Report of the

GOVERNOR'S TASK FORCE *on*

Biotechnology

A Strategic Plan for Biotechnology
Development in Tennessee

EXECUTIVE SUMMARY

STATE OF TENNESSEE

DON SUNDQUIST
GOVERNOR

August 29, 2001

Mr. G. Robert Morris
Butler, Snow, O'Mara, Stevens & Cannada, PLLC
Post Office Box 171443
Memphis, TN 38187-1443

Dear Bob:

The biotechnology industry has become increasingly important to the nation's economy in the 21st century. Tennessee has made significant strides over the past few years in developing an emerging biotechnology industry.

Through our efforts, we are making important discoveries in the area of biotechnology. This also provides the know-how and the technical expertise to support further development of private technology companies, and the high-paying jobs they attract in Tennessee. We could do so much more.

In an effort to compete with our neighboring states, I am creating a Biotechnology Task Force in Tennessee. It would be an honor to have your participation. Our Task Force will represent the fields of education, economic development, finance and business. The overall mission of the Task Force is to study the current status of the biotechnology industry in Tennessee and make recommendations designed to promote the future development of the industry. The Task Force is scheduled to issue a report no later than July 1, 2002.

I appreciate your consideration and also any input you may have which will help with the creation of the task force. Please contact Susan Hadley at 615-532-9058 to confirm your role as a member of the Biotechnology Task Force.

Best regards,

Don Sundquist

DS/jah

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Telephone No. (615) 741-2001

LETTER FROM TASK FORCE CHAIRMAN G. ROBERT MORRIS

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Tennessee's children deserve to participate in the rewards offered by our new knowledge-based economy. If we are going to provide them with that opportunity, we must cooperate regionally, limit duplication of efforts, and compete nationally and internationally. We must retain our best and brightest graduates, entrepreneurs and technologies and use those key assets to build Tennessee's next wave of Fortune 100 companies. Traditional economic development efforts must be enhanced to focus significant resources on entrepreneurial efforts; technology commercialization and new educational curricula must be designed to foster the successful creation and growth of technology-based enterprises.

Thanks to Governor Don Sundquist and his vision that Tennessee must utilize the technology created here as a catalyst for economic growth, the members of this Task Force on Biotechnology were given the opportunity to build a strategic plan for our emerging biotechnology industry. Imagine twenty of Tennessee's premier biotechnology leaders joining together to create a blue print for Tennessee's biotechnology infrastructure. The report, which follows, is just such a plan, the result of an exceptional team spending hundreds of hours over the course of almost a year.

We have world-class resources available in St. Jude Children's Research Hospital, Oak Ridge National Laboratory, Vanderbilt University and our public colleges and universities. What we have not done is coordinate our assets and efforts so that there is a seamless delivery and a single-minded execution. Our report provides Tennessee's public and private leaders with a carefully crafted plan designed to meet this challenge.

As Chairman of the Biotechnology Task Force, it has been my pleasure to report to, and work with, the 19 other members of the Governor's Task Force on Biotechnology. I want to personally thank all of the members of the Task Force and the scores of other volunteers who worked with the Task Force Committees in the production of this report. I would be remiss if I did not acknowledge my personal biotechnology mentors, Drs. Gene Banton and Timothy O'Brien, and thank Anu Menon, Susan Hadley, Patricia Gray, William Gillon and Jim McElroy, our volunteer "staff" and editorial board, without whom we would have never successfully organized the first meeting, much less delivered the final report.

G. Robert Morris

G. Robert Morris

EXECUTIVE SUMMARY

If Tennessee is to successfully participate in the emerging technology-driven economy, technology commercialization must be empowered throughout the state. The economic well-being of future generations depends upon the ability of our public and private institutions to forge cooperative alliances, limit internal competition, eliminate duplicative efforts, and enhance intellectual property development, technology transfer and entrepreneurial activities statewide.

CURRENT SITUATION

Tennessee has built a national reputation as a low-cost manufacturing center with a willing and well-trained workforce. Although Tennessee is not known for technology development, significant intellectual property, including biotechnology, has been and is being created in Tennessee's research institutions, laboratories and universities. Tennessee's most successful technology commercialization efforts to date are essentially limited to the licensing of the technology created in Tennessee to companies residing out of state. Tennessee's most promising graduates often leave the state to participate in the rewards of the commercialization process and advances in biotechnology. Tennessee risks becoming a "third world" participant in the emerging biotechnology economy with Tennessee providing the raw materials, people and ideas and receiving a very limited return on the process through license fees and limited research funding, while other states and regions enjoy the economic rewards created by the commercialization process.

Tennessee and many of our neighboring states lag far behind in providing affirmative support for an emerging biotechnology industry. Tennessee's leaders do recognize the importance of a strong biotechnology development effort and commissioned this Task Force to design a Strategic Plan for enhancing Tennessee's biotechnology industry.

KEYS TO SUCCESS

Tennessee must carefully leverage available resources and join with surrounding states' biotechnology and economic development efforts in order to compete more effectively on a national and international level for recruitment of biotechnology-based businesses. Tennessee's education system and economic development efforts must be focused on creating and nurturing Tennessee's own biotechnology companies, in addition to competing to recruit established biotechnology-based businesses.

Tennessee must:

- **strengthen core educational programs in math, science, information technology, life sciences, agriculture, biology, and entrepreneurship;**
- **transform the path for technology transfer from area institutions into a well-traveled interstate leading to resident biotechnology companies;**
- **develop and motivate a technology-savvy, entrepreneurial, and well-educated workforce;**
- **establish a system of biotechnology clusters or corridors which cooperate to attract external venture capital and nurture entrepreneurial activities and technology creation; and**
- **streamline efforts and focus momentum for the region as a biotechnology-based center of excellence.**

FINANCIAL OBSTACLES

Tennessee faces significant budget constraints, making it difficult for State government to provide direct financial support for biotechnology or to risk future tax revenue through tax incentives. Despite similar pressures, other states are committing considerable resources to long-term infrastructure development. Significant steps can be taken to foster biotechnology business development within the state and the region without large infusions of public monies. However, a commitment of public resources is imperative if Tennessee is to play catch up in this very competitive environment.

VISION

It is the vision of the Task Force on Biotechnology that Tennessee will, through centers of excellence in research and education, attract the necessary capital and talent to promote the internal development of biotechnology-based businesses in this state. The growth of these businesses will attract research dollars which will engender more business development – creating a self-perpetuating circle of economic growth. Development of this sector over the next five years can provide Tennessee with higher wage jobs, a better educated population and dramatic increases in opportunities for wealth creation.

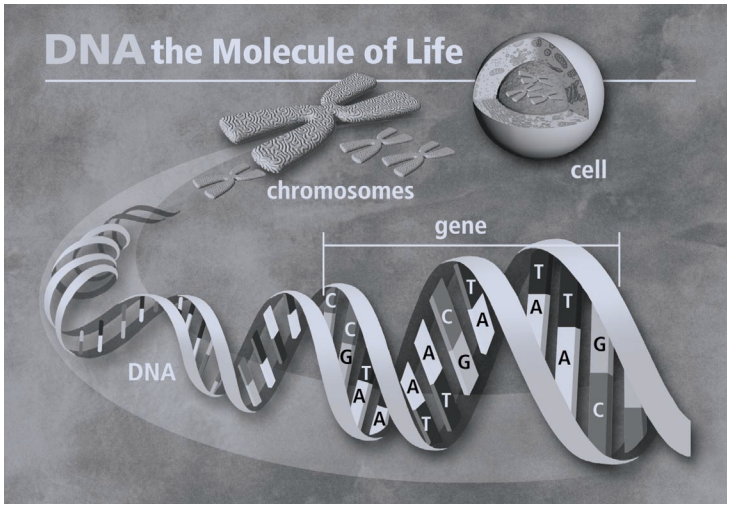
THERE ARE SIGNIFICANT ACTIONS THAT SHOULD BE TAKEN WITHIN THE NEXT 12 MONTHS:

- Enact biotechnology framework legislation defining biotechnology and making biotechnology business development a statewide priority, including tax incentives for research and development; sales and use tax exemptions to cover laboratory equipment; and tax credits for new, high-wage job creation.
- The State should utilize a portion of state pension funds for venture capital investment programs targeted toward Tennessee-based, early-stage biotechnology companies.
- Recognize and empower the Tennessee Biotechnology Association (TBA) as the central organization representing the entire biotechnology industry in the state.
- TBA should develop a complete inventory of Tennessee's current biotechnology companies and a process for maintaining the database.
- The Tennessee Technology Development Corporation (TTDC) and TBA should conduct a statewide labor demand and supply study to assess the needs for various technical positions and the capacity of Tennessee's educational institutions to deliver qualified candidates.
- TBA and TTDC should increase the availability of venture capital in the region by promoting legislation which would use a portion of tobacco settlement funds to create an investment guarantee program to be available for investors in Tennessee-based technology companies (similar to an SBA loan guarantee).
- The Tennessee Department of Economic and Community Development (ECD) and TBA should employ statewide a comprehensive business recruitment and marketing plan and maintain the plan for at least three years.
- ECD should lay the foundation for regional cooperation by calling for a meeting with its counterparts in Arkansas, Mississippi, Alabama and perhaps Virginia to explore biotechnology business development.

[1] BIO's Editors' and Reporters' Guide to Biotechnology, 2002-2003, page 3. The BIO report can be found at www.bio.org. Much of the industry statistics contained in that report are credited to Ernst & Young.
[2] The Economic Contributions of the Biotechnology Industry to the U.S. Economy, Ernst & Young Economics Consulting and Quantitative Analysis, May 2000, page 1.
[3] See, BIO's Editors' and Reporters Guide, supra, page 3.
[4] "The Emerging Bioeconomy, Summary of Trends and Opportunities," New Economy Strategies, Inc., March 2002.
[5] In the last four years, ten states have reportedly completed strategic plans for promotion of biotechnology according to the report, State Government Initiatives in Biotechnology, 2001, prepared by Technology Partnership Practice, Battelle Memorial Institute and State Science and Technology Institute, page 2.

INDUSTRY DATA

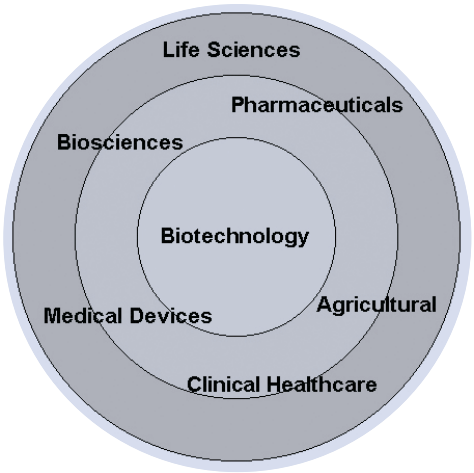
Biotechnology is this nation's most promising emerging economy. The central focus accomplished by
the U.S. Department of Energy and the National Institutes of Health (working closely with private sector participants, led by Celera) in the Human Genome Project resulted in a working draft sequence of the entire human genome in June 2000. That accomplishment and the emerging high quality version of the genome have served as catalysts for rapid expansion in this field.



DOE Human Genome Program, www.ornl.gov/hgmis

Biotechnology in the United States is composed of over 1,457 companies, 342 of which are publicly held. The total value of these publicly traded companies was estimated at $224 billion in 2002.[1] The sector has generated 437,400 jobs, $47 billion in additional revenues, and $10 billion in tax revenues.[2] Through advances in genetics and the mapping of the human genome, scientists are unlocking the mysteries of life.

With $15.6 billion in research and development, 350 biotech drug products and vaccines in clinical trials, and a dramatic surge in the number of patents granted per year,[3] the industry seems poised to undergo a transition which could potentially double the number of commercialized biotech entities in the marketplace. The Wall Street Journal, the Federal Reserve and others believe that health care and life science activities will be responsible for 15-18% of the gross domestic product over the next two decades.[4] Given the rapid growth of the biotechnology industry, a successful biotechnology strategic plan for Tennessee is vital if the State is to have significant participation in this emerging economic sector. [5]



Biotechnology is the use of cellular and molecular processes to solve problems or make products. Within Tennessee, there are numerous applications of biotechnology in the life sciences.

Biotechnology includes a wide range of market segments. Presently, the most lucrative commercial opportunities are in the healthcare markets, particularly therapeutics and diagnostics. Biotechnology research dollars fuel the discovery, development and delivery of revolutionary medicines and vaccines. Biotechnology research has already led to the development of completely new treatments for a range of diseases through genetic testing and gene therapy.

Beyond therapeutics and diagnostics, biotechnology has broad applications in the agricultural and environmental fields. Farmers have rapidly accepted genetically altered crops that are designed to decrease the need for pesticides and which promise significant improvements in desirable commodity traits. Agriculture is still one of the largest industries in Tennessee, and support of biotechnology will also benefit this vital sector.

New discoveries are expanding the importance of biology due to the convergence of technologies and disciplines. With its need for vast databases, collaborative research, and precision instruments, biotechnology is driving extraordinary developments in bioinformatics, nanotechnology, bio-manufacturing, and even the electronics industry. This report proposes strategies for Tennessee that will enable the state to realize the economic and other benefits of the emerging biotechnology industry.

KEY COMPETITIVE ADVANTAGES

In certain high growth segments such as healthcare, agricultural biotechnology, bio-engineering, devices, and bio-materials, Tennessee has the assets to be nationally competitive in bioscience commercialization. Centers of excellence in research, medical technology, bio-engineering, medical devices, bio-materials and agricultural biotechnology are already established in Tennessee and include the Oak Ridge National Laboratory; St. Jude Children's Research Hospital; the Hartwell Center of Bioinformatics & Biotechnology at St. Jude; Vanderbilt University; the University of Tennessee Health Science Center; the University of Tennessee Medical Center; and the U.T. Center for Environmental Biotechnology.

With the presence of Smith & Nephew, Medtronic and Wright Medical, Memphis ranks #2 in the country in medical device and instrument manufacturing. Nashville is widely recognized as a health care industry capital and has nurtured more than 220 entrepreneurial health care companies that operate on a national or international basis. Over 30 bio-medical companies are already located in Nashville.

The Tri-Cities area in Upper East Tennessee has impressive and established biopharmaceutical and chemical research-based industries led by Eastman Chemical in Johnson City and King Pharmaceuticals, Inc., at Bristol. In addition, East Tennessee State University's College of Medicine is providing a valuable contribution to the state's biotechnology focus, and a medical technology research park is in place to nurture biotechnology companies. Biotechnology and high-technology business incubators are being developed in Oak Ridge, Nashville and Memphis.

Tennessee also has significant agricultural resources and a world-renowned transportation and distribution system.

VISION IN THE WEST

St. Jude Children's Research Hospital in Memphis is the world's leading institution for research and treatment of catastrophic pediatric disease. Physicians and scientists at the hospital and in their Hartwell Center for Bioinformatics and Biotechnology perform cutting-edge research on the causes and treatment of all types of cancer as well as other catastrophic illnesses. A planned billion dollar expansion, which already is underway, will further strengthen this institution's capabilities and international importance. Currently under construction is a $36 million GMP production facility to manufacture novel therapeutic agents on the St. Jude Campus. The research at St. Jude, combined with the research at the University of Tennessee Medical Center and the University of Memphis, and the presence of large manufacturers of biomedical devices, make Memphis a significant biotechnology center for Tennessee.

FIRMLY ESTABLISHED IN THE CENTER

Vanderbilt University is one of the nation's leading research universities in several areas that are vital to biotechnology, including medical engineering, pharmacology and nephrology. Vanderbilt has the state's largest and most active university technology transfer office. Funding for related start-ups often is available through Vanderbilt's Chancellor's Fund, a controlled venture capital investment fund. The depth of experienced entrepreneurial and managerial talent in Nashville from the healthcare industry provides Tennessee with a significant competitive advantage.

A JEWEL IN EAST TENNESSEE

Oak Ridge National Laboratory has long been known for its nuclear and energy related research, but it also does significant work in the life sciences, with an emphasis on functional genomics and proteomics, biotechnology, bioengineering, computational biology and bioinformatics. With an annual economic contribution of over $800 million in funded research and over 450 patented technologies which are available for licensing to private business and one of the fastest computers in the country, ORNL represents a significant financial resource and provides a competitive advantage for Tennessee—an advantage that is strengthened by cooperative research at nearby UT-Knoxville.

KEY COMPETITIVE WEAKNESSES

Tennessee now lags behind all southeastern states, save Mississippi, in expenditures for K-12 education.[6] Additionally, Tennessee is far behind Mississippi, Arkansas, Kentucky, Virginia, North Carolina and Georgia in state investments in technology development.[7] The State's investment in higher education, technology parks, business incubators and other similar facilities, also fails to keep pace with most states in the southeast region. Tennessee has not joined most of its neighboring states in investing tobacco settlement funds into long-term research, healthcare, and economic development projects.

Certain state laws and programs either impede, or at least do not promote, development of biotechnology. These laws and programs were well intentioned and generally have been beneficial to the state. The problem is that they were enacted or instituted before technology became the principal driving force in the nation's economy and have not been amended to address the new needs of the new economy.[8]

The public higher education system in Tennessee is split between two, sometimes competing, systems. The University of Tennessee is the State's federal land grant institution with campuses in Knoxville, Chattanooga, Martin, Memphis and the Space Institute in Tullahoma and is governed by the University of Tennessee System and its Board of Trustees. The Board of Regents separately oversees the State University and Community College System of Tennessee which is the 7th largest system of higher education in the nation, with 6 state universities, 14 community colleges and technical institutions, and 26 technology centers. Both overseeing boards are made up of appointed and statutory members.

The Tennessee Higher Education Commission is tasked to coordinate between the two systems, to control for duplicative efforts or degree programs and foster communication, as well as serve as the point of contact for state legislative activities. This bifurcated system can exacerbate the difficulties inherent in coordinating and prioritizing between universities.

Tennessee's educational system is not generating adequate focus on the sciences and its university system does not benefit from a single institutional structure. The latest information available to the Task Force on degrees awarded in Tennessee is 1997-98. In that year, state universities awarded 1,099 Bachelor's degrees, 120 masters degrees, and 102 PhDs in the area of biological / life sciences. These numbers ranked Tennessee 22nd nationally, 7th in the region (southeastern US, 12 states, including Arkansas and Missouri and Kentucky), and 8th in the region on a per capita basis. While 52 percent of Tennessee's public K-12 schools offer chemistry, biology or science classes, only 7 percent of Tennessee's public school teachers are endorsed to teach science.

Tennessee also suffers from current lack of identification as a center of biotechnology development, both nationally and compared to the neighboring states of North Carolina and Georgia. Other neighboring states, such as Kentucky and Arkansas, significantly lead Tennessee in public promotion of biotechnology, but their competitive position has not significantly out-paced Tennessee. Fortunately, due to the pace of technological innovation, Tennessee can quickly close the gap if it makes a concerted effort.

The lack of a reputation as a biotechnology center contributes to other competitive weaknesses, such as a lack of venture and angel capital for investment in local technology companies. In fact, in public meetings that the Task Force held in all areas of the state, the lack of investment capital was probably the most frequently cited impediment to development of a strong biotechnology industry in Tennessee.

[6] Source, The New Economy Strategy, Tennessee Technology Development Corporation, page 7, citing "Rankings & Estimates Ranking of States," Estimates of School Statistics, 2001, NEA.
[7] Source, The New Economy Strategy, supra, page 7, citing "State Technology Development Budgets," State Science & Technology Indicators, 2001.
[8] One example is the existing job creation tax credit, which is based solely on the number of jobs rather than the total amount of payroll created by a company. Another is the "TIIP" program, which provides state funds for infrastructure improvements for certain facilities, but which traditionally has been interpreted too narrowly to benefit a biotechnology company.

THE STRATEGY

Building upon Tennessee's existing strengths and addressing its weaknesses will require a multi-faceted strategy involving both the public and the private sector. The strategy should include efforts in the areas of education and research; technology transfer; workforce development; promotion of the development of biotechnology clusters around existing centers of excellence; and enacting a legislative framework that will be conducive to recruiting, retaining and fostering the growth of biotechnology companies.

1. Organize an Education Task Force to strengthen core educational programs in math, science, information technology, life sciences, agriculture, biology, and entrepreneurship.

Key Tactics:

- **Develop a statewide "Centers of Excellence Plan" that includes an inventory analysis of assets and a formal evaluation of those assets and their competitive position relative to other centers around the country.**
- **Coordinate resources to secure greater support for research activities within Tennessee and the surrounding region.**
- **Develop an entrepreneurial culture through educational and outreach programs directed to the private sector and to members of universities and research institutions.**
- **Enhance the public's understanding of biotechnology and its appreciation of the positive impact this technology has on lives and on careers through web-based informational centers, innovative educational programs involving the private sector, and age-appropriate materials for K-12 classes.**
- **Make investment in Tennessee's educational system a priority.**
  - **Allocate funds for new or adapted K-12 biotechnology "outreach" programs, giving priorities to proposed programs that "teach the teacher" in the course of teaching the students, so that teachers can convey content on a year-by-year basis after the initial "jump-start" training.**
  - **Foster and fund innovative course proposals by teachers, and when a course works well, such as the experimental molecular course developed by a Nashville public high school teacher, encourage schools and school systems across the state to offer similar courses.**

Although Tennessee has significant resources among its universities and research institutions, there are significant shortcomings in education, particularly K-12. The state also lacks a readily available and adequately trained workforce. Recent decreases in State support for higher education, research and institutional funding, have caused the State's current educational and research resources to wither. Far from becoming a leader in biotechnology development, there are sectors of the State's education base that are falling further behind national norms.

Increased funding levels are not answers in and of themselves. A sharpened emphasis on biotechnology education, research and worker development will be successful only if these resources are channeled into effective and innovative programs that catapult the State's students, workers and institutions into a significantly higher aptitude of technology development and production. The State must generate more interest in the sciences among its K-12 students; it must do a better job teaching science to these energized students; it must provide resources at the university level to enable these young scientists and engineers to explore their talents; and it must encourage and enable professors and researchers to protect and commercialize their inventions, returning dollars both to the individual and to the institutions that fostered their work.

A better public understanding of biotechnology and an appreciation of the impact this technology can have on lives and on careers is required in order to generate support for the necessary public and private investment needed to develop this sector of the Tennessee economy.

The state should survey and carefully analyze the clearly defined existing "centers of excellence" in research and education among public colleges and universities, and make these centers the focus of cooperative efforts to capture more research dollars. There are three crucial paybacks for more research funding - 1) the institution and the community benefit from the increased investment; 2) the center's reputation and capabilities are strengthened; and 3) the number of inventions developed by the institution increases proportionately.

Unfortunately, scientists and inventors do not generally make successful entrepreneurs. Without the entrepreneurial spirit and know-how, the best inventions may remain locked in the laboratory, or may fail to gain even a modicum of commercial interest. It is critical that educational institutions teach entrepreneurship and business management as it relates to high-technology companies.

IT WORKS...

Missy Bunch, a biology teacher at Nashville's M.L. King Magnet High School, developed a course on "Molecular Research" that was so innovative she had to create her own syllabus and assemble her own reading materials. After convincing school administrators to allow her to offer the course, she raised private contributions to build and equip an adequate laboratory. She finally offered the course during the 2000-01 school year.

- Twenty-five students enrolled, and all were invited to submit projects for a regional science fair.
- Four students received research grants of $300 each from the Tennessee Junior Academy of Science ("TJAS"), based on proposals the students wrote.
- Nine students submitted papers to the TJAS, four of which were selected to be presented at the annual TJAS meeting and to be published in the 2001 Journal of the Tennessee Academy of Science.
- Four of the students plan to enter research as a career.
- Two of the students are choosing colleges based on molecular programs offered by the various institutions.
- This was the only high school class that was invited to meet and participate in an informal question and answer session with Dr. Francis Collins, the Director of the Human Genome Project for the National Institute of Health, in October 2000.

The biotechnology emphasis program within the biology major at Middle Tennessee State University (Dr. Rebecca Seipelt, Director) has created four curricular focus areas (including biotechnology; microbiology; animal husbandry and animal sciences) and apprenticeship opportunities for students in biomedical and biotechnology research laboratories. The Vanderbilt School of Engineering and Owen School of Management have two masters programs focusing on managing technology (School of Engineering) and Entrepreneurship (Owen).

"COME FOR A DEGREE... LEAVE WITH A COMPANY!"
This was the slogan for the cutting-edge technopreneurial leadership center and program established by the University of Tennessee and the Tennessee Technology Development Corporation. At one point 30 students were involved in the innovative program that was designed to teach business establishment, finance, operations and growth issues as they specifically relate to technology companies. Working in close cooperation with the Oak Ridge National Laboratory, the students could select a technology, create a Small Business Innovative Research (SBIR) grant proposal in one class, incorporate a business and create the operating structure in another class, research market potential, perform technology due diligence, and complete the other steps required to commercialize a technology.

The program, which so clearly reflects many of the recommendations in this report, has been terminated.

