

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 497 Health Care Delivery and Research
SPONSOR(S): Farkas
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 1116 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Health Standards (Sub)</u>	<u>9 Y, 0 N</u>	<u>Rawlins</u>	<u>Collins</u>
2) <u>Health Care</u>	<u></u>	<u></u>	<u></u>
3) <u>Health Appropriations (Sub)</u>	<u></u>	<u></u>	<u></u>
4) <u>Appropriations</u>	<u></u>	<u></u>	<u></u>
5) <u></u>	<u></u>	<u></u>	<u></u>

SUMMARY ANALYSIS

This bill creates the Florida Center for Universal Research to Eradicate Disease (CURED) within the Department of Health (DOH). The center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use, with the goal of finding cures for diseases. The center is funded through private, state, and federal sources. The center must submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives with recommendations for legislative change necessary to foster a positive climate for biomedical research in Florida.

The bill establishes an advisory council for the center, which must meet at least annually, consisting of the board of directors of the Florida Research Consortium and 17 representatives of organizations named in the bill which support research and public awareness regarding diseases.

The bill amends s. 215.5602, F.S., the James and Esther King Biomedical Research Program, expanding the long term goals of the program to include the expansion of biomedical knowledge relating to cures, in addition to prevention, diagnosis, and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease. The bill requires the program to give priority to research to prevent or cure disease.

The bill establishes the Florida Cancer Research Cooperative for the purpose of making Florida a world-class center for cancer research. The bill authorizes a not-for-profit corporation, acting as an instrumentality of the Florida Dialogue on Cancer, to govern the affairs of the cooperative. A 25-member board of directors will manage the affairs of the not-for-profit corporation. The cooperative must issue an annual report. The cooperative must develop and centralize the processes and shared services for expanding cancer research in Florida and must work in concert with the Florida Center for Universal Research to Eradicate Disease.

The bill establishes the Florida Public Health Foundation, Inc., in law, for the purpose of disseminating biomedical research breakthrough findings and promoting health awareness in Florida. The corporation must be established as a not-for-profit entity. The corporation's duties include procuring funds necessary for accomplishing the purpose and mission of the corporation. The affairs of the not-for-profit corporation are managed by an executive director appointed by a board of directors, as specified in the bill. The corporation, in consultation with DOH and the Florida Center for Universal Research to Eradicate Disease, must facilitate communication between biomedical researchers and health care providers each month according to the health awareness schedule established by the Florida Public Health Foundation, Inc.

The DOH and the Florida Health Awareness Corporation must coordinate monthly health awareness campaigns with national, state, and local health care organizations and government entities targeting a wide range of the public.

See comments in the "fiscal" and "amendments" section of this analysis.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0497a.hc.doc
DATE: February 25, 2004

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

- | | | | |
|--------------------------------------|---|--|---|
| 1. Reduce government? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Lower taxes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. Expand individual freedom? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 5. Empower families? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |

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

This bill creates additional governmental involvement in the coordination and advancement of biomedical research and health awareness campaigns.

B. EFFECT OF PROPOSED CHANGES:

America leads the world in developing and commercializing new medical innovations and technologies. From information technology to biotechnology to materials science, United States (U.S.) scientists and high technology workers are making new discoveries and developing new products every day that are steadily improving the quality of lives. According to U.S. Commissioner of Food and Drugs, Mark McClellan, M.D., Ph.D., this progress is critical to our health and our economic prosperity.¹

Innovations resulting from breakthroughs in science and technology fuel economic growth. According to the Department of Commerce, the information technology sector accounts for just seven percent of all businesses in the U.S. economy, yet between 1996 and 2000, it drove 28 percent of the overall U.S. real economic growth and created jobs at twice the pace of other sectors. These jobs paid twice as much on average as well. Many leading economists now believe that new discoveries in information technology led to investments over the last couple of decades that helped account for the historic surge in economy-wide productivity growth in the 1990s.

