well as its possible perils.

Among the numerous biotech research and educational resources we claim are the Biotechnology Education Facility, the Bioinformatics Research Center, the DNA Sequencing & Mapping Facility, the Genome Research Laboratory, and the Forest Biotechnology Laboratory.

As Chancellor of this institution, I take great pride in the commitment that N.C. State has made to biotechnology and in its capacity to support the growth of this industry in North Carolina.

A central focus of our efforts in biotechnology and other new areas at the frontiers of science is the Centennial Campus. I believe it is the most innovative and dynamic university research and economic development center of its kind in the nation.

At the Forum, I announced a new venture for Centennial Campus: the Institute for Emerging Issues. This new Institute will expand the Emerging Issues Forum into a comprehensive public policy organization that bridges the gap between the world of public policy and the world of science, engineering, and technology.

As an initiative of the Kenan Institute for Engineering, Technology and Science, the Institute for Emerging Issues will draw on the expertise of all our universities and will marshal knowledge from government and the private sector to address a wide range of challenges. We are pleased that former Governor Jim Hunt has accepted our invitation to serve as chairman of its board.

Marye Anne Fox
Chancellor
North Carolina State University

FROM THE CHAIRMAN

"Biotechnology today is where the computer industry was in 1975." With this analogy, Charles Hamner, retiring President of the N.C. Biotechnology Center, drove home to the Emerging Issues Forum the enormous economic potential the industry holds.

When we created the Biotechnology Center in 1979, it was the first state-supported biotechnology initiative in the nation. Since then, North Carolina has emerged as a center for biotech growth and development. Further, biotech applications in agriculture, health care, and the environment hold the potential to spread the industry beyond the Triangle and into economically distressed rural areas of the state.

But North Carolina is not the only dog in the hunt. Forty-two states have biotech programs. More than 200 international sites have been established. Several speakers at the Forum challenged North Carolina to remain among the international leaders.

So what will it take?

It will take strong cooperation among government, business, and academia to sustain the energy that led to the creation of the Research Triangle Park and the N.C. Biotechnology Center. It will take a focus on education, because the biotechnology industry needs a skilled workforce and attracting firms here requires good schools at every level. And it will take connecting all parts of the state in our efforts.

This Report addresses these and other tasks and I commend it to you with great enthusiasm and hope. The new Institute for Emerging Issues is expanding the work of the Forum to take on these urgent tasks. I am tremendously excited by this new venture and the potential it offers to take on the critical issues that will face our state and nation in the 21st century.

James B. Hunt, Jr.
Chairman, Board of Advisors
Institute for Emerging Issues

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EXECUTIVE SUMMARY

The Challenges

Biotechnology is the science of altering life at the molecular level. It creates unprecedented potential to prevent and cure disease, to create new crops, to harness living organisms for use in manufacturing and mining. As we harness the opportunities, we also have the responsibility to consider the broader picture.

Steven Burke, Vice President of the North Carolina Biotechnology Center, described the challenge this way: "We can now do the stuff that before was the stuff of our mythology. We are changing our relationship with nature. We have seldom addressed in our human history anything so demanding of our imagination."

The question is: Are we ready?

Is North Carolina ready to seize the economic opportunity that biotech offers? Are our public institutions—especially government and universities—ready to advance the science, to support its technological applications, and, at the same time, to strengthen our understanding of biotechnology's implications? Are we as individuals and a society ready to resolve the moral, ethical, and legal issues that arise with the prospect of altering life, crossing boundaries between species and blurring distinctions between plants and animals?

Are we as individuals and a society ready to resolve the moral, ethical, and legal issues that arise with the prospect of altering life, crossing boundaries between species and blurring distinctions between plants and animals?

The Emerging Issues Forum focused on these and similar questions in February 2002, in a debate that has already been followed up by other organizations and civic bodies. This report describes the Forum deliberations as well as some of these additional programs.

While the Forum participants disagreed on a number of issues, their views converged in several key areas. To respond to the challenges it faces, panelists urged North Carolina to:

- Review all science- and technology-driven efforts to spur economic development and strengthen growth-from-within strategies.
- Strengthen basic science at the K–12 level and biomanufacturing at community colleges and invest in strong research universities where independent, creative thinkers are free to think boldly.
- Find new and creative ways to boost technology transfer and commercialization.
- Develop a statewide strategy for universities and community colleges to contribute to economic development in their region.
- Challenge biotechnology companies, universities and community colleges to foster broader, deeper, and sustained public debate about biotechnology.

The Road Ahead

During the Forum, North Carolina's readiness to meet the challenges and promises of biotechnology was compared to those of other states. Maryland was spotlighted as an emerging leader in biotech initiatives. But that state's program came with a hefty price tag, including investments in venture capital, incubators, and technical support, as well as a 70 percent increase over seven years in the public university system's budget.

One panel at the Forum agreed unanimously that North Carolina's education system must be strengthened top to bottom in order to take advantage of the opportunities. "Our economy is a knowledge economy," noted Jim Mullen, CEO of Biogen, one of the nation's largest biotech companies. On the same note, Governor Mike Easley reiterated his commitment to protect public school classrooms against budget cuts.

Other panelists addressed the unique role universities can play—and the issues that arise as a result. Max Wallace of Durham, President and CEO of Cogent Neuroscience, warned, "We need to get over the schizophrenia as a society about how we see universities in the development and technology transfer process." Wallace also expressed concern over what he sees as a divide between the Triangle and Charlotte: "We have one of the great money centers in the United States and one of the great technology centers, but we don't talk to each other."

Charles Hamner, the Biotechnology Center's outgoing president, called for increased funding for the Center's efforts. North Carolina's Secretary of Commerce, Jim Fain, said the state has strengthened its competitive position by moving the Board of Science and Technology into his department, focusing on ways science and technology can support economic development.

But other states are making far greater investments than North Carolina to attract biotech companies. Further, Mullen and other speakers warned that North Carolina's education system and public infrastructure—air transportation, roads, energy, water, and sewer—could prove inadequate to meet the competition.

Perils as Well as Promise

Other barriers loom. The Forum's speakers took note of controversies that can arise over issues including bioterrorism, cloning, genetic screening, and genetically modified crops.

Tommy Thompson, the U.S. Secretary of Health and Human Services, noted that he saw firsthand the dark side of bioterrorism in the wake of the September 11, 2001, terrorist attacks. Senator John Edwards and Representative Bob Etheridge addressed the need to protect the nation against bioterror. "There are fewer barriers to bioterrorism than to other means of mass destruction," Etheridge said.

Arthur Caplan, Director of the University of Pennsylvania's Center for Bioethics, offered hope—and a cautionary note: "Biotechnology is probably the best defense

The Forum's speakers assessed controversial issues including bioterrorism, cloning, genetic screening, and genetically modified crops.

against bioterrorism, but the greatest threat to biotechnology is bioterrorism, or the link some people inevitably make."

Elizabeth Kiss, Director of the Kenan Institute for Ethics at Duke University, directly addressed the ethical concerns that dominate controversial issues such as President Bush's decision on stem cell research: "With biotechnology the policy challenge we face is that of crafting public policy in the face of our deepest moral disagreements. Some have dismissed attempts at compromise as cynical and not worth considering. I'd like to persuade you otherwise."

Agricultural uses of biotechnology can be controversial, too. Witness the European rejection of genetically modified food crops. "Farmers in the United States have had to reconsider the wholesale adoption of GM crops in light of European opposition," said Sandy Thomas, Director of the Nuffield Council on Bioethics in Great Britain. Panelists at the Forum debated the role that federal agencies such as the Food and Drug Administration, the Environmental Protection Agency, and the Department of Agriculture should play in regulating the industry. Congress and the North Carolina General Assembly also face pressures to enact legislation governing agricultural applications of biotechnology.

The remainder of this report offers a more extensive review of the startling advances being made and the difficult policy issues they raise.

A number of Forum speakers agreed that North Carolina and the nation must find better ways to confront these disagreements. As the Biotechnology Center's Steven Burke charged, "Too often we've addressed the ethical and societal implications of technology too late, at the end of the process. Sometimes we've done it thoughtfully, but sometimes we've done it to induce public acceptance. We must do better. We must pay attention to numerous difficult issues from the beginning, at all points and continuing."

Next Steps

The Emerging Issues Forum made clear that issues surrounding biotechnology are complex, far-reaching, and contentious. The remainder of this report offers a more extensive review of the information, issues, and ideas presented during two days of keynote speeches and multisectoral panels. The Forum produced no final answers. But it laid the groundwork for a greater effort to involve thoughtful North Carolina leaders and citizens in a constructive dialogue.

This dialogue is now being extended by the Institute for Emerging Issues. The mission of the Institute is to bridge the gap between public policy and the fields of science, engineering, and technology. Perhaps nowhere is this bridge needed more than in biotechnology. The startling advances being made—and their velocity—have outpaced public policy. To address this gap, the Institute has launched or collaborated on a series of interrelated projects, including:

- A special Forum briefing for the board of the N.C. Economic Developers Association on biotechnology and new approaches to economic development. Hosted by Womble, Carlyle, Sandridge & Rice, and featuring Jim Hunt,

Institute Chairman, Jim Fain, N.C. Secretary of Commerce, and John Merritt, Senior Assistant to Governor Easley, this breakfast led NCEDA to organize a day-long workshop on the same subject for its members. Hosted by Novozymes in Franklinton, and spearheaded by Leslie Stewart, the workshop included presentations by John Bardo, Chancellor of Western Carolina University; Anthony Laughery, President and CEO of KBI BioPharma, Inc.; and Scott Ralls, Vice President of Economic Development for the N.C. Community College System.

- A public symposium on biotechnology, workforce, and intellectual property issues at the Museum of Natural Sciences in conjunction with its Genomic Revolution exhibition, and, in collaboration with the Center for Genome, Ethics, Law and Policy and the Kenan Institute for Ethics, a university-private sector conference at Duke Law School on commercialization, innovation, and patent law related to the human genome.
- Leadership consultations in eastern North Carolina on biotechnology and biomanufacturing and on challenges and opportunities in technology-driven economic development. In partnership with the Genomics and Bioinformatics Consortium and the North Carolina Biotechnology Center, these consultations aim to give a range of leaders the opportunity to think creatively and practically about biotechnology, about new approaches to economic development, and about how universities and community colleges can best forge community development.