2. Transform the path for technology transfer from area institutions into a well-traveled interstate leading to resident biotechnology companies

Key Tactics:

- **Standardize and improve technology transfer from state universities within Tennessee by developing a model technology transfer policy similar to those promulgated by the National Laboratory Association.**
- **Expand the standardization effort to all universities and research centers in the region.**
- **Establish a statewide technology transfer office with authority to evaluate intellectual property, allocate resources and foster the protection of intellectual property developed at state universities.**
- **Develop efficient and prudent methods to establish value for, and to market, technology available in regional universities and research institutions.**
- **Allocate and focus resources to develop laboratory facilities and business incubators in close proximity to universities and research institutions.**[9]
- **Promote business mentoring and start-up investment programs that have economic development as the priority—not return on investment.**
- **Stress the development of an entrepreneurial culture through education and outreach programs directed to the private sector and to members of universities and research institutions.**

Technology transfer is the deliberate movement of new knowledge as embodied in technology from sources or "generators" to commercial developers and, ultimately, end users. Sources, or technology generators, may include colleges and universities, federal laboratories, and the private sector.

Most of Tennessee's universities and research institutions have established offices of technology transfer whose mission is to promote the commercialization of discoveries and inventions developed at the institutions. Unfortunately, budget constraints and limited staff resources have hampered their effectiveness. For example, often Board of Regents universities lack the funds to prosecute patent applications for inventions by their faculty. While the University of Tennessee and the University of Memphis have been able to obtain patents for their inventions, other universities have not, and there is no system in place for the technology transfer office at one university, such as the University of Tennessee, to prosecute patents and promote technology transfer on behalf of other public institutions.

The Task Force learned that many faculty members at public universities believe that conflict of interest laws and policies prevent them from participating in companies that receive licenses to develop technology owned by the universities. While this perception is mistaken, it highlights the fact that administrators at our public universities have not adequately supported their faculty members in attempting to commercialize their discoveries. In short, the scientists need to be educated as to the value, the methodology and the importance of protection and commercialization of technology. The state can play a vital role, not as gate-keeper, but as an overall coach, teaching a state-wide game plan that encourages commercialization.

Technology will only be commercialized locally if the inventor has an entrepreneurial spirit and the desire to initiate the process or an outside resident entrepreneur becomes familiar with the technology at a particular research location and understands its commercial value. The likelihood of these events occurring can be greatly enhanced by 1) teaching researchers entrepreneurship; 2) making the technology transfer path more uniform statewide; 3) marketing available technology; and 4) promoting the paybacks to researchers, institutions and communities provided by commercialization.

The strategy, then, is to teach scientists how to recognize, protect and share their inventions; to standardize and simplify technology transfer, so virtually anyone can do it; to develop mechanisms through which research institutions can safely value and shop their technology; and to ensure that all participants receive fair and visible returns on their investments. Technology protection and transfer must be treated as a business opportunity as opposed to an academic exercise.

ONE STEP FORWARD, TWO STEPS BACK...

Nashville State Technical Community College was set to premier an associate degree in the fall of 2002 where a two-year biotechnology program and related apprenticeship would lead to graduates capably trained in areas related to laboratory research in the biological, chemical, and physical sciences. However, the Tennessee Board of Regents put all new course proposals on hold due to the State's budget crisis. Given possible delays, the director of the program decided to return to Texas.

Nashville State Tech still plans to continue with the course, and other entities, such as the Memphis Biotech Foundation, are working to establish similar programs in other parts of the state.

3. Develop and motivate a technology-savvy, entrepreneurial, and well-educated workforce

Key Tactics:

- **The Tennessee Technology Development Corporation (TTDC) and the Tennessee Biotechnology Association (TBA) should design and commission a statewide labor demand and supply study to assess the needs for various technical positions and the capacity of Tennessee's educational institutions to deliver qualified candidates.**

- **State-of-the-art "biotechnology" training at the vocational and technical and associate levels must be developed or adapted from existing programs. Such biotechnology programs already are emerging in various locations in Tennessee, and could serve as a model for development in other cities to accelerate the rate of capture of young talent into these areas.**

Probably more than any other industry, biotechnology businesses rely on highly skilled workers to be successful. Currently, there is no reliable assessment of the supply and demand for labor to sustain the growth of the biotechnology industry. Tennessee must undertake a statewide labor demand and supply study to assess the needs in the industry for various technical skills and the capacity of our educational institutions to deliver qualified candidates for the positions. This study should form the basis for restructuring curricula, increasing the number of facilities and faculty devoted to select programs, and linking graduates with prospective employers.

In order to hasten the development of the necessary workforce, Tennessee must aim to attract these workers from elsewhere. However, relying on the recruitment of highly skilled workers to the state is not a sustainable long term strategy. It is expensive for companies to recruit and relocate employees from other areas and it overlooks the potential of the current state population that need good paying jobs. In order to fully develop the biotechnology workforce within Tennessee, it is essential to also focus attention on educational and training opportunities for individuals already in the workforce who find themselves in a career transition and/or seek positions with higher monetary compensation. Appropriate educational and training opportunities would enrich the relevant scientific or entrepreneurial background of these individuals and enhance their success in competing for positions in the biotechnology workforce.

Individuals and students not destined for the laboratory should have available to them the opportunity to participate in innovative technical training programs housed in community colleges and other locations throughout the state that will teach them the technical skills to change their lives. The private sector can, through the right set of incentives, get more involved in training programs that will help supply the workers they need. This avenue for job opportunities can transform the future of individuals that do not, and will not, possess university degrees. The high-paying biotechnology jobs can be vehicles that lead out of poverty and into a progressive and growing middle-class.

4. Establish a system of biotechnology clusters or corridors which cooperate to attract external venture capital and nurture entrepreneurial activities and technology creation

Key Tactics:

- **The Tennessee Biotechnology Association (TBA) should develop a complete inventory of Tennessee's current biotechnology companies and a process for maintaining the data base.**

- **The Tennessee Department of Economic and Community Development (ECD), Tennessee Technology Development Corporation (TTDC) and TBA should create a comprehensive business recruitment and marketing plan and maintain the plan for at least three years, focusing on -**
    - **marketing the State's "centers of excellence" as premier locations for biotechnology-based businesses;**
    - **advertising existing biotechnology-based industries in Tennessee; and**
    - **enhancing and promoting the facilities and operations of existing and planned biotechnology business incubators in the State.**

- **TBA and TTDC should increase the availability of venture capital in the region by promoting legislation which would use a portion of tobacco settlement funds to create an investment guarantee program to be available for investors in Tennessee-based technology companies (similar to an SBA loan guarantee).**

- **Utilize a portion of state pension funds for venture capital investment programs targeted toward Tennessee-based, early-stage biotechnology companies.**

- **Establish "Grant Assistance Centers" in each of the regions of the state to increase access for Tennessee's entrepreneurs to federal and foundation grants.**

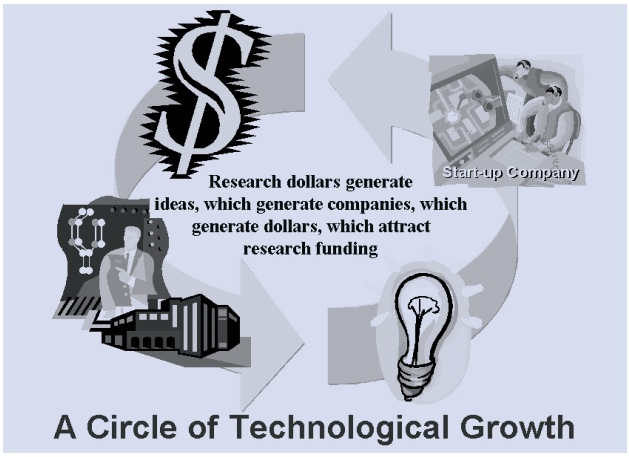
- **ECD should initiate cooperative arrangements with centers of excellence in neighboring states—creating a regional magnet for capital, talent and research dollars.**

Experience in other states has shown that, in the field of biotechnology, the key to competing nationally and internationally is through the formation of technology "clusters".

According to Michael Porter of the Harvard Business Review, clusters are geographic concentrations of interconnected companies and institutions in a particular field that encompass an array of linked industries and other entities important to competition. These broader partnerships, which are not restricted by state boundaries, attract talent, capital and attention. An example of a nationally-recognized cluster already in the state is the for-profit healthcare industry in Nashville. Biotechnology clusters could emerge anywhere in the state, and they should be promoted whenever and wherever they begin to develop. Currently, the basis for biotechnology clusters exists in 1) Memphis, due to the research being conducted at St. Jude, the University of Tennessee College of Medicine, and the University of Memphis, the presence of a significant biomedical device manufacturing industry, and the plans to develop a major biotechnology incubator and research center; 2) Nashville, due to the research at Vanderbilt University, the abundance of proven entrepreneurs from the for-profit healthcare industry, and the emerging incubators in Williamson County and downtown Nashville; 3) the Knoxville-Oak Ridge area, due to the research at Oak Ridge National Laboratory and the University of Tennessee; and 4) upper East Tennessee, due to the research at East Tennessee State University, the presence of major companies such as King Pharmaceuticals and Eastman Chemical, and the planned incubator at East Tennessee State University.

Establishing centers of excellence is only the first step. Tennessee's nationally recognized research centers must become full-fledged partners with commercially-minded entrepreneurs and encourage business development and growth. Through the identification and utilization of existing resources, a coordinated and determined marketing campaign, and a commitment of resources to improve the environment for biotechnology businesses, Tennessee and its communities can complete a self-perpetuating circle of economic growth.

In the development of technology clusters, higher education has a pivotal role in creating innovation, providing highly trained talent, and recruiting individuals and companies to a region. In Tennessee this critical component is divided between two governing systems that do not interact but often compete for state dollars and programs that may or may not be critical to developing biotechnology or other technologies in the State. Improved coordination is crucial if the State is to effectively leverage its resources and focus its priorities. Similarly, Tennessee and its neighboring states should also strive to reduce or eliminate barriers to technology transfer and entrepreneurial cooperation.



A Circle of Technological Growth

Fostering the development and deployment of bio-business incubators in Tennessee is an essential step required to increase life science commercialization. Successful bioscience clusters offer shared laboratory

facilities which mitigate the costs of research and development and also serve as "incubators" of new companies. The cost of constructing and outfitting a laboratory varies but can range between $250 to over $400 per square foot, much higher than it costs to build an office (between $100 and $150/ft). In the high-risk commercialization process, both existing and new companies suffer from this cost, which too often prevents new technologies from being commercially developed.

In addition, new companies may need assistance in planning and monitoring clinical trials as required by the Food and Drug Administration. It is difficult for a young company to afford such specialized individuals either as full time employees or consultants. By sharing the costs of expensive personnel and services across many companies, the large capital requirement and risk of biotech companies is mitigated.

The financial condition of Tennessee state government and surrounding states makes a significant commitment of public funds difficult to secure. Nevertheless, other states have chosen to invest tobacco settlement funds into technology and business development activities - an investment that does not directly involve tax dollars. In addition, state pension funds have billions of dollars that are generally invested outside the state of Tennessee. A small portion of these two sources of revenue, if properly leveraged, could dramatically shift the playing field in Tennessee, taking the state from capital deficient to capital rich in a very short time.

CLUSTER INCUBATION

In Memphis, prominent businessmen have committed substantial personal funds to develop a biotechnology incubator and research center on the site of the former Baptist Hospital, which the hospital foundation had given to the University of Tennessee Center for Health Sciences.

In Nashville, private businesses along with Vanderbilt University are developing two incubators, one in the Cool Springs area of Williamson County and the other near downtown Nashville.

5. Streamline and focus momentum for the region as a biotechnology-based center of excellence

Key Tactics

- **TBA and TTDC should enhance the commitment of the state by successfully promoting legislation to provide incentives for biotechnology business growth in the state, including—**
  - **biotechnology framework legislation that defines biotechnology and makes biotechnology business development a statewide priority;**
  - **appropriate tax incentives to encourage research and development;**
  - **sales and use tax exemptions to cover laboratory equipment; and**
  - **tax credits for new, high-wage job creation**

- **Foster the activities of the TBA as the central organization representing the entire biotechnology industry in the state and in conjunction with that association—**
  - **encourage the development of local and regional associations designed to foster commercialization, education and investment in biotechnology;**
  - **help organize and focus state, regional and local marketing campaigns establishing the region as a biotechnology center; and**
  - **serve as a central resource for information about biotechnology, biotechnology-based businesses, and business resources.**

- **The Governor should consider the proper mechanisms to receive advice on ethical issues stemming from advances in biotechnology.**

- **The state should establish a significant presence at the annual BIO trade fair, and work with adjoining states to present a regional emphasis at that show.**

The establishment of the Governor's Task Force and the positive reaction to it both within Tennessee and throughout the adjoining regions demonstrate the importance given to this effort by the business community. The delivery of the Task Force report effectively completes the Task Force's mission, but the torch must be passed on in order for these recommendations to yield the results the state deserves.

Within Tennessee, the Tennessee Biotechnology Association (TBA) is established as the central organization which can promote biotechnology business initiatives, organize and focus campaigns designed to attract venture capital and new businesses, and work with the Tennessee Technology Development Corporation (TTDC) to influence the state government on issues of importance to the biotechnology community. The continued presence and independence of this association are crucial to the biotechnology initiatives in Tennessee as is its ability to serve the industry in a single-minded fashion. One important initiative will be to develop and promote enactment of framework legislation designed to foster biotechnology and technology commercialization in the state of Tennessee and the mid-south region as a whole.

Advances in biotechnology have engendered weighty ethical considerations as science is able to actually change the structure of life. Although many of these issues are being debated on a federal level, it is likely states will ultimately be called upon to make decisions on funding, research and medical applications. The Task Force therefore recommends that the Governor consider establishing mechanisms, such as a Biotechnology Ethics Advisory Group, that can be available to informally advise state government with respect to these serious ethical issues.

OF MICE AND MORE MICE

The Tennessee Mouse Genome Consortium is a collaborative research effort undertaken by East Tennessee State University, ORNL, Meharry Medical College in Nashville, St. Jude, the University of Memphis, the University of Memphis Health Science Center in Memphis, Vanderbilt University and the University of Tennessee in Knoxville. The Consortium seeks to pool the expertise and resources of all participating institutions for the study of complex biological systems, and in particular, promote mouse model systems as a biomedical and clinical research resource. Consortium researchers and other staff have a wide variety of expertise that includes mouse genetics, basic biomedical research, clinical research, laboratory animal care, research administration, bioinformatics and bioanalytical techniques. The first Consortium project, which was funded with nearly $15 million from the National Institutes of Health, is led by a professor at the University of Tennessee, as principal investigator.

If Tennessee is to be successful in recruiting established biotechnology companies to locate in the state and in promoting the growth of indigenous companies, it is critical that the state offer the types of tax incentives that many states already offer. These incentives include establishment of a credit against franchise and excise taxes for research and development expenditures within the state, with a carry-forward for unused credits; creation of a sales and use tax exemption for laboratory equipment, which would be an extension of an existing exemption for industrial equipment; expansion of the existing tax credit for new job creation, to focus on total payroll as well as number of jobs; and allowing the carry-forward of net operating losses in the computation of excise tax liability. The Task Force recognizes that establishment of new tax incentives is difficult in this time of chronic fiscal crisis. However, most of these tax incentives can be structured to minimize or avoid any immediate loss of tax revenue. More importantly, the Task Force believes that the payback, in terms of economic growth, new jobs at high wages, and the new tax revenues they would generate would more than offset any lost tax revenues.

PRIORITIES OF RECOMMENDATIONS AND TIME FRAMES

Tennessee is already behind in its efforts to capitalize on the economic benefit associated with biotechnology-based businesses. It cannot afford to saunter through this race. With or without state financial assistance; with or without a thoughtful use of tobacco settlement funds; the biotechnology-based business effort must move forward.

The Task Force strongly believes that the state can dramatically increase its drawing power through cooperative arrangements with centers of excellence in neighboring states - creating a regional magnet for capital, talent and research dollars.

Despite the significant budget constraints that face Tennessee, the Task Force suggests that action should be taken on the following recommendations within the next 12 months:

- **Enact biotechnology framework legislation defining biotechnology and making biotechnology business development a statewide priority, including tax incentives for research and development; sales and use tax exemptions to cover laboratory equipment; and tax credits for new, high-wage job creation.**

- **Recognize and empower the TBA as the central organization representing the entire biotechnology industry in the state.**

- **TBA should develop a complete inventory of Tennessee's current biotechnology companies and a process for maintaining the database.**

- **TTDC and TBA should conduct a statewide labor demand and supply study to assess the needs for various technical positions and the capacity of Tennessee's educational institutions to deliver qualified candidates.**

- **ECD and TBA should implement statewide a comprehensive business recruitment and marketing plan and maintain the plan for at least three years.**

- **ECD should lay the foundation for regional cooperation by calling for a meeting with its counterparts in neighboring states to explore biotechnology business development.**

With this foundation, the state and the surrounding region can accelerate the development of biotechnology-based companies and begin to reap solid returns from the region's intellectual capital.

Report of the

GOVERNOR'S TASK FORCE *on*

Biotechnology

A Strategic Plan for Biotechnology
Development in Tennessee

ECONOMIC DEVELOPMENT

SUMMARY

A coordinated, statewide economic development strategy must be developed to seize the opportunity that is currently available in the area of biotechnology based business. The strategy must include components to facilitate the expansion of existing companies, attract companies from other regions in the U.S. and abroad, and grow companies within the State.

While Tennessee has significant assets in biotechnology, other states and regions are significantly more advanced and competition is growing. Other states are investing substantial funds in higher education, technology parks, incubators and other facilities; incentives to attract companies; and work force development and post secondary education.

Tennessee must leverage existing assets such as Oak Ridge National Laboratory, St. Jude Children's Research Hospital, Vanderbilt University, University of Tennessee Health Science Center, pharmaceutical companies, health care providers, device manufacturers, and a variety of emerging biotechnology companies that have been spawned from research conducted in the State.

The State is at a turning point and will either commit the resources to nurture the growing biotechnology industry or fall behind Tennessee's competitors that are aggressively moving forward.[1] Many of the resources required to support biotechnology companies are already available through current incentive programs, but they must be revised to accommodate these companies' special needs.

GOALS

To diversify Tennessee's economy, it is imperative that the State expand the number of technology companies.

Technology is a growth engine nationally, and the sector has grown four times faster than the overall economy in the last ten years. Sixty percent of new job growth during that period has come from the technology sector, and technology jobs pay 50 to 70 percent above the average private-sector job. Tennessee has not traditionally been known for technology, but rather as a low cost manufacturing center.

ECONOMIC DEVELOPMENT MISSION STATEMENT

The economic development mission statement of the Task Force reflects the two-fold objective of economic development programs—jobs and capital investment.

"To stimulate the creation of jobs and capital investment in the biotechnology sector throughout Tennessee."

Progress made in these two components produce opportunities and income for citizens to provide for themselves and their families and revenues for state and local governments to provide services and enhance the quality of life for residents of the State.

[1] In the last four years, ten states have reportedly completed strategic plans for promotion of biotechnology.

KEY RECOMMENDATIONS

Economic development is multi-dimensional. When effectively carried out, it represents the convergence of infrastructure, finance, incentives, education, work force development, and entrepreneurship. The following recommendations address these issues and provide a basis for launching the State into the biotechnology revolution:

- **A complete inventory of Tennessee's current biotechnology companies should be developed as soon as possible and a process for maintaining the database should be put in place.**
    - **A statewide industry association such as the Tennessee Biotechnology Association should be recruited as a clearinghouse to store and maintain the updated inventory.**
- **Tennessee should develop a statewide "Centers of Excellence Plan" that includes both an inventory of existing assets and a serious evaluation of their competitive position relative to other centers around the country.**
- **The State should develop and implement an "Existing Industry Strategy".**
- **A comprehensive business recruitment and marketing plan should be undertaken statewide and maintained for at least three years.**
- **Tennessee should enhance the facilities and operations of the existing and planned incubators in the State.**
- **Tennessee should devote a portion of state pension funds to investment in biotechnology companies, and should use a portion of its tobacco settlement funds to assist this sector.**
- **The State should establish "Grant Assistance Centers" in each of its regions.**
- **The State should offer business technical assistance in every region staffed with professionals that have expertise in technology business development.**
- **The State should review its incentive programs and take necessary steps, whether legislative or administrative, to revise its incentives to reflect the needs of technology businesses.**
- **Tennessee must undertake a statewide labor demand and supply study to assess the needs in the industry for various technical positions and the capacity of Tennessee's education institutions to deliver qualified candidates for the positions.**

BIOTECHNOLOGY PROFILE

National Perspective

The biotech industry is concentrated in six clusters on the East and West coasts; California (Bay Area and San Diego), Massachusetts (Boston area), Maryland (suburban Washington DC), Washington (Seattle), North Carolina (Research Triangle Park) and the Philadelphia/New Jersey area. Top reasons for location are: (a) proximity to founding science/major research centers, (b) areas where clusters have already formed, and (c) availability of specialized R&D facilities.[2]

[2] The location factors for biotech companies were documented in a KPMG survey of CEOs in 1995.

Biotechnology in the U.S. is composed of over 1300 companies, 400 of which are publicly traded, with a combined market capitalization in excess of $450 billion. With annual revenues in excess of $28 billion and about 130 products in commercialization and approximately 50 publicly traded companies being profitable, the industry has been viewed as largely composed of emerging companies. But with $18 billion in research and development and over 1400 proto-products in various stages of clinical development and over 400 in late stage pivotal clinical studies, the industry is about to undergo a transition which could potentially double the number of commercialized biotech entities in the marketplace.
The biotechnology industry has made, and continues to make, significant economic contributions to the U.S. economy. Ernst & Young prepared a report outlining the financial contributions for 1999:

- **437,400 U.S. jobs. Of these, 150,800 jobs were generated directly by biotechnology companies, while the remaining 286,600 jobs were generated by companies supplying inputs to the industry, or by companies providing goods and services to biotechnology employees.**

- **$47 billion in additional revenues. Even though the industry as a whole remains unprofitable, biotechnology companies produced revenues of $20 billion. Companies supplying inputs or selling goods and services to biotech employees generated revenues of $27 billion.**

- **$11 billion in research & development spending. This includes R&D conducted by biotechnology firms, but does not include R&D conducted by firms supplying the biotechnology industry with inputs or workers with goods and services.**

- **$10 billion in tax revenues, including federal, state and local taxes. The largest components of the tax revenues were individual income taxes, social security and property taxes, with a little over two-thirds of total taxes going to the federal government.**

Research and development spending has grown to $15.6 billion since the Ernst & Young study was completed.

In many states, tobacco settlement funds have been used to give the local biotech industry a boost. The tobacco settlement of $206 billion calls for the tobacco companies to make payments to 46 States over a period of 25 years (Y2000 – Y2025). The list below identifies just a handful of States and how they have earmarked the use of the millions of tobacco settlement dollars:

- **Connecticut - Established a new $4 million Biomedical Research Trust**
- **Florida- Earmarked $150 million to create an endowment for biomedical research**
- **Georgia- Appropriated $5.7 million for cancer scientists, clinicians, and scholars**
- **Illinois- Appropriated $34.5 million for research projects at their universities**
- **Indiana- Allocated $3 million to conduct research on tobacco-related illnesses**
- **Kansas- Appropriated $29.2 million for children's programs including research**
- **Michigan- Appropriated $50 million to provide grants to Michigan universities and research facilities for life science research**
- **Ohio-The Biomedical Research & Technology Fund will receive $493.5 million through Y2012.**

Tennessee Perspective

From Memphis to Oak Ridge, the State of Tennessee has core assets that have created a foundation from which the State can grow the biotech economy. These assets have so far followed a similar development path to other clusters noted above.

Tennessee has bragging rights to one of the world's premier scientific research centers, Oak Ridge National Laboratory (ORNL), representing a marriage between science and industrial technology forged for national defense during the throes of global war. With almost 60 years of service to the United States, Oak Ridge National Laboratory has changed the history of the nation and the world. Currently employing about 4500 people, the Laboratory's research agenda ranges from global warming to energy conservation to high-temperature superconductivity to ozone-safe substitutes for chlorofluorocarbons. It is committed to improving national science education and to speeding the transfer of its technological developments to the commercial marketplace.

Examples of applications of ORNL efforts are isotopes and instruments for medical diagnosis and treatment; ultra-pure vaccines that have minimal side effects; regulations to protect human health and safety; bone marrow transplants for radiation accident victims; higher-quality meat resulting from use of the technology to freeze and thaw embryos from superior animals and implant them in foster mothers; nuclear reactors that supply one-fifth of U.S. electricity; a more powerful U.S. Navy; energy-efficient refrigerators, hot-water heaters, and other appliances; and stronger alloys and ceramics for use at high temperatures.

Another State jewel is St. Jude Children's Research Hospital® in Memphis. Founded in 1967 with a vision to be the leading institution worldwide in advancing the treatment of children with catastrophic illnesses, the research hospital continues to make remarkable progress in the battle to save lives. A five-year, $1 billion expansion plan is well underway. The expansion includes the Integrated Research Center, Children's Infection Defense Center, Genetic Diseases Center, Translational Trials Unit, and the Good Manufacturing Practices Facility. The hospital's commitment is clearly reflected in the ambitious expansion plan along with the unyielding effort put forth by more than 2,200 employees.

The Hartwell Center of Bioinformatics & Biotechnology was established at St. Jude to provide St. Jude investigators access to state-of-the-art biotechnology and the bioinformatics resources to support their research programs. These include DNA micro array laboratories, proteomics and mass spectrometry laboratories, high-throughput DNA sequencing and genotyping, macromolecular synthesis, and molecular interaction laboratories. A high-performance computing facility was established to support the Center's bioinformatics group in providing the analytical tools needed for contemporary research. This facility is unique in integrating these informatics and biotechnology resources and provides St. Jude with one of the leading facilities of its kind in the world.

Bristol is home to King Pharmaceuticals, Inc., a vertically integrated pharmaceutical company that manufactures, markets, and sells primarily branded prescription pharmaceutical products. The company started in January of 1994 as a contract manufacturer for big pharmaceutical companies like Smith Kline, Beecham and Novartis. In 1996 the company began to focus more on brand name pharmaceutical product lines through their subsidiary, Monarch Pharmaceutical. The company went public in June 1998 and was added to the S & P 500 more quickly than any other company. With net sales of $872,262,000 and more than 1,800 employees, King Pharmaceuticals has had and will continue to have a tremendous economic impact in East Tennessee.

With the presence of Smith & Nephew, Medtronic and Wright Medical, Memphis ranks number 2 in the country for the medical device and instrument manufacturing industry. Viral Antigens, Inc., a University of Tennessee success story, has been manufacturing infectious disease antigens since 1982. Another success story in the making is GTx, Inc. Founded in 1997, GTx is an emerging biopharmaceutical company dedicated to the development of innovative therapies.

Nashville, widely recognized as a health care industry capital, has nurtured more than 220 health care companies that operate on a national or international basis. Biotechnology represents a strong potential growth segment, with over 30 biomedical companies already located in Nashville. With this base of

companies, renowned academic and research institutions (e.g., Vanderbilt University and Medical Center), strong infrastructure support, the newly announced Cool Springs Life Science Center designed for growing biotechnology companies, and another incubator near downtown being readied for its first tenants, the biotechnology industry in Nashville is poised to flourish.

The Tri-Cities of Upper East Tennessee area have impressive and established biopharmaceutical and chemical research-based industries including King Pharmaceuticals and Eastman Chemical. In addition, East Tennessee State University's College of Medicine is providing a valuable contribution to the State's biotechnology focus, and a medical technology research park is being planned to support new biotechnology companies.

Strategy Overview

Tennessee's economic development strategy for biotechnology must include all components that foster new company recruitment, existing company expansion and entrepreneurship. This three part corporate strategy includes financing and incentive programs; job training, education and workforce development; and research and development and production facilities during the early stages of the company's development.

Tennessee has a variety of programs already in place that can accommodate biotechnology companies with modest revisions at the legislative level. There are also a variety of public, private and institutional facilities including incubators, technology centers, and wet labs that support emerging biotechnology companies. In each of these areas Tennessee is losing ground to other states because of a lack of funding and directed programs that are a catalyst for growth in this industry sector.

The available resources need to be incorporated into a targeted strategy for the State, tailored specifically for biotechnology companies. The following paragraphs provide specific recommendations for developing this strategy.

ECONOMIC DEVELOPMENT RECOMMENDATIONS

Research & Database Development

To effectively grow the biotechnology industry in the State, it is critical to have a profile and baseline of the industry in the State as it currently exists. The Task Force estimates that there may be 300 to 500 pharmaceutical and biotechnology companies in the State with an economic impact in multiple billions of dollars. However, to date there is no comprehensive statewide listing of companies nor has the economic impact been quantified.

A complete inventory of Tennessee's current biotechnology companies should be finished as soon as possible and a process for maintaining the data base should be implemented. The inventory should include at a minimum: number of companies, jobs, payroll, capital investment in the State, expenditures for goods and services purchased in the State, and stage of development (e.g. early stage, start up, mature, public company, product codes, descriptions, etc.).

A statewide industry association such as the Tennessee Biotechnology Association can serve as a clearinghouse to store and maintain the updated inventory. Each region of the State should designate a regional entity to provide updated information on companies to the statewide clearinghouse entity. This could include chambers of commerce, industrial development agencies, or biotechnology associations.

One of the cardinal principles of economic development is to target efforts to qualified prospects based upon assets or competitive advantages that an area may have. To accomplish this task, it is important to

develop a statewide *"Centers of Excellence Plan"* that includes both an inventory of existing assets and a serious evaluation of their competitive position relative to other centers around the country. A variety of communities, such as Pittsburgh and Boston, that have already completed comparable studies would serve as good models for the State. A plan of this nature and scope would likely cost at least $500,000. Because of the magnitude of this effort at the state level, it may be preferable for local communities and regions to begin conducting their own inventory and assessments and let the State coordinate a statewide plan based upon the local results and fill gaps where necessary.

Existing Company Strategy

Traditionally 60%-80% of new investment and jobs in an area can be attributed to existing companies. Furthermore, existing companies often represent the best opportunity for new growth because they are already doing business in the State and do not have to be sold on the assets of a Tennessee location. For these reasons, the State should develop and implement an "Existing Company Strategy" that utilizes the biotechnology inventory referenced in the previous recommendation.

This strategy should include:

- **Establishment of an existing company team comprised of state and local officials in each region of the State.**
- **Team visits to each company at least every other year.**
- **Adoption of a local preference for purchasing goods from Tennessee companies.**
- **Targeting of venture and early seed capital to Tennessee companies.**
- **Identification of products and services of Tennessee companies that can be offered to other Tennessee companies to support the "Buy Tennessee" efforts.**

Business Recruitment

Recruitment of companies to the State from other locations nationally and worldwide is an essential component of the proposed economic development strategy. While Tennessee is attempting to grow companies from within and to expand existing companies, attracting new companies is critical. This process must be tailored to niche markets that have been identified in the Centers of Excellence Strategic Plan referenced earlier. Candidates for recruitment may be companies with time-sensitive processes, medical devices, bio-informatics, pediatric oncology, nanotechnology, and other areas where Tennessee has a competitive advantage.

To provide a framework and specific agenda for this effort, a comprehensive Business Recruitment and Marketing Plan should be undertaken statewide and maintained for at least three years. The State must begin the rebranding process from a low cost manufacturing State to a State that supports next generation technology and fosters research and development at a world class level. Components of the marketing plan should include:

- **Direct mail to companies in the targeted niches.**
- **Ads in biotechnology trade journals, site selection publications, and similar media.**
- **Attending and obtaining a booth at industry trade shows such as the international biotechnology conference held in June of each year.**
- **Sales trips/trade missions to specific markets.**

- **Site visits to companies that express initial interest by responding to ads and direct mail pieces.**

- **Web site development and promotion.**

Among the secondary benefits of the marketing strategy is that it contributes to the rebranding of the State as a biotechnology center, which supports efforts to recruit highly skilled and talented workers and researchers.

One important ingredient of the marketing plan is database management and tracking the results and return on investment of the program. The point of contact for the State is also critical and it should be a single agency and preferably a single individual that has expertise in the technology industry. There are organizations already in place that are marketing Tennessee. Of course, the Tennessee Department of Economic and Community Development currently markets the State and has a focus in technology. Another organization that has been involved with marketing the State is the Tennessee Economic Partnership (TEP). TEP was established to support the State in its economic development efforts and because it is a public/private partnership, it provides some additional flexibility in its operations.

When rebranding a State's image, it is important that a marketing plan continue over at least three years with the same message. To run a successful marketing plan of this caliber will likely cost between $500,000 and $1.5 million per year. The range depends upon the number of ads, trips, and advertising venues employed, but a minimum is essential to make any measurable impact. Economic development efforts over the years have proven that the amount of prospect activity is directly proportional to the marketing and advertising undertaken. Consequently, the return on investment from the marketing plan can be factored up or down depending upon where the State decides to invest within the range noted.

Entrepreneurship

Tennessee has a rich history in entrepreneurship and particularly in the biotechnology and medical industries. Among the companies started in the State that are highly respected in their industry segment are: King Pharmaceuticals, HCA, Wright Medical, Sofamor Danek/Medtronic, and Smith-Nephew (Richards Medical). There are currently a considerable number of small start-up and emerging companies that have been fostered by researchers in the State that are taking their discoveries through the product development and production phases.

Tennessee should enhance the facilities and operations of the existing and planned incubators in the State including the ones located at Cool Springs near Nashville and near downtown Nashville, TriStar at UTCHS in Memphis, East Tennessee State University, and UT Baptist Research Park. These facilities are strategically located in each of the major regions of the State, and once these facilities are in full operation, the need for additional facilities can be evaluated.

To provide the resources for the development of facilities and early stage and seed capital for growing the biotechnology industry sector, Tennessee should devote a portion of its annual allotment of tobacco settlement funds to biotechnology. A portion of Tennessee's settlement allocation would pay big dividends in terms of economic development and thus revenues to the State if it was used to support a loan guarantee program for biotechnology investments. Tennessee should follow the lead of other states, which have allocated settlement proceeds for endowment of chairs at state universities, funding of targeted research at state universities, support of incubators, and direct investment in biotechnology companies.

One of the drivers of entrepreneurship is the mining of intellectual capital and intellectual property developed within research institutions within the State. Several years ago Tennessee passed legislation to remove some of the barriers from State supported institutions being able to contract with private industry

for research projects and grants. This is clearly a step in the right direction. However, more needs to be done to improve the transfer of technology to commercial channels. To ensure that there is a constant pipeline of discoveries that can be considered, the amount of research must be increased dramatically and this requires funding. There are estimates that there is one discovery for every $2.0 million spent on research.

In addition to allocating tobacco settlement funds to bioscience research, Tennessee must increase its share of federal and foundation grants. To accomplish this objective, the State could establish *"Grant Assistance Centers"* in each of the regions of the State to provide assistance to faculty at State universities in producing grant applications and securing grant funds. Federal Small Business Innovation Research (SBIR) and National Institute of Health (NIH) grants should be initial targets for the centers and private foundation grants can follow based upon the research in question.

Another area of issue for technologists in attempting to make the transition from the laboratory to establishing and running a business is business and management acumen. Researchers are often more comfortable in the academic or institutional environment and their careers may not have provided them an opportunity to be grounded in the business world. The State should consider offering business technical assistance in every region staffed with professionals that have expertise in technology business development. Assistance provided should cover the range of services required for businesses in all stages of development from business plans, intellectual property protection, financing, marketing, and management.

Financing required to support new biotechnology businesses is vital. A financial community that has the expertise to evaluate technology business proposals and also the resources to provide sufficient funds to launch a promising business is essential. Currently Tennessee does not have the critical mass of companies to attract these venture capital and financial firms to match the desired rate of business growth for the State. Tennessee should: 1) continue to sponsor statewide venture forums for prospective companies, 2) seek to build capacity of venture capital and early stage funds in the State, and 3) attract new financial enterprises to the State. An immediate step to enhance the State's ability to generate economic development, to support promising companies, and to produce an economic return for the State, is for the legislature to authorize the investment of state pension funds in venture capital funds for technology companies in the State.

Economic Development Incentives

Incentives are not often the primary reason a company locates to a particular region, but when regions are comparable, incentives clearly sway a company that is making a decision between several locations that meet the other criteria. Tennessee has never been known for extensive give-away programs. Instead, the State has devised incentives that make business sense for the company and are tailored to its business and construction cycle. Unfortunately, Tennessee's current incentive programs are geared more to manufacturing companies than to the next generation of technology businesses. Technology businesses are typically smaller, do not generate a profit in the first few years of operation, require very specialized job training and expertise, and may have limited need for traditional infrastructure such as utilities and roads. Consequently the State should review its incentive programs and take necessary steps, whether legislative or administrative, to revise its incentives to reflect the needs of technology businesses. The legislative section of this report includes several workable proposals.

Workforce Development

Probably more than any other industry, biotechnology businesses rely on highly skilled workers and knowledge workers to be successful. Given the current capacity of Tennessee's educational institutions, it is questionable whether the State can produce enough skilled labor to meet the demands of this growing industry. Currently, there is no reliable assessment of the supply and demand for labor to sustain the

growth of the biotechnology industry. Tennessee must undertake a statewide labor demand and supply study to assess the needs in the industry for various technical positions and the capacity of Tennessee's educational institutions to deliver qualified candidates for the positions. This study will form the basis for restructuring curricula, increasing facilities and faculty devoted to select programs, and linking graduates with prospective employers.

Highly skilled workers are in great demand nationally and worldwide, and the supply is not keeping pace with the demand. As a component of the marketing plan and rebranding the State, the message should be tailored to attract knowledge workers. These workers can be very selective in the jobs they take and the state and community in which they chose to live. Key characteristics that attract these workers include: quality of life, an urbane environment, diversity and tolerance, a critical mass of companies in their field of interest, and extensive recreational and cultural opportunities. The State needs to consciously develop this type of environment and to promote the assets that the State has in these areas.

However, a strategy that relies on recruitment of highly skilled workers to the State is not a sustainable long term strategy. It is expensive for companies to recruit and relocate employees from other areas and it overlooks the potential of the current State population that need good paying jobs. Consequently, Tennessee must adopt a three-fold strategy of 1) increasing its capacity to produce qualified students in K-12 education through post doctoral programs, 2) preventing the brain drain from Tennessee's institutions of higher education, and 3) attracting highly skilled workers from other areas.[3]

[3] See the Education and Workforce Development section of this report for more discussion on education.

LEGISLATIVE INITIATIVES

SUMMARY

The Task Force worked to identify and propose legislation for enactment in Tennessee that would promote the development of the biotechnology industry in the State. In carrying out this mission, the task force reviewed legislation that has been enacted in other states, focusing principally on the states that neighbor Tennessee, and received and considered comments from business leaders, professors at public and private research universities, various participants and observers at meetings of the Task Force and its Sub-committees, and the Chairs of other Sub-committees.

While Tennessee has an abundance of research and scientific institutions, and the depth of resources to support the biotechnology industry, Tennessee lags substantially behind other states, including virtually all of its neighbors, in supporting biotechnology. One area in which Tennessee is deficient is direct financial support for biotechnology, through the funding of incubators, the establishment of seed capital or other investment funds, and sponsorship of biotechnology research at state universities. Tennessee also has not enacted tax incentives necessary to create a favorable environment for either the recruitment of companies from elsewhere or the growth of biotechnology companies already located here.

In formulating its recommendations, the Task Force is aware of the persistent budgetary problems that Tennessee has faced. These problems render it difficult for our State government to provide direct financial support for biotechnology or to risk future tax revenue by providing tax incentives. Therefore, when possible the Task Force has proposed variations on its recommended tax incentives that would eliminate any decline in current tax revenues, although they would potentially cause the State to forego receipt of some tax revenues in the future. The Task Force also has proposed some incentives that will neither affect tax revenues nor require expenditures of tax dollars, which therefore can be enacted immediately at little or no cost. Although the Task Force has proposed measures that, if properly structured, would have little effect on existing tax revenues and require no direct expenditure of tax dollars, the Task Force stresses that a number of incentives are necessary if Tennessee is to catch up with its neighboring states, that halfway measures will not permit the State to catch up as fast as it otherwise could, and that the longer it takes to enact these incentives, the farther behind our State will fall.

By definition, these legislative recommendations can only be adopted by the Legislature. Additionally, the Task Force will disband before another session of the Legislature. Therefore, neither the Sub-committee nor the Task Force as a whole will be able to play a role in implementation of the recommendations. Ideally, the next administration will make the recommendations a part of its legislative agenda, and the Task Force urges the next Governor as well as future administrations to press for enactment of these recommendations. The Task Force also counts upon the Tennessee Biotechnology Association, a statewide trade organization, and the Tennessee Technology Development Corporation, a quasi-governmental body, to press for enactment of the recommendations.

GOALS

The overriding goal of the Task Force has been to propose legislation, for enactment as quickly as possible, to promote the growth of biotechnology in Tennessee. The Task Force is aware of the budgetary pressures currently facing the state and recognizes that some of its recommendations may be difficult to adopt in the current budgetary environment. However, the Task Force believes that its mission is to propose steps that need to be taken, even if fiscal pressures will cause a delay in their implementation.

Some of the legislative recommendations can be enacted immediately with no impact on tax revenues and no expenditure of tax dollars. These recommendations include proposals to make available, for investment in biotechnology companies, funds from sources other than tax revenues.

Some of the legislative proposals involve creation of tax credits or exemptions, which could negatively impact tax revenues. These goals are principally enactment of amendments to existing franchise and excise tax, and sales tax, statutes. In view of the budget situation, the Task Force, where possible, has proposed alternative ways of drafting the legislation that would avoid any immediate decline in tax revenues. While the Task Force believes that its recommended tax incentives would have a relatively small effect on tax revenues and prefers adoption of the incentives in a form that would immediately benefit all biotechnology companies operating in the State, the Task Force has proposed variations on the tax incentives to minimize any adverse impact on revenues.

MISSION STATEMENT

The Task Force's mission concerning legislation is simply stated – to identify and propose legislation to promote biotechnology in Tennessee. The subcommittee sought to identify existing impediments to development of biotechnology, which could be cured by legislation. Additionally, the subcommittee sought to identify legislation that could provide positive incentives both for the recruitment of biotechnology companies to the state and for the formation and growth of indigenous biotechnology companies.

STRUCTURE OF PROCESS

The task force appointed a Subcommittee to work on legislative issues. The Legislative Subcommittee held three meetings: an initial meeting by conference call early in 2002, at which the members discussed the sub-committee's mission and assigned particular tasks to individual members; and a meeting in person in conjunction with the second meeting of the entire Task Force, on February 13, 2002, and a meeting by conference call on March 13, 2002, at which the subcommittee discussed a detailed outline of its report. The subcommittee co-chairs also circulated among the full subcommittee a draft of the final report in May, for comments prior to submitting the draft to the full Task Force.

In developing its recommendations, the subcommittee reviewed legislation that other states have adopted for promoting biotechnology and determined which initiatives from other states would be appropriate for Tennessee. The subcommittee also actively solicited suggestions from other subcommittees, particularly regarding types of legislation that should be proposed to promote the other subcommittees' goals. At various meetings of the entire Task Force, interested persons who attended but who were not Task Force members offered useful ideas on needed legislation. The Committee also benefited immensely from comments made by persons attending various local meetings of the Regionalism Subcommittee. That subcommittee's meetings provided a forum for persons from across the State to point out issues and opportunities that could be addressed by legislation.

OBSERVATIONS

Certain existing state laws and programs either impede, or at least do not promote, development of biotechnology. In each case, these laws and programs were well intentioned and generally have been beneficial to the state. The problem is that they were enacted or instituted before technology became the principal driving force in the nation's economy and have not been amended to address the new needs of the new economy. One example is the existing job creation tax credit, which is based solely on the number of jobs rather than the total amount of payroll created by a company. Another is the Tennessee Industrial Infrastructure Program(TIIP), which provides state funds for infrastructure improvements for certain facilities, but which traditionally has been interpreted too narrowly to benefit a biotechnology company.

Tennessee lags far behind many other states, including virtually all of our closest neighbors, in providing affirmative support for the biotechnology industry. Adjacent states, as well as others, have provided various tax incentives for biotechnology, have established biotechnology incubators at state universities, have allocated a portion of tobacco settlement proceeds to establish investment funds to support biotechnology research and to provide other benefits, and in some cases have allocated general tax revenues for similar purposes. Given the head start that other states have achieved, Tennessee should act promptly or risk being left hopelessly behind.

On the positive side, Tennessee generally has been a *laissez-faire* state, which has not enacted drug price controls, onerous food labeling laws, and similar measures that would create an overtly hostile environment for biotechnology. Tennessee should continue to avoid such legislation, which could negate any efforts to foster biotechnology through the other measures recommended in this report.

Tennessee also thus far has not attempted to legislate solutions to the difficult issues that have arisen lately in the area of "bio-ethics." Such issues include stem cell research, cloning, medical records confidentiality, use of genetic data, and limitations on human research. The Task Force believes that issues such as these raise important policy considerations, which can be much more effectively dealt with at the national rather than the state level. Therefore, the Task Force hopes that our state government will continue to leave issues such as these to the federal government, where unified national policies can be developed and implemented, although the Governor may wish to identify leaders in this area who can be readily called upon to discus these issues.

The Department of Economic and Community Development (ECD) recently has awarded a grant of TIIPs funds to support a biotechnology project that would not have qualified under traditional interpretations of eligibility criteria for the program. Traditionally, TIIPS funds have been earmarked for infrastructure improvements at new manufacturing facilities. By making the grant to provide infrastructure at a proposed biotechnology research facility in Williamson County, the Department commendably has shown the interpretive flexibility that is necessary to adapt programs which were designed for a manufacturing economy to the needs of the new, information-based economy.

RECOMMENDATIONS

Tax Incentives

The Task Force is aware of the budget problems that have plagued the state for the past few years, and it has attempted to be sensitive to those problems. Nevertheless, the Task Force firmly believes that Tennessee will never achieve its full potential in the biotechnology arena unless it adopts the types of tax incentives that a majority of other states, including many of Tennessee's neighbors, have adopted.

Research and Development Credit

At least 27 states, including the nearby states of Arkansas, Georgia, North Carolina and South Carolina, provide a credit against franchise and/or excise taxes for costs of research and development performed within the state. Adoption of such a credit would not immediately benefit start-up or development stage biotechnology companies, since they typically generate operating losses and thus have little or no state tax liability against which to apply the credit. It would, however, provide a benefit to established biotechnology companies that might move into the state. In addition to the tax benefits to established companies, adoption of the credit would constitute a powerful message that Tennessee welcomes and will support biotechnology companies. Therefore, adoption of the credit would greatly assist in the recruitment into our state of large, established companies.

Details of legislation establishing the credit would include the definition of qualifying research and development expenditures. As a starting point, the definition should track the definition of "research and experimental expenditures" contained in Section 174 of the Internal Revenue Code. Using this definition would promote consistency in federal and state tax reporting and greatly ease administration both for taxpayers and the Department of Revenue. Another important detail concerns the amount of the credit. The amount of the credit allowed in other states ranges from around 6% of expenditures, on the low end, to as much as 15% on the high end. Tennessee should establish the credit closer to the high end, in order to provide meaningful incentives for the relocation of existing biotechnology companies to the State and for the growth of indigenous biotechnology companies. The final important detail of the credit involves the length of the carry-forward period for unused credits. This is particularly important for start-up and development stage biotechnology companies, which typically generate operating losses in the first few years and thus have no ability to use a tax credit. Companies should be allowed to carry unused research and development credits forward for not less than 10, and preferably for 15, years.

Two states, recognizing that developing biotechnology companies need cash more than tax credits, permit companies to sell their research and development credits, either to other companies that can use the credits or to the state government. Connecticut, for example, permits a company to sell its credits to the state, for 50% of the amount of the credit. This provides a source of cash for the companies, and it increases future tax revenues for the state, once the companies become profitable and generate taxable income that otherwise would be sheltered by the credit. The Task Force does not recommend that the legislation initially establishing the tax credit include a provision allowing the credit to be sold, but it does recommend that such a provision be strongly considered in the future, after a few years of experience with the credit provides data to assess the fiscal impact more accurately.

The principal objection to adoption of a research and development credit is that it would result in revenue loss to the State. The Task Force has not had the resources to assess the extent of potential revenue loss, but it does not expect the impact to be significant. First, only 8.9% of total State revenues are provided by corporate franchise and excise taxes that could be affected by a credit. Second, the Task Force's research regarding existing biotechnology companies, which is summarized more fully in the section on Economic Development, indicates that a relatively small number of companies in Tennessee are performing significant research and development work and that those companies tend to be small and are unlikely to generate significant franchise and excise tax payments. As other sections of this report point out, by far the most significant sources of biotechnology research and development in Tennessee are universities, St. Jude's Research Hospital, and Oak Ridge National Laboratories, none of which are subject to franchise and excise taxes.

If more thorough analysis indicated that adoption of the research and development credit would produce a material loss of tax revenue, the impact could be minimized by applying the credit only to research and development expenditures in excess of those in a base year. If the credit were adopted effective for tax years beginning in January 2003, the credit could apply only to R & D expenditures within Tennessee to the extent they exceeded the taxpayer's in-state R & D expenditures in 2002. This would eliminate any immediate revenue loss, and any loss of incremental future tax revenues would likely be more than offset by other tax revenues resulting indirectly from the increased R & D expenditures. Such an incremental approach would not hinder the State's ability to recruit mature biotechnology companies from other states, since such companies' base year R & D expenditures in Tennessee would be zero and the credit would apply to all of their future R & D expenses here.

Sales and Use Tax Exemption.