While all economists appreciate the contribution of such economic growth to the well-being of the U.S., there is often less appreciation of the contribution of innovations in biomedical technology. A primary reason is that technological change in medicine brings benefits in addition to direct economic gains, including increased longevity, improved quality of life, and less time absent from work. These benefits are not taken into account in standard measures of aggregate economic output. If a country had real gains in its overall health, but not in its material well being (most often measured by per-capita income) the national income accounts would not change, even though those accounts are often thought to measure the well being of a population. In addition, the direct economic and public health benefits of developing important new medicines often takes considerable time to be realized.

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.

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.

¹ Testimony before the Joint Economic Committee, United States Congress, JULY 9, 2003

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.

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.

Pharmaceutical Research and Manufacturers of America

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that improve the health and longevity of patients. The industry invested more than \$30 billion

in 2001 in discovering and developing new medicines. PhRMA companies are involved in the search for new cures.

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 Florida Dialogue on Cancer

The Florida Dialogue on Cancer (FDOC) is a collaboration of Florida leaders of hospitals, research centers, universities, professional medical groups, community-based organizations, private business groups, as well as government officials. FDOC is an initiative designed to expand the state's capacity to reduce the incidence and mortality rates of cancer. The goals of FDOC are to:

- Create a coalition that speaks with one voice on major statewide cancer issues for Florida;
- Enhance and promote Florida's capacity to conduct cancer research, professional education, clinical trials and treatment programs; and
- Identify and promote the replication of best practices in providing access to cancer prevention, education, screening, diagnosis, and treatment programs for all Floridians and to reduce the disparities that exist.

The Florida Division of the American Cancer Society sponsors FDOC, which is based on the work of the National Dialogue on Cancer. Florida is the first state to establish a dialogue on cancer.

The Cancer Control and Research Advisory Council

The Cancer Control and Research Advisory Council (often referred to as the C-CRAB) was created by the 1979 Legislature. The council is located at the H. Lee Moffitt Cancer Center and Research Institute, Inc. Under s. 1004.435, F.S., the Council's mandate includes:

- Advising the State Board of Education, the Secretary of Health and the Legislature, on cancer control and research issues.
- Developing the Florida Cancer Plan.
- Recommending to the Secretary of Health a plan for the care and treatment of cancer patients and make recommendations for the operation of cancer units in hospitals and clinics in Florida.
- Allocating funds, if available, for research and demonstration projects that address the priorities of the Florida Cancer Plan.

The Florida Public Health Foundation, Inc.

The Florida Public Health Foundation, Inc., is a Florida non-profit corporation operating within the exemption established by 26 U.S.C.A., Internal Revenue Code, Section 501(c)(3). The purposes of the foundation are to engage in charitable programs dedicated to improving the health of Florida citizens and to conduct educational programs for those working and interested in public health.

Health Awareness Campaigns

The Department of Health conducts public information campaigns on diseases and other health risks to the extent that funding is available. The department implements a comprehensive, statewide tobacco control program that focuses on young people with the goal of preventing initial use of tobacco and reducing tobacco use. General information about diseases and health conditions is available on the department's web site (<http://www.doh.state.fl.us>).

HB 497

HB 497 creates the Florida Center for Universal Research to Eradicate Disease (CURED) within the Department of Health (DOH). The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use. The goal of the center is to find cures for diseases such as cancer, heart disease, lung disease, diabetes, autoimmune disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.

The center must hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings in order to expedite the discovery of cures for diseases. Summit attendees will be required to cover, or obtain sponsorship for, the costs of their attendance.

The center must:

- Encourage clinical trials in Florida on research that holds promise of curing a disease or condition;
- Facilitate partnerships between researchers, treating physicians, and community hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating voluntary donations to ensure an adequate supply of adult stem cells, placentas and cord blood;
- Facilitate the formation of partnerships between Florida researchers and institutions in other states and countries where research with rare plants or animals could lead to cures;
- Encourage Florida's agricultural colleges and agricultural businesses to be active in the search for cures and the provision of public information about disease prevention;
- Facilitate partnerships among researchers working to cure all types of diseases, including those that are prevalent in developed countries and those that occur in developing countries; and
- Encourage the discovery and production in Florida of vaccines that prevent disease.