This report sets the stage for these upcoming consultations and conferences. We hope to stimulate discussion, debate, and decision making. Is North Carolina ready to reap the economic bonanza that biotech promises? Are government and the universities ready to play the proper role—both in advancing the technology and advancing society's understanding of it? And are we—as citizens—ready to face this exciting and sometimes frightening new world? These are the questions the Institute for Emerging Issues will continue to address. We invite you to read more, to reflect on your own reactions, and to join us in charting the future.

Noah Pickus
Director
Institute for Emerging Issues

This report sets the stage for these upcoming consultations and conferences. We aim to advance biotechnology —and our capacity to manage it.

2 BIOTECHNOLOGY BASICS
The Science and Applications

The Origins of Biotechnology

Through presentations in the Forum's various panels, a picture emerged of the development of biotechnology from its earliest beginnings up to the present day.

For as long as humans have been farming, we have been selectively breeding crops and animals. For centuries, we used microorganisms such as yeast to make bread rise, beer ferment and cheese ripen. In the 20th century, we discovered how to transform bacteria into medicines. By the oldest definition of the word, all of these uses of living organisms were biotechnology.

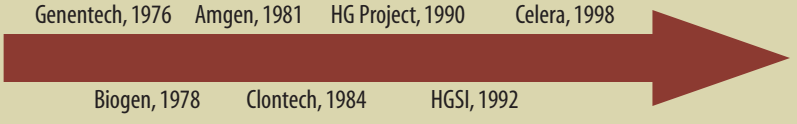
Then, in 1971, two California scientists developed the first technique for inserting one organism's genes into another—and allowing the genes to function in their new home. In the three decades since, the word "biotechnology" has come to refer to the manipulation of life at the cellular level: splicing genes, cloning tissue, and separating strands of DNA. In those three decades, the field of biotechnology altered science for all time. In the 21st century, it promises to fundamentally alter our lives.

Advances in biotechnology create the prospect of whole industries built on genetically engineered life forms. The possibilities grow almost daily as scientists improve their ability to detect which genes determine growth patterns, susceptibility to disease, and other characteristics and to decipher the way genes carry out those functions through the production and control of proteins.

On the Shoulders of Giants

Biotechnology Milestones

- **Discovery of the Structure of DNA – 1953**
- **Synthesis of Recombinant Human Insulin – 1978**
- **Invention of Automated Gene Sequencer – 1986**
- **Patenting of Genetically Altered Mouse – 1988**
- **Funding of Human Genome Research Center – 1989**
- **Approval of Recombinant Interferon for Treatment of MS – 1996**
- **Completion of Human Genome Draft – 2000**



Source: Cogent Neuroscience

Medical and Pharmaceutical Applications

In helping explain how diseases progress, biotechnology has given medical researchers valuable information in how to fight them. Thus, the discovery that one "cancer gene" causes the disease by emitting a certain protein has led to tests of a drug designed to prevent the release of that protein.

Biotechnology improves the speed and precision of drug development, said Max Wallace, President and CEO of Cogent Neuroscience. The pharmaceutical industry used to be based on trial and error with chemistry—developing and testing one chemical compound at a time. This cumbersome and costly process generally requires eight to 10 years to develop and test a new drug.

Because biotechnology provides better information about the disease process up front, researchers can now bypass large parts of the classic drug discovery process. "We have the potential for more targets, better drugs with characteristics that really treat the problems we're facing, better clinical trials, tailored treatments, improved preventive medicine, and a more affordable health care system," Wallace said.

New types of treatment are in the works, too. One day gene therapy may allow the defective portion of a gene to be replaced with a "healthy" segment of DNA, freeing people forever from deadly diseases such as cystic fibrosis, while stem cells are coaxed into growing new tissue to repair the damage of Parkinson's disease, spinal cord injury, and heart attack.

Among new medical diagnostic tools are a blood test that screens for ovarian cancer and another test that detects colon cancer through abnormal cells in a stool sample. Couples concerned about inherited diseases can learn whether they could pass disease genes on to their children.

Mapping the Human Genome

It would be a mistake to assume that such advances have become commonplace or easy. As science moves from gene identification to gene function and the interplay of genetics and environment, progress becomes far more difficult. Mapping the human genome made the scale of the difficulties clear. Forum participants discussed these issues in several sessions. With three billion pieces of genetic material to be read and interpreted, explained Craig Venter, who led one of the competing research groups, the project would not have been possible without high-powered computers and even higher powered software for sorting and storing the tremendous amount of data generated.

Even with its release, the first draft of the human genome—delineating the sequence of 30,000 genes—raises as many questions as answers. "It's like being on the outside of a huge stadium and hearing cheering, but you don't know what the event is or who's playing," said Robert Nussbaum, Chief of the Genetic Diseases Research branch of the National Human Genome Research Institute. "Sequencing lets us into the stadium. We can see how many players are on the field, how many

Sequencing the human genome lets us into the stadium. We can see how many players are on the field, how many are on each team, and what kind of ball they're using, but we still don't know what the rules are.

ROBERT NUSSBAUM
NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Zip Codes and Smart Bombs

We now understand at the fundamental biologic level that on the surface of the cancer cell there are little proteins that are exactly like the zip code on an envelope that you put in the mailbox.

When that cancer cell goes through the bloodstream, there are letter boxes at different organs and they are specific so each particular envelope goes to that specific address.

Now that research gives us that sort of insight, we at the therapeutic end can use that information to perhaps erase that zip code so the cancer cell can never find a home, or to attach to the zip code a "smart bomb" that sends therapeutics directly to that specific location to only destroy the offender there.

Andrew C. Von Eschenbach
Director
National Cancer Institute

are on each team, and what kind of ball they're using, but we still don't know what the rules are."

The rules are certain to be complex. The relatively small number of human genes—about a third as many as scientists had expected—suggests that environment plays an even greater role in disease than previously recognized, noted Kenneth Olden, Director of the National Institute for Environmental Health Sciences. "You can't explain the complexities of the human body through so little," he concluded.

Agricultural and Environmental Applications

In the panels that discussed agricultural applications of biotechnology, it became clear that despite some resistance among consumers, the new science has a lot to offer farmers. U.S. farmers quickly accepted some of the earliest biotechnology applications developed for agriculture. Both corn and cotton have been genetically modified to produce an insecticide commonly called Bt that occurs naturally in certain bacteria. Insects feeding on the crops ingest the pesticide as well.

Proponents of these genetically modified crops say their use has reduced widespread use of chemical insecticides, particularly in cotton fields. Environmental benefits include reductions in the amount of insecticide making its way into groundwater and increases in the populations of nondestructive species of insects.

Herbicide resistance has been built into crops as well, enabling farmers to spray their fields with relatively benign herbicides, such as Roundup, without damaging their crops. This has allowed them to reduce their reliance on more toxic herbicides while adopting no-till practices that in turn reduce topsoil erosion.

Other developments may lead to crops with increased yield, improved drought tolerance, and higher nutrient content. In addition, new uses are being developed for traditional agricultural commodities. Current research may eventually yield tobacco

genetically modified to produce proteins for use in pharmaceuticals, bananas that protect against hepatitis or tooth decay, and other plants that yield new dyes or fibers for industrial uses.

Genetically modified animals are also possible. Like tobacco, cows' milk may some day yield the ingredients for drugs, while sheep produce blood-clotting agents. Some scientists are investigating the possibility of genetically modifying animals to make them better research subjects for human disease and to grow organs for transplantation into humans. Some believe there is potential as well for cloning to be used in building herds of genetically superior animals. Success already has been announced in cloning sheep, cows, pigs, and goats.

Other applications of biotechnology appear to be limited only by the imagination. Specially designed bacteria already are being used to extract oil from the ground. Meanwhile, researchers are investigating the use of TNT-sensitive bacteria in detecting land mines, zebra fish modified to detect pollutants in surface water, and plants with an enhanced ability to clean up polluted sites.

Biotechnology and Bioterrorism

While it is important to understand what biotechnology is, it's also important to understand what it is not. For many people, the aftermath of September 11, 2001, and the incidences of anthrax spores distributed through the mail have left a confused sense of where biotechnology leaves off and bioterrorism begins.

For many people, the aftermath of September 11, 2001, and the incidences of anthrax spores distributed through the mail have left a confused sense of where biotechnology leaves off and bioterrorism begins.

As participants in the Forum's panels stressed, biological warfare predates the development of biotechnology. Conventional science can and has been used to deliver pathogens that sicken and kill crops, livestock, and people. But just as biotechnology is used to create new drugs, it also could be used to create and replicate disease-carrying bacteria or viruses.

Concern arises because of the ease with which this might be done. "It's easier to obtain the building blocks of a lethal genetic combination than it is to get enriched uranium," said U.S. Rep. Bob Etheridge. "Biological weapons are much less expensive to develop, and they wouldn't even need suicide bombers."

But if biotechnology creates a threat, it also provides at least part of the solution. Biotechnology may yield the systems for early detection and treatment of agents of biological warfare.

3 NORTH CAROLINA'S ECONOMIC POTENTIAL
The Opportunities and the Competition

Achievements to Build On

The Forum's panels reinforced the perception that the biotechnology industry is poised for explosive growth. Continued breakthroughs in genomics, proteomics, and bioinformatics promise that expansion is likely to remain strong for the next 50 years. For North Carolina, these growth projections represent the opportunity to capitalize on more than 20 years of investments since the General Assembly established the Biotechnology Center. The state has already achieved much:

- North Carolina is now on everyone's list of the top five places for biotechnology in the United States.
- In agricultural biotechnology, North Carolina ranks second only to California. Thirteen agricultural biotechnology companies employ about 2,500 North Carolinians.
- North Carolina ranks fourth in the pharmaceutical industry, and it is a national leader in the number of clinical research organizations, which provide vital services to that industry.

In the past, capital followed cheap labor. In the future, capital will follow skilled labor.