Tennessee has enacted exemptions from sales and use taxes to encourage certain types of industrial development. Existing exemptions cover, among other types of equipment, industrial machinery, farm equipment and certain pollution control equipment. Most recently, the sales and use tax statute was

amended to provide a specific exemption from use taxes on specific equipment (comprising a spallation neutron source facility) being installed at Oak Ridge National Laboratories, in order to enable this equipment and the research it would support to remain in the State. All of these exemptions reflect a policy decision by the Legislature that the benefits of economic development, new jobs, and the tax revenues they would generate should more than offset the limited loss of sales and use tax revenues resulting from the exemptions. The exemptions, however, primarily cover equipment that would be used in manufacturing and agriculture, and they clearly do not cover laboratory equipment.

The Task Force recommends that similar exemptions be enacted to cover laboratory equipment of the type needed for modern biotechnology research and production of products. At least 9 other states, including the neighboring states of Arkansas and Missouri, have enacted exemptions (or credits against sales and use taxes) covering types of equipment used in the biotechnology industry. Creation of this exemption would bring existing policies, which are designed to encourage investment in productive manufacturing equipment, from a manufacturing-based economy to an information-based economy.

The principal drafting issue in establishing an exemption for biotechnology equipment is in defining the types of equipment to which the exemption will apply. The other states that exempt such equipment have taken many approaches. The clearest and most comprehensive exemption is provided by Connecticut, and the Task Force recommends that Tennessee enact an exemption substantially similar to the exemption in Connecticut. That state exempts from sales and use taxes "machinery, equipment, tools, materials, supplies and fuel used in the biotechnology industry." The law defines "biotechnology" in great detail, but broadly enough to include both research and production of biotechnology products.

Sales and use taxes currently provide by far the largest portion of tax revenue to Tennessee, and the Task Force has not had the resources to assess what impact such an exemption might have. If creation of an exemption would significantly reduce sales and use tax revenue, the loss could be minimized by applying the exemption only to property purchased or placed in service initially after 2002. This limitation would prevent any immediate loss of sales and use tax revenue but would encourage new investment in biotechnology that should indirectly generate other tax revenues to offset any direct loss.

Job Creation Tax Credit

Current Tennessee law also provides an incentive for workforce expansion, by allowing companies to claim a credit against franchise taxes based on newly-created jobs. Under existing law, the credit is $2,000 for each new full time job created within the tax year, but it requires among other things that at least 25 new jobs be created. The focus on the number of jobs created, like the sales and use tax exemptions for industrial machinery, reflects policies that are geared to a manufacturing economy, in which wages tend to be relatively low. Since biotechnology operations tend to generate fewer jobs than manufacturing operations, but at significantly higher wages, the Task Force recommends modifying the statute to take into account gross payroll as well as numbers of jobs created.

An example of this approach in another state is the Oklahoma Research and Development Incentives Act. That Act provides a tax credit (against sales and use taxes) for "any new or expanding business" which adds and maintains for at least thirty-six months at least ten new full time equivalent employees at an average salary of at least $35,000 per year. Although the Task Force recommends that the credit in Tennessee apply against franchise and excise rather than sales and use taxes, the Oklahoma statute provides a useful model for drafting the legislation.

Capital Investment Stimulus

One of the most consistent themes in all of the meetings of the Task Force and its various committees was the lack of access to investment capital for start-up and development stage technology companies in

Tennessee. The Tennessee Technology Development Corporation attempted to remedy this situation recently by forming TennesSeed Fund, which was funded primarily with private capital and which received a license from the United States Small Business Administration to operate as a small business investment company ("SBIC"). Unfortunately, regulatory restraints on SBICs have limited this fund's flexibility in choosing investments, so a need remains. The Task Force recommends two measures to address the need for capital, neither of which will require the use of tax revenues.

Retirement Fund Investments.

First, the Task Force recommends that the statute governing investment of state retirement funds be amended to authorize specifically the investment of a relatively small percentage of state retirement funds in privately-held technology companies located in Tennessee. Current law, at T.C.A. § 8-37-104, arguably would permit such investments. However, the Task Force believes that the Board of Trustees of the Tennessee Consolidated Retirement System ("TCRS"), which oversees investments of the retirement funds, will be deterred by fiduciary and similar concerns from making such an investment without specific authorization.

It is difficult to determine the number of states that permit retirement funds to be invested in local, privately-owned, technology companies, since many statutes give broad investment discretion to the boards overseeing investments. States in which public retirement funds are invested in privately-owned technology companies, without specific statutory authority, include Wisconsin, California, Illinois, Massachusetts, Pennsylvania and Maryland. In Maryland, state retirement fund investments in venture capital funds historically have been only two-tenths of one percent of fund assets, but a recent report by Ernst & Young recommended increasing the investment to one percent of fund assets, with half of the investments being earmarked specifically for biotechnology companies. Other states have amended the statutes governing pension fund investments to specifically authorize, and in some cases require, investment of a specified portion of the funds in local technology companies. Examples include North Carolina, which limits investment in venture capital funded companies to $30 million (with legislation pending that would increase the cap to $130 million), Oregon, New Jersey, and Texas.

One objection to such investments is that they tend to be illiquid and relatively risky. Lack of liquidity, however, should not be a significant deterrent so long as the funds retain sufficient liquid investments to cover annual payment obligations to retired state employees. The increased risk of private investments can be minimized by limiting the percentage of the overall fund that may be invested in this manner. Additionally, the history of venture capital investing strongly indicates that losses in particular portfolio investments tend to be more than offset by the extremely large returns that are realized from those that succeed; an example is the experience of the State of Maryland, which is discussed elsewhere in this report.

While the Task Force believes that high returns on some investments would more than offset possible losses on others, the Task Force is sensitive to the overriding need to protect the financial strength of public retirement funds. Therefore, the Task Force's recommendation is that such a small portion of the fund be allocated for private investments that neither lack of liquidity, nor risk of loss, would materially harm the overall retirement fund. Additionally, the Task Force recommends that these funds not be invested in start-up companies, which would entail additional risk, but rather in private companies that are at least in the development stage and have a product or technology with reasonably foreseeable prospects for commercial success.

Another objection is that the TCRS Board lacks the time, resources and experience to make sound decisions regarding the choice of private companies in which to invest, the amount that prudently should be invested in any particular company, and the appropriate terms of an investment. As a practical matter, however, the Board already delegates investment decisions regarding individual stocks to professional money managers, and there is no reason why it could not do the same regarding private technology investments. Most, if not all, states that currently invest public retirement funds in comparable companies

have retained investment professionals to make investment decisions and monitor the investments once they are made, and there are a number of capable managers from which the Board could choose.

The State pension fund currently has approximately $23 billion invested. The Task Force recommends that the governing statute be amended to require 1% of the amount in the pension fund be allocated for investment in private technology companies located in Tennessee, and that another 1% of such investments be permitted. Any losses on such a small percentage of overall funds would be well within the range of losses that can result from traditional investments, and not likely to be as large as the $18 million that the retirement fund lost on its investments in Enron, a large, public company. The modest amount recommended by the Task Force would create a significant source of capital for developing Tennessee technology companies, without causing significant risk to the financial soundness of the retirement fund.

Seed Capital Fund.

The Task Force's investigation has made it clear that technology companies in Tennessee badly need seed or start-up capital as well as growth capital during the development stage. The Task Force believes that Tennessee should follow the lead of at least 28 other states, which have publicly-supported venture or seed capital funds, in establishing a fund to make seed capital investments in start-up and early stage biotechnology companies.

One example is Maryland. Its Department of Business and Economic Development, which has both the budget and the authority to make direct investments in Maryland companies, has invested $26 million in technology companies, including $10.5 million in biotechnology companies since 1994; that $10.5 million already has earned a $20 million return, and most of the portfolio companies are still active. Based upon this experience in Maryland, as well as the returns that private biotechnology venture capital funds have earned, the Task Force believes that Tennessee, over time, would earn sufficient investment returns on a seed capital fund to more than recover the money allocated to the fund. However, the Task Force recognizes the risk inherent in seed capital investments and recognizes that the General Assembly might be reluctant to authorize investment of tax dollars in early stage companies, particularly in light of the budget crisis confronting the state. Therefore, the Task Force recommends that a portion (at least $10 million) of the proceeds of the tobacco settlement be allocated for this purpose.

A variation on this program would use these monies to guarantee a portion of investments by private investors in early stage biotechnology companies. This variation would operate similarly to the United States Small Business Administration loan guarantee program. Investors in local biotechnology companies could apply to the state fund for a guarantee of a portion, such as 75% to 80%, of their proposed investments in particular portfolio companies. If the state fund issued the guarantee, it would receive a small amount of equity in the portfolio company to compensate for the risk of the guarantee. The private investor would have a right, exercisable after a certain period of time, such as 5 years, to put its equity to the state fund, at a price equal to the amount the fund guaranteed. This approach would allow the state fund to assist more early stage companies than it could by investing directly, since the actual expenditure of funds would be only contingent. It also would leave the primary investment decision primarily in the private sector, and the fact that a portion of the private investment remained at risk would assure careful investment decision-making.

It is difficult to determine exactly how many states have allocated part of their tobacco settlement proceeds for similar purposes. One that clearly has done so is Pennsylvania, which earmarked $60 million of tobacco settlement proceeds to establish a privately managed venture capital fund to provide equity for in-state biotechnology companies.

Some entity would need to administer and make investment decisions regarding these funds. The Task Force recommends that the funds be put under the general control of the Tennessee Technology Development Corporation, which either could invest them in local venture capital funds that make early-stage biotechnology investments or use them to create a second investment partnership under the TennesSeed Fund.

Education

Other portions of the report address both the importance of a strong educational system to the growth of biotechnology and the low ranking of Tennessee in public support for education. There is no need to repeat those portions of the report here. Since funding for education is a legislative matter, however, the Task Force must go on record as strongly recommending increased appropriations for public education at all levels, with an emphasis on education in the life sciences.

Tennessee's current higher education system contains certain inefficiencies that can be addressed without increased expenditures. One example is that some state universities lack the budget to apply for patents on discoveries and inventions by their own faculty members. This is a case of being "penny-wise and pound-foolish," since the relatively small amount needed to prosecute a patent application can and often does result in large financial returns in the form of future royalty payments from licensing the technology. Not only does the inability to pursue patents deprive our higher educational institutions of a potential source of significant revenue, it also tends to demoralize the faculty members who perform basic research and makes it difficult to recruit and retain top research scientists. Finally, the situation highlights a structural inefficiency, since other state institutions, such as the University of Tennessee at Knoxville and the University of Tennessee Medical Center, have both the budgets and the staffs needed to protect and commercialize their professors' discoveries and inventions. Inefficiencies such as this need to be corrected, either through unification of all state institutions of higher education under one governing body, or, at a minimum, through creation of a central office to provide services such as patent prosecution and commercialization of intellectual property, for all state supported colleges and universities.

There is a fairly widespread belief among scientists at the University of Tennessee that state conflict of interest laws prevent faculty members from owning equity in a company to which the University licenses technology for commercial development. While this belief is not justified under the language of the conflict of interest statutes, the mere fact that faculty members hold the belief is itself a deterrent to commercialization of technology created by UT faculty. The situation can be corrected without legislation, through encouragement of inventions and commercialization at all state universities and better communication among college administrators and faculty. If it is not corrected by college administrators, legislation may be needed to make clear that faculty involvement in companies that develop technology licensed from the University will not constitute a violation of the conflict of interest laws.

EDUCATION AND WORKFORCE DEVELOPMENT

SUMMARY

The Task Force adopted the following mission statement concerning education and workforce development issues:

- **To promote excellence in education, inextricably linked to research, in biotechnology in the State of Tennessee.**

- **To serve as a national model for integrated strategies to develop and sustain a continually evolving workforce to support the biotechnology industry in Tennessee and across the nation.**

Although Tennessee has significant resources among its Universities and research institutions there are significant shortcomings in education, particularly K-12, and the ready availability of an adequately trained workforce. Recent decreases in State support for higher education, research, and institutional funding have caused the State's current educational and research resources to wither. Far from becoming a leader in biotechnology development, there are sectors of the State's education base that are falling further behind national norms.

While public funding of educational resources is crucial to the State's ability to achieve the mission established by the Task Force, there are other steps that must be taken. Increased funding levels are not answers in and of themselves. A sharpened emphasis on biotechnology education, research and worker development will be successful only if these resources are channeled into effective and innovative programs that will catapult the State's students, workers and institutions into a significantly higher tier of technology development and production.

Very simply, the State must generate more interest in the sciences among its K-12 students; it must do a better job teaching science to these energized students; it must provide resources at the University level to enable these young scientists and engineers to explore their talents; and it must enable professors and researchers to commercialize their inventions, returning dollars both to the individual and to the institutions that fostered their work.

The interest in science is not only for the budding researcher. Other students, not destined for the laboratory or even for higher education, will benefit from a renewed ability to grasp the pragmatic importance of scientific discovery and the scientific method. These students will be willing participants in innovative technical training programs housed in community colleges and other locations throughout the state. This avenue for job opportunities can transform the future of individuals who do not and will not possess university degrees. The high-paying biotechnology jobs can be vehicles that lead out of poverty and into a progressive and growing middle-class.

GOALS

The Task Force adopted several goals for the State to nurture the development of biotechnology research, education and business development. The Task Force determined that priority educational and workforce goals for the State of Tennessee should be to—

1. **Enhance public understanding and appreciation of the application and benefits of biotechnology.**
2. **Provide a competent workforce for biotech industries.**
3. **Develop mechanisms to enhance intellectual property transfer in Tennessee.**
4. **Develop sites for biotechnology growth in Tennessee.**
5. **Improve educational materials regarding biotechnology for use in schools st**atewide.

In order to accomplish these goals, the State must overcome several serious impediments, including a lack of facilities and personnel to support development of biotechnology educational programs; inadequate funding to maintain current educational systems and to implement and maintain the needed new programs and infrastructure; a weak national image with respect to technology development; the lack of a properly educated workforce; a low percentage of college degrees among its population; a sometimes confused State University system that often has difficulty allocating and prioritizing resources; and low per-capita spending on K-12 education.

SUMMARY OF RECOMMENDATIONS

The Task Force established a number of actions designed to accomplish these goals. These recommendations are set out in summary fashion below, with a more in-depth presentation contained in the discussion section.

- **Adapt or develop educational materials for gaining public and legislative support of biotechnology initiatives.**
- **Develop a volunteer speaker directory of persons with a variety of expertise in the biotech industry who have agreed to make presentations at meetings of volunteer or community groups, educational institutions, or other venues.**
- **Create a web-learning site for educating the news media and the public.**
- **Create an expertise network.**
- **Adapt or develop age-appropriate educational materials regarding biotechnology for use in public and private schools statewide that are appropriate adjunct materials for use in courses on mathematics, computer sciences, natural sciences, and economics.**
- **Create an annual funding competition for various K-12 outreach programs, giving priority to those that "teach the teachers" how to convey this content on a yearly basis.**
- **Utilize existing programs, such as the Junior Achievement Program, to encourage entrepreneurial activities in biotechnology.**
- **Sponsor biotechnology career days in major metropolitan areas in Tennessee and web-cast statewide.**
- **Provide relevant, state-of-the-art biotechnology training at the associate, bachelor, masters doctoral, and postdoctoral levels, with opportunities for training the emerging workforce as well as for retraining the existing workforce.**

- **Create internships and cooperative programs to enhance individual competencies and to bring necessary skills to emerging biotechnology enterprises in the State.**

- **Facilitate ways to share opportunities (i.e. faculty, scientists, support personnel, facilities, funding) in biotechnology research between universities and the biotechnology industry.**

- **Promote entrepreneurship among faculty at public and private institutions of higher learning.**

- **Identify mechanisms to foster linkages between universities and biotechnology companies.**
    - **Examples might include holding a competition for the best biotechnology business plan between a university and a private sector partner during Biotechnology week; prize might be as much as $50K.**

- **Establish biotechnology parks and incubator space.**

- **Create a network of professionals willing to mentor scientists who have established new biotechnology companies**

THE IMPLEMENTATION PLAN

These recommendations cannot be achieved at once. The Task Force, therefore, broke these items down into stages of implementation activities.

Short Term

- **Share the plan with legislators, biotech companies and educational institutions (K-12 and universities).**
- **Develop networking strategies.**
- **Establish a subcommittee for biotech education in the Tennessee legislature.**

Medium-Term

- **Develop funding sources to support educational efforts in biotech.**
- **Educate children to educate parents.**
- **Use media and extension service (4-H etc) to promote biotechnology in Tennessee.**
- **Grow the intellectual property emerging from Tennessee, particularly in academic settings.**

Medium- to Long-Term

- **Train the emerging workforce and retool the existing workforce for biotechnology careers.**
- **Establish sites for biotechnology development, incubator space, and apprenticeships.**

STRUCTURE OF THE PROCESS

The Task Force addressed the issues of education and workforce development to advance biotechnology initiatives in Tennessee by designating a subcommittee to conduct additional research and report to the Task Force.

The composition of the subcommittee, which grew due to interest and a desire to broaden the representation and expertise within the working group, is set out in the membership section of this report.

Iterative versions of the goals and proposed strategies for addressing them were shared among all subcommittee members and additional individuals who volunteered information and insights. Early draft documents were strengthened by the addition of data concerning existing programs in Tennessee, as well as

nationally, that serve as models for what strategies are most or least effective in achieving certain goals in recruiting and educating talented youth and mid-career staff to join the biotechnology workforce.

These plans were synthesized with those of the other working groups of the Governor's Task Force on Biotechnology at an April 4, 2002 meeting in Memphis, Tennessee, and during June 2002 meetings in Oak Ridge, Tennessee.

OBSERVATIONS

According to the Chronicle of Higher Education, Tennessee ranked sixteenth among the states in educational attainment of adults in the year 2000. The results are as follows: 8.9% of Tennesseans have an educational level of an 8th grade student or less; 13.3% of Tennesseans have some high school education but received no diploma; 32% of Tennesseans received a high school diploma; 20.2% of Tennesseans have some college education but no degree; 4.6% of Tennesseans obtained an associate's degree; 13.8% of Tennesseans obtained a bachelor's degree; and 7.1% obtained a graduate degree.

According to the same report, nationally 16.1% of the population obtained a bachelor's degree and 9.0% obtained a graduate degree.

In Tennessee, there are nine (9) state universities, thirty-five (35) independent colleges and universities, thirteen (13) 1-year community colleges under the Tennessee Board of Regents system, and twenty-six (26) technology centers.

Data are not currently available on the number of institutions that provide degrees in biotechnological fields nor indicating the number of students matriculating – and earning science degrees – at these institutions. Consequently, the Task Force recommends data be collected for use in compiling reports of this type and specifically for biotechnology.

The Task Force was unable to retrieve data which ranked Tennessee in terms of science graduates. However, of Tennessee's 1999-2000 graduates of public institutions, approximately 20% received their certification, associate's degree, or bachelor's degree in agriculture, health, life sciences, or physical sciences. Moreover, approximately 12% of 1999-2000 graduates from Tennessee's public institutions received their masters or doctorate in agriculture, health, life sciences, or physical sciences.

Individual educators in Tennessee have taken the initiative to advance biotechnology in the State's educational systems. The most notable example is Missy Bunch, a biology teacher at Nashville's M.L. King high school, who developed a course on "Molecular Research" that was so innovative she could not locate a syllabus or text and had to create her own syllabus and assemble her own reading materials. After creating the course materials, Ms. Bunch's next hurdle was to convince school administrators to allow her to offer the course. After succeeding at that task, she then raised private contributions to build and equip a laboratory that was adequate for the course she had developed. She finally was able to offer the course during the 2000-01 school year. The success of the course and the amount of interest it engendered among students are shown by the following facts:

- **Twenty-five students enrolled in the class, and all were invited to submit projects for a regional science fair.**

- **Four students received research grants of $300 each from the Tennessee Junior Academy of Science ("TJAS"), based on proposals the students wrote.**

- **Nine students submitted papers to the TJAS, four of which were selected to be presented at the annual TJAS meeting and to be published in the 2001 Journal of the Tennessee Academy of Science.**
- **Four of the students plan to enter research as a career.**
- **Two of the students are basing their choice of college on the molecular programs offered by the various institutions.**
- **This was the only high school class that was invited to meet and participate in an informal question and answer session with Dr. Francis Collins, the Director of the Human Genome Project for the National Institute of Health, in October 2000.**

This experience illustrates that Tennessee has innovative science teachers who are willing to go the extra mile to offer advanced courses of study in biotechnology and students who are eager and able to excel in it. Unfortunately, it also illustrates that it is far too difficult for teachers actually to be able to offer such innovative courses. To the Task Force's knowledge, the course has not been replicated in any other Tennessee school, which unfortunately indicates a lack of institutional mechanisms to build upon the individual successes that our teachers and students achieve.

Discussion of Existing Impediments:

Included in the list of problems facing the State in its effort to strengthen biotechnology-based business development are 1) a lack of infrastructure (facilities and personnel) to support development of effective biotechnology educational programs; 2) a lack of funding to implement the needed education programs; 3) lack of a national image in biotechnology; 4) the lack of a properly educated workforce; 5) a perceived lack of commitment to education by state legislators; and 6) low per-capita spending on K-12 and higher education.

DISCUSSION

A better public understanding of biotechnology and an appreciation of the impact that biotechnology can have on lives and on careers is required in order to generate support for the necessary public and private investment needed to develop this sector of the Tennessee economy.

A starting point for the development of a workforce with the scientific and technical skills necessary for biotechnology-based businesses includes generating a renewed interest in the sciences.

It will be important to develop or adapt available age-appropriate educational materials about the sciences in general, and how they relate to biotechnology in particular, for K-12 classes. Adjunct materials for use in courses on mathematics, computer sciences, and economics also should be adapted or developed for use in middle through high school classrooms and in associate degree programs. The importance of introducing concepts related to biotechnology in courses beyond the natural sciences is to assure that Tennessee captures the largest audience of potential talent to work in the comprehensive field of biotechnology

One strategy for developing age-appropriate educational materials is to invest funds in a competitive request for proposals for new or adapted K-12 biotechnology "outreach" programs. These competitive programs should give priority to proposed programs that "teach the teacher" in the course of teaching the students, so that the teachers can convey the content on a year-by-year basis after the initial "jump-start" training. Such a strategy empowers each school, and will lead to school-based refinements that optimally integrate the information to be provided, based on other curricular expectations as well as an awareness of the cultural background and career aspirations of those in the school. As an example, agricultural benefits

of biotechnology and opportunities for careers in agro-technology would be a useful emphasis of biotechnology outreach programs in rural areas.

Develop a volunteer region-focused speaker directory on the Web, providing a list of those within the state of Tennessee who have agreed to make presentations at meetings of volunteer or community groups, at educational institutions, or in other venues. Volunteer speakers would likely focus on various specialty areas, including the economics of biotechnology; the workforce enrichment opportunities of biotechnology; or the science inherent in biology and engineering which, when integrated, lead to new advances in biotechnology.

Develop a web-learning site and expertise network. Ongoing education of the media and the public would be served by developing both an expertise network on which news professionals can rely (dynamic; one-on-one) and a companion Web-based learning site (static; access as needed). To identify members for the expertise network, leaders of the research entities at Tennessee's universities and current biotechnology companies could identify members at their institutions who are effective in communicating particular areas of content to the lay public. In addition to one-on-one conversations with journalists, a parallel effort could provide "crash course" opportunities for news correspondents in different thematic areas, allowing for immediate feedback in question/answer sessions. A point person for the news media in each of the three regional cities (Knoxville, Memphis, Nashville) could serve as rotating hosts for monthly video conferences that focus on one area of biotechnology in particular. Clips of these video conferences could then be captured on the biotechnology Web Site developed for educating the news media (below).

The Web-based biotechnology learning site could capture already printed news reports or newscasts as indicated above, while also providing a "short course" of background on the science, economics, or related educational issues of these news releases. The development of the learning site could be done economically by funding a research project for a graduate student in science education at any of Tennessee's institutions of higher education, in response to a competitive request for proposals to achieve this goal.

Other media, such as volunteer speakers bureaus and extension service activities such as 4-H should be used to promote biotechnology in Tennessee

In order to attract and retain biotechnology-based business, the State must provide a competent workforce for biotech industries.

Training the emerging workforce: State-of-the-art biotechnology training at the associate, bachelor, masters, doctoral, and postdoctoral levels must be developed or adapted from existing programs. Such biotechnology programs already are emerging in various locations in Tennessee, and could serve as a model for development in other cities to accelerate the rate of capture of young talent into these areas.

An outstanding example of a biotechnology training program at the four-year undergraduate level is the biotechnology emphasis program within the biology major at Middle Tennessee State University (Dr. Rebecca Seipelt, Director). The program has four curricular focus areas (including biotechnology; microbiology; animal husbandry and animal sciences) and apprenticeship opportunities for students in biomedical and biotechnology research laboratories.

An example of a biotechnology relevant postdoctoral program exists at Vanderbilt University where the Vanderbilt School of Engineering and Owen School of Management have two masters programs focusing on managing technology (School of Engineering) and entrepreneurship (Owen).

