HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1585 Biomedical Research and Training
SPONSOR(S): Johnson and others
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 2748 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care	22 Y, 1 N	Rawlins	Collins
2) State Administration			
3) Appropriations			
4)			
5)			

SUMMARY ANALYSIS

According to a recent study by the Brookings Institution [Signs of Life: The Growth of Biotechnology Centers in the U.S., by Joseph Cortright and Heike Mayer, 2002], the biotechnology industry is currently concentrated within nine of the nation's largest metropolitan areas (Boston, San Francisco, San Diego, Raleigh-Durham, Seattle, New York, Philadelphia, Los Angeles, and Washington-Baltimore). These areas account for more than three-fifths of all National Institute of Health (NIH) spending on research and about two-thirds of all biotechnology-related patents.

According to the Brookings report, Jacksonville, Orlando, and West Palm Beach are classified as having no significant biotech research or commercialization. None of these areas have a major medical school or other medical research institution and receive little if any NIH funding.

The nine areas which are leaders in biotechnology possess two necessary elements for growth: strong research capacity; and the ability to convert research into successful commercial activity.

This bill creates the Center for Excellence in Biomedical Training and Investigation that is established upon designation by the Board of Governors of the State University System of the institution responsible for operating the center. The center shall be designated by the Board of Governors no later than September 1, 2004.

The bill requires the Board of Governors to designate the institution responsible for operating the center based on the following criteria:

- ✓ The institution must be a public university.
- ✓ The institution must include colleges of medicine, dentistry, pharmacy, and veterinary medicine.
- ✓ The institution must be accredited by the appropriate accrediting bodies.
- ✓ The institution must be authorized to confer earned M.D., Ph.D., D.M.D., D.V.M., and Pharm.D. degrees.
- ✓ The institution must be able to raise up to $10 million in private funding to match $10 million in state revenue.

The University of Florida is the largest research facility in the Southeast. The University of Miami, School of Medicine's medical center is ranked fifth in the nation in sponsored research. The University of Florida is ranked 19th in the receipt of biomedical research and development funding. *Technology Transfer Business Magazine* has ranked both universities in the top 25 that have licenses linked to new research funding.

The bill includes a $10 million appropriation out of nonrecurring general revenue to the Center for Excellence in Biomedical Training and Investigation.

The bill provides for an effective date of July 1, 2004.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[]	N/A[x]
2. Lower taxes?	Yes[]	No[]	N/A[x]
3. Expand individual freedom?	Yes[x]	No[]	N/A[]
4. Increase personal responsibility?	Yes[x]	No[]	N/A[]
5. Empower families?	Yes[x]	No[]	N/A[]

For any principle that received a “no” above, please explain:

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Background on Biotechnology Centers

According to a recent study by the Brookings Institution [Signs of Life: The Growth of Biotechnology Centers in the U.S., by Joseph Cortright and Heike Mayer, 2002], the biotechnology industry is currently concentrated within nine of the nation’s largest metropolitan areas (Boston, San Francisco, San Diego, Raleigh-Durham, Seattle, New York, Philadelphia, Los Angeles, and Washington-Baltimore). These areas account for more than three-fifths of all National Institute of Health (NIH) spending on research and about two-thirds of all biotechnology-related patents.

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Florida is the nation's fourth largest populated state and is third in consumption of pharmaceutical products. The Florida health and biotechnology industry encompasses all entities operating in the state whose business activities involve life science, including medical research and discovery, device and pharmaceutical manufacturing, education, service, and the manufacture and sale of related products.

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Florida is poised for growth in the biomedical industry because of its growing pool of scientific, technical and management labor. In addition, as the "Gateway to Latin America," Florida is well positioned to serve international markets. As mentioned above, a main component for a strong biomedical industry is the presence of either a major medical school or a medical research institution.

Coordination of Biomedical Research

Biomedical research contributes ultimately to the health of a population, and biomedical discoveries and the resultant products or treatments contribute to the economy of the area where they are produced. For both health and economic reasons, governments have an interest in furthering the work of biomedical researchers and in helping researchers collaborate and share resources. A number of states have initiatives to coordinate cancer research. Some state governments, as well as private

foundations and companies, are addressing the needs of researchers who are conducting stem cell research.