GOVERNOR MIKE EASLEY

Total payroll for biotechnology firms in North Carolina comes to $850 million. Two-thirds of those firms are homegrown, most originating with university discoveries. Among the rest are several multinational corporations. In addition, approximately 135 companies—including 70 clinical research organizations—supply products and services for the biotechnology industry.

Over the past five years, North Carolina's biotechnology industry has been growing at a rate of 15 percent annually, creating 2,000 new jobs every year. Moreover, the United States today has only one-fifth of the bioprocess manufacturing capacity of the need projected for 2005–6. Building those facilities will cost the private sector $3.5 billion. "That's a big economic development plum for somebody," the Biotechnology Center's Charles Hamner said.

Governor Mike Easley expressed confidence that by 2025 biotechnology in North Carolina will account for 125,000 jobs and $24 billion of sales. "An educated work force," he observed, "will be the fuel that will drive this remarkable industry." The industry provides high-end wages and benefits—a bioprocess technician with four to five years of experience can earn as much as $40,000 a year.

Better yet, newer applications hold the potential to spread the industry beyond Research Triangle Park and provide a much-needed stimulus for rural areas of the state. Tobacco genetically modified to produce proteins for the pharmaceutical industry, for instance, could not only provide income for farmers but jobs in nearby processing plants.

A Challenging Road Ahead

However well North Carolina has done in building its biotechnology potential to date, the next phase promises to be challenging.

Panelists contrasted biotechnology's long-term, group effort with the computer industry's model of a teenager who launches a multimillion-dollar company from his parent's garage. Despite advances that speed gene sequencing and identification, it takes time to make discoveries, prove their value and safety, and then move them into the marketplace.

Nor is it enough to put a biotechnology company in an incubator and give it some seed money and a little technical support. As businesses move up the ladder, they demand new kinds of support and services, including large infusions of capital and technical assistance regarding sound business practices. In short, developing the biotechnology industry requires long-term strategies.

The competition will be stiff. Regions across the globe are rushing to join the biotechnology club. The Netherlands has Bio Delta; Switzerland claims two clusters, BioAlps near Geneva and BioValley near Basel; Saudi Arabia is planning a Jeddah BioCity; and Singapore calls itself the Biopolis of Asia.

In the United States, California and Massachusetts are the unquestioned leaders in developing a biotechnology industry overall. These states offer a dynamic entrepreneurial culture, large venture capital communities, and universities strong in biosciences. North Carolina falls in the next tier of states, which also includes Maryland, Wisconsin, Pennsylvania, and New Jersey.

The Maryland Story

To see just how serious the competition is, the Forum invited Maryland Lieutenant Governor Kathleen Kennedy Townsend and Lawrence Mahan, the state's senior bioscience executive, to report on the way Maryland has developed its biotechnology industries.

During the last decade, the number of biotechnology firms in that state has tripled, to 300 in 2001, giving Maryland the third largest industry cluster of bioscience companies in the United States (second largest on a per capita basis). These companies employ 20,000 people, with another 25,000 working in related research and development, for a total payroll of $2.1 billion and a market capitalization of $28 billion.

Townsend, in prepared remarks, and Mahan, appearing in person, provided an overview of the initiatives in a 10-year plan that has propelled the states' development. Townsend acknowledged that Maryland benefits as the location of several significant federal research facilities, including the National Institutes of Health. But, she said, the credit also "goes to a handful of Maryland luminaries who 20 years ago saw the future while it was still hiding over the horizon."

We have one of the great money centers in the United States and one of the great technology centers, but we don't talk to each other.

MAX WALLACE
COGENT
NEUROSCIENCE

Among specific measures, the Maryland officials especially cited:

- More than $566 million in overall technology-based economic development programs and infrastructure. This includes $26.5 million in venture capital funds, of which $10.5 million has been invested in 51 biotechnology firms since January 1994. The state also offers low-interest loans for research and development and for manufacturing facilities. It has invested in incubators, shell buildings, and technical support programs for young companies. "We do some of the early due diligence on the start up companies," Mahan said. "Sometimes I think we see these companies after their mother or father heard the business plan." This early assistance can make the difference in the success or failure of a company.

- The creation of a supportive public policy and business environment. The Technology Law Council provides a venue for technology companies to advise government about impediments. In addition, Mahan explained, "sometimes it's important just to bring people together." Townsend recently called a meeting of industry representatives to have them define their concerns and suggest ways the state could help. Ten task forces were organized as a result of that meeting on issues ranging from technology transfer to tax incentives.

North Carolina is poised for a strong future as a center of biotechnology, but must invest in the resources it needs for success.

Jim Hunt Institute for Emerging Issues

- Strengthening the state's colleges and universities. Maryland has increased funding for its public universities by 70 percent over the last seven years. As a result, it now has 61 programs rated in the top 25 in the country, compared with only one a decade ago. It is first in the percentage of residents holding Ph.D.'s in the biological, health, and agricultural sciences; second in the percentage of Ph.D.'s in computer and mathematical sciences; second overall in doctoral scientists; and fourth in doctoral engineers. At the same time, Mahan said, the state is encouraging both universities and two-year colleges to establish multidisciplinary programs that expose students to the realistic demands of the biotechnology industry.

- Support for university technology transfer offices. "Not all great scientists are entrepreneurs," Mahan said. "They're very happy sitting in the lab making discoveries in basic sciences. This puts a lot of burden on those poor people in the office of technology transfer who have to take a wealth of information on one side, figure out what is important and help to transfer it out of the university. So a key pathway is supporting those individuals and the ancillary groups around them."

- Overall enhancement of education. The state has increased funding for public schools by $1 billion a year. "Education is not merely a workforce issue," Mahan said. "Biotechnology, because it spreads through and incorporates so many academic disciplines, is all around us, and it is not going away." The population at large will need to understand the fundamentals of the science to make decisions individually and as part of establishing public health policy.

Building Dreams

Let me tell you how we created the biotechnology revolution in Maryland.

A healthy, well-financed, and daring education system is the indispensable foundation for success in biotechnology. But you also need entrepreneurs, capital, partnerships, and a long-term strategy for reaching your goal—Maryland has all that and more.

How did we go so far so fast? By not standing on the sidelines. It is a truism that biotechnology is a speculative, high-risk business. You come up with an idea, spend years on research and development, and hope that idea can make it past a long train of scientific, regulatory, manufacturing, and marketing barriers.

For biotechnology, a 10-to-15-year development cycle—costing as much as $400 million for a single product—is not unheard of. With that kind of risk, the attitude of most banks and lending institutions is: Thanks but no thanks. Since 1991, however, that has not been the attitude of the State of Maryland. Instead, we decided to meet the investment issue head on.

Our success is not just because of how much we've invested. It's also because of the creativity and breadth of our investments.

But our success is not just because of how much we've invested. It's also because of the creativity and breadth of our investments. We set up a variety of financing mechanisms. A very small percentage of the total assets managed by the State Retirement and Pension system has also been invested in venture capital funds.

Our Department of Business and Economic Development invested another $26 million directly in technology companies—most of them in the life sciences. This is not corporate charity. These investments made money for the people of Maryland. Direct investment worked for us. And it will work for you too.

I sometimes think of launching a successful biotechnology company the way I think of kite flying. It's not very difficult to get the kite bobbing around 15 feet in the air. The hard part is to get the kite aloft and not in danger of crashing to the ground with one ill wind. That's why we've done more than make loans and invest in individual companies. We've built an entire support system for biotechnology.

That support system is not just about investment capital. And it is not just about infrastructure. It's about investment capital, plus infrastructure, plus the creation of an economic climate that focuses on attracting and retaining strong, environmentally clean technology companies with great potential for long-term growth.

What is critical to creating the kind of strong kind of business climate I mentioned is our willingness to work hand in glove with the biotechnology industry. We build partnerships that are not just about seed money, tax incentives, and incubator space—but are also about offering technical assistance, setting up a system of one-stop shopping, and meeting regularly with leaders in the industry.

Building a biotechnology industry—whether in Maryland, North Carolina, or anywhere—is really about building dreams. Yes, if you build it—they will come. But you can only build it after you dream it.

Kathleen Kennedy Townsend
Lieutenant Governor
State of Maryland

Is North Carolina Ready?

As Maryland's approach indicates, successful biotechnology initiatives will encompass a broad spectrum of programs and policies. How do North Carolina's efforts stack up?

Biogen President and CEO James Mullen, whose Massachusetts-based company built its manufacturing facility here, told Forum participants that the best thing North Carolina has going for it is the spirit of cooperation between business and

U.S. Biotechnology Regions

State	# of Biotechs	Mkt. Cap	Approved Drugs	Drugs in Phase III	Biotech Emp.	COL
Mass.	230	$50B	21	40	28,000	144.4
N. Calif.	500	$103B	26	61	20,000-30,000	164.3 (SF) 135.6 (SJ)
San Diego	230	$17B	12	19	32,000	119.4
Seattle	100+	$30B	4	13	N/A	114.8
NJ	110	$14B	8 (14)	31	7,500	132.6
NC	140	$2B	0	8-33	–	100.3 (Raleigh) 99.5 (C'lotte) 92.7 (G'boro)

Source: Biogen

government. "Believe me, it's not the way people in other parts of the country think," he observed. "It's probably the single most important reason why 10 years ago we decided to invest here in Research Triangle Park."

While pronouncing himself "a satisfied corporate citizen," Mullen also delivered some of the Forum's most forceful criticism. He cautioned that North Carolina lags behind California and Massachusetts despite having considerable advantages in work ethic, business environment, weather, and cost of living, *and* despite its concentration of clinical research organizations. "In researching this speech," he said, "we could not find an example of an approved human therapeutic that came from research and development at a biotechnology company headquartered in North Carolina."

Mullen defined North Carolina's problems first and foremost as inadequate public schools and second, as a diminishing infrastructure capacity. He didn't stop there. "Despite the quality of North Carolina's medical centers, the lack of depth is a real

A New Business Environment

We usually talk about life sciences and information technology as though they are two totally separate and independent fields. Today, the juncture of biology and IT is the focus of new technologies that are yet again changing the ways drugs are discovered.

Here's an example: biotechnology drugs are based on proteins. IBM has a major new program designed to apply computer simulated biology to protein science. This means companies like Biogen will be able to identify promising drugs and drug targets more quickly, more efficiently and more economically.