However, significant hurdles remain for these new courses. The Nashville State Technical Community College planned to premiere an associate program in the fall of 2002 designed to combine courses with a related apprenticeship to train graduates in areas related to laboratory research in the biological, chemical, and physical sciences. Approval of the program was delayed by the Board of Regents due to Tennessee's budget difficulties. Frustrated, the director of the program accepted a position in Texas. Other community colleges have faced similar difficulties.

Rather than duplicating efforts across Tennessee, the Task Force recommends creating *Centers of Excellence* in focus areas related to biotechnology at different institutions or in different regions. These efforts could be integrated, in a complementary fashion, so that Tennessee provides comprehensive training in biotechnology. Such programmatic and apprenticeship integration would indeed serve as a national model for workforce development and continual enhancement. Such programs not only would offer the best opportunities for Tennesseans to be trained and thus contribute to the biotechnology initiatives in Tennessee, but also would allow Tennessee to recruit talent for its training programs, hopefully capturing the most outstanding graduates as long-term residents for the rest of their productive and creative careers.

Training the existing workforce: In order to fully develop the biotechnology workforce within Tennessee it is essential to focus attention on educational and training opportunities for working individuals in a career transition and/or seeking positions with higher monetary compensation. Appropriate educational and training opportunities would enrich the relevant scientific or entrepreneurial background of these individuals and enhance their success in competing for positions in the biotechnology workforce. The nature of these educational opportunities would focus on strategies that allow individuals to continue earning an income while taking night and weekend classes or, alternatively, distance-learning classes available via the Web.

Although some distance learning opportunities concerning biotechnology already exist, more are needed. Some of these training activities focus on the management of biotechnology, economic issues, and resources appropriate for fostering the development of biotech companies from the financial and management perspectives – not just on laboratory research.

Hands-on teaching programs, or apprenticeships, will be necessary to provide research laboratory skills and training. Prospective employers might fund stipends for "graduates" of Web-based didactic programs in order to free up trainees from their existing employment obligations for 6-12 weeks of training. The employer funding the apprenticeship might, as an example, gain the right of first-hire for the most outstanding performers in the apprenticeship.

Develop mechanisms to enhance intellectual property transfer in Tennessee, particularly from academic settings.

There are considerable data that suggest that a significant fraction of new biotechnology startups nationwide have evolved from technology that was developed, or to which value was added, in the academic arena. Since enactment of the Bayh-Dole Act in 1980, investigators funded by federal grants are required to optimize the probability of commercialization of intellectual property that is developed in the course of their academic research. Nonetheless, this intellectual property often is under-claimed, under-developed, and thus under-commercialized – which means that society does not gain all that it can by its investment in federally funded research, and the positive economic impacts of this new technology also are not realized.

To increase the intellectual property captured in the State of Tennessee, entrepreneurial thinking will need to be further developed among the faculty at the various academic institutions within the State. To a certain extent, this can be done by the Offices of Technology Transfer at these institutions. However, many state colleges and universities do not have separate technology transfer offices and the offices that exist have

budget constraints and have limited staff resources. As a consequence, these offices tend to focus on those individuals who already understand entrepreneurship and seek out the Office of Technology Transfer to appropriately protect their intellectual property for commercialization. Resources and strategies are needed to provide comprehensive education about the Bayh-Dole Act, its implications, and the value of entrepreneurship for all faculty. In addition, a central technology transfer office needs to be established and adequately funded to protect and commercialize intellectual property developed at all state universities. Faculty tend to be individuals who cannot be "trained" in a mass way, but have to be "educated" in a one-on-one manner, which is time intensive. One strategy for providing this educational framework for faculty would be to develop a few resource people to aid technology transfer offices across the State by serving as peripatetic educators who provide introductory input about claiming intellectual property for faculty who have not yet been exposed or do not fully understand the implications of the Bayh-Dole Act, in particular, and biotechnology, in general. Perhaps 3-4 individuals could be recruited and trained to work with faculty in engineering, physics, chemistry, the biological sciences, as well as in economics and management to achieve this entrepreneurial education in a directed and "personalized" fashion.

In order to more effectively capture intellectual property developed in Tennessee for successful commercialization, it is essential to foster linkages between biotechnology incubators, startup companies, and also universities. Strategies to accomplish this goal could occur at multiple levels. Undergraduate or graduate programs in biomedical sciences, natural sciences and engineering could be encouraged to develop apprenticeships with biotechnology initiatives within the State. Such apprenticeships would be particularly attractive to postdoctoral fellows, whose next step is to enter either academia or the for-profit workforce. Preliminary data and proof of concept information critical for biotechnology development could be provided by a well-trained postdoctoral fellow while, at the same time, the accelerating postdoctoral investigator's research by access to high throughput or otherwise non-available technology under development by the startup company. Additional incentives for biotech incubators or companies to provide short-term apprenticeships could be favorable leases for research space at an academic institution in exchange for providing these apprenticeships.

While there is no doubt that there could be win-win synergism via such a partnership strategy, it is also clear that an office that identifies these apprenticeship opportunities and matches them with appropriately trained postdoctoral, doctoral, or undergraduate trainees will be an essential investment by the State to achieve the desired integrated success.

Develop sites for biotechnology growth in Tennessee.

It is essential to provide nascent biotechnology companies with incubator space to further develop their proof of concept, business strategy, and market audience. Such growth of biotechnology may be best served by the establishment of biotechnology parks, offering incubator space as well as necessary services for small businesses, including human resources, financial management, internal audit, and administrative support. One particularly attractive suggestion for the location of such parks would be to utilize current Agriculture Extension sites in Tennessee as a source of land offered at a nominal fee to developers of such biotechnology parks. That land, which is no longer needed for its intended purpose of agricultural research, can be put to productive use at little or no cost to the state.

Long-term nominal leases of the land would accelerate building of biotechnology parks and incubator spaces, which is essential. For example, in many cases it would foster their location near academic institutions, unoccupied space could be leased by nearby academic institutions for incubators for their own intellectual property or for other temporary space needs, thus assuring the developer of the biotechnology parks that space would always be occupied.

It will be essential to develop industry internships within Tennessee and, via liaisons, nationally that would enhance individual competencies and bring necessary skills to an emerging biotechnology enterprise in Tennessee. Thus, in a manner linked to the integrated Centers of Excellence training programs at the associate, bachelor, masters, doctoral, and postdoctoral levels outlined above, an Academic-Industry Biotechnology Partnership office in Tennessee could assure that apprenticeships were available in key technological areas at leading institutions throughout the state, the country, or even the world.

COMMERCIALIZATION

SUMMARY

Biotechnology businesses face specific, significant hurdles as they work to become commercially viable. In certain high growth segments such as healthcare, agricultural biotechnology, bioengineering, devices, and bio-materials, Tennessee has the assets to be nationally competitive in bioscience commercialization. However, the question is how these assets are to be assembled to compete. Key efforts must be undertaken to build Tennessee's commercialization strengths and opportunities, while addressing the weaknesses and threats found in the region's position in the biosciences. The following efforts need specific attention:

- **Improving the region's technology-transfer capabilities through investments in infrastructure and strengthening and simplifying the technology transfer process;**
- **Enhancing the region's research and development base, especially in selected core focus areas;**
- **Establishing a critical mass of firms through entrepreneurship and alliances with the pharmaceutical, device and instrumentation industries; and**
- **Creating a business climate supportive of the biosciences, including addressing capital gaps and creating incentives for new ventures.**

In particular, effective commercialization of biotechnology requires the right people, sources of capital, and a specialized infrastructure.

GOALS

In order to participate in the growing biotechnology sector, Tennessee should implement a successful commercialization program that will enable the state to "grow its own" companies.

Commercialization Mission Statement

The commercialization mission of the task force is to:

- **Examine the State's ability to create and commercialize new bioscience technology through venture efforts in existing businesses and startups, and**
- **Assess the key components required for success and recommend ways to improve the State's commercialization effectiveness.**

[4] For example, the Memphis community has the Biotech Foundation, a public private partnership comprised of CEO's and/or Presidents of hospitals, businesses, Research Centers and academic institutions all aligned behind the goal of making the region an internationally recognized area for research and commercialization of bioscience technology.

Key Commercialization Recommendations

The Task Force recommends that the major first year priorities include the following actions:

- **Establish Public/Private Partnerships in key regions or corridors targeted for bioscience. These formal collaborations of academic, business, healthcare and government entities facilitate the alignment of resources and policies around the building of bioscience clusters.** [4]
- **Fund programs to solicit, receive, review, and approve the research universities' core competency strategic plans for major technology generators. Establish private focal points for key regions and corridors within the State.**
- **Create the capital sources for research and infrastructure grants, development funds, and pre-seed funds, including securing funding for the initiatives.**
- **Expand value-added networking by interaction with local job boards, venture capital forums, and academic conferences with the goal of stimulating interaction, collaboration and the entrepreneurial process.**
- **Complete and secure funding for a bioscience incubator in each regional area.**
- **Support a statewide marketing program to increase the visibility of the State within the biotechnology community.**
- **Establish clearly definable goals that help the State monitor the success of its investments and results. Such goals are included in the implementation plan shown at the end of this report.**

STRUCTURE OF PROCESS

The Commercialization subcommittee was formed from entrepreneurs, researchers, technology transfer executives and business leaders from around the State. The subcommittee met twice in person, but otherwise used conference calls and email for most of the work.

OBSERVATIONS AND RECOMMENDATIONS

Tennessee has the biotechnology assets

In certain high growth segments such as healthcare, ag-bio, bioengineering, devices, and bio-materials, Tennessee has the assets to be nationally competitive in bioscience commercialization. Many of these assets are highlighted in other sections of this report. However, the question is how these assets are to be assembled for the State to compete.

The Biotechnology Market is Broad

Biotechnology can be applied to a wide range of market areas. The most lucrative outlet remains the healthcare markets, i.e. therapeutics and diagnostics. Biotechnology is critically important to the discovery, development and delivery of medicines and vaccines (there are estimates that 70-90% of all new pharmaceutical R& D is biotechnology related).

Beyond therapeutics and diagnostics, biotechnology has broad applications in the agricultural and environmental fields. In addition, new opportunities are expanding the importance of biology due to the

[5] Benchmark analysis from Phase III report, Pittsburgh Bioventure/LifeSciences Greenhouse Prospectus, Battelle Technology Partnership Practice, October 2001.

convergence of technologies and disciplines. With its need for vast databases, collaborative research, and precision instruments, biotechnology is driving developments in bioinformatics, nanotechnology, biomanufacturing, and even the electronics industry. The Bio-economy extends to the health care services arena where reductions in overall health care costs are a main focus.

Table 1: Summary of Benchmarking Lessons Learned and Gap Analysis for Tennessee [6]

Lessons Learned	Benchmark Other Regions	State Perspective/Gap Analysis
Engaged research universities across research, technology commercialization, and industry partnerships.	The best are on par in overall academic strength. Other regions often have more balance between university and industry drivers.	• View Universities as tremendous resources for furthering bioscience development in the State • Close-knit relationships exist between universities and start-ups. • Many existing relationships in accessing facilities and equipment, but high cost burden placed on start-ups and difficulty in establishing broader collaborations • Interest in clinical trials and product development testing linkages • Despite some notable successes, technology transfer is viewed as an area of improvement
Networking	Effective Industry and geographical networks for bioscience.	• Notable lack of value-added networking activities in the region • Lack of critical mass to draw upon from management expertise, guidance and resources.
Indigenous Venture Capital	Varies by region with almost all finding new mechanisms for seed capital. On a more limited basis, other regions are addressing pre-seed areas.	• Shortage of venture capital at all stages for life sciences from pre-seed to expansion • Many firms have to go outside the region for venture financing. • Early stage financing from TTDC and MB Bioventures (Memphis) viewed positively. • Absence of bioscience incubators and accelerators. UT/Baptist Research Park (Memphis) and Cool Springs (Nashville) are good initial efforts
Discretionary Funding	Strong Success in securing state, foundation, and discretionary Federal Funds	• Track Record of success in winning Federal Grants • Significant State resources beginning to flow: Tobacco Settlement, Memphis Biotech Foundation • Viewed as potential value added, but needs to connect research and commercial sectors
Workforce	Many focused efforts on developing specific degrees and programs tailored to the biosciences	• Lack of bioscience management experience in region is key gap • Competition among Industry and higher education/hospitals for technicians • Region lacks sufficient number of high-level experienced bioscience expertise • Little focused workforce effort for bioscience. Workforce committee in Memphis viewed as great step
Business Climate and Long term perspective	Development of specific technology infrastructure for supporting start-up and emerging bioscience companies Specific Incentives established for bioscience firms 12-14 year minimum time period (Baltimore-Washington) or longer	• Examples of success in Biomedical Device and pharmaceutical manufacturing across the State. • Biotech Companies having difficulty finding needed wet lab space • Strong interest in clustering of emerging bioscience companies, especially near medical schools • Lack of image or brand of State in biosciences • Concerns with impact of state and local taxes on start-ups • General satisfaction with business service providers • Concern that community too critical and too impatient to let initiatives develop • Need to broaden measures of success beyond just number of jobs generated, especially in initial years

Keys to Commercialization

To better understand the dynamics of how to improve commercialization within Tennessee, it is essential to learn from successes and failures elsewhere. Several examples of leading regions and up-and-coming areas exist. For the purposes of this analysis [5], peers were selected, including Atlanta, Baltimore-Washington Maryland, Cleveland, St. Louis, Salt Lake City, Birmingham, and San Diego. The bullets to the right

[6] ibid, page 33

identify the "best practices" in bioscience development among regions in the United States. Table 1 above compares these benchmarking "best practice" lessons learned with the gap analysis for Tennessee.

Three Components for Commercial Success

Commercialization in the biotechnology arena takes unique skills, knowledge and resources but as with any business, it comes down to 1) people with talent, good ideas, and entrepreneurs with passion and tenacity, 2) capital, usually in the form of grants, seed and venture funds, and 3) infrastructure, such as laboratories, equipment and other tools to convert technology in a research laboratory to a viable product.

People–today versus vision for tomorrow

The most important requirement for stimulating commercialization within the State is to increase Tennessee's talent pool of skilled labor, managers, and knowledgeable personnel in the biosciences. *Effective and directed education is the single most important contributing factor to an improved workforce.*

Lack of a skilled workforce is an impediment to commercialization

Tennessee has a wealth of organizations engaged in workforce development efforts but until recently, none have focused on the specific needs of the bioscience community. In addition, technical biomedical and clinical health care careers receive only limited attention from existing workforce initiatives. However, the need to hire experienced management and scientific talent raises the need for more than just typical workforce skill upgrading and training initiatives.

The lack of bioscience management expertise in Tennessee and the difficulty of attracting expertise to the region are noted as key workforce issues by all new business ventures.

Given the shortage of talent, many emerging bioscience companies have difficulty competing with major universities and hospitals for technicians. This enhances competition for technician-level workers and ratchets up pay scales beyond the reach of emerging bioscience firms.

Tennessee needs access to more skilled entrepreneurs

A large crop of high-level scientific expertise with corporate management experience resident in the region is not available. The speed that is required in the process of filling management positions in start-up situations has reportedly forced new ventures originating in Tennessee to consider alternative locations. Few researchers and inventors, who are often the entrepreneurs behind new biotechnology ventures, have anything like a working comprehension of manufacturing industry, raising capital, or sales and marketing.

Tennessee has a shortage of experienced entrepreneurs who can successfully manage the transition from technology to product and disseminate the knowledge of how to achieve it. To investors, a credible management team is a key factor considered in the analysis of the investment opportunity. Attracting successful entrepreneurs to the State is critical to expanding Tennessee's commercialization success.

Rebranding the State can help attract the needed talent

Tennessee' strengths, including numerous quality of life factors such as a relatively low cost of living, short commute times, an extensive and varied set of cultural opportunities, are not by themselves enough to attract bioscience expertise to the region.

There is no national or international image of Tennessee as a bioscience hub. Even with the success of St. Jude Children's Research Hospital, King Pharmaceuticals, and Oak Ridge National Laboratory, there have not yet been sufficient bioscience business successes to promote the region as a leading national center for the biosciences and draw talent and expertise to the State.

Some of these concerns are perceptions or programmatic deficiencies that must be addressed through such

efforts as branding, promotion, and focusing of efforts toward the biosciences. Others result from specific and remediable deficiencies in the Tennessee occupational and educational infrastructure that must be addressed if Tennessee is to be competitive in the future bioscience arena.

To attract the best and brightest entrepreneurs from around the nation (as well as retain its current work force) it is crucial that Tennessee present itself as attractive and conducive to bioscience activity, with respect to both cutting-edge research and high-powered workforce. There are distinctive regional characteristics and amenities valued by bioscience workers, and another set of characteristics that serve to attract and support bioscience firms.

Types of Jobs and Skills required

Commercialization of bioscience requires a broad range of jobs ranging from high school vocational tasks to Post Doctoral Researchers. The Task Force recommends a gap analysis be performed in each life science region to determine the difference between supply from Tennessee's high schools and colleges and the demand by life science businesses.

Entrepreneurship Programs in Tennessee

Entrepreneurship training programs available in Tennessee include the following:

1. **Memphis Regional Chamber of Commerce Enterprise Process Series**
    - An eight-week (one night per week) program normally scheduled for the fall of the year.
    - Subjects cover business planning, company formation, capital formation, intellectual property, and accounting and legal issues.
2. **The University of Memphis Continuing Education Program**
    - Eight courses taught normally twice per year in the spring and fall
    - Summer courses offered based on instructor availability
3. **The Tennessee Small Business Development Center (SBDC)**
    - Offers a full range of assistance through seminars/workshops and individual help to the entrepreneur
4. **Entrepreneurship coursework offered by the Owen Graduate School of Management at Vanderbilt**
    - Offers a well-recognized program in business and entrepreneurship

While important, these programs need to be enhanced, expanded, strengthened and joined by additional entrepreneurship training efforts.

People – Recommendations to Strengthen Commercialization

- **Ensure that workforce development programs are in place in Tennessee. Monitor the growth of bioscience personnel and ensure that significant gaps in staffing are addressed through high school, vocational, and college programs.**

- **Identify and support specific market/recruiting programs for attracting expertise to the State.**

- **Encourage entrepreneurship programs to development in each region of the State. Work through public private partnerships to implement programs within the State.**

- **Encourage regional branding efforts through public private partnerships and regional chambers. Identify State supported efforts to brand and market the State as a Bioscience region.**

Capital

A robust venture capital community is essential to support small and start-up companies and the commercialization process. Biotechnology is a research-intensive, emerging industry with tremendous financial potential. However, because it is a risky business the capital requirements are unique. One of the key differences between product development in the life sciences and that in other industries is the involvement by the government in virtually every phase of the product development cycle. The development of most biomedical products requires approval by the Food and Drug Administration (FDA) before they may be sold to the public or prescribed by a physician.

Intellectual property protection is a vital component for the biotechnology company, but is often not an acceptable expense to put against small business grants. The cost of international protection accelerates dramatically in the first five years of the patenting process, but without it, the perceived value of the technology is lowered, especially if licensing to established pharmaceutical companies is seen as a viable commercialization strategy. The development process is capital intensive and requires specific expertise. The amount of capital needed as a biotechnology application progresses from research through to development and then, if a therapeutic or diagnostic, through the formal FDA regulatory processes, increases dramatically. Unless a sufficient pipeline of capital is envisaged at the outset, difficulties can arise to impede progress, particularly through later stages of development.

Capital Options for Biotechnology Companies in Tennessee[7]

Private Grants
- Assisi Foundation of Memphis
- Plough Foundation (Memphis)
- McKnight Foundation
- Rockefeller Brothers Fund
- Other private grants

Grant Writing Support
- Grant center (Memphis)

Government Grants
- Small Business Innovation Research (SBIR)
- Small Business Technology Transfer (STTR)
- Appalachian Funds
- Federal Funds (NIH, USDA…)

Seed Funds (with Life Sciences Experience)
- Angels Network of the Nashville Healthcare Council
- Salix Ventures
- Pharos Funds
- Chancellor's Fund of Vanderbilt University
- Memphis Biomed Ventures
- Clayton Associates
- Coleman Swenson Booth Inc.
- Richland Ventures

Capital—Today versus vision for tomorrow

Today, Tennessee is not typically perceived in national capital markets as an existing "center" of biotechnology, and consequently investors might question backing a biotechnology company in the State. In fact, many venture firms prefer to invest in companies that are close by to make it easier to watch their investments. For these reasons, relatively little capital is available in Tennessee for the biotechnology/life sciences industries, compared to other traditional venture capital investments.

There is capital in the State, but it tends to be invested elsewhere geographically and in other business sectors. For example, an analogous business sector based on intellectual property rights (e.g., copyrights) is very familiar to the Nashville capital markets. This lack of capital for biotechnology is true for seed, venture and other equity capital. Since local banks do not understand the biotechnology business model, they are usually not willing to consider standard debt financing for this business sector.

Ideally, the State will grow its biotechnology base and become a recognized center for this type of commercialization. This will attract a range of options for private capital experienced in this field that will encourage commercialization.

Capital—Recommendations

The primary issues are not whether capital is needed, but how Tennessee can increase the capital available to stimulate the commercialization of life science products.

- **The State's leading business schools, such as Vanderbilt's Owen Graduate School, MTSU, University of Memphis, and University of Tennessee-Knoxville, should run courses to familiarize the financial community with the issues of science-based industry and biotechnology in particular.**

[7] There are numerous private funding agencies that specialize in healthcare. However, few, if any of these organizations focus on capital grants for the purpose of commercialization.

- **Establish a comprehensive program of investment credits that make Tennessee a more viable option for new biotech ventures.**

- **Mandate that the State's employee retirement funds put some of the high-risk venture capital investments in their diversified portfolio into Tennessee-based venture funds.**

- **Aggressively pursue existing capital funds, especially those already in medical areas such as devices and services, to expand into biotechnology companies in Tennessee.**

- **Facilitate development of clusters of biotechnology companies that can gain a critical mass for fostering biotechnology generally, and gain the attention of adequate sources of capital in particular.**

- **Focus on specific areas of strength and expertise for developing viable clusters in each individual geographic location. Combine this with an aggressive policy of existing companies in the sector of biotechnology in which a particular cluster has strength. There is serious national and international competition to establish successful biotechnology clusters, and capital will follow where the conditions favor its best use and where there are the most high quality opportunities and credible infrastructure.**

Infrastructure

Biotechnology has special infrastructure requirements. Two stand out as key opportunities for Tennessee—1) laboratory incubators and 2) university technology transfer.

Key Role of Bioscience Laboratories and Incubators

Fostering the development and deployment of bio-business incubators in Tennessee is an essential step to increase life science commercialization. Most Biotechnology research is conducted in laboratory facilities suitable for chemicals and other materials. The cost of constructing and outfitting a laboratory varies but can range from $250 to over $400 per square foot, much more than the cost of an office facility (between $100 and $150/ft). In the high- risk commercialization process, both existing and new companies balk at this cost which prevents new technologies from being developed. Beyond the costs of construction, outfitting the laboratory with special equipment and operating and maintaining a laboratory facility costs much more than typical businesses face. Maintaining certain state and federal standards are essential, not only for the health and safety of the employees, but also to insure that new technology development, especially new pharmaceuticals, meet standards required for eventual commercialization.

Successful bioscience clusters offer shared laboratory facilities which mitigate the costs of research and development that serve as "incubators" of new companies. In addition, new companies may need assistance in planning and monitoring clinical trials as required by the FDA. It is difficult for a young company to afford such specialized individuals either as full time employees or consultants. If strict FDA requirements are not met during the development stages, the clinical trials can be invalidated and the company suffers a serious, and costly, setback. By sharing the costs of expensive personnel and services across many companies, the large capital requirement and risk of biotech companies are mitigated.

Tennessee's Incubators

Currently, Tennessee has only one incubator that is truly oriented on the development of biotechnology companies. This is the incubator operated by Tristar Enterprises, Inc. in Memphis. Tristar Enterprises, Inc. is a not-for-profit organization created by The University of Tennessee Health and Science Center and the UT Medical Group, Inc. with the mission of facilitating new company growth and development within the

Memphis medical community. Tristar operates a facility comprising over 5,000 square feet of laboratory space and a complementary amount of supporting office space. This facility will be expanded to include an additional 5,000 square feet of laboratory space that will be available for occupancy in the second quarter of 2003.

Tennessee BioScience Incubators	City	Site description	Incubator Size
Tristar Enterprises	Memphis	26,000 sq.ft.	10,000 sq.ft.
Cumberland Emerging Technologies	Nashville	Up to 20,000 sq.ft.	Up to 20,000 sq.ft.
Cool Springs (planned)	Nashville	140,000 sq.ft. campus	20,000 sq.ft.
East Tennessee State University (planned)	Johnson City	22,000 sq.ft.	10,000 sq.ft.
UT/Baptist Research Park (planned)	Memphis	1.2 million sq.ft. campus	100,000 sq.ft.