The center must monitor the supply and demand for types of human tissue relating to research, including stem cell research, and other needs of researchers. If the center determines that there is a need for increased donation of human tissue, it must notify hospitals licensed under ch. 395, F.S., that have entered into partnership agreements with research institutes conducting stem cell research located in the same geographic region as the researchers demanding the stem cells or other tissues. The hospitals must then implement programs that encourage voluntary donations of cord blood or other needed tissues.

The center will be funded through private, state, and federal sources. The center will serve as a registry of all known biomedical grant opportunities and may assist any public or private biomedical research program in this state in preparing grant requests. The center must maintain a website with links to peer-reviewed biomedical research. The website must contain a list of all known biomedical research being conducted in Florida and must facilitate communication among researchers and other interested parties.

The center must submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 15 which contains recommendations for legislative change necessary to foster a positive climate for biomedical research in Florida. The duties of the center may be outsourced by the Department of Health to a private entity or state university.

An advisory council, established within the center, must meet at least annually. The council will consist of the members of the board of directors of the Florida Research Consortium and at least one representative from:

- The Emerging Technology Commission.
- Enterprise Florida, Inc.
- BioFlorida.
- The Florida Biomedical Research Advisory Council.
- The Florida Medical Foundation.
- Pharmaceutical Research and Manufacturers of America.
- The Florida Tri-Agency Coalition on Smoking and Health.
- The Florida Cancer Research Cooperative, Inc.
- The American Cancer Society, Florida Division, Inc.
- The American Heart Association.
- The American Lung Association of Florida.
- The American Diabetes Association, South Coastal Region.
- The Alzheimer's Association.
- The Epilepsy Foundation.
- The National Parkinson's Foundation.
- The Florida Public Health Foundation, Inc.
- Scripps Florida, or the entity formed by the Scripps Research Institute in Florida.

Members of the council will serve without compensation and each organization represented must cover all expenses of its representative.

The bill creates the James and Esther King Biomedical Research Program, to require that the long-term goals of the program include the expansion of biomedical knowledge relating to cures, in addition to prevention, diagnosis, and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease. The bill requires the program to give priority to research to prevent or cure disease. The Biomedical Research Advisory Council must submit a copy of its annual report to the Florida Center for Universal Research to Eradicate Disease, as well as to the Governor, the Secretary of Health, the President of the Senate and the Speaker of the House of Representatives.

The bill establishes the Florida Cancer Research Cooperative for the purpose of making Florida a world-class center for cancer research. The bill authorizes a not-for-profit corporation, acting as an instrumentality of the Florida Dialogue on Cancer, to govern the affairs of the cooperative. The cooperative may create not-for-profit corporate subsidiaries to fulfill its mission, and those subsidiaries could receive, hold, invest, and administer property and any monies acquired from private, local, state, and federal sources as well as technical and professional income from the mission-related activities of the cooperative.

A board of directors will manage the affairs of the not-for-profit corporation. The 25-member board will be comprised of:

- The Secretary of Health, or his or her designee,
- The Chief Executive Officer of the H. Lee Moffitt Cancer Center or his or her designee,
- The President of the University of Florida Shands Cancer Center, or his or her designee,

- The Chief Executive Officer of the University of Miami Sylvester Comprehensive Cancer Center, or his or her designee,
- The Chief Executive Officer of the Mayo Clinic, Jacksonville, or his or her designee,
- The Chief Executive Officer of the American Cancer Society, Florida Division, or his or her designee,
- The President of the American Cancer Society, Florida Division Board of Directors, or his or her designee,
- The President of the Florida Society of Clinical Oncology, or his or her designee,
- The Chief Executive Officer of Enterprise Florida, Inc., or his or her designee,
- Three representatives from large Florida hospitals or institutions which treat a large volume of cancer patients, one of whom will be appointed by the Governor, one by the President of the Senate and one by the Speaker of the House of Representatives,
- Three representatives from community-based, statewide organizations serving populations that experience cancer disparities, one of whom will be appointed by the Governor, one by the President of the Senate and one by the Speaker of the House of Representatives,
- One member of the House of Representatives, to be appointed by the Speaker of the House of Representatives,
- One member of the Florida Senate, to be appointed by the President of the Senate,
- Three university presidents, one of whom will be appointed by the Governor, one by the President of the Senate and one by the Speaker of the House of Representatives, and
- Five representatives from other statewide public health organizations whose missions include public education and the eradication of cancer, three of whom will be appointed by the Governor, one by the President of the Senate and one by the Speaker of the House of Representatives.

Appointments made by the Senate President and House Speaker will be for 2-year terms concurrent with the terms of the presiding officers who make the appointments. Appointments made by the Governor will be for 2-year terms, and the Governor may reappoint members.

The cooperative must issue an annual report to the Governor, President of the Senate, the Speaker of the House of Representatives, and the Florida Center for Universal Research to Eradicate Disease by December 15 of each year. The report must contain policy and funding recommendations regarding cancer research capacity in Florida.

The bill establishes the mission and duties of the Florida Cancer Research Cooperative. The cooperative must develop and centralize the processes and shared services for expanding cancer research in Florida through:

- Support through bioinformatics to create a cancer informatics infrastructure that enhances information and research exchange;
- Technical coordination, business development, and support of intellectual property;
- Development of a statewide cancer clinical trials network; and
- Other activities to support multidisciplinary research.

The cooperative must work in concert with the Florida Center for Universal Research to Eradicate Disease.

The bill establishes the Florida Public Health Foundation, Inc., in law, for the purpose of disseminating biomedical research breakthrough findings and promoting health awareness in Florida. The corporation's mission will include disseminating information about innovative biomedical research and clinical trials in Florida, as well as making Floridians and their treatment providers aware of specified diseases and conditions and of available methods of preventing, diagnosing, treating, and curing those diseases and conditions.

The corporation must be established as a not-for-profit entity qualifying under section 501(c)(3) of the Internal Revenue Code, and is authorized to receive, hold, invest, and administer property and any moneys acquired from private, local, state, and federal sources, as well as technical and professional income generated, or derived, from the mission-related activities of the corporation.

The corporation's duties will include procuring funds necessary for accomplishing the purpose and mission of the corporation. The corporation must complement, supplement, and enhance the missions of the various organizations, entities, and departments represented on its board by serving as the lead overall public health awareness corporation in the state.

The affairs of the not-for-profit corporation will be managed by an executive director appointed by a board of directors consisting of:

- The Secretary of the Department of Health or his or her designee.
- A former member of the Florida Senate appointed by the President of the Senate,
- A former member of the Florida House of Representatives appointed by the Speaker of the House of Representatives,
- A representative of the American Heart Association,
- A representative of the American Cancer Society, Florida Division, Inc.
- A representative of the American Lung Association of Florida,
- A representative of the American Diabetes Association, South Coastal Region,
- A representative of the Alzheimer's Association,
- A representative of the Epilepsy Foundation,
- A representative of the National Parkinson's Foundation,
- A representative of the March of Dimes, Florida Chapter,
- A representative of the Arthritis Foundation, Florida Chapter,
- A representative of the American Liver Foundation,
- A representative of the Florida Council for Behavioral Healthcare, Inc.,
- A representative of the Florida Alcohol and Drug Abuse Association, Inc.,
- A representative of Pharmaceutical Research and Manufacturers of America,
- A representative of the Florida Public Health Association,
- A public health academician selected by the state health officer,
- A representative of the Florida Academy of Family Physicians, and
- 3 consumers who have demonstrated an interest in promoting public health, appointed by the Public Health Association.

Members of the board of directors will serve for 2-year terms and shall serve without compensation.

The corporation, in consultation with DOH and the Florida Center for Universal Research to Eradicate Disease, must facilitate communication between biomedical researchers and health care providers each month according to the health awareness schedule established by the Florida Public Health Foundation, Inc. The corporation and DOH must enter into partnerships with providers of continuing education for healthcare practitioners to ensure that practitioners are aware of the most recent and complete diagnostic and treatment tools. The corporation must provide an annual report concerning its activities and finances to the Florida Center for Universal Research to Eradicate Disease, the Governor, Senate President, and House Speaker.

The bill requires the Department of Health and the Florida Health Awareness Corporation to coordinate monthly health awareness campaigns with national, state, and local health care organizations and government entities targeting a wide range of the public, including: parents, teachers, and other school employees; students in 4th through 12th grade, colleges, and universities; state agency employees; county and local government employees; patients of county health departments; Medicaid recipients; health care professionals and providers; and the public in general.

The awareness campaigns must include the provision of educational information about preventing, detecting, treating, and curing specified diseases or conditions. Additional diseases and conditions which impact the public health may be added. The following diseases and conditions must be included in a public awareness campaign during at least one month in any 24-month period:

- Cancer, including breast, prostate, cervical, ovarian, colorectal, and skin cancer as well as leukemia;
- Heart disease;
- Stroke;
- Lung disease, including asthma and smoking-related diseases;
- Neurological disorders and disease, including Alzheimer's disease, Parkinson's disease, and Epilepsy;
- Gastrointestinal disease;
- Kidney disease;
- Diabetes;
- Liver disease;
- Autoimmune disorders;
- Birth defects and prenatal care;
- Obesity and malnutrition;
- Sexually transmissible diseases;
- Hepatitis A, B, and C;
- Arthritis;
- Vaccine-preventable diseases;
- Infectious diseases including HIV/AIDS;
- Substance abuse; and
- Mental illness.

The health awareness campaigns must be funded by the Florida Public Health Foundation, Inc., and the Florida Department of Health to the extent that funds are available from public and private sources. Health awareness information must be disseminated through all available methods, including print, audio, visual, and electronic media.

The bill will take effect upon becoming law.

C. SECTION DIRECTORY:

Section 1. Creates the Florida Center for Universal Research to Eradicate Disease within the Department of Health, provides legislative findings and intent; specifies the purpose and duties of the center; requires an annual report to the Governor and Legislature; authorizes the department to outsource the duties of the center; and creates an advisory council.

Section 2. Amends s. 215.5602, F.S., expanding the long-term goals of the James and Esther King Biomedical Research Program to include the cure of specified diseases.

Section 3. Amends s. 215.5601, F.S., relating to the Lawton Chiles Endowment Fund.

Section 4. Creates the Florida Cancer Research Cooperative; and provides for a board of directors.

Section 5. Provides the Florida Cancer Research Cooperative's mission and duties; and requires an annual report to the Florida Center for Universal Research to Eradicate Disease, the Governor, and the Legislature.

Section 6. Establishes the Florida Public Health Foundation, Inc., and provides the foundation's mission and duties; and provides for a board of directors.

Section 7. Requires the foundation to coordinate monthly health awareness campaigns to disseminate information about specified diseases and conditions.

Section 8. Provides that the bill will become effective upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

According to the Department of Health, the fiscal impact of this bill is estimated at \$691,815.80 for FY 04-05, and \$315,877.72 for FY 05-06. Also see "DRAFTING ISSUES OR OTHER COMMENTS" section of this analysis.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Expand state economy, creating new jobs, by attracting biomedical researchers and companies to the state.

D. FISCAL COMMENTS:

See "DRAFTING ISSUES OR OTHER COMMENTS" section of this analysis.

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:

The Department of Health has adequate rulemaking authority to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Department of Health provided a list of comments in an analysis of the bill but did not provide further explanation in the Committee. Their comments are as follows:

"There is not a clear-cut conflict with state law but there are issues that should be explored in relation to the Florida law governing structure of state agencies, public records law, ownership of developments/discoveries, delegation of legislative authority and conflicts of interest.

Section 20.04, Florida Statutes, establishes the structure of the executive branch of government. The bill proposes establishment of a "center" (Florida Center for Universal Research to Eradicate Disease) but this is not a subdivision of government recognized in Florida law. This could make the status of the entity unclear and its legal authority possibly subject to legal challenge.

The entities created by the bill will be subject to the public records act. Accordingly, there could be difficulties associated with protecting research developments from competitors.

It is unclear from the bill whether the taxpayers of the state will have an ownership interest in developments and products produced as a result of the bill. This is compounded by the fact that the bill will join private individuals and corporations, educational institutions, and agencies of government (Florida and others), which could claim ownership of developments and products.

Additionally, many of the activities of the center are currently performed by the state's universities. It is unclear whether the intent of the bill is to supplant or supplement those activities.

Since resources are always limited, the DOH will be required to exercise discretion in determining which clinical trials should be encouraged (Page 4, lines 97-99), which partnerships between researchers will be facilitated (Page 4, lines 104-107), which agricultural colleges and businesses will be encouraged to be active in the search for disease cures (Page 4, lines 108-111). There is not sufficient specificity in the bill to properly execute the proposal. This could be an unlawful delegation of legislative authority.

The bill creates potential conflicts between the DOH and those targeted by the "center." For example, the bill directs the center to encourage discovery and production of vaccines, while the DOH, purchases and administers vaccines to thousands of Floridians. The DOH would have an interest in those vaccines it encouraged in the production stage which could be translated into an impermissible conflict in the purchasing arena. Similarly, the DOH regulates many of the people (health care providers) who would be involved in the "center's" activities and therefore a conflict of interest might be created.

The financing mechanism also creates a potential conflict for the DOH in that many current activities of the Department are funded by private, state, and federal grants. The DOH could be forced to choose between seeking funding for the "center" and its current programs and activities.

The "center" is directed to assist public and private biomedical research program in preparing grant requests. Again, the DOH has unbridled discretion in choosing which to assist and further, by such assistance, becomes a "partner" in the request.

Each time the "center" chooses to "encourage" a clinical trial that holds promise of curing a disease or condition, any trial not chosen for such "encouragement" would be afforded the right

to challenge that agency action through a hearing pursuant to Sections 120.569 and 120.57, Florida Statutes.

Given that the CURED will hold an annual biomedical conference, facilitate communication between all partners, encourage clinical trials and vaccine development, as well as stem cell research, serve as a registry, maintain a website, establish an advisory council which meets annually, and satisfy the outlined purpose, the budget for the CURED should be allocated sufficient funding to cover start-up costs as well as contract development and monitoring. Because outcomes for disparate populations are different, language should be added to target disparate populations.

Some terms used in the bill would require definitions to prevent legal challenges for vagueness such as the terms “biomedical research program” and “bioinformatics.”

These entities listed in the bill appear to be doing many of the same things. There does not appear to be a hierarchy to determine overall direction to ensure consistency of approach and avoidance of duplication of effort, dollars, and conflicts of policy. Entities may be competing for the same public and private dollars. To whom are these entities accountable?

Section 1 (1)

“Biomedical technology sector” needs to be defined.

Section 1 (3)

Outsourcing the functions of CURED requires additional contract management support. Operating CURED in-house requires a significant increase in staff and funds. The source of funds for the annual summit are not identified.

Section 1 (3)(c)

It is unclear as to whether this section limits the cures referenced in Section 1 (3)(e), (f), (g), and (h).

Section 1 (3)(e)

The center must encourage clinical trials in this state on research that holds promise of curing a disease or condition. Language should be included that defines the criteria for “promising research.” This section does not provide any criteria or definition of “research that holds a promise of curing a disease or condition.” The lack of definition may dilute the intent of the bill.

One effort of the Florida Center for Universal Research to Eradicate Disease (CURED) is clinical trials. CURED will have a broader application for clinical trials for diseases other than cancer, however, the National Cancer Institute has a website for clinical trials that provide information on understanding clinical trials, conducting clinical trials, recent development, and much more that should be coordinated to avoid duplication. The Florida Dialogue on Cancer also has work groups specifically for clinical trials and expanding research capacity.