IBM calls this marriage of Big Blue and genetic engineering by the name "Blue Gene." They predict that the market opportunity for IT in life sciences will exceed $30 billion by 2004.

This means that IBM believes their future is in healthcare. There are people at IBM headquarters who say their company will be a life sciences company within three years. And they won't be alone.

If we're in a business environment where some of the world's leading high tech companies talk about getting into the life sciences marketplace, we're no longer talking about well-defined industries that fit into tidy little intellectual boxes. In the years to come, we won't be talking about discrete industries like biotechnology, or Big Pharma, or IT, or telecommunications. The business environment of the future will be interdisciplinary and interdependent.

And that future is not something off in the distance. It will be here within this decade.

There are people at IBM headquarters who say their company will be a life sciences company within three years.

More than 40 years ago, the leaders of North Carolina looked at some pine forests and envisioned a world-class science park. Today, there are more than 100 research and development facilities in RTP—many in industries like biotechnology and biocomputing that didn't exist back in the 1950s. Research Triangle Park was the original "Field of Dreams" and demonstrates the truth of saying "If you build it, they will come." But it is now a different century, with different needs, and we need a new vision.

Jim Mullen
President and CEO
Biogen, Inc.

concern here," he said. "North Carolina is not yet world-class in the medical research area. Nor is your technology transfer yet generating the number of new commercial enterprises that regularly come out of an institution like MIT. You need to concentrate investments in research in academia as well as private industry."

Another industry leader had a more favorable outlook on North Carolina's university contributions. "The enabling research coming out of the universities is one of the things we do best," said Max Wallace of Cogent Neuroscience. "We generate cool new ideas, and we're starting to turn them into businesses."

He also saw strength in the breadth of the state's scientific and academic community, including its information technology and communications industries that play vital roles in advanced research and development. "But these things are not unique to us," he warned. "We're good, but not unique."

By most measures, North Carolina falls short on needed venture capital. The N.C. Biotechnology Center has helped seed 62 companies and operates the Bioscience Investment Fund. With $70 million in capital, the fund has invested in 11 biotechnology companies since it was established in 1997. Panelists, however, cited the need to increase the amount of venture funding available and, in particular, to build the capacity to finance companies as they expand into manufacturing.

"We learned we needed to think five, ten, fifteen years in front," the Biotechnology Center's Charles Hamner said. "If you don't understand where we're going to be ten years from now and plan to be in operation to do those things, it's very difficult to deal with new technology." To stay ahead of the curve, Hamner called for spending $15 million a year over ten years, to be spread equally among research universities, business support, and the N.C. Genomics and Bioinformatics Consortium. He predicted that this investment would lead to the creation of 100 to 150 new companies, $3 billion in investments, and 30,000 new jobs.

We're not quite sure how to tolerate audacity in North Carolina, but we need to permit, even encourage the audacity to reach high.

MAX WALLACE
COGENT
NEUROSCIENCE

N.C. Commerce Secretary Jim Fain also spoke of the importance of continuing support for new economy initiatives. The Board of Science and Technology, he said, will make recommendations to the governor about where to make investments and how to accelerate the process of moving products to the marketplace. In addition, his department is conducting "a clean sweep" of business incentives to see how to reshape tax credit and other programs to encourage research organizations as well as manufacturing.

Planning and funding, several panelists noted, are necessary but insufficient conditions for high-tech, high-growth economic development. In particular, a region needs to invest in individuals whose reach may seem to exceed their grasp. Craig Venter, the maverick genomics researcher who led the private effort to sequence the human genome and was selected by Time Magazine as its 2000 Scientist of the Year, recounted how the NIH had refused to fund his research. He had promised to decode the human genome within a year, which by other projections seemed an impossible goal. As the world now knows, Venter not only came through, but completed the work in only seven months.

Wallace suggested that North Carolina would not have known what to do with Venter either. "We're not quite sure how to tolerate audacity in North Carolina," he observed, "but we need to permit, even encourage the audacity to reach high."

4 EDUCATION AND EQUITY IN A NEW ECONOMY

North Carolina's Long-Term Challenges

Prerequisites for Success

Panelists at the Forum stressed that two equally important issues had to be addressed: education and equity. To be successful in building a biotechnology industry, North Carolinians must develop an educational infrastructure that is appropriate to new knowledge-driven industries. They also must engage in a sustained, critical discussion of the best way to leverage regional initiatives across the state. The growing chasm between the prosperous urban areas and struggling rural counties demands attention. An emerging competition among urban centers must also be channeled to the state's overall advantage.

Educational Imperatives

Future scientific advances, several panelists noted, will require a broader set of skills. The science is getting more complex as it moves from gene identification to gene function, protein expression, and disease pathway, explained Roger Beachy, President of the Donald Danforth Plant Science Center in St. Louis. As a result, the skills needed for advanced research in the life sciences now require computational science, molecular science, cell biology, biochemistry, physiology, and pathology, as well as genetics. "It's no longer one scientist belly to the bench," he said. "It's a group of scientists who work together to define the project and then use their combined skill sets to address the important goals."

It's no longer one scientist belly to the bench. It's a group of scientists who work together to define the project and then use their combined skill sets to address important goals.

ROGER BEACHY
DONALD DANFORTH PLANT SCIENCE CENTER

Panelists unanimously agreed that North Carolina must step up its efforts to strengthen education, beginning at the public school level and continuing through community college preparation of laboratory technicians and university training for Ph.D.-level scientists. From no one was the criticism of North Carolina's schools more pointed than from Mullen:

> Our economy doesn't depend on land, or manufacturing equipment, or even natural resources. It depends on worker knowledge and skill at every level. North Carolina's educational system isn't keeping pace. That means it will become more difficult to recruit families to relocate here. It also means the quality of local employees available to companies that site here will deteriorate. Companies whose competitiveness depends on intellectual capital will lose incentive to locate or remain here.

Governor Easley echoed Mullen's analysis. The new economy, he said, "requires so much more participation by the university and community college system. In the past, capital followed cheap labor. In the future, capital will follow skilled labor."

Specific attention was given to the state of science education and the need to incorporate biotechnology into the science classroom early on, to develop both an educated citizenry and a cadre of biotechnology workers. At the current level of growth, the

A Comprehensive Academic Infrastructure

While community college and research universities do excellent jobs training technicians and researchers, there is increasingly a need for workers capable of filling the gap between these two areas, a gap characterized by equal parts science, engineering, and management skills.

Some suggest that now is the time to develop a comprehensive academic infrastructure, from grade schools to universities, to support the needs of the emerging work force.

At the university level, James Madison University in Virginia launched a new curriculum that combines basic science education with product development. This curriculum counts biotechnology as one of its seven strategic sectors, and includes a biomanufacturing facility specially designed by CRB Consulting Engineers from Cary, North Carolina.

At North Carolina State University, the College of Agricultural and Life Sciences and the College of Engineering have created a minor in biotechnology. In addition, university and industry representatives are discussing the creation of a BioProcessing Technology Center that would enable students to take courses emphasizing industrial laboratory and regulatory practice and that require effective teaming of students across disciplinary lines.

Are such programs the wave of the future? How specialized and commercially oriented should the training be?

Like the community college courses, such programs raise educational policy issues: Are such programs the wave of the future? How specialized and commercially oriented should the training be?

state's biotechnology industry will need 2,000 new workers every year evenly divided between those educated at the community college and university levels.

Two considerable challenges surfaced:

1. Biotechnology is complex and requires significant investments in basic science at the elementary and high school level, and in biology in high school and college. Moreover, Max Wallace stressed, students need to be instilled with a passion for the subject and a love of learning through inquiry more than they need to learn specific skills, facts, and formulas.

A hallmark of new economy industries like biotechnology is the speed by which they change. As a result, knowledge workers need to be agile and able to adapt quickly.

These comments led Shawna Young, a science teacher from Hillside High in Durham, to pose a difficult question: How, she asked, could she create that passion

and agility in an educational culture driven by testing? Others emphasized the need for stronger science education at the elementary level.

2. More than tax incentives or good weather, biotechnology companies need to know that their specialized staffing needs can be met. One of North Carolina's strongest advantages in developing and in attracting biotechnology companies is its workforce.

Nonetheless, shortly after the Forum some observers identified the absence of trained labor as the single most important factor in North Carolina's loss to Virginia in the competition to land a $425 million Eli Lilly plant.

To address the labor need, the North Carolina community college system has pioneered the development of a course called BioWork, a 129-hour program that prepares bioprocess technicians for jobs in biomanufacturing. Participants in the post-Forum workshop organized by the N.C. Economic Developers Association noted that colleges lose money on these complex courses. The continuing education funding formula does not account for the amount of instructor time or the lab and scientific supplies needed. From an economic development perspective, should cosmetology and biotechnology courses count the same?

Throughout the Forum, it was obvious that a major dilemma was how best to capitalize on the concentration of biotechnology in the Triangle while addressing the need for statewide economic growth.

Regional Initiatives

Throughout the Forum, it was obvious that a major dilemma was how best to capitalize on the concentration of biotechnology in the Triangle while addressing the need for statewide economic growth. The state's political leaders spoke of the need to ensure that rural communities reap the benefits of biotechnology's growth.

Industry leaders countered, emphasizing the need for regions to develop their own niches. Wallace cautioned that the democratic desire to treat everyone equally risked undermining the concentration of resources needed to compete internationally.

"Put money in what works, not in trying to bring everyone else along," he urged. "We hear that we can't put any more effort in the Research Triangle because it's doing well and so many areas of the state aren't. I don't mean to denigrate [those other areas], but if you want excellence in biotechnology, you'd better put your backing where you'll win—the universities and places with the infrastructure to support it."

Wallace also argued that overcoming the distance between RTP and Charlotte would provide a major boost in making capital available for biotechnology companies in the Research Triangle area. Research biotech companies seeking venture capital, he lamented, can "find it closer to London, Zurich, or Boston than Charlotte 120 miles away."

In interviews after the Forum, Charlotte researchers suggested that biotechnology companies should establish locations in the Queen City. "We've been looking for niches not covered in the eastern part of the state, areas we can develop," Mark

Steering Committee to Strengthen Biotechnology in Western North Carolina

Shortly after the Forum, a Steering Committee to Strengthen Biotechnology in Western North Carolina issued a report for finding effective ways to fit the western part of the state into the larger picture.

The report asked: "How can an area not traditionally directed to technology effectively incorporate it into planning, resources, and vision?"

The Steering Committee adopted a multisectoral approach to considering whether biotechnology can yield an effective tool for *community* development, broader in impact and more progressive in intent than traditional economic development.

The Committee's report focused on how biotechnology can offer gain to crops, growers, and processors important to the area and enrich the health care endeavor created by area hospitals, companies, and service providers. It targeted biomanufacturing as an especially good fit for the West, since this work can be undertaken in locations different from research and trials, especially if educational institutions provide a well-trained workforce.

The Committee modified the RTP model of "build it and they will come." Instead, the Committee said, work together, identify strengths, and, most of all, provide educational training now, and companies will come.

Clemens, chairman of the Biology Department at UNC-Charlotte told *Local Tech Wire*. "It would be stupid to compete head-to-head with Chapel Hill, Duke, or NCSU. Even if we could compete effectively, it doesn't make sense. So many areas (of biotech) need development."

Both during and after the Forum, government and university leaders emphasized the need to think carefully about whether and how to expand the state's biotechnology infrastructure and resources statewide. "No matter how good the Research Triangle is," noted the Dean of the College of Information Technology at the University of North Carolina, Charlotte, Mirsad Hadzikadic, "without support from throughout the state it will get nowhere. Decades ago there was no Research Triangle and if people had thought like that, we wouldn't be in the position we are now in biotechnology. Right now a dialogue is not taking place. None of us benefit from a divided state."

5 THE "STUFF OF MYTHOLOGY"

Ethical, Social, and Environmental Cautions

Not Just Another Technology

From the very beginning of the biotechnology revolution, it has been obvious that this was neither "just another technology" nor a simple extension of selective breeding. Scientists preparing the first gene-splicing experiments in the early seventies recognized the implications and paused in their work to allow time for debate over its ethical dimensions. Similarly, federal funding for the Human Genome Project has included money to foster discussions about the social and ethical implications.

Biotechnology creates the possibility of altering life, of crossing the boundaries between species, of blurring the distinctions between plants and animals. This "stuff of our mythology," as Biotechnology Center Vice President Steven Burke called it, imposes serious demands on our capacity as citizens, and as humans, to imagine what the future might look like and to gather ourselves to prepare for that future now.

Compounding the complexity of the basic issues is the speed at which the technology is forging change, enabling scientists to make leaps well in advance of the ability to foresee all the consequences. Kenneth Olden of the National Institute for Environmental Health Sciences emphasized this point as he noted the widespread use of genetically modified plants and the possible long-term effects of their release into the environment.

What emerged from the Forum discussions was that these combined factors—the social implications, complexity of the issues, and speed of change—create a pressing need to stimulate broader, deeper, and sustained public debate about biotechnology.

Fundamental Questions

Panelists noted that for some religious and ethical leaders, humankind is overextending its grasp when it tinkers with the building blocks of life and in some cases transplants genes from one species to another. Some refer to scripture; others, to a secular belief in the sanctity of all life. Once the first high-tech steps are taken across the boundary between creator and creation, or between socially acceptable and morally questionable science, does humanity find itself on a slippery slope where it will be difficult, if not impossible, to stop the momentum?

While some critics question the wisdom of pursuing all attempts to manipulate genetic material through biotechnology, others grapple with specific applications and possible unintended consequences. Many would forbid the use of human embryos in research. Some Jews, Muslims, Hindus, and vegetarians fear that genetically modified foods could put them at risk of unwittingly violating religious and ethical restrictions against mixing plant and animal products.

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Who Owns Life?

As genes and gene sequences are being identified, companies have been rushing to patent that information.

Tens of thousands of genes have either been patented or have patents pending.

If granted, university and government researchers as well as other companies could be restricted from using pieces of genetic information or have to pay royalty fees for their use.

The U.S. Patent Office has issued more stringent guidelines, saying that a patent applicant now has to delve deeper to lay out "a specific, substantial, and credible use" for the gene.

This new standard is insufficient for some. A pharmaceutical industry initiative seeks to stop individual companies from patenting genetic markers. The Council for Responsible Genetics goes further, calling for legislation to "exclude living organisms and their component parts from the patent system."

Still others oppose the release of genetically modified organisms into the environment out of concern they could spread beyond their intended confines, perhaps altering the delicate balances in nature. Even if humans have created the technology to alter life, they may not know enough to use it safely. How can scientists be sure it is safe to alter genes if they do not understand the ramifications down the line? Crossing boundaries between species, some say, bypasses natural safeguards with unknown consequences.

The risk of unintended consequences was brought home with a different kind of example by panelist Martin Scott, past Director of Research for the Cystic Fibrosis Trust of Great Britain. Cystic fibrosis patients are prone to potentially lethal bacterial infections that, because of their recurring nature, become antibiotic-resistant. In England, a new antibiotic-resistant infection cropped up that proved to be contagious among CF patients.

Medical researchers traced the source of the bacterium to a substance the agrochemical industry had introduced to help keep golf courses green. While this bacterium did not hurt the public in general, it did have serious, unpredicted consequences for CF patients.

Cloning, Stem Cells, and Genetic Screening

Nowhere does the debate about biotechnology rage more intensely than around the issue of cloning. Since Dolly, the first cloned sheep, was introduced to the world, scientists have announced successful cloning of cows, pigs, goats, and cats. Arthur Caplan, Director of the University of Pennsylvania's Center for Bioethics, believes the prospect of reproductive human cloning, that is, cloning for the purpose of creating genetically identical human beings, has set back the discussion of biotechnology. "Most of the fears expressed are not based on facts of what clones are and can do," he contended.

The Debate in the United Kingdom

The promise of human embryo stem cells has led a number of countries to re-examine their regulations on embryo research.

In the United Kingdom, the existing legal framework has been amended to allow embryo stem-cell research. The amendment was achieved after three years of public debate: time taken was in part a reflection of the lessons learned from the GM crops experience.

Questions raised included: Should parents of embryos donated for research give specific consent for stem cell research? Was there a moral distinction to be made between existing kinds of research already permitted and that proposed for stem cells? Would allowing therapeutic cloning in any way prepare the ground for reproductive cloning?

The answer to the first question was yes, because DNA could be traced. The answer to the second question was no. No clear distinction could be justified between using embryos for research on infertility and contraception and their use for the development of therapies for serious diseases. And the third was: not if strengthened by additional legislation.

Sandy Thomas
Director
Nuffield Council on Bioethics

Opponents raise the specter of super armies and robot-like replicas that duplicate a person's thoughts and actions as well as genetic makeup, Caplan said, but cloning carries limits. More than genes go into the development of human personality and intellect, and each clone would begin life as an infant subject to all the variables of any other individual. "What's bad about cloning now is that it doesn't work," he said. "But I don't know that it would be unethical to do if we got past the safety reasons."

For safety and ethical reasons, most scientists and public leaders reject reproductive cloning. The main argument is over "therapeutic" or research cloning and extends to embryonic stem cell research in general. Scientists are intrigued by the possibility that the undifferentiated cells of a fertilized egg—embryonic stem cells—could be coaxed into specific form, for example, nerve cells that could then be used to repair damage caused by spinal cord injuries or Parkinson's disease. Therapeutic cloning would create an embryonic clone of a patient by placing the patients DNA into a human donor egg.

This use of human life at its earliest stage sits uneasily with a broad range of people. Is the embryo then destroyed? Are human embryos to be created for utilitarian purposes? Critics worry that, as Charles Krauthammer, a member of the President's Council on Bioethics, puts it, "the very act of creating embryos for the sole purpose of exploiting and then destroying them will ultimately predispose us to a ruthless utilitarianism about human life itself."

Who Sets the Research Agenda?

Several observers have noted increasing domination of agricultural biotechnology by the large agrochemical companies.

These large corporations, Michael Jacobson, Director of the Center for Science in the Public Interest, charged, focus almost exclusively on blockbuster applications with large profit potential at the expense of niche products that could make a large difference in a small market or advances of great environmental benefit but of limited bottom-line incentive for farmers.

Similar points have been made about the pharmaceutical industry.

Robert Ingram, CEO and President of GlaxoSmithKline, vigorously defended the critical role of large pharmaceutical companies as the only institutions with the resources and capability to drive drugs from discovery through clinical research and approval to consumers' medicine cabinets.

"It's increasingly difficult to balance the public demand for new and improved medicines with a willingness to pay the price for developing them."

"How much is too much to spend to save or improve human life?" he asked. "It's increasingly difficult to balance the public demand for new and improved medicines with a willingness to pay the price for developing them."

"Medicines reduce the need for costly surgery, prevent more serious disease, and save lives," Ingram pointed out. "But those accountable for controlling prescription drug budgets often fail to see this simple economic equation because they view pharmaceutical costs in a silo rather than looking across all their health expenses."

Pharmaceutical companies possess exclusive rights to their discoveries, he acknowledged, but noted that "by the time the typical drug reaches the pharmacy shelf, the drug often has only about half of its 20-year patent remaining."

Panelists discussed how even widely accepted and used technologies raise ethical issues. Genetic testing is a case in point. Women with family histories of breast cancer now can learn whether they have the cancer gene. Those lacking the gene receive peace of mind. Those who have the gene know to heighten their vigilance; some go so far as to undergo preventive mastectomies. Genetic screening also can inform the reproductive choices of prospective parents whose families have histories of such genetic illnesses as Huntington's disease and cystic fibrosis.

For all of the benefits, ethicists are concerned about the potential uses of genetic screening. Will employers or insurance companies gain access to test results and use the information to discriminate against individuals? As the technology develops, will parents seek to select—or engineer—children based on sex, hair color, intelligence, or height? Will people learn more than they really want to know about their parents and grandparents? "More than any other form of medicine, genetics can tell you things about others as well as yourself," Caplan said.