A new bio-business park and incubator facility is under development in the Cool Springs area, just south of Nashville. This facility is being developed on a 10-acre campus with the initial building being approximately 40,000 sq. ft. half of the first building will be dedicated to emerging companies, and the other half will be a bio-business incubator. Additional buildings may be built on the campus as required.

A new laboratory facility is currently being developed for small biotechnology companies by Cumberland Emerging Technologies Inc, which recently leased up to 20,000 sq ft in downtown Nashville for the project. Its first tenant specializes in water-soluble nanotechnology for drug, gene and antigen delivery.

An incubator facility is being planned for development at East Tennessee State University and should be operational within 2 years. The property consists of an old armory and Marine Corps facility and an unused building at the Veteran's Administration Medical Center. Total area in these facilities is approximately 22,000 square feet. Although not complete, plans call for a mixture of office, laboratory, and manufacturing space.

The largest life science laboratory and incubator facility planned in the State is the UT/Baptist Research Park that is being developed by the Memphis Biotech Foundation. The Research Park began with a $40 million gift of properties and buildings in downtown Memphis by the Baptist Memorial Healthcare organization. The Memphis Biotech Foundation plans for 1.2 million square feet of laboratory research space adjacent to the University of Tennessee Medical School. The facility is central to the Medical District in Downtown Memphis and surrounded by three clinical care hospitals and the St. Jude Children's Research Hospital®. The Memphis Biotech Foundation is an unprecedented public/private/ academic partnership aligned behind the common goal of creating a world-class facility to serve as a hub of a bioscience research and commercialization cluster in Tennessee.

Regions seeking to advance in biosciences typically develop aggressive efforts in commercial bioscience space development. The Subcommittee reviewed the experiences in Worcester, Massachusetts; New Jersey; and Connecticut and reached several conclusions.

- **A speculative approach to building a research park can work.**[8]

- **Success with one research park can lead to additional, successful speculative buildings within the same area. Cross-collateralization can help spur momentum.**

[8] Worcester Biotech Research Park
[9] New Jersey Biotech Park
[10] Connecticut Biotechnology Facilities Fund

- **The building design can minimize risks. At Worcester Biotech Research Park, for example, lab and office space that was friendly for lab fit-outs with higher than standard floor loading, height, air handling, power, plumbing, and emergency back-up power were constructed. This enhanced office design was only 15 percent more expensive than typical office building construction and made the facility attractive to non-bioscience tenants.**

- **Unique partnerships with new, unique funding arrangements can fill the gaps in costly development of bioscience space. Traditional public/private development arrangements can be stretched, even turned inside out, in order to fund these economic development generating units.[9] For example, there are examples of facilities with significant private funding being managed by the public sector.**

- **Ability of the landlord to finance tenant improvements along with speculative building development can help spur use of the incubator.**

- **Biotech investment funds need to evaluate opportunities on a deal-by-deal basis, structuring financing to meet the specific situation. These facilities often must adopt creative approaches to financing in order to provide the level of assistance needed by their tenants.[10]**

- **Funds that do not have return on investment as the primary goal but are more geared to economic development generally will be more willing to invest in early stage companies and riskier endeavors. These funds can, in return, often secure commitments from those companies concerning location, workforce and other issues.**

Critical Role of Technology Transfer

Technology transfer is the deliberate movement of new knowledge as embodied in technology from sources or "generators" to commercial developers and, ultimately, end users. Sources, or technology generators, may include universities, federal laboratories, and the private sector. In Tennessee, such key university players include the University of Tennessee, Vanderbilt University, St. Jude Children's Research Hospital, the University of Memphis, and East Tennessee State University. Additionally, Oak Ridge National Laboratory is an internationally recognized institution that produces outstanding technology. Because of the unique relationship of Oak Ridge's Management and Operating Contractor (UT-Battelle), it is also possible to use Oak Ridge as a bridge to the National Renewable Energy Laboratory, Brookhaven National Laboratory, and the Pacific Northwest National Laboratory.

Developers are generally private sector players endeavoring to enhance such technologies with the ultimate goal of providing the resulting products and services to the end users. End users are the "last link" in the technology transfer chain, those who actually apply the technology to economic ends.

- Technology transfer is meaningful to economic development in Tennessee because of the new firms that can result from these activities. In 2000, for example, at least 454 new companies based upon an academic discovery were formed in the United Sates and Canada, 80% of them in the state/province of the academic institution where the technology was created.

- Since 1980 at least 3,376 new companies have been formed based on a license from an academic institution, including the 454 established in fiscal year 2000.

- Adjusted gross license income received from licenses and options was $1.26 billion, compared to $862 million in fiscal year 1999.

Universities are using the licensing revenue generated from the successful transfer of technology to augment their funding sources, as shown in the attached table.

Institution	Patents	Gross Income	Start-ups
University of California System*	281	$74,133,000	13
Massachusetts Institute of Technology	154	$16,131,334	17
Johns Hopkins University	111	$10,353,453	7
Stanford University	90	$27,699,355	19
University of Pennsylvania	82	$2,984,000	6
University of Wisconsin-Madison*	79	$18,011,400	4
Columbia University	77	$89,159,556	5
Harvard University	72	$9,886,404	2
Cornell Research Foundation Inc.	70	$6,070,000	4
Michigan State University*	63	$23,711,867	1
California Institute of Technology	62	$6,500,000	7
University of Florida*	58	$21,649,577	2
University of Michigan*	56	$3,472,671	2
University of Minnesota*	56	$5,662,088	5
SUNY Research Foundation*	53	$13,538,619	3

**Public institutions (or their affiliated Foundations)*
Source: Association of University Technology Managers

Given the growth in start-up activity based on new technology transfer, consider too the multiplier effect of not just the licensing revenues, but also the companies' overall revenues and the second tier effects as a result of the jobs created. Start-up technology companies tend to have a multiplier effect, as the license revenue they pay to the university funds more research, which can lead to more discoveries and start-ups, and as second-tier suppliers and service firms arise to serve the technology companies. Technology transfer is an untapped revenue source for Tennessee and must be supported at the University and with bioscience incubators for successful commercialization in Tennessee.

Infrastructure —Recommendations

Tennessee must focus on Centers-of-Excellence within the State's technology generators. These "generators" are found in the academic, governmental, and commercial sectors.

As a start, State funding should be made available to assist the completion of promising incubators within the State. This includes helping planned incubators attract funding for demolition, abatement, and construction.

Ensure that future tobacco funds are directed towards bioscience investment.

Legislative initiatives that can assist the development of incubators in general and biotechnology incubators specifically are discussed in the section on legislation and include:

- **Incentives to facilitate the growth of start-up businesses:**
  - Net operating loss carry forward provision for biotechnology companies.
  - Tax credit on qualified expenses related to research and development.
  - Tax credit on the cost of cooperative research with state universities.
  - Tax credit on the cost of training necessary to prepare employees to work in the area of biotechnology.
  - Tax credit on the costs of construction, expansion, renovation or purchase of biotechnology facilities and equipment.
  - Reduction of utility costs to qualified biotechnology companies.
  - Tax abatement for qualified biotechnology companies until their products begin to appear in the marketplace.

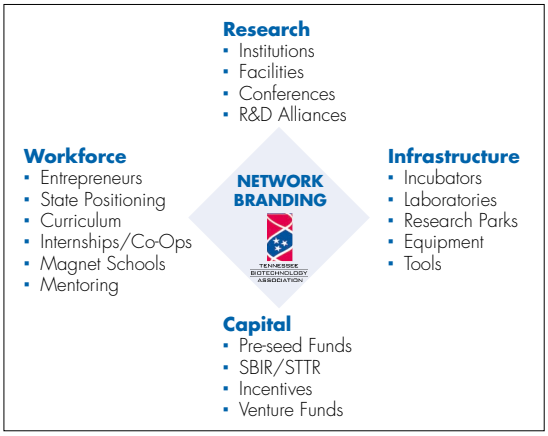
[11] See for instance Michael Porter, Harvard Business Review

- **Incentives to help support the growth of for-profit and not-for-profit business incubators:**
  - Provide tax incentives/matching funds for organizations, municipalities, and institutions that are seeking to develop and operate business development facilities or incubators.
  - Provide support for the passage of US Senate Bill 432/US House 1418 entitled 'Entrepreneurial Incubators Development Act of 2001' which provides multi-year funding for the development and operations on business incubators.

- **Provide a more conducive environment for the submission of Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) proposals by small businesses in the State:**
  - State-provided SBIR/STTR matching funds. In other words, if a small business wins a Phase I or Phase II SBIR or STTR grant, the State would match the federal grant.
  - Establish a Phase 0 SBIR/STTR proposal fund. This would be a competitive grant fund that small companies could use to help them prepare and submit a Phase I SBIR or STTR proposal.
  - Augment the capability of the Tennessee Department of Economic and Community Development, and its constituent programs such as the Tennessee Technology Development Corporation, to provide greater support for the federal SBIR/STTR programs.

Growing biotechnology in Tennessee means building clusters

Clusters are "geographic concentrations of interconnected companies and institutions in a particular field that encompass an array of linked industries and other entities important to competition".[11] The Task Force recommends that to grow bioscience in Tennessee means to strengthen the emerging clusters of bioscience within the State. Conversely, only through investing in Tennessee's clusters will the State reach the critical mass to compete in the national marketplace.



Laboratory facilities/ incubators are the missing link

Without laboratories and bioscience incubators, Tennessee cannot participate in this emerging industry. New bioscience incubators in Memphis, Nashville and Johnson City are in various stages of development to help meet these needs. The State must support these efforts in a timely fashion to ensure that the infrastructure is growing with Tennessee's economic development potential and interest.

IMPLEMENTATION STRATEGY

The most important actions for the success of this effort include actions grouped into four equal areas of emphasis:

1) **Strengthening Research**
   a. Fund research Universities
   b. Broaden networking between entrepreneurs, researchers, educational leaders and venture capital organizations
   c. Establish alliances between universities, research institutions, government and the private sector

2) **Building the workforce**
   a. Attract entrepreneurs
   b. Build the image of the State
   c. Augment high school, vocational, and college curricula
   d. Increase mentoring programs

3) **Improving Infrastructure**
   a. Financially support bioscience laboratories and incubators
   b. Support incubators with tools and equipment

4) **Increasing Capital**
   a. Establish pre-seed capital funds
   b. Structure incentives targeted at bioscience
   c. Support access to Federal funds

To accomplish these objectives, the Task Force recommends that the major first year priorities include the following actions:

- **Establish Public/Private Partnerships in key regions or corridors targeted for bioscience. These formal collaborations of academic, business, healthcare and government entities facilitate the alignment of resources and policies around the building of bioscience clusters.**

- **Fund programs to solicit, receive, review, and approve the research universities' core competency strategic plans designed to grow major technology generators. Establish and support centers of excellence in key regions and corridors within the State.**

- **Create the capital sources for research and infrastructure grants, development fund, and pre-seed funds, including securing funding for the initiatives.**

- **Expand value-added networking by supporting existing regional public/private partnerships.**

- **Secure funding for a bioscience incubators/accelerators in each regional area.**

- **Support a statewide marketing and recruiting program to increase the visibility of the State within the Bioscience community.**

- **Identify successful workforce development programs and ensure that plans for workforce in each region successfully address the range of workforce needs.**

- **Establish clearly definable goals that help the State monitor the success of its investments and results.**

ACCOUNTABILITY AND MEASURES OF SUCCESS

The statewide initiative in bioscience commercialization will be measured in terms of its progress and success by adopting a comprehensive list of measures to chart both process and outcome and impact data attributed directly or indirectly to the bioscience portfolio of investments within the State. Some of these measures are directly attributable to this effort; others are surrogate measures because precise data are difficult or impossible to collect.

Twelve measures to chart progress are broken into the following two categories: short- to mid- term (1-5 years) and long-term (5-10 years or more).

Short- and Mid-Term Measures

1. **Federal, industry, philanthropic, and other outside funds leveraged to support the region's bioscience pillars/tools**

2. **Venture dollars invested in bioscience firms in the Tennessee region, and the region's share of regional and national totals**
3. **Number of bioscience firms in the region and measures of their market success (products, sales, employees) including IPO value, employment, and sales**
4. **Number of spin-off firms formed out of university intellectual property, IPO value, sales, and employment**
5. **Number of graduates of pillar/tool fields and percent remaining in region after graduation one and five years out**
6. **Number of new degrees, certificates, multidisciplinary programs introduced in core/tool areas.**

Long -Term Measures

1. **Incremental growth in jobs attributable to the bioscience area, both businesses, research and support jobs.**
2. **Industry concentration in bioscience sectors compared with nation (share)**
3. **Market penetration of total Federal bioscience R&D resources and ranking among regions/cities in the United States**
4. **Net business formation (birth rate minus death rate) of bioscience firms in the State compared with region and nation**
5. **Citation analysis of core research/tools compared with other universities**
6. **Periodic market surveys to gauge regional citizen satisfaction with health care quality and knowledge of the region**

The bioscience activities, outcomes, and impacts cost money and resources will need to be identified to implement this financial plan. Potential sources of funding include state tobacco settlement funds available to the universities, the state capital budget, the universities' endowments, philanthropic sources, and private sources including alumni.

All of these first year actions cannot be completed over the first 12 months after initiating Tennessee's bioscience program. However, these actions must be initiated and addressed in the first year, since they are critical to achieving the vision established for the State.

THE REGIONAL PERSPECTIVE

SUMMARY

Our nation's economy is rapidly transitioning to a knowledge-based or technology driven economy. If Tennessee is to participate and lead in this new economy, it must diversify its reputation from one tied principally to the manufacturing and agrarian sectors and expand into the technology sector. The growing biotechnology movement provides Tennessee with a unique opportunity to reposition its economic development efforts. Tennessee is home to a sizable and robust bioscience research capability, which includes four medical schools, St. Jude Children's Research Hospital, Oak Ridge National Laboratory, as well as significant drug, device, and instrumentation expertise. Tennessee can quickly position itself as a nationally recognized research hub for biotechnology research. However, Tennessee lags far behind other states in its biotechnology development and presently lacks the resources in capital, publicly available funds, and expertise required to effectively grow and attract biotechnology investments on a national or international level. After conducting a variety of meetings, obtaining information from Tennesseeans in a plethora of occupations, and examining the successful biotechnology initiatives in other regions of our country, the Subcommittee determined that we must think regionally if we are to compete nationally and internationally for biotechnology expansion. In order to create a national audience for Tennessee's biotechnology research capability, it is absolutely essential to involve the entire state, and neighboring states, in the effort.

Although multiple factors dictate a regional approach, several key elements underpin the decision:

(1) The biotechnology industry has concentrated in six clusters, generally structured around research and development centers and R & D facilities. These clusters are not tied to or limited by state borders;

(2) Tennessee's three grand divisions have historically competed internally for resources and development, which has created three distinct economic regions, with each grand division's economy tied almost as closely to the surrounding states' economic success as to Tennessee's;

(3) Many of Tennessee's biotechnology resources and population centers are located at or near its borders, which creates natural cross-border economic ties;

(4) Although certain of Tennessee's bordering states have significant biotechnology efforts underway, (Kentucky, Alabama and Georgia by example), certain of its neighboring states are already working with it in regional economic initiatives and can help strengthen the overall availability of biotechnology resources; and

(5) Tennessee's efforts should be divided into three regional approaches tied together through the Tennessee Biotechnology Association and Nashville.

When compared to other areas in the U.S. where biotech enterprises are proliferating, Tennessee's resources are disjointed and very limited. A regional approach can harness the resources in the state's internal regions and combine those resources with others in neighboring states. As a region, each area can muster the necessary resources and impetus to attract the other essential elements to successful biotech business development.

Other impediments also exist, which must be overcome before this region can position itself as a leader in the industry. A critical need is access to very early stage "seed capital" and entrepreneurial expertise. The lack of seed capital and management expertise is further exacerbated by the difficulty biotech companies in the State face in attracting venture capital investment, mainly because Tennessee does not have a national reputation for successful biotechnology commercialization.

The key to competing nationally and internationally in biotechnology is through the formation of technology "clusters." Without these broader partnerships, which ignore State boundaries, success will not be possible. The identification of regional strengths and the development of partnerships and communication that support the biotech initiatives within the region are critical to Tennessee's success. Tennessee has nationally recognized research centers, but we must expand that reputation to include successful commercialization efforts and in order to succeed, a regional effort must be organized.

GOALS

The overriding goal of the task force concerning regionalism was to identify and recommend the optimal means by which Tennessee could organize a regional framework in which to foster the biotechnology industry to a level competitive nationally.

MISSION

The Regionalism Subcommittee was to develop a workable framework to foster regional cooperation and coordination, which will accelerate the successful creation and profitable operation of biotechnology-based businesses in the region.

KEY RECOMMENDATIONS

In the short-term, Tennessee must:

- **Define the regions within which a cooperative effort should take place;**
    - identify assets and areas within the regions that have active technology development efforts;
    - identify common goals among the biotech entities in the regions;
    - identify primary areas of coordination among the same;
    - identify primary impediments to coordinated, regional approaches;
    - identify potential sources of early-stage seed capital funding and management expertise through the regions; and minimize duplicative and competing programs, so as to maximize the efficient utilization of each region's resources.

- **In the mid and long-term, Tennessee must:**
    - develop a structure to facilitate regional coordination in each technology cluster supported by the highest offices of the relevant state governments;
    - develop working relationships among universities and research centers in each region—explore ways to maximize efficiencies, minimize unnecessary overlaps in work, and benefit from all research being conducted in each region;
    - develop a center in Tennessee with funding from federal sources (e.g. National Institutes of Health, USDA) on an identifiable sector of the industry that is recognized as a strength or emerging strength; and identify and organize a core of experienced biotech financiers, and entrepreneurs that can be accessed for use on boards, or as senior management, of regional entrepreneurial biotech enterprises.

STRUCTURE OF PROCESS

The Subcommittee had a membership of twenty-six individuals from three states representing a broad cross section of the biotech industry, including higher education, research and business institutions, scientists, policy makers, and individuals committed to the development of biotechnology based businesses. The subcommittee held town hall meetings and several teleconferences to discuss issues, define data gathering techniques and develop a plan for rapid acquisition of necessary information. The subcommittee also met at various times in conjunction with meetings of the Governor's Biotechnology Task Force.

As a result of the regional town hall meetings, well over one hundred and fifty individuals, including members of higher education, local business owners, economic development leaders, state policymakers, biotechnology CEOs from established and start-up companies in Tennessee, pharmaceutical executives, entrepreneurs, research institution leaders, and staff members from Oak Ridge National Laboratories contributed to the process and generated data, opinions, and thoughts to improving Tennessee's opportunity in establishing a fertile state for biotechnology business growth.

Early in the planning phase biotechnology was defined as "any technology that bears on a biological system."

Through its town hall meetings, the subcommittee asked for an accounting of regional resources available to and interested in biotechnology business development. In order to understand the impact of cooperative regional efforts, specific inquires were made regarding the availability of meaningful capital for investment in biotechnology; potential availability of additional financial resources for research and development efforts; evaluation of business potential of technology in an efficient manner; the ability to limit or substantially reduce business mistakes and failures; regulations and laws that possibly impede biotechnology development and how these statutes are dealt with; access to technology developed in the region; identification of overlap and duplicate programmatic issues that strangle or slow the growth potential of biotechnology; deficiencies in the workforce and in educational curricula that impede biotechnology business growth and development; and the ability to identify and attract highly trained and successful employees to support the biotechnology industry.

OBSERVATIONS

Tennessee has historically divided itself into three grand divisions; East, Middle and West Tennessee. In many ways, Tennessee conducts itself as three separate states within the State, with the three internal regions competing with each other for resources and development. This competitive approach exists today in practically all aspects of business, education and economic development across the State and has a negative impact on the potential success the State may enjoy in developing a biotechnology initiative.

Many participants reported that success had come when the various communities banded together to compete economically, i.e. TriCities. A coordinated regional approach utilizing a workable interplay of resources appears critical in order to share information easily and efficiently. All three regions recognized that "selling" a region as one unit for supporting technology with a structural coordination increased chances of attracting biotechnology and technology industries. Participants agreed that a central communication source focusing and coordinating the regional effort increased the likelihood of success.

Biotechnology tends to grow in clusters. The driving force in an area or region may not be the same for other areas or regions. The state's three divisions could serve as regional hubs for multistate biotechnology development efforts. The Mississippi Delta to the west with Memphis as the hub; the mid-state region with Nashville as the epicenter, and the Appalachian region encompassing the east end of the State. In all of the town hall meetings, individuals generally recognized states' divisional boundaries would continue to exist,

but believed that broadening regional partnerships through incentives from the State or from other sources, were needed for academic institutions and business to form meaningful cross border alliances.

Without a doubt, the primary impediments for developing biotechnology in Tennessee was the lack of early stage investment money and entrepreneurial expertise. Tennessee lacks investors either fitting into the "angel" or the venture capital categories. Both types of investors are viewed to be critical in supporting start-up initiatives and capitalization projects requiring considerable investment for a start-up to make the next level of business development and expansion.

Meeting participants noted that the lack of communication between institutions of higher education was cited across the State. For example, in development of technology clusters, higher education has a pivotal role in creating innovation, providing highly trained talent, and recruiting individuals and companies to a region. In Tennessee this critical component is divided between two governing systems that do not interact but instead compete for state dollars and programs that may or may not be critical to developing biotechnology or other technologies in the State. There is no coordinated effort between the University of Tennessee and the Tennessee Board of Regents Systems. To further point to the problem, the Tennessee Higher Education Commission (THEC) was not seen as effective at coordinating the two systems. Many participants questioned the duplication of facilities, programs and ineffective partnering with business and industry.

Generally, meeting participants suggested that Tennessee would be better served if the UT and TBR Systems were combined and a coordinated effort begun to define strengths of each individual institution by mission. Others noted that further savings in higher education dollars would occur with the dissolution of THEC, combining the higher education systems and the implementation of a plan to minimize duplication of costly programs and facilities. Additionally, the Subcommittee learned that a staggering 80% of the individuals obtaining a Ph.D. degree from a Tennessee institution would leave the State to find employment. This contributes substantially to the brain drain that is occurring in Tennessee.

Another area of concern in attracting and sustaining the biotech industry to Tennessee is the lack of experienced CEOs and other individuals to serve as mentors or board members for start-up and young companies. In order to decrease failure and accelerate success, this observation is critical to fostering the biotech initiative in Tennessee.

Although biotechnology is often identified with the medical and pharmaceutical industries, agriculture has led the way in many aspects of biotechnology. With farmers planting more genetically altered crops in the U.S. in terms of total acres planted and the fact that one of Tennessee's biggest businesses is agriculture, it only seems natural that an increased focus should be given to this industry. All participants in the meetings generally agreed that excitement as well as understanding of and for biotechnology, increase when agriculture becomes the focus of the discussion. There is opportunity for a concerted "buy-in" by citizens across the State and the surrounding regions when individuals realize that there is truly something in it for them and economic gain can be a part of rural and farming communities.

The Subcommittee observed a disjointed effort in presenting information and seeking the assistance of State Legislators when it comes to the State's technology initiatives. On more than one occasion it was noted that there were competing biotech / technology initiatives being advanced for support from the State and through the lobbying of State Legislators leading to confusion with legislators, leaders in State government and others as to the true needs of biotechnology and research institutions.

An overriding precept was that the State's budgetary dilemma overshadows most other issues in the State and whether perceived or real, impacts negatively any real cooperative effort across the State. Generally, participants agreed that a plan of action is needed and without viable solutions, Tennessee will not

successfully advance any initiative having an impact on the attraction, and expansion, of the biotechnology industry in the State and region.

Recommendations

Develop clusters in Tennessee and across the region:

Biotechnology grows in clusters. As noted by Michael Porter, Harvard Business Review, "no single policy or strategy will work for all regions"; however, he notes the undeniable importance of universities and specialized research centers in acting as "the driving force behind innovation in nearly every region" where clusters are successfully developed and fostered.

Defining Clusters in Tennessee

In Porter's 1998 Harvard Business Review article on clusters he references several notable clusters within the United States such as the movie industry in Hollywood, the finance industry in New York, and the gaming industry in Las Vegas. He also referenced a healthcare services cluster in Nashville-Louisville.

Porter's reference to a Nashville-Louisville cluster is interesting for several reasons. First of all, this was the only cluster he identified in our state. Secondly, this reference – as did others in his article – supported the notion that a cluster can have "poles" and that clusters can legitimately develop along corridors that often cross state boundaries. Another example of this is the carpet industry in Dalton, Georgia, that bleeds over to Chattanooga.

Unfortunately, due to the size and dispersion of Tennessee's larger cities, the critical mass that Nashville has developed in Healthcare Services may prove difficult to replicate in the Biotech arena in any single city in Tennessee due to the physical dispersion of our major population centers. Put another way, no single city has the scale and concentration of resources necessary at this point to develop a vibrant cluster on its own. Therefore, the only legitimate means of achieving critical mass is to adopt a regional perspective and consider opportunities along geographic corridors.

Memphis-Nashville Life Sciences Corridor

In Memphis, resources at St. Jude, UT School of Medicine, The University of Memphis, and a significant industry base, are being leveraged to build a biotechnology cluster. But Memphis is also reaching out to nearby resources at the University of Mississippi and the University of Arkansas Health Sciences group in Little Rock to broaden its research and commercialization base. Memphis can also leverage its logistics and transportation expertise in biotech sectors that are either logistics-intensive or time-sensitive. Indeed, this was a key factor in the recent location of Cell Genesys' new production facilities here in the State.

In Nashville, Vanderbilt lies at the heart of opportunities in biotechnology with support from other area schools such as Meharry University, Tennessee State University, and Middle Tennessee State University. But Nashville can also leverage its vast healthcare services sector. In the Porter article, he discusses how clusters can overlap and complement one another in mutually supportive manners. He gives an example of California's wine industry and complementary clusters in agriculture and tourism. The same can happen with Nashville's health services cluster despite the fact that this linkage has, thus far, been slow to develop.

But perhaps the real opportunity for Memphis and Nashville lies in their ability to work together in creating a biotech corridor in which research institutions exist at each pole and the area along I-40 is developed to accommodate industrial and agricultural capabilities that complement the knowledge resources at each end – biomedical engineering research that leads to needs for high-compliance manufacturing.

Tennessee's Appalachian Corridor—Johnson City, Knoxville, and Chattanooga
On the eastern side of the state, there are obvious opportunities at Oak Ridge National Laboratories and UT Knoxville. Farther east, there are opportunities with East Tennessee State University, Virginia Tech, and significant corporate groups such as Tennessee Eastman and King Pharmaceuticals. These resources along Tennessee's Appalachian Corridor could span the eastern side of the state from top-to-bottom.

Taking this regional perspective further, it is clear that opportunities in Tennessee can be created through further interaction with research groups and businesses in Huntsville, Birmingham, Lexington, Louisville and others that are nearby, yet suffer from similar challenges due to their lack of scale and critical mass.

But to make cluster development work, business, academic, civic, and governmental stakeholders must find ways to cooperate and coordinate activities with one another in a manner that has proved elusive since the birth of our great state over 200 years ago. One early success story on this front is the Mouse-House Consortium in Oak Ridge that is supported by Oak Ridge National Laboratory, University of Tennessee, and Vanderbilt University.

Streamline and improve the State's Higher Education System and foster regional cooperation between educational institutions in the region.

The *most important* recommendation coming forward from the Subcommittee on Regionalism, is to streamline the State Higher Education System in order to minimize overlap, maximize communication, and focus upon workforce development through education curricula to "grow our own" highly trained and biotechnology oriented employees. Many, if not all, of the surrounding contiguous states have already moved to a single system initiative for the administration and coordination of higher education efforts. Not to mention the dollars saved from moving to one system for higher education, the State's universities would benefit from a single, coordinated effort to define strengths through mission and avoid being omnibus. Recognizing that broader partnerships foster an increase in potential for attracting biotechnology-oriented businesses, the unified system would provide a better conduit for communication and interaction between and among the State's institutions. A concerted effort should be undertaken to develop a State portfolio that highlights the intellectual property (patents) that is produced through the initiatives of faculty and staff. Bundling patents and providing a central registry for brokering these technologies is one of the first steps in attracting seed money for technologies to reach commercialization.

Further, an increased effort must be undertaken by Tennessee's institutions to reach across State borders in order to partner with other institutions in their region. This provides an additional advantage of complimenting strengths and weaknesses as well as reducing redundancy, increases the potential for facilities sharing and provides critical mass to the biotech initiative that Tennessee and other contiguous states are lacking. This cannot be accomplished without leadership and coordination by a single administering board. The two State systems have competed to their detriment with a broader implication to the loss of many promising initiatives for supporting economic development in Tennessee.

Develop a center in Tennessee with funding from federal sources (e.g. National Institutes of Health, USDA) on an identifiable sector of the industry that is recognized as a strength or emerging strength.

Developing a center in Tennessee with funding from federal sources on an identifiable topic recognized as a strength or an emerging strength in the State should be considered. Higher education institutions and research centers will be critical to attracting and developing such an initiative; however, leadership, coordination and brokering strengths and weaknesses to the State's advantage will be needed.

Further Recommendations

The Task Force believes that regionalism is the key to Tennessee competing nationally and internationally. Intuitively, many of the groups providing input across the State to this report realize how they have been able to have the success they currently enjoy. Without these broader partnerships that blur state boundaries, success would not be possible. For biotechnology initiatives, the states to the west of Tennessee (Mississippi, Arkansas) do not have a nationwide reputation as technology centers. The same assessment is made for the states located on the eastern border (Virginia, Georgia, North Carolina) of Tennessee. With the possible exception of North Carolina, several of the states bordering Tennessee have limited opportunities for individualized efforts or strategies to establish a reputation in biotechnology. Again to quote Michael Porter, "when members of a cluster are in close proximity, they capture synergies that increase productivity, innovative capacity, and new business formation". Viewing the State in three distinct regions allows for the close proximity that is needed to foster an economic advantage for biotechnology. The Mississippi Delta with Memphis as the hub, the Mid-State Region with Nashville as the epicenter and the Appalachian Corridor with Knoxville as the center provides a picture of regional clusters for Tennessee.

Diverse groups contribute to cluster strength; however their association and contribution in not automatic. An organization dedicated to mobilizing these groups does much to strengthen a cluster (see Michael Porter, Harvard Business Review). It is recommended that the regions outlined above initiate the formation of cluster partners for identifying and developing of mutual biotechnology interests and strengths. A method that "sells" regional technology assets as one unit and underpins that product with structural coordination among the regional technology centers will provide these states with the needed critical mass to compete on a national basis. Regional actions, as well as statewide efforts, will present a united front for biotechnology. This applies to state and federal government initiatives and funding. One method of forming partnerships is through the chambers of commerce and economic development boards. Although each region will have a different approach to attracting biotech industries, one mechanism to foster the discussion is the formation of a biotechnology task force to specifically seek biotech initiatives in the region and to include other area or regional chambers to increase the potential for success.

Further initiatives supporting a regional approach would be to encourage the governors of Arkansas, Tennessee, Mississippi, Virginia, North Carolina and Kentucky to meet and endorse a regional approach to biotechnology economic development. Government can have a significant influence on the education, business and the vesting of state funds to foster cluster development. The Mississippi Delta Commission

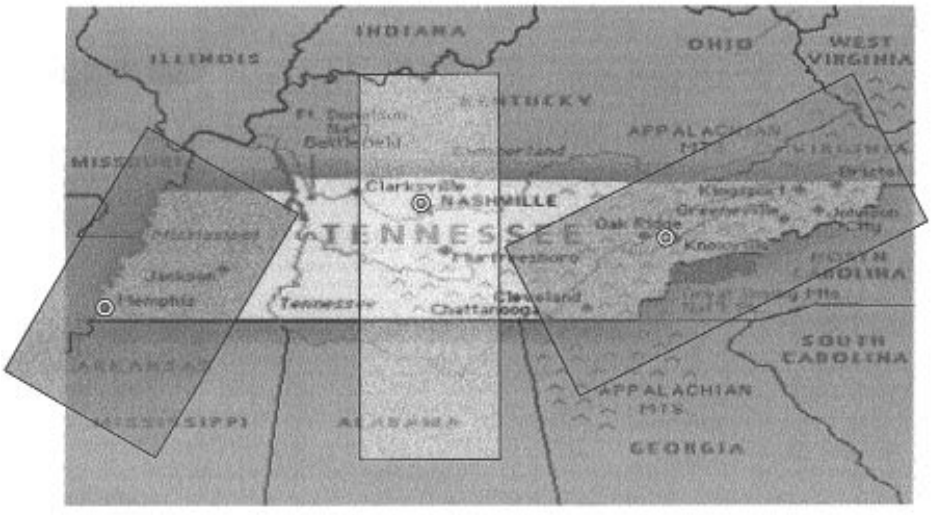


Figure 1. Potential regional clusters for biotechnology initiatives in Tennessee.

and the Appalachian Regional Commission are established working partnerships that can have a significant impact on regional business environments. These Commissions should likewise through the governors that sit on the commission, insure and promote regional cooperation even to the point of blurring boundaries, in order to support biotechnology business development. The regional partnerships can result in the brokering of federal initiatives and focus.

If the map (Figure 1) is examined closely, another picture begins to emerge. The Tennessee Valley Authority shares the same land area and has economic development offices (at least two in each of the three proposed regions) positioned in each region. TVA has as part of its mission to promote economic development as well as its historical interest in agriculture by teaching farmers in the 1930's to develop higher crop yields and in the development of fertilizers. TVA should be considered as a viable partner to help develop and foster the biotech industry in Tennessee and throughout the Valley.

Agriculture is a key buy-in for the average citizen in Tennessee. The biotechnology discoveries in agriculture dwarf those that have occurred in medicine and strengthen the agricultural economy by providing farmers with disease resistant plants, increased potential to yield more profit per acre through biotech advances and to develop plants that are more nutrient dense than their non-genetically engineered counterparts. Farmers are planting more genetically altered plants than in previous years (Fig. 2) and there appears to be no decrease in that trend for the future.

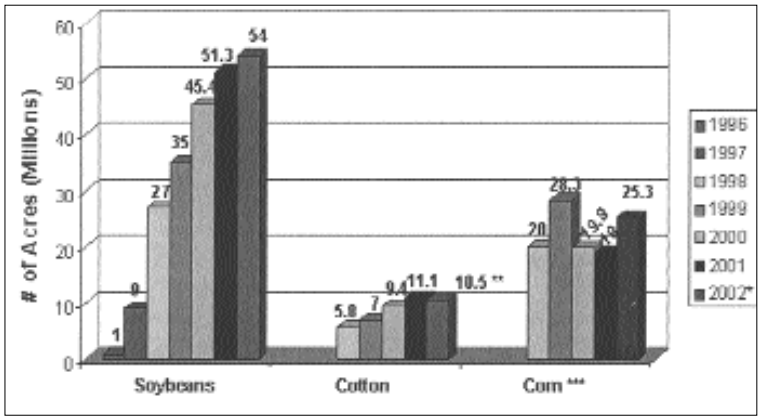


Figure 2. Examples of genetically altered agriculture crop acres planted in the U.S. (Source: BIO, 2002)

The rural and farming communities currently have little understanding regarding the potential economic gains not only to the State but also for them individually. With a basic understanding of "what is in it for me", agriculture communities across the state and its regions can become valuable partners in promoting biotechnology and actively participate in regional processes to secure support for the biotech industry in Tennessee. The Tennessee Farm Bureau has an active voice in Nashville and participates in a wide variety of legislation relating to agriculture and farming issues. Active participation in the regional process for biotechnology by agri-business and agriculture leaders is imperative.

The lack of "seed capital" in Tennessee is of critical concern. Biotech initiatives require capital to commercialize technologies. Currently, no fund exists that provides pre-profitable companies or start-up with adequate capital. Tennessee needs to develop a source for seed monies either through public or private initiatives. While many other states have used and are using Tobacco Settlement Funds to finance their biotech initiatives, Tennessee has not followed this initiative and it will prove to be detrimental in biotech development. It is recommended that a source of funding, either public or private, be identified to support biotech start-ups and pre-profit companies.

In terms of intellectual capital, the lack of biotech CEO's to serve as mentors or board members for start-up companies should be addressed. Developing a core of individuals with experience in the biotech industry for Tennessee companies is needed. It is recommended that the Tennessee Biotechnology Association provide leadership in addressing this issue and possibly develop through BIO a list of individuals around the country who could serve in these capacities.

The Tennessee Biotechnology Association established in 1998, serves as the mouthpiece for biotechnology in the State. It is key to the success of developing the biotech industry across the State as well as leading any potential regional effort. It is recommended that the TBA continue in its central role in State and regional endeavors and provide the long-term momentum in leading the biotechnology effort in Tennessee.

As observed, Tennessee has many "pieces of the puzzle" to advance the success of biotechnology. Oak Ridge National Laboratory as a user facility has been sited as underutilized by individuals and institutions across the State and region. Whether the research and scientific community as well as business and industry across the State and region are uninformed or do not understand the user facility concept, it is recommended that this be addressed.

The following sources were used in the preparation of this section of the report:
State Government Initiatives in Biotechnology 2001 - www.bio.org/tax/battelle.pdf
Information on biotechnology in Maryland was found on the North Carolina State University website under "Emerging Issues Forum – Biotechnology in Maryland - Remarks of Maryland Lt. Governor Kathleen Kennedy Townsend", February 12, 2002, North Carolina State University - www.ncsu.edu/ncsu/cont_ed/out_ex/emerging_issues/townsend.htm

Information on the Illinois State Pension Fund investments was found on the State of Illinois website under the "State of Illinois Executive Order Creating the Venture TECH Advisory Committee" - www.state.il.us/tech/technology/vtech/eorder.cfm

Information on the Pennsylvania State Pension Fund investments was found on the Andersen website under "A message from Mike Celano, Andersen partner in charge of the Philadelphia Life Sciences practice" - www.andersen.com/website.nsf/content/NorthAmericaUnitedStatesPhiladelphiaResourcesEmergingGrowth!OpenDocument

Information on the Texas State Pension Fund investments was found on the State of Texas website under the "Governor's Council on Science and Biotechnology Development Committee" - www.governor.state.tx.us/Biotech/committeecharges.htm

Information on the Tennessee State Pension Fund investments was found on The Oak Ridge Online website under the "Tennessee Loses $18 Million in Enron Collapse" article dated January 16, 2002 - www.oakridger.com/stories/011602/stt_0116020046.htm

Information on sales and use tax exemptions in Connecticut was found in Conn. Gen. Stat. Ann. § 12-412(89).

Information on sales and use tax credit in Oklahoma was found in the Oklahoma Research and Development Incentives Act, Ok. Stat. Anno. §§ 54001-54006.

Information on sales and use tax credit in Tennessee was found in the State of Tennessee Comprehensive Annual Financial Report for the Year Ended June 30, 2001 on the report entitled "State of Tennessee Comparative Schedules of Revenues by Source General Fund for the Fiscal Years Ended June 30, 2000 and 2001." - www.state.tn.us/finance/act/cafr02/cafr01.pdf

ETHICAL ISSUES

While the 20th century will go down in history as the century of physics fueled by the atom, the 21st century is being touted as the century of life sciences propelled by the "gene". The burgeoning field of biotechnology encompasses all technologies and research associated with the field of life sciences. While biotechnology clearly represents one of the most exciting, fastest growing and useful industries in the world today, it does not come unencumbered. Its very nature – the study of life – crosses the bounds of some of the most prominent ethical and moral issues of our day. These issues emanate from our definition of life, its sources, and the time scale relative to when life begins.

The Committee determined that the report of the task force on biotechnology needed to address ethical issues surrounding the development of biotechnology – issues which have become some of the most prominent and sensitive moral and ethical issues facing scientists, industrialists, governmental leaders, and the public. The Governor's Task Force prepared this Chapter on bioethics not to direct the Governor and other State leaders, but to apprise them of the critical issues facing the biotechnology industry and research community as well as the citizens of Tennessee.

These issues involve questions no less difficult than debate over when life begins or whether man, through genetic engineering, is recklessly upsetting the balance of nature.

Our objective is to provide a balanced view of these issues and articulate the concerns and passions of all sides.

While there are additional topics of discussion relative to bioethics, this section highlights several of the major issues as understood by the members of the Task Force to enable our Governor and legislators to better understand the science and the passion behind them. As the burgeoning science and industry of biotechnology grows within the State of Tennessee and the citizens of this State become more and more knowledgeable of, and sensitive to, bioethical issues, the Governor may consider formation of a bioethics advisory board to assist him or her in maintaining a critical balance between biotechnology and its exciting economic potentials and the ethical and moral sensitivities of the State's citizens.

For an update on bioethical issues, we recommend a website maintained by the US Department of Energy at the Oak Ridge National Laboratory. The URL for this site is http://www.ornl.gov/hgmis/elsi/elsi.html.

The following observations include discussions about stem cell research, cloning, privacy of medical records, using humans as primary research subjects and genetic engineering.

STEM CELL RESEARCH

Stem cells are the unique cell precursors capable of becoming one of the 220 cell types, such as skin, heart, muscle, bone and brain cells, that comprise the human body. Stem cells are "undifferentiated" because the type of cell they will become has not yet been determined. Moreover, stem cells are immortal in nature and can replicate over and over again without losing their biological properties. They represent a potential "fountain of youth" which medical researchers hope can be used to replace cells for patients with all kinds of degenerative diseases and disorders such as Type I diabetes, hepatitis, muscular dystrophy, Parkinson's disease and a host of cancers.

An important point relative to the ethics of stem cell research is the fact that there are three major types of stem cells – totipotent, pluripotent and multipotent. Totipotent stem cells can not only give rise to every cell and tissue type in the body, they also have the ability to develop into a fully functional organism or being. Pluripotent stem cells on the other hand may develop into almost any cell or tissue type, but cannot

develop into a functional being. Finally, multipotent stem cells can develop into many different tissues, but not all, and like pluripotent cells they are unable to divide into an independent organism. The differences between these stem cell types are paramount to understanding and appreciating the scientific, ethical and religious controversies surrounding stem cell research.

Use of stem cells for limited therapeutic purposes has been ongoing for quite some time. Oncologists have employed stem cells in bone marrow transplants in which these originating cells give rise to new blood cells within the bone marrow replacing cells destroyed in high-dose chemotherapy. Although stem cells have been used in this rudimentary fashion, recent breakthroughs in stem cell research are pointing the way to harvesting stem cells from human embryos for subsequent in-situ growth. It may be possible to control the differentiation of these cells (i.e. direct the type of cell they will become) so that they could be used for replacement of diseased or lost cardiac tissue, neural cells, skin, etc.

Pluripotent stem cells have been obtained in different ways. These are outlined below.

- **Embryonic Stem (ES) Cells - Cells emanating from human embryos are referred to as embryonic stem cells or simply ES cells. They have been isolated directly from the inner cell mass of human embryos. Once they are removed from an embryo they are no longer capable of producing a fully functional being, but they can develop into virtually any type of cell or tissue and are therefore pluripotent in nature and offer significant therapeutic potential. A normal embryo contains about 100 of these ES cells and they begin to differentiate into functional cells within 48-72 hours. Initially, they will form a circular ring or blastocyst that will act as the "scaffolding" for the developing embryo. Once one or more of these cells have been removed from the embryo, the embryo is no longer viable and cannot develop into a new life. Herein lies the ethical dilemma. While the harvested ES cell may prove valuable for research and therapeutic purposes, it has been contended, often by religious groups, that a life has been destroyed in the process. The crux of this issue revolves around the question: when does life begin? Is it at the point of conception, the point at which the embryonic cells begin to differentiate, or at a point in which the life can be self-sustaining (i.e. birth)? This question has always been highly controversial. The way the embryo is formed is also controversial. In many research studies, embryos were obtained from IVF (In Vitro Fertilization) clinics (which are themselves controversial) and were already scheduled to be destroyed because they were in excess of the clinical need for infertility treatment. These embryos were created for fertilization purposes. However, it is also possible to fertilize an egg specifically to harvest the stem cells.**

There are significant ethical questions involved:

- Does society have the right to extract or produce embryos for research or therapeutic purposes?
- Can society prohibit actions of this kind when they could eventually save large numbers of lives?

- **Embryonic Germ (EG) Cells - Pluripotent stem cells have also been isolated from fetal tissue obtained from terminated pregnancies. These embryonic germ cells (EG cells) are being studied by a number of research centers as possible substitutes for ES cells. The potential within EG cells is somewhat limited compared to the embryonic cells because the cells are derived from fetuses and are therefore much further along in development. They are frequently harvested after 5-9 weeks as opposed to 5 days or so for ES cells. Ethical issues and concerns with EG cells may even be greater than use of embryonic cells because they are generally harvested from aborted fetuses, even though this is done only after the donors independently decide to terminate their pregnancy.**

- **Somatic Cell Nuclear Transfer (SCNT) / Therapeutic Cloning - Another method of producing pluripotent stem cells was recently demonstrated by Advanced Cell Technology, a biotechnology company based in Massachusetts. Using a technique called Somatic Cell Nuclear Transfer (SCNT), the nucleus is removed from an egg cell. The material left behind in the egg cell contains nutrients**

and other energy-producing materials that are essential for embryo development. A somatic cell (any cell other than an egg or a sperm cell) is then fused to the egg. The resulting fused cell, and its immediate descendants, are believed to be totipotent. These cells will soon form a blastocyst and cells from the inner portion of this blastocyst can be used to develop pluripotent stem cell lines. Indeed, any method by which a human blastocyst is formed could potentially serve as a source of human pluripotent stem cells. By using SCNT, scientists hope to understand how the protein factors in the egg cell cause these already specialized somatic cells to become stem cells. Once scientists learn how this cell "de-differentiation" occurs, they will no longer need to use egg cells. SCNT is highly controversial because it forms a fertilized cell that could perhaps develop into a fetus. For this reason, it has been called "therapeutic cloning". In January of 2002, the National Academy of Sciences called for a legal ban against reproductive cloning but said that therapeutic cloning (SCNT) should be allowed to continue.

- **The least controversial stem cell type is the adult stem cell, which is found within fully developed tissue. Although these cells are used to repair and replace degenerated or damaged tissue, they are multipotent and can only differentiate into limited cell or tissue types. Nevertheless, research with adult stem cells is advancing, and now includes bone marrow cells, mesenchymal adult cells involved in bone and cartilage regeneration, and adult neural stem cells. Researchers have found that new cells are generated throughout the central nervous system (CNS) well into adulthood in all mammals, including humans. Research continues as to the efficacy of harvesting and using these cell types for therapeutic purposes. However it is important to note that many cells of medical interest cannot yet be obtained from adult derived cells and production of large numbers remains more difficult at this point in time. While research into adult stem cells is valuable, only ES cells have been proven to be pluripotent (able to form any cell in the body) and immortal (capable of replication without losing their biological properties). This conclusion was reached by the NIH last year and was recently supported by studies published in Nature in March, 2002.**

Cloning

The term "cloning" can be defined in two ways. The first, and most obvious, is reproductive cloning in which a new duplicate life form is produced. The second type of cloning is therapeutic cloning in which specific cell types, genes or tissues are reproduced for use in new medicines, diagnostics, and vaccines to treat many diseases. Therapeutic cloning technology could also be used in replacing skin, cartilage and bone tissue for burn victims, and potentially to regenerate retinal and spinal cord tissue. Cloning these tissues from a patient's own cells would eliminate problems caused by the body's immune response system. When foreign cells, including donated organs, tissues or blood, are transplanted or transfused, the recipient's body mounts a rejection response, attacking these cells. If a patient's own cells were the source of stem cells used to create therapeutic cells or tissues, it is believed that immunological rejection would be avoided since the cells and tissues would genetically match his or her own. Therapeutic cloning could allow an individual's own cells to be used to treat or cure that person's disease, without risk of introducing foreign cells that may be rejected.

Most researchers recognize the inherent risks and moral dilemmas associated with reproductive cloning of humans and practically all major medical research groups and organizations in the US have said that reproductive cloning should not be allowed at this time. Yet it is important to acknowledge the fact that some ambitious entrepreneurs and rogue scientists are aggressively pursuing such cloning and the technologies required to successfully clone humans are under development and not that far away.

In February 2002 a report from the National Academy of Science concluded that while human reproductive cloning is unsafe and should be banned; therapeutic cloning, "because of its considerable potential for developing new medical therapies for life-threatening diseases", should continue. Again, in scientific circles

therapeutic cloning is referred to as somatic cell nuclear transfer (SCNT) and has been regarded as one method of producing pluripotent stem cells. While therapeutic cloning offers exciting potential, certain groups and religious organizations take exception to the artificial "production" of life for use in the generation of replacement cells or parts. Again, in producing this chapter on bioethics, the Governor's Task Force is not recommending a stance on one side of these issues or the other, but simply apprising our State leaders of the issues at hand.

Privacy Issues / Medical Records Confidentiality

Given the fact that the future of medicine may lie in the genome, research on human genomes and the differences between those who have a propensity for certain diseases and those whose DNA may suppress these same diseases is exploding worldwide. Gene tests (DNA tests) are already available for a number of diseases and conditions such as amyotrophic lateral sclerosis (ALS; Lou Gehrig's Disease), Alzheimer's disease, inherited breast and ovarian cancer, hereditary nonpolyposis colon cancer, cystic fibrosis, certain forms of muscular dystrophy, hemophilia A and B, Huntington's disease, adult polycystic kidney disease, sickle cell disease, spinal muscular atrophy, and Tay-Sachs disease. Clearly, for development of future tests, it is useful to not only determine an individual's genetic information but also to correlate that information with his or her medical records. Acquisition of tissue or cell samples coincident with the donor's medical records is therefore becoming a burgeoning business. With both the genotype (DNA) and phenotype (clinical diagnosis or prognosis) in hand, researchers can analyze things such as single nucleotide polymorphisms (SNPs) and begin to better understand disease etiology and why diseases are expressed in some, but not in others. However, the inherent risks to the release of records as an individual's private property are obvious relative to his/her ability to obtain insurance, their employability, and a number of other issues. Less obvious, but also potentially as important, is the impact of a person's genetic information on the same issues for his or her offspring, siblings, parents or other direct relatives.