Section 1 (3)(i)

It is unclear if the discovery and production of vaccines is limited to the diseases specified in section 1 (3)(b). Clarification is needed to determine if it is limited to the production of new vaccines or can it promote production of presently existing vaccines in Florida based facilities.

Section 1 (3)(j)

If no state operated hospitals have any agreements as specified, there is no impact.

Section 1 (3)(l)

This section needs to provide a definition of what is expected of the biomedical grants registry and what type of assistance may be provided to public or private biomedical research programs in preparing grant requests.

Section 1 (3)(m)

The Department of Health and Human Services (DHHS) through the National Institutes of Health (NIH) maintains a database of all federally funded biomedical research. The database is called CRISP (Computer Retrieval of Information on Scientific Projects). It is searchable and contains information from 7 offices/centers within DHH including, NIH, FDA, and CDC. NIH is the single largest source of biomedical research dollars flowing into Florida.

Section 1 (4)(b)

In the listed members of the CURED Advisory Council, the Tri-Agency Coalition on Smoking and Health is listed in 7. The Tri-Agency is made up of The American Cancer Society, The American Heart Association and the American Lung Association. Each of these organizations is separately given a seat on the Advisory Council as well (9.-11.).

Section 2

The James and Esther King Biomedical Research Program funds basic biological and behavioral research. It is virtually impossible to determine a priori which research programs will ultimately lead to cures or lead to vaccines to prevent diseases related to tobacco use. The proposed bill does not specify how such research is to be identified. Consequently, the program might not be able to give priority to research designed to prevent or cure disease.

Section 6

The Florida Public Health Foundation is already a non-profit organization that may accept contributions and is uniquely connected to public and private health care providers. It is unclear how the mission and purpose of the entity created in this bill relate to the existing entity.

Section 6 – General Comments

Awareness campaigns should be designed using social marketing principles and/or be tested with the target population (evidence-based). This will target funds where most needed.

Section 7 (3)

This section does not provide specific funding source or appropriation for DOH.

Section 8

The Department of Health will only be able to implement these activities with the necessary funding that is outlined in the fiscal note.”

The DOH suggests the following amendment:

On page 12, line 314, insert:

(f) Members of the board of directors of the not-for-profit corporation or any subsidiaries shall serve without compensation and each organization represented on the board of directors shall cover all expenses of its representative.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 17, 2004, the Subcommittee on Health Standards considered HB 497, and reported the bill favorably with one amendment. The amendment renames the Florida Cancer Research Cooperative to the

Florida Cancer Research Council, and establishes the Council within the Department of Health. The Council is granted authority to create not-for-profit corporate subsidiaries to fulfill its mission.

Similar to the Cooperative, the Council will be managed by a board of directors. The number of appointed positions is expanded to include the Chairman of the Florida Dialogue on Cancer, who shall serve as Chair of the Council. The President of the American College of Surgeons, and five representatives from American College of Surgeons approved cancer programs, three which are appointed by the Governor and one each by the President of the Senate and the Speaker of the House, are added to the appointed positions of the Board. The requirement to include University Presidents and five representatives from statewide public health organizations is removed from appointed positions of the Board.

The Council's mission is expanded to identify and attract new research talent and attendant national grant producing researchers to Florida-based cancer research facilities and to implement a peer review, competitive process to identify and fund the proposals to expand Florida's cancer research institutions. The provision regarding the clinical trials requirements is expanded by:

- ✓ Identifying ways to increase adult enrollment in cancer clinical trials;
- ✓ Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials;
- ✓ Providing tools to cancer patients and community-based oncologists to aid in the identification of cancer clinical trials available in the state; and
- ✓ Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks.

The mission is expanded to include efforts to reduce the impact of cancer on disparate groups by:

- ✓ Identifying those cancers that disproportionately impact certain demographic groups; and
- ✓ Building collaborations designed to reduce health disparities as they relate to cancer.