Caplan proposed guidelines for the use of genetic screening. "Biotechnology must make it clear that its first priority is the war on disease, not indulging people's tastes or prejudices." He cautioned medical practitioners to make certain they have counseling available to help people cope with the results of genetic tests and not to conduct therapeutic testing in the absence of effective treatment for the disease it tests for. To ensure that genetic information cannot be used to discriminate against individuals, he said it should always be voluntary and confidential. "There is work to be done in our legislatures," he urged, "to make sure biotechnology empowers people and that they have to right to choose when it will and won't be used."

Agricultural Applications and Consumer Responses

A distinct feature of the biotechnology revolution is the rapid convergence of a number of previously unconnected areas. This convergence, noted Tom Hoban, Professor of Food Science and Sociology at North Carolina State University, cuts across traditional lines demarcating humans, animals, and plants and requires a coordinated response among different sectors and institutions in our public life. Consider, for example, hogs engineered to serve as donors for replacement human body parts, tobacco modified to produce industrial feedstocks and cosmetics, and foods designed to deliver medicine that fits an individual's unique genetic profile.

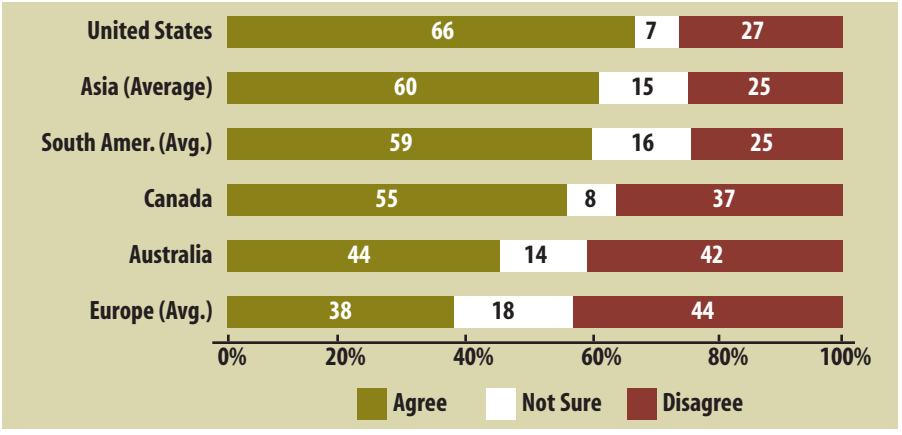
Panelists noted that although no human health consequences have been documented to date, critics have especially raised questions about the safety and sustainability of genetically modified crops.

Panelists noted that although no human health consequences have been documented to date, critics have especially raised questions about the safety and sustainability of genetically modified crops. With so much unknown about the way genes function, they worry that proteins might be introduced into food that can cause allergic or toxic reactions. As the StarLink corn incident last year showed, even products not intended for human use can make their way onto the grocery shelves. These were among the concerns cited by Europeans objecting to the introduction of genetically modified foods.

Challenges also focus on Bt- and herbicide-resistant crops. Critics of industry dispute claims about reductions in pesticide use attributable to GM crops and argue that overreliance on Bt-crops and herbicide-resistant varieties threatens the long-term value of what have been relatively benign treatments. They predict that, with constant exposure to Bt, insects, too, will soon adapt, which will lessen the effectiveness not only of Bt-crops but of topical applications of the insecticide, one of the few aids available to organic farmers.

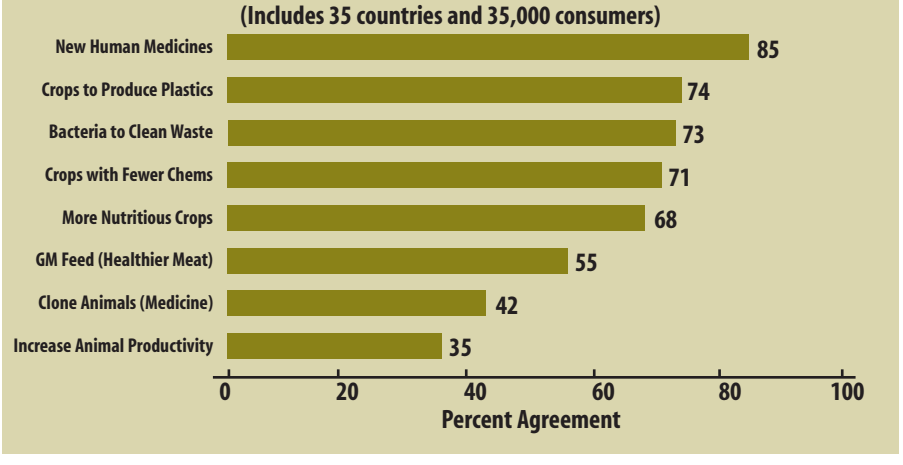
Proponents of biotechnology respond that most of the concerns raised about genetically modified foods are not unique to those foods; they apply to any new breed of conventional crops. Further, they point out that genetically modified foods are more heavily tested than conventional plants. Similarly, while insects developing resistance to Bt is a potential problem, this is true of all insecticides and herbicides currently in use. And while we do not know everything about how genes control proteins, we do know enough about how gene regulation works such that any gene which might give rise to unexpected changes can be screened out in extensive testing.

Belief that Biotechnology's Benefits are Greater than the Risks



Source: Environics, 2000

Public Support Varies for Different Applications of Biotechnology



Source: Environics, 2000

For Michael Jacobson, of the Center for Science in the Public Interest, the enormous value of biotechnology is being threatened by both its advocates and its critics. "In some circles," he lamented, "it is 'politically correct' to oppose biotech foods. . . . Meanwhile, the biotech industry had done a lousy job of presenting its products to the world and winning over public opinion. Food processors have used ingredients from genetically engineered foods without any disclosure or explanation to the public. The result is that many people, in the U.S. and abroad, feel as though genetically engineered foods were snuck into the food supply."

Who Benefits from Publicly Funded Research?

Both Roger Beachy, the plant scientist, and Michael Jacobson, the public interest advocate, used the Forum panel to caution universities to protect the greater good in any agreements to license university discoveries.

A great deal of university research is financed with public funds, they said, and the public—rather than a private company—deserves to benefit from it. Humanitarian purposes also must be served, they urged.

Beachy and Jacobson encouraged universities either to withhold certain rights when licensing technology, such as the right to use the technology in applications for developing nations, or to keep large portions in the public domain.

Beachy and Jacobson encouraged universities either to withhold certain rights when licensing technology, such as the right to use the technology in applications for developing nations, or to keep large portions in the public domain.

"It is critical that government and university scientists have the funding to develop new methods and new crops and then to help disseminate them in a way that diffuses knowledge, not limits it," Jacobson stressed.

"Ideally," he suggested, "U.S. universities, which collectively have tremendous knowledge about all aspects of agriculture, would actively share their resources with farmers, companies and developing nations. Furthermore, the federal government, as well as international agencies and philanthropic foundations, need to help developing nations and not just to develop beneficial crops, but to use biotechnology to protect the environment, consumers, and small farmers."

Beachy emphasized that the public needs sources of information it can trust for objective, third-party review of technology and its applications. Universities once claimed that role, he said, but the increasing reliance on corporate funding for research has tarnished academics' reputation. "Universities need to regain the public trust," Beachy urged. "They need to regain the confidence not only as developers of new knowledge but as protectors of the environment and as protectors of those that are technologically disadvantaged."

The biotechnology entrepreneur Max Wallace also referred to the sporadic debates about the appropriate use of university-generated ideas. For Wallace, universities properly play a key role in the development and transfer to the market of technology. "You have to do it ethically and properly," he stressed, "but it's what we expect from public universities."

Jacobson suggested that there is broad, but thin, public opposition to, or at least suspicion of, genetically engineered foods. Tom Hoban confirmed that support among European consumers for all applications of biotechnology dropped significantly between 1996 and 1999. American consumers, however, continue to support applications of biotechnology, he said. About two-thirds of U.S. consumers consistently say they appreciate and will accept the use of biotechnology to reduce the amount of chemical pesticides that farms use.

Risks and Benefits

For Michael Rodemeyer, Director of the Pew Initiative on Food and Biotechnology, the contrast between public acceptance of biomedical and agricultural applications provides an important lesson in risk-benefit analysis.

Biomedical applications have been largely accepted, even in Europe, he said. Consumers, on the other hand, are more wary of agricultural uses. Genetically modified crops have been all but banned in Europe and Japan. Even in the United States—where an estimated two-thirds of packaged foods contain GM products—surveys indicate that consumers at the very least want to be informed on food labels which products contain genetically modified ingredients.

Hoban noted that agricultural companies and food packagers resist labeling. They say GM products are safe and indistinguishable from non-GM foods but fear that labeling will stigmatize their products. Some scientists worry that labeling foods that contain GMO's is giving into fears that lack sufficient basis in evidence. If people are concerned about eating GMOs, they suggest, nothing prevents companies from labeling their food as GMO-free, similar to Kosher or organic products. This approach avoids increasing the cost of food to all consumers because a small group want a label that regulators and scientists have so far determined not to be necessary.

In the agricultural uses adopted first, Michael Rodemeyer pointed out, it is largely the farmer who gains through lower production costs.

The University of Pennsylvania's Arthur Caplan explained that, while he was happy to eat GMO food, "a lot of folks are not." While the public often misunderstands biotechnology, he warned that the biotech "industry has gotten itself in the position of opposing consumer choice. And that is a losing position. I've never in my career in ethics seen any public policy win that tries to take choice away from the consumer. Never."

Rodemeyer argued that the reasons for the disparity between biomedical and agricultural applications largely come down to the individual risk-benefit equation. People are accustomed to risk-benefit tradeoffs in medicine, but there the patient who takes a risk also stands to gain. With an ample food supply, at least in the United States, consumers question why they should assume any risk—particularly since they are not the ones who stand to benefit.

In the agricultural uses adopted first, Rodemeyer pointed out, it is largely the farmer who gains through lower production costs. There also are potential risks and benefits for the environment, but any benefits stay in the community where the crop is grown, which may be far removed from where the consumer lives.

"Technology is only a tool," he stressed, "and whether those tools develop in a way that creates value and consumer trust and acceptance will depend in large measure on the wisdom of the technology developers."

6 THE ROAD TO CONSENSUS

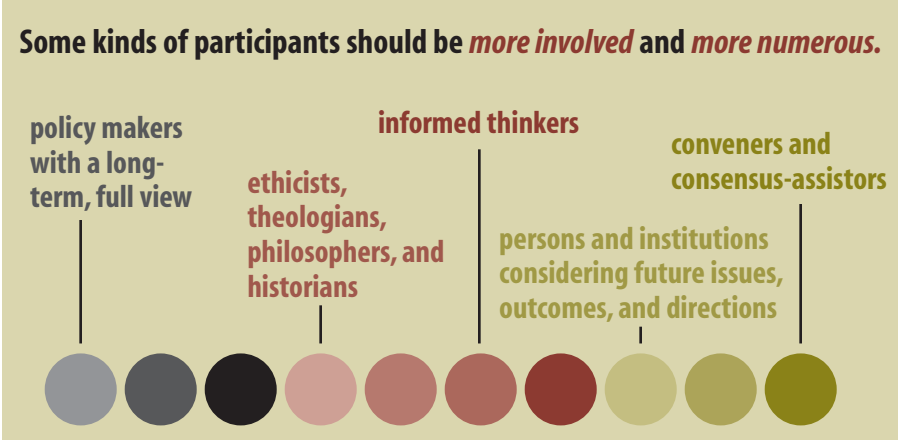
A Role for Regulation and Dialogue

Can We Reach Consensus?

European rejection of genetically modified food crops provided a valuable lesson to proponents of biotechnology. "Farmers in the United States have had to reconsider the wholesale adoption of GM crops in light of European opposition," said Sandy Thomas, director of Britain's Nuffield Council on Bioethics. "Further, in increasingly globalized economies, the failure of new technologies in one region naturally has implications for other countries."

Clearly, if the economic and humanitarian potential of biotechnology is to be achieved, societal values must be addressed in advance and appropriate policies put into place to account for them. Failure to do so "might cripple or delay innovation and translation of biomedical research into strategies to prevent, diagnose and cure diseases," Kenneth Olden of the National Institute of Environmental Health Sciences said in remarks equally pertinent to nonmedical applications.

The Process of Biotechnology



Source: North Carolina Biotechnology Center

"These are important issues and thoughtful solutions must be found that represent the proper balance between legitimate concerns and the need to find cures for devastating diseases. This will require local and national leadership with the social, political and intellectual skills and moral commitment to ensure that science is translated in a manner that protects and safeguards societal values and public health."

Thomas emphasized the critical importance of anticipating and addressing future controversies. So far, government and industry have played the deciding hands in decision making. Society as a whole needs to build the ethical and social institutions to create and maintain long-term discussions that can both inform public

opinion and represent it. But with divisions so deep, will it be possible to reach consensus?

To illustrate how principled compromise might be achieved, Elizabeth Kiss, Director of the Kenan Institute for Ethics at Duke University, focused on the embryonic stem cell debate. The basic issue, she said, boils down to whether the eight-celled blastocyte—a fertilized egg at its earliest stage—is a person with full human rights, "a blob of cells to be used however we see fit," or something in between. "It's important to me to recognize that I live in a democratic society with people who in good faith occupy the two ends," she said.

Thoughtful people disagree

Embryonic stem cell research [on embryos left over from IVF] is not only justifiable, but admirable. . . it enables scientists to fulfill a duty to aid others. "It is virtuous to eliminate suffering in actual lives when we may do so at no cost in potential lives."

Louis Guenin, Harvard University

". . . we should not kill innocent life unless it is absolutely necessary, unless we know that all other means for producing the good intended have been exhausted. . ."

Amy Laura Hall, Duke University

Source: Elizabeth Kiss, Duke University

"What we're trying to do in the public debate is to balance the interests of scientific and medical discovery and the great benefits it can bring against the duty to respect blastocytes up to some point, not to treat them like any other bit of organic matter."

Kiss reminded everyone that President Bush concluded that the more he learned about stem cells the less certain he became. "In ethics, as in so much else," she observed, "the devil as well as the angel is in the details. It's important to look at the details of these issues and how we propose to regulate them. We need to foster broad, critical public discussion of the issues and recognize that principled disagreement can exist."

The Regulatory Process: One Route to Consensus

Since 1986, federal regulatory agencies have operated under a policy that assumes the process of biotechnology in and of itself introduces no special hazards or concerns. Based on this assumption, the policy allows biotechnology research and products to be regulated in the same manner as other scientific and commercial practices. This means that several different agencies play a role in the regulation and oversight of biotechnology, applying and revising rules and regulations as needs

State Regulation

In 2001, the debates over human cloning and over genetically modified foods also raged in state legislatures. Indeed, as legislation stalled at the federal level it picked up steam at the state level.

Six states banned human cloning and 22 states considered a variety of measures to ban or limit either reproductive cloning or stem cell research.

Virginia banned reproductive cloning, but the absence of any reference to embryos in what research the law would permit has led some to argue that the ban applies to all research involving cloning. In Iowa, a ban on stem cell research passed the Senate but was not included in the final bill. North Carolina did not consider any bills related to cloning in 2001.

In 2001, the Pew Initiative on Food and Biotechnology reports, 36 states also considered legislation pertaining to genetically modified foods. No state has yet established a tougher set of requirements than the federal government, although a few states have sought to strengthen their control of genetically modified crops. Maine, Maryland, and North Dakota require producers of such crops to separate them from non-genetically modified crops. Other states considered more restrictive legislation such as complete bans on GM crops.

North Carolina passed one bill related to GM crops, a law that established financial penalties for destruction of agricultural commodities or production system.

North Carolina passed one bill related to GM crops, a law that established financial penalties for destruction of agricultural commodities or production system; the House Committee on Agriculture also considered a bill that would require a license and a $1 million bond for anyone working with genetically modified tobacco.

occur—the U.S. Food and Drug Administration, the U.S. Department of Agriculture, and the U.S. Environmental Protection Agency.

Some observers are seeking a significant overhaul of this regulatory system, particularly as it applies to food and agricultural products. Michael Jacobson called for Congress to give the FDA a mandate to approve the safety of all genetically modified foods and open the process to public scrutiny and participation. The agency also should outline required testing protocols and ban the introduction of allergens into foods, he said. He would charge the EPA with reviewing the potential ecological impact of every crop, animal, or microorganism resulting from biotechnology. To protect companies from being held in regulatory limbo, he recommended incorporating deadlines for action into the regulatory process.

Rodemeyer, a former Assistant Director for Environment in the Office of Science and Technology Policy in the Executive Office of the President, and Chief Counsel to the House Committee on Science, offered a different assessment. He believes the current

system has largely proved effective—"There is no evidence that any of GM products now on the market pose health or environmental risks." But he noted that the challenges ahead will require more stringent oversight. He began with a few examples:

- Plants that produce industrial chemicals or new disease-resistant super trees will be reviewed by the agriculture department under its authority to quarantine plant pests like the Mediterranean fruit fly.
- The EPA may review the super trees under its authority to review new chemical substances, which are defined as any organic or inorganic substance.
- A salmon modified to grow much faster will be reviewed by the FDA under laws designed to review the safety and efficacy of new animal drugs. The FDA will use the same law to approve genetically modified animals that make human proteins.

"Can these laws credibly be stretched to reach products for which they clearly were never intended?" Rodemeyer wondered. "Certainly agencies have discretion, and over the years have created legal interpretations to cover developments, but even if the current patchwork of authorities covers all of the relevant concerns—and I think that's a question worth exploring—there remains the question of its credibility."

Can these laws credibly be stretched to reach products for which they clearly were never intended?

MICHAEL RODEMEYER
PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY

"Simply put," he asked, "will this system retain the confidence of consumers? Will it be seen as sufficiently rigorous as new products reach the market to ensure the safety of food and the protection of the environment? If those threshold conditions cannot be met, technology developers will find it difficult to sell to skeptical consumers."

A cautionary note also came from Beachy, who said that even if necessary, regulations add to the cost of research. The rising costs associated with the evaluation of safety, nutrition, and efficacy, he worried, may stymie research into new varieties of crops by university researchers and start-up companies.

Beyond Regulation: Broadening the Dialogue

Reshaping federal regulations will address only part of the basic question. Regulation, after all, should take account of societal values and public opinion. Surveys, however, have found the American public relatively uninformed about biotechnology and its opinions correspondingly vague.

The question remains how to engage citizens in active, thoughtful discussion. One example comes from the Center for Information Society Studies at N.C. State University. During the summer and fall before the Forum, the Center brought together two groups of average, nonexpert citizens to develop policy recommendations on genetically modified foods. The organizers hosted two conferences, one in which participants met on campus for seven days, spread over three weekends, the other over the Internet during the same period.

Participants were selected from community volunteers to represent the general population of the Research Triangle area, excluding any involved in biotechnology

Managing Our Newfound Power

The potential benefits of biotechnology will never be realized if society does not accept the science and resulting products as effective and safe.

Such acceptance is not guaranteed. Some groups are concerned that these changes are taking place too quickly. They worry that our culture and institutions are not able to keep pace.

Such a reaction has been observed with other technological revolutions, but the sense of anxiety here is even deeper and more profound. Basic questions are being raised about the nature of life and the sanctity of human heritage.

On one hand, public policies are being adopted that would either ban areas of scientific development or establish such stringent regulations that innovation will be stifled. On the other hand, some within the business community argue that the market should be able to sort out the winners from the losers.

Neither of these extreme positions will be socially responsible or effective over the long term. The science and technology are simply too powerful and pervasive. What is needed is a major commitment toward an open societal dialogue about the issues associated with biotechnology. This in turn requires a much greater commitment to communication among all the segments of society with an interest in our collective future.

For more than a century, research universities have played a major role in the development and promotion of new science and technology. We now must ensure that our knowledge and tools are used ethically and safely.

Universities also have the unique opportunity to facilitate the interaction and involvement of a wide range of stakeholder groups. These issues require the active involvement of all disciplines found within the university. We can bring public and private sector leaders together with citizen groups and other interests.

Universities have the unique opportunity to facilitate the interaction and involvement of a wide range of stakeholder groups.