Stem Cell Research

Stem cells are cells that have the ability to divide for infinite periods in culture. They give rise to specialized cells. Research involving stem cells shows the possibility of treating diseases and conditions such as Alzheimer's and Parkinson's diseases, spinal cord injury, stroke, burns, heart disease, and arthritis. The possibility that an organ could be grown from stem cells has implications for tremendous changes in organ transplants.

A significant debate about stem cells involves the source of the cells. Human stem cells can be harvested from human embryos (embryonic stem cells) or from the tissue of an adult (adult stem cells). Human embryos are the source for pluripotent stem cells—cells that are capable of giving rise to most tissues of the human organism. The development of embryos for the sole purpose of harvesting the stem cells is considered immoral by many because the embryo is killed. In August 2001, President Bush announced that he would allow federal funding of research using the 60 existing stem cell lines. Thus, federal funds will not pay for stem cell research that involves the destruction of human embryos.

In November 2001, President George W. Bush created The President's Council on Bioethics "to advise the president on issues that may emerge as a consequence of advances in biomedical science and technology" (Executive Order 13237). In particular, the council was authorized to study ethical issues connected with specific technological activities such as embryo and stem cell research. After studying the issue of human cloning, the majority, ten members of the council, voted to ban cloning for the production of children and to place a 4-year moratorium on cloning for biomedical research. The minority, seven members, voted to ban cloning for the production of children and to regulate the use of cloned embryos for research.

The Emerging Technology Commission

Under s. 240.72, F.S., the "Florida Technology Development Act," the Emerging Technology Commission is a commission created within the Governor's Office for the purpose of guiding the establishment of centers of excellence within, and in collaboration with Florida's universities.

ITFlorida and The Florida Research Consortium

ITFlorida is a private umbrella organization comprised of both public and private technology leaders for high-tech in Florida. ITFlorida's stated mission is to make Florida a leader in high tech advancement, providing guidance to the state on technology issues and initiatives, guiding the Governor, the Legislature and Enterprise Florida on the strategic technology direction and initiatives of the state and working to ensure the successful integration of technology infrastructure statewide.

The Florida Research Consortium, an affiliated entity of ITFlorida, is governed by a board of high-tech industry leaders and university heads whose mission is to advise the Legislature and Office of the Governor on strategic policy initiatives for expanding and strengthening Florida's high-tech industries. The consortium aims to identify specific disciplines in science and technology where Florida has the greatest potential to achieve economic and academic successes –and to promote collaboration between academic and industrial researchers, scientists and engineers.

Enterprise Florida, Inc.

Enterprise Florida, Inc., created under part VII of ch. 288, F.S., is a partnership between Florida's business and government leaders and is the principle economic development organization for the State of Florida. The organization's mission is to increase economic opportunities for all Floridians by

supporting the creation of quality jobs, a well-trained workforce and globally competitive businesses. It pursues its mission in cooperation with its statewide network of economic development partners.

BioFlorida

BioFlorida's mission is to promote biotechnology and related science in Florida by creating a favorable business and legislative environment; to provide the platform for business, academia and government to work jointly to support and encourage development of existing companies in the state and to attract new business and organizations to Florida.

BioFlorida's Goals:

- ✓ To provide an infrastructure for companies and others to exchange information and ideas.
- ✓ To provide education and other programs to assist biotechnology companies.
- ✓ To attract financial resources for BioFlorida members.
- ✓ To promote interaction between BioFlorida members and the research community, both private and governmental.
- ✓ To advocate legislative action at the state and federal level which is in the best interest of BioFlorida members.