The United States Congress has enacted legislation pertaining to patient's rights and medical record confidentiality. Legislation promulgated in 2001 by the U.S. Department of Health and Human Services is supported by the Biotechnology Industry Organization (BIO) as well as other research and industry groups. However, many states have also taken an active interest in protecting the privacy of medical patients. During the 2000 state legislative session, 26 states debated laws concerning privacy. This turbulent environment may slow research efforts as legislatures struggle to balance an individual's right to confidentiality with the need to facilitate research on genetic differences.

Human Research Subjects

There is no question that volunteers participating in clinical research trials deserve the utmost protection and respect. For this reason, medical research with human subjects is a heavily regulated activity - research protocols are reviewed and scrutinized by Institutional Review Boards (IRBs) under an extensive set of federal regulations governing research (the federal Common Rule). BIO points out several flaws in existing regulations. These include:

- Patients are protected by IRB review and federal informed consent requirements only in research conducted where there is federal funding or where the sponsor is engaging in regulated research (e.g., FDA approval is required).
- Research using medical records or archives is subject to review using the same criteria as clinical research rather than review that is appropriate to the different character of the risks to data subjects.
- There are multiple overlapping layers of review for sponsors of every clinical protocol: FDA regulations require the sponsor to obtain review by an IRB; and each investigator affiliated with academic institution must have its IRB separately review and approve every aspect of the research protocol under federal regulations that apply to institutions that receive federal grant money.
- For multi-center clinical trials, differing state laws govern the form of review and format of additional documentation of consent required in each state. For example, new state laws

pertaining to genetic analysis are quite restrictive, requiring additional separate consents and imposing requirements regarding the use and retention of tissue and blood samples that sometimes are inconsistent with FDA requirements.

These issues point out the need for balance between protecting volunteers in clinical trials and allowing research to progress so that new medical advances can save lives and improve the quality of life for future patients.

Genetically Modified Organisms and Genetically Modified Food

Combining genes from different organisms is known as recombinant DNA technology. The resulting organism is said to be "genetically modified (GM)," "genetically engineered," or "transgenic". In some respects, man has been genetically modifying plants and animals for centuries by selective breeding. Biotechnology now offers new tools, and even allows the transfer of genes between different species. The US Department of Energy's Human Genome Project reports that GM crops are grown commercially or in field trials in over 40 countries on 6 continents. Among the benefits of genetic modification of plants are enhanced disease resistance, increased vitamin content, improved taste, tolerance to weather extremes, and greater yield at a faster rate. GM animals can show increased resistance to disease, productivity, hardiness, and feed efficiency. Plants and animals can also be genetically modified to produce pharmaceuticals or other products.

However, GM foods are controversial. One of the biggest issues is safety. Controlled experiments indicated that pollen from corn that was genetically modified to produce a pesticide called Bacillus thuringiensis (Bt), killed some larvae of the monarch butterfly. But others dispute there is a significant safety issue. A January, 2001 report from the American Medical Association indicated that harmful effects from GM plants containing Bt have not been observed in the field and concluded that bioengineered foods are "substantially equivalent" to their conventional counterparts.

Another major issue regarding the production of GM food is labeling. Does the consumer have a right to know that food they are purchasing has been genetically modified? Consumer rights advocates want all GM food to be clearly labeled as such, but the food industry claims that labeling would be equal to a ban because grocery stores and markets, to appease a vocal minority of customers, would simply remove all GM labeled food from their shelves. Additional labeling problems are caused by intentional or accidental mixing of GM and non-GM foods.

Other issues related to GM food include:

- increasing dependence on industrialized nations by developing countries;
- biopiracy—foreign exploitation of natural resources;
- violation of natural organisms' intrinsic values;
- tampering with nature by mixing genes among species;
- objections to consuming animal genes in plants and vice versa;
- mixing GM crops with non-GM confounds labeling attempts;
- new advances may be skewed to interests of rich countries; and
- confusion relating to food allergies should a component of a food product that causes allergies be engineered into a different food.

SUMMARY AND RECOMMENDATION

In summary, a number of bioethical issues confront any state that seeks to develop a biotechnology industry. As is evident from the continued success of California, North Carolina, and other states, issues surrounding the ethics of the industry can be managed effectively with a measure of preparation and with the development of clear guidelines from the inception.

APPENDIX A

MEMBERSHIP OF SUBCOMMITTEES

Regionalism Issues

Dr. Bob Acuff	ETSU - East Tennessee State University	Co-Chair
Bob Morris	Butler Snow Attorneys	Co-Chair
Bob Bean	Transnetyx	
Tom Bell	Accredo Health Care	
Dr. Alice Clark	University of MS Med Center	
Roger Clark	N. MS Industrial Assn.	
Charles Cook	Arkansas Bioventures	
Richard S. Copeland	TN Tech. Dev. Corp.	
John Crisp	Akins-Crisp Strategies	
Wayne Culbreth	Global Associates	
Dr. David Dzielak	University of MS Med Center	
Dr. Angie Dvorak	MS Technology Alliance	
Terry Edwards	Greystone	
Cathy Elliott	Memphis Chamber	
Matthew Gallivan	Nashville Health Care Council	
Bill Gillon	Butler, Snow Attorneys	
Johnny Healy	Butler Snow Attorneys	
Mike Philpot	West TN Industrial Assn.	
Chuck Shoopman	Tennessee Valley Authority	
Thomas Stovall	HealthyMe MD	
Andy Taggart	Legal and Strategic Counsel	
Michael Thompson	Delta State University	
Cary Vaughn	SCB Computer Tech.	
Dan Walker	Thompson Dunavant	
Lewis Weiss	SCB Computer Tech.	

Commercialization Issues

Dr. Steve Bares	Memphis Biotech Foundation	Chair
Dr. David Altman	VDDI Pharmaceuticals	
Dr. Germain Boer	Vanderbilt University	
Dr. Walt Chambliss	University of MS	
Kelly Durham	TN Tech. Dev. Corp.	
Dr. Bill Evans	St. Jude Hospital	
Dr. James Green	Cumberland Engineering Technologies	
Dr. Jan Haerer	UT-Battelle./ORNL	
Dr. Lee Harness	Consilience Group	
Kim Jenkins	Morgan Keegan	
Paul Ketchel	E.P. Griffin Int'l.	
Dr. Lee Limbird	Vanderbilt University Medical Center	
Chris McKinney	Vanderbilt University	
Dr. Timothy O'Brien	University of Arkansas	
Robert Palmer	UT Research Corp.	
Glenn Perdue	S3 Digital	
Joan Stadler	University New Media	
Dr. Rob Zimmer	Apocom Genomics	

Education Issues

Dr. C.A. Speer	UT College of Agricultural Science & Natural Resources	Chair
Dr. Steve Bares	Memphis Biotech Foundation	
Dr. Jerry C. Collins	Vanderbilt University	
Dr. Mike Dockter	UT-Center for Health Sciences	
Dr. Bill Evans	St. Jude Children's Research Hospital	
Bill Gillon	Butler, Snow Attorneys	
Dr. Jan Haerer	Topaz Consulting	
Lee Harness	Consilience Group	
Dr. James Hill	Vanderbilt University	
Edward Kraft	Arnold Engineering Dev. Center	
Dr. Lee Limbird	Vanderbilt University Medical Center	
Cynthia McClard	Consultants, Inc.	
Michael Magill	State of Tennessee	
Hunter Rost	Waller, Lansden, Dortch & Davis Attorneys	
Harlan Scott	Nashville State Tech	
Dr. Robert Trigiano	UT-Knoxville	
Anna Scott Thorsen	Waller, Lansden, Dortch & Davis Attorneys	
Dr. Jim Willis	Southwest TN Comm. College	

Economic Development Issues

Dexter Muller	Memphis Regional Chamber of Commerce	Chair
Dr. David Altman	VDDI Pharmaceuticals	
Jim Anderson	State of Tennessee	
John Autian	A. Zaker Associates	
John Bradley	Memphis Regional Chamber	
Jim Campbell	East TN Econ. Council	
Richard S. Copeland	Tennessee Technology Development Corporation	
Kim Denton	Oak Ridge Chamber	
Cathy Elliott	Memphis Regional Chamber of Commerce	
Joe Guthrie	Southeast Development	
Susan Hadley	TN Dept. of Econ. & Community Dev. (formerly)	
Drew Kim	TN Tech. Dev. Corp. (formerly)	
Mike Montgomery	Tennessee Valley Authority	
Allen Neel	East TN Economic Dev.	
Bill Shuff	Middle TN Industrial Dev	

Legislative Issues

Dennis Grimaud	Tennessee Biotechnology Association	Co-Chair
Jim McElroy	Attorney	Co-Chair
Dr. Bob Acuff	East TN State Univ.	
Jason Epstein	Baker, Donelson, Bearman & Caldwell, Attorneys	
Matthew Gallivan	Nashville Health Care Council	
Joe Gregory	King Pharmaceuticals	
Susan Hadley	TN Dept. of Economic & Community Dev. (formerly)	
Tom Rogers	TN Technology Dev. Corp.	
Tom Whitaker	Atom Sciences Inc-TBA	

APPENDIX B

BIO-SCIENCE COMPANIES

Biotechnology Companies in Middle Tennessee

(Includes select academic institutions, biotechnology firms, clinical labs, medical product and device companies, technology firms, and other resources) Updated 3.27.02

Aegis Analytical Laboratories, Inc. David L. Black, Ph.D. - Chairman & President www.aegislabs.com	Forensic laboratory focusing exclusively on drug and chemical analysis.
Biocon Associates, Inc. Claudia Hitchcock - CEO	Specializes in providing temporary senior management for biotechnology and bio pharma companies, particularly early-stage ventures, through team and individual assignments.
BioMimetic Pharmaceuticals, Inc. Samuel E. Lynch, DMD - Chairman & CEO www.biomimetics.com	Focused on the development and marketing of biopharmaceutical products. The company's lead products, currently in clinical trials, are for the treatment of bone defects.
BioVentures, Inc. www.bioventures.com	Genetic discovery tools and products.
CarboMed, Inc. John G. Watson - President & CEO	Biotech development of therapies to treat cancer, spinal cord injury, and inflammatory diseases.
Celeris Corporation Barbara A. Cannon - President & CEO www.celeriscorp.com	Provides specialty clinical research services to pharmaceutical, biotechnology, and device clients to accelerate and maintain market approval.
Covance Clinical Development Services Ramesh Amatya, Ph.D. - Director, Statistics www.covance.com	One of the world's largest and most comprehensive drug development services companies.
Cumberland Emerging Technologies, Inc. James S. Green, Ph.D. - Vice President & General Manager www.cet-fund.com	Biomedical company formed to help commercialize technologies and products conceived at Vanderbilt University and other regional laboratories.
Cumberland Pharmaceuticals Inc. A.J. Kazimi - President & CEO www.cumberlandpharma.com	Pharmaceutical firm focused on acquisition and marketing a portfolio of niche prescription products to specific physician segments.
EBM Solutions Paul H. Keckley, Ph.D. - President & CEO www.ebmsolutions.com	Clinical decision support company providing evidence-based guidelines and data collection tools overseen by six leading academic medical centers in the U.S.
Esoterix Oncology, Inc. Gary Kitos - Vice President & General Manager www.esoterix.com	Uses advanced technology and medical expertise to offer fully integrated oncology testing.
EyeVU	Develops and markets the world's first biochemical contact lens (BCL). A VUTC portfolio company.

GeneRx+, Inc. Kenneth Brigham, M.D. - President & CEO www.generxplus.com	Develops therapeutic agents for treatment of diseases of the respiratory tract. These novel products are based on pairing of proteins or nucleic acids with novel lipid delivery formulations and novel delivery choices.
Genetic Assays, Inc. Eric B. Dahlhauser - Chairman & CEO www.geneticassays.com	Gene level diagnostics laboratory which performs highly specialized DNA testing and is conducting R&D involving a novel genetic mutation platform technology.
Genetics Associates, Inc. Joe Rolwing - CEO www.geneticsassociates.com	Cytogenetic analysis for prenatal and postnatal abnormalities and cancer diagnosis.
GenHunter Corporation Peng Liang - President, Founder	Exclusive licensee for the manufacturing /marketing of differential display reagent business.
ICON Clinical Research Bill Taaffe - President & CEO www.icon-icr.com	Global clinical research management organization dedicated to providing the pharmaceutical and biotech industries with exceptional product development services.
IPR Consulting, Inc. David Altman - Principal	Consulting services for biotechnology start-ups, focused on financial and intellectual property senior management.
MDS Laboratory Services, Inc. Robin Walsh - Sr. VP Hospital & Physician Markets www.mdsintl.com	Establishes partnerships with regional, multi-hospital systems to create regional integrated laboratory networks that reduce hospital operating costs and create new revenue streams.
Meharry Medical College Dr. John E. Maupin, Jr. - President www.mmc.edu	Largest private, historically black academic health center located in Nashville. Leading educator of African American physicians and dentists and biomedical scientists.
Meretek Diagnostics, Inc. John Heinrich - President & COO www.meretek.com	Specialized medical device and laboratory analysis for the Meretek UBT Breath Test Collection Kit for diagnosis of Helicobacter pylori bacteria.
Microarrays, Inc. www.microarrays.com	Formed in response to demand within the pharmaceutical/biotechnology sectors for products and services related to production of microarrays (DNA chips). A VUTC portfolio company.
Micro Diagnostics, Inc. Jeff McCormack, Ph.D. - Senior Lab Director www.lifecodes.com	A Lifecodes company with a mission to provide accurate identity testing, prompt turnaround of reports, total attention to clients seeking a personal yet highly professional genetic identification lab and testing.
Micro International/Nova Bionics, Inc. Robert V. Allen - CEO www.novabionics.com, www.microlid.com	Develops and commercializes implantable micro-component and portable devices for animal research, human monitoring, and wildlife tracking.

MXISystems, Inc. Howard Motter - Chief Executive Officer www.mxisystems.com	Developer of a new generation of lasers and imaging systems for use in medicine and the biological, chemical and material sciences. A VUTC portfolio company.
Nashville Health Care Council Matthew S. Gallivan - President www.healthcarecouncil.com	Association of health care industry leaders working together to further establish Nashville's position as the nation's health care industry capital. Key economic development initiatives include fostering the biotechnology industry.
Protherics Plc Andrew J. Heath, M.D., Ph.D. - CEO www.protherics.com	International biopharmaceutical company that has two platform technologies, the development and production of immunotherapeutics and computer-aided material design.
Rare Disease Therapeutics, Inc. Milton H. Ellis - President www.raretx.com	Develops and markets pharmaceuticals for orphan diseases.
RyMed Technologies, Inc. Dana Wm. Ryan - President & CEO	"Needle-free" injection port technologies for intravenous fluid therapies.
Tennessee Biotechnology Association Dennis Grimaud - Chairman www.tnbio.org	State association that fosters, develops, and supports biotechnology industry in Tennessee.
TheraTech Ventures	A wholly owned subsidiary of Heritage Group, LLC that seeks to partner with physicians in the ownership of outpatient-based ventures providing innovative therapeutic technologies.
Titan Corporation David Riling	A bioinformatics company, a division of Titan Systems Corporation's Communications Engineering Group.
TransCell Therapeutics	Develops and commercializes a new technology that renders bioactive peptides, proteins, and other therapeutics cell-permeable. A VUTC portfolio company.
Vanderbilt University Technology Company (VUTC) Mick Stadler - President & CEO www.vutc.net	VUTC manages the Chancellor Fund, a venture capital fund organized by Vanderbilt University and capitalized from its endowment.
Vanderbilt University Medical Center Harry R. Jacobson, M.D. - Vice Chancellor for Health Affairs www.mc.vanderbilt.edu	Health care provider, educational institution, and center for biomedical research.
Virtual Drug Development, Inc. (VDDI) R. Stephen Porter, PharmD, FCP, MRCP - President & CEO www.virtualdrugdevelopment.com	Biotechnology firm that licenses attractive product development opportunities from academic institutions, biotech firms, and pharmaceutical companies.
Vanderbilt University, Office of Technology Transfer Christopher D. McKinney - Director	Provides a mechanism through which intellectual property developed at Vanderbilt University is protected and promoted. Brings technology forward to public use and for the benefit of the inventor, the University, and the community.

MEMPHIS METRO AREA

Manufacturing

Orthopedics:
Smith & Nephew Richards
Medtronic Sofamor Danek
Wright Medical Technology
CFI Prosthetics and Orthotics

Pharmaceuticals:
Viral Antigens (with GMP facility)
Edge Biologicals
Block Drug Company
United Labs
Smith, Kline, Beecham Animal Health

Ophthalmic Products:
Cole Vision Corp.
Precision Optical Laboratories
Contact Lens Corporation of America
EagleVision
Premier Contact Lens
Odyssey Medical

Medical Supplies:
Crews, Inc.
Vollrath
United Medical Inc.

Logistics

Pharmaceuticals:
Baxter Healthcare Corp.
Pfizer Logistics Center
McKesson
Glaxo-Wellcome
Schering-Plough Health Care Products
Nova Factor Biotech Pharmacy Services
Faulding
Accredo Health
(Parent of Nova Factor & other companies)
DDN Pharmaceutical Logistics

Medical Equipment/Supplies:
GE Medical Systems
Siemens Medical Systems
Boston Scientific Corp.
Philips Medical Systems
Stuart Drug & Surgical Supply

Medical Devices:
Gyrus ENT

Laboratories and R & D (Private)

Genotherapeutics (GTx)
Cell Therapeutic Incorporated
Micro Dexterity Systems
Genome Explorations
Sure-Test Laboratories
Cell Genesys

Research Institutions

St. Jude Children's Research Hospital
Medical Education & Research Institute (MERI)

Biotech Industry Development

Memphis Biotech Foundation

APPENDIX C

USE OF TOBACCO FUNDS BY STATES, SUMMARY

The following discussion was taken from the BIO report on State initiatives, see http://www.bio.org/tax/battelle.pdf

Use of Tobacco Settlement Funds for Bioscience-Related Research and Development

A recent study by the National Conference of Sate Legislatures showed that 15 states have passed budgets and/or enabled legislation to use some portion of their tobacco settlements for bio-science-related efforts. In addition, in Missouri, the governor has signed an executive order to spend $22 million of its tobacco settlement for bioscience-related research next year.

The 16 states that have appropriated funds for biotechnology research have done so in many different ways. Michigan, the first state to dedicate tobacco settlement funds for bioscience research, has allocated $50 million a year of a 20-year period for an effort called the Michigan *Life Sciences Corridor*. Of this $50 million, 40 percent will be used to fund basic research at four Michigan research institutions, 50 percent will be used to fund collaborative university/industry research projects aimed at developing commercial products and processes, and 10 percent will be used for commercialization activities aimed at bringing products to market. Ohio created a bio-medical research and technology transfer trust fund and allocated 2.7 percent of its first year settlement dollars to it. The allocation will increase to 13 to 14 percent for the following three years. This means that the research fund will be funded at $4.4 million initially and will increase to as much as $24.3 million a year over the first four years. Other states that have appropriated or dedicated tobacco settlement funds to biomedical or tobacco-related research include Colorado, Connecticut, Illinois, Kansas, Louisiana, Massachusetts, Maryland, Minnesota, Missouri, New Jersey, New Mexico, Pennsylvania, Utah, and Wisconsin.

Interesting aspects of states' use of tobacco settlement funds for bioscience-related efforts include the following:

- **The participation of federal laboratories and non-profit research institutions in addition to universities. Illinois is not only funding research at five universities, but is involving two of its DOE federal laboratories – Fermi and Argonne – as funding recipients.**

- **Strong focus on tobacco-related research. Several states have limited the research effort to control or use of tobacco (Massachusetts) or research focused on tobacco-related illnesses (Colorado, Connecticut, Maryland, and New Mexico).**

- **Lack of emphasis on commercialization. Only three states have explicitly targeted some or the funding for technology transfer and commercialization. Michigan has directed that 10 percent of the funding for the Life Sciences Corridor be used for commercialization. Ohio is also requiring that funds be used for commercializing research findings. Pennsylvania is using $100 million from the state's tobacco settlement to establish Life Sciences Greenhouses in three regions of the state. Pennsylvania is also using a portion of the tobacco settlement funds to invest in several privately managed life sciences venture funds and for basic research.**

APPENDIX D

RESEARCH PARKS BY STATES

The following discussion was taken from the BIO report on State initiatives, see http://www.bio.org/tax/battelle.pdf

Increased Interest in Research Parks and Incubators throughout the United States

As industrial parks manifested the increase in manufacturing in post-World War II America, so technology research parks, with or without incubator facilities, are emerging phenomenon across the nation. Research parks are being built near medical centers and teaching hospitals and generally are offering incubator space. A few also offer multi-tenant/accelerator space.

While 26 states reported research parks that can or do house bioscience companies, only nine states reported research parks focused exclusively on bioscience companies (although a number of initiatives to develop bioscience parks are in the planning stages). These nine states' research parks are summarized in Table 5. Some of the bioscience research parks identified have been publicly supported; others are private operations. Fifteen states reported bioscience incubators, and another 19 states reported technology incubators that include wet lab space for bioscience companies as well as space of other technology companies, often information technology companies. Bioscience incubators are summarized in Table 6.

Table 5: Bioscience Research Parks

State	Research Park
Colorado	Colorado Bioscience Park Aurora (under development)
Connecticut	300 George Street Hamden BioScience Campus
Maryland	The Shady Grove Life Sciences Center
Massachusetts	Massachusetts Biotechnology Research Park Bio-Square University Park at MIT One Kendall Square, Cambridge Cambridge Center, Cambridge Charlestown Navy Yard, Boston Longwood Medical Area, Boston Kendall Square Project (Cambridge Research Park)
New Jersey	Technology Centre of New Jersey
New York	Audubon Biomedical Science and Technology Park
Oklahoma	Oklahoma Health Research Park
Tennessee	Med Tech Research Park
Virginia	Virginia Biotechnology Park Virginia Biotechnology Park at Meadowville

Examples of publicly sponsored bioscience research parks and incubators include the following:

Table 6: Bioscience Incubators

State	Incubator
Alabama	Office for the Advancement of Developing Industries
Arkansas	Arkansas Bioventures
Colorado	Bioscience Park Center
Florida	Sid Martin Biotechnology Institute
Georgia	The Center for Applied Genetics Technology (AGTEC) Em Tech Biotechnology Development, Inc. CollabTech at Georgia State University
Maine	Thomas M. Teague Biotechnology Park
Maryland	The AlphaCenter; owned by Johns Hopkins University and the Hopkins Health System Association for Entrepreneurial Science Bard Laboratories, Baltimore City Community Colleges The Medical Biotechnology Center, UMBI The Technology Development Center in Montgomery County, operated by the Maryland High Technology Council Technology Enterprise Center, UMBC Commercial/Wet Lab Office Building
Massachusetts	MBIdeas Innovation Centers
Michigan	The Michigan Biotechnology Institute International/Biobusiness Incubator
Minnesota	Biodale
Ohio	BioEnterprise BIO/START
Oregon	Portland Biotechnology Center (PBC)
Tennessee	The University of Tennessee Environmental Biotechnology Center
Texas	TEKSA Innovations
Virginia	City of Norfolk Biotechnology Incubator

- The **Office for the Advancement of Developing Industries (OADI) at the University of Alabama at Birmingham (UAB)**. OADI, an incubator facility with 20,000 square feet of laboratory space of the bioscience companies, currently houses 26 tenants. It is located in the UAB Research Park at Oxmoor.

- **Maryland's Shady Grove Life Sciences Center** houses, in addition to corporate tenants, the University of Maryland Biotechnology Institute's Center for Applied Research in Biotechnology, a University of Maryland teaching facility, a Johns Hopkins University campus, and an incubator.

- **A 160-acre Colorado Bioscience Park Aurora** is under development at the former site of the Fitzsimmons Army Medical Center. Located in the park is the Bioscience Park Center, a 60,000-square-foot facility designed to house start-up bioscience companies. The Center opened in 2000.

- **Massachusetts Biotechnology Research Park**, created in 1985, currently includes about 1 million square feet of building space on 105 acres. It is home to more than a dozen biotechnology companies and also includes several non-profit and academic institutions. It houses an MBIdeas Innovation Center that offers fully equipped wet lab space; use of existing permits; and business assistance, consulting, and mentoring to start-up biotechnology and bio-medical companies.

APPENDIX E

ECONOMIC DEVELOPMENT INCENTIVES BY STATE

The national trade association, BIO, has excellent resources at its website concerning state investments in biotechnology development. For this information, we suggest the following URLs:

- www.bio.org
- www.bio.org/tax/battelle.pdf
- www.bio.org/govt/survey.html