North Carolina is positioned among the top five states in the country for taking advantage of biotechnology as a key economic engine. Our state also has the chance to lead the world in developing new societal institutions and the wisdom to properly manage our newfound power.

Thomas Hoban
Professor of Sociology and Food Science
North Carolina State University

or public debates about its use. Both groups included participants dubious about the role of large corporations and participants strongly in favor of market incentives and limited government regulations.

NCSU Professors Patrick Hamlett, Carolyn Miller and Jane Macoubrie, the organizers of the Citizens' Technology Forum, reported that the project demonstrated how ordinary citizens could participate effectively and intelligently in debates about

complex issues. "The members of both panels engaged with the issues and the background materials. They raised pointed questions for the content experts and pursued follow-up questions with energy."

Among their conclusions, both groups:

- Agreed that biotechnology offers the prospect of important social benefits, but both were concerned about the depth and effectiveness of existing governmental regulations, especially concerning potential public health problems.
- Worried that the long-term health effects of genetically modified foods were unknown, and were dismayed by the apparent lack of mechanisms to track those effects.
- Endorsed strong programs of public education to overcome the lack of unbiased and reliable information.
- Agreed that some form of labeling for genetically modified foods is necessary to insure public choice, but disagreed on the feasibility of segregating genetically modified foods within the larger food stream.
- Differed as to whether the European Union's "precautionary principle," which halts the approval of new foods if there is insufficient, inconclusive, or uncertain scientific data concerning potential risks, should be applied to biotechnology.

7 BIOTECHNOLOGY IN CONTEXT

One Piece of the Larger Economic Development Picture

Much of the 2002 Emerging Issues Forum focused on biotechnology and its potential as a significant contributor to North Carolina's future economic growth. This report has likewise called attention to the opportunities offered by this remarkable scientific and commercial enterprise.

Panelists at the Forum made clear, however, that the state's economic development strategy must be broader than any single industry. Biotechnology, after all, will account for only a piece of the economy. In a recent national study, the Brookings Institution also cautioned that even leading states like North Carolina need to recognize that biotechnology firms can spend enormous sums quickly and then disappear if a drug fails to work in expensive human experiments.

North Carolina needs to assess its biotechnology strategy in the context of a broader review of all science and technology driven efforts to spur economic development. The N.C. Board of Science of Technology undertook such a review in 1999. Its *Vision 2030* report presented a scathing assessment of the state's readiness for growth in high-tech industries.

"Even as other states make twenty-year commitments to science and technology, North Carolina's overall science and technology policy focus has become increasingly reactive and short-term in perspective," the report concluded. "Almost 20 years have passed since our state's last serious science and technology planning effort."

North Carolina again needs visionary leaders who understand what is necessary to maintain and strengthen the state's competitive advantage in the knowledge economy. It also needs to reinvigorate the mechanisms for building public support for implementing new approaches to economic and community development.

Happily, the current situation offers an ideal opportunity for North Carolinians to chart the future. The state's economic crisis provides an opening for rethinking old strategies and identifying new ones.

The public sector, battered by daily budget battles, is actively seeking to stimulate a broader debate over new policies. Universities, too, are stepping up their efforts to make their intellectual capital more accessible to policy makers and to firms of all kind throughout the state. Finally, the state now has a critical mass of successful entrepreneurs and companies that are poised to make significant contributions to reshaping our entire economy.

To capitalize on this unique opportunity, new strategies for economic development will need to be forged, strategies that contrast in some ways with those that have long played a leading role. Biotechnology, Forum panelists said, serves as example of why the state needs these new approaches.

To capitalize on this unique opportunity, new strategies for economic development will need to be forged, strategies that contrast in some ways with those that have long played a leading role.

Up to now, both state and local economic developers have focused in large measure on luring new branch plants and relocating industries. Biotechnology companies, however, grow where they originate. Two-thirds of North Carolina's biotechnology companies are smaller, homegrown operations. About half of those originated with university research discoveries. This suggests that economic development policy should be expanded to include a greater emphasis on growth-from-within strategies.

Similarly, the old selling points no longer sell as well. Neither California nor Massachusetts is noted for low costs, ease of doing business, low taxes, or—at least in the latter's case—good weather, yet they dominate the biotechnology industry. Instead, panelists agreed, more emphasis should be placed on strengthening education at all levels and boosting university research and technology transfer.

Now is the time to launch a major initiative aimed at sustaining and strengthening the new economy in North Carolina. That initiative will require a continuous strategic planning process that identifies and promotes policies for ensuring technology-driven growth throughout the state. While not a replacement for market forces, this process must effectively bridge the gap between analysis and action by ensuring that leaders from industry, government, and academia are involved at every step and take ownership of the results.

Now is the time to launch a major initiative aimed at sustaining and strengthening the new economy in North Carolina.

As the North Carolina Progress Board said in its *N.C. 20/20* report: "The question is not whether we should pursue new economy opportunities, but *how*."

That is the question that the programs of the Institute for Emerging Issues will address and one we focus on next February at the 2003 Emerging Issues Forum "Jump-Starting Innovation: Government, Universities, and Entrepreneurs." We look forward to seeing you there.

2002 EMERGING ISSUES FORUM

Biotechnology and Humanity at the Crossroads of a New Era

Monday and Tuesday, February 11-12, 2002

Monday, February 11

The National Perspective

Marye Anne Fox, Chancellor, N.C. State University
James B. Hunt Jr., Chairman, Institute for Emerging Issues
Tommy Thompson, U.S. Secretary of Health and Human Services
Andrew von Eschenbach, Director, National Cancer Institute

Biotechnology: Past, Present, and Future

John Edwards, U. S. Senator from North Carolina
Charles Hamner, President and CEO, N.C. Biotechnology Center
Steven Burke, Sr. Vice President, N.C. Biotechnology Center

Values and the Value of Biotechnology

Carmen Hooker Odom, Secretary, N.C. Dept. of Health and Human Services
Robert Ingram, COO and President of Pharmaceutical Operations, GlaxoSmithKline

Living in the Biotech Century

David Price, U.S. Congressman from North Carolina
Arthur Caplan, Director of the Center for Bioethics, University of Pennsylvania

Medical Promise and Ethical Peril

Robert Nussbaum, Senior Investigator, National Human Genome Research Institute
Martin Scott, Past Director of Research, Cystic Fibrosis Trust of Great Britain, London
Sandy Thomas, Director, Nuffield Council on Bioethics
Elizabeth Kiss, Director, Kenan Institute for Ethics, Duke University
Thomas Hoban, Professor of Sociology, N.C. State University

Tuesday, February 12

Genomics: Implications for Environmental Health

Marye Anne Fox, Chancellor, N.C. State University (Chair)
Kenneth Olden, Director, National Institute of Environmental Health Sciences

Agricultural Biotechnology: Benefits and Risks

Marye Anne Fox, Chancellor, N.C. State University (Chair)
Roger Beachy, President, Donald Danforth Plant Science Center
Michael Rodemeyer, Executive Director, Pew Initiative on Food and Biotechnology
Michael Jacobson, Executive Director, Center for Science in the Public Interest
Bob Etheridge, U.S. Congressman from North Carolina
Meg Scott Phipps, Commissioner, N.C. Dept. of Agriculture and Consumer Services

Sequencing the Human Genome

Molly Corbett Broad, President, The University of North Carolina
Craig Venter, Chairman, Scientific Advisory Board, Celera Genomics Corp.

Governor's Panel on Biotechnology and New Economic Opportunities for North Carolina

Michael Easley, Governor of North Carolina (Chair)
James Mullen, President and CEO, Biogen, Inc.
Max Wallace, President and CEO, Cogent Neuroscience
Ken Tindall, Sr. Vice President, N.C. Biotechnology Center
Lawrence C. Mahan, Senior Bioscience Executive, Dept. of Business and Economic Development, State of Maryland
Jim Fain, N.C. Secretary of Commerce

Next Steps in Biotech Policy

Open Discussion Hosted by the Institute for Emerging Issues
Noah Pickus, Director, Institute for Emerging Issues (Moderator)
James B. Hunt Jr., Chairman, Institute for Emerging Issues
Steven Burke, Sr. Vice President, N.C. Biotechnology Center
Charles Hamner, President and CEO, N.C. Biotechnology Center
Ken Harewood, Director, Biomedical/Biotechnology Research Institute, N.C. Central University
Robert M. Kelly, Director, Biotechnology Program, N.C. State University
Shawna Young, Teacher, Hillside High School, Durham, N.C.

Making Genomics Investments Pay Off Through Chemistry

A Workshop

Bruce Eaton, Professor of Chemistry, N.C. State University (Chair)
Adrian N. Hobden, President, Myriad Pharmaceuticals, Inc.
Lee Babbis, Senior Vice President, Preclinical Research and Development, Hoffman-LaRoche, Inc.
John Reardon, Senior Vice President, Discovery Research-Biology, GlaxoSmithKline

2003 EMERGING ISSUES FORUM

February 10–11, 2003

Jump-Starting Innovation: Government, Universities, and Entrepreneurs

Scientific advances, new technology, and entrepreneurship have dramatically changed the national and international economy. But the New Economy has taken Americans on a dizzying ride, and many are now questioning its fundamental soundness. At the state level, debates rage over how to promote technological progress, economic innovation, and entrepreneurship while ensuring robust oversight and a regional distribution of benefits. The 2003 Emerging Issues Forum will focus on these debates.

At the Forum, a range of national and international leaders from business, government, and academia will assess traditional means of economic development and analyze new strategies for fostering high-growth entrepreneurial firms and applying new technologies to traditional firms. At the center of these discussions will be the proper and most effective roles for research universities in a knowledge-driven economy. We invite you to join us next February in charting the future of economic development in the U.S. and in North Carolina.

For information, registration, and sponsorship opportunities:

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James B. Hunt, Jr., Chairman
Noah M. J. Pickus, Director

The Emerging Issues Forum is a program of the Institute for Emerging Issues. The Institute bridges the gap between public policy and the fields of science, engineering, and technology. It brings together North Carolina, southern, and national leaders to analyze and respond to problems at the intersection of technology, economics, and politics. The Institute sponsors interdisciplinary studies and public affairs projects that increase understanding of scientific and social research, generate innovative policies, and spur multisectoral collaborations.