BioFlorida's Key Strategies include:

- ✓ **Training and education**: Establish symposia (Executive Briefing Series) to initiate transfer of technology, understanding of research and manufacturing issues, and identify other methods for developing mutual understanding and support of biotechnology matters.
- ✓ **Financial resources**: Establish network of investors and investment businesses to encourage investment in BioFlorida members. Use publicity to improve general recognition of Florida investment climate. Use legislative advocacy to help improve investment climate.
- ✓ **Information exchange:** Establish symposia (Executive Briefing Series), develop newsletter, develop internet website and hold annual conference.
- ✓ **Advocate legislative action**: Establish legislative caucus for industry matters. Use publicity to keep legislature informed on industry positions and activities

BioFlorida's corporate office is located in Gainesville, Florida.

The Florida Medical Foundation

The Florida Medical Foundation is the Florida Medical Association's philanthropic organization for medical education, research, community service, and physician support programs. The foundation emphasizes support for physicians at all stages of their professional careers. The foundation has a current project relating to doctor patient communications as a way of addressing the problem of low health literacy among patients.

The James and Esther King Biomedical Research Program

The 1999 Legislature established the Lawton Chiles Endowment Fund (ch. 99-167, L.O.F.), through which the state will use funds received as a result of its settlement with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research. Section 215.5602, F.S., establishes the James and Esther King Biomedical Research Program funded from earnings of the endowment fund and provides that funds appropriated to the program are to be devoted to competitive grants and fellowships in research relating to prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke and pulmonary disease. The Biomedical Research Advisory Council in the Department of Health assists the Secretary in establishing criteria and guidelines for the competitive grant programs. Grants and fellowships are awarded on the basis of

scientific merit, as determined by an open, objective peer-review process. The council is required to submit a progress report to the Governor, Secretary of the Department of Health, President of the Senate, and Speaker of the House of Representatives by February 1 of each year.

The goals of the James and Esther King Biomedical Research Program were expanded by the 2004 Legislature with the intent of finding cures of specified diseases; provides funding priority for research designed to prevent or cure diseases; and provides for an annual distribution and appropriation of $6 million within the Department of Health, beginning July 1, 2004, and stipulates that $250,000 of these funds shall be available annually for operating costs of the Florida Center for Universal Research to Eradicate Disease.

HB 1585

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The bill requires the Board of Governors to designate the institution responsible for operating the center based on the following criteria:

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- ✓ The institution must be able to raise up to $10 million in private funding to match $10 million in state revenue.

The duties of the center shall include, but not be limited to:

- ✓ Training biomedical investigators, including medical and academic doctors, under the auspices of the college of medicine of the institution operating the center.
- ✓ Developing a program to provide a professional workforce to enhance the quality and amount of biomedical research conducted in the state.
- ✓ Creating a cadre of investigators to develop and conduct translational research initiatives that are the direct outgrowth of fundamental research in areas such as drug discovery, genetics, cancer, and neuroscience, including Alzheimer's disease, brain trauma, and memory loss.
- ✓ Creating research and educational opportunities for medical students, graduate students, and postdoctoral fellows on regional campuses to be developed in concert with local health care and research facilities.
- ✓ Providing training opportunities with investigators from colleges of medicine, pharmacy, dentistry, and veterinary medicine who are funded by the National Institutes of Health.
- ✓ Providing technology-intense environments for both training and research.

HB1585 requires that the center work in partnership with Scripps Florida and other entities involved in biomedical research and training as appropriate and report findings and achievements of the center to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Board of Governors no later than September 1, 2005.

The bill provides an appropriation in the sum of $10 million out of nonrecurring general revenue to the Center for Excellence in Biomedical Training and Investigation to carry out the purposes of this act.

The bill provides for an effective date of July 1, 2004.

C. SECTION DIRECTORY:

Section 1. Provides for establishment of the Center for Excellence in Biomedical Training and Investigation upon designation by the Board of Governors of the State University System of the institution responsible for operating the center; provides criteria for such designation; provides duties of the center; requires the center to work with Scripps Florida and other such entities; and requires a report to the Governor, Legislature, and Board of Governors.

Section 2. Provides for an appropriation of $10 million.

Section 3. Provides an effective date of July 1, 2004.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill provides a $10 million appropriation.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The Center shall have a positive impact on the state economy, by creating new jobs, by attracting biomedical researchers and companies to the state.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES