

STORAGE NAME: h1985a.hcs

DATE: April 13, 1999

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE SERVICES
ANALYSIS**

BILL #: HB 1985

RELATING TO: Biomedical Research

SPONSOR(S): Reps. Fasano & Littlefield

COMPANION BILL(S): SB 2558 (i)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH CARE SERVICES YEAS 12 NAYS 0
- (2) GOVERNMENTAL OPERATIONS
- (3) GOVERNMENTAL RULES AND REGULATIONS
- (4) GENERAL APPROPRIATIONS
- (5)

I. SUMMARY:

HB 1985 provides for the creation of a biomedical research program to support research initiatives that address the health care problems of Floridians in the areas of cancer, cardiovascular disease, stroke, and pulmonary disease, to be established within the Department of Health.

The bill provides for funds to be appropriated from the Tobacco Settlement Trust Fund to the Department of Health for the exclusive purpose of awarding grants and fellowships under the biomedical research program and for administrative expenses. Such research must relate to the diagnosis and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

In addition, the bill provides for a Biomedical Research Advisory Council to be created within the Department of Health. The council is to consist of nine members and advise the Secretary of Health as to the direction and scope of the biomedical research program.

Any university or established research institute in the state may submit applications for biomedical research funding under the program, and grants and fellowships will be awarded by the Secretary of Health, after consultation with the council, on the basis of scientific merit.

The bill requires an annual progress report on the state of biomedical research in Florida, to be submitted by the council to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives.

An appropriation of \$150 million from the Tobacco Settlement Trust Fund to the Department of Health for FY 1999-2000 to fund the biomedical research program is provided.

II. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Chapter 385, F.S., is the Chronic Disease Act and states that the Legislature finds that "chronic diseases exist in high proportions among the people of this state. These chronic diseases include, but are not limited to, heart disease, hypertension, diabetes, renal disease, cancer, and chronic obstructive lung disease. These diseases are often interrelated, and they directly and indirectly account for a high rate of death and illness." The Department of Health Chronic Disease Control Program established under s. 385.103, F.S., is responsible for mobilization of scientific, medical, and educational resources under one comprehensive chronic disease program. The primary goals of the program are to reduce the incidence of disease, delay the onset of disability, alleviate the severity of disease, and prolong life by identifying and addressing factors affecting chronic disease.

Section 381.85, F.S., is the Biomedical and Social Research Act, and "the purpose of this section is to provide a procedure by which proposed research on children or adults will be supported with funds appropriated to the department, and can be efficiently and expeditiously assessed for compliance with the substantive and procedural requirements established by the Review Council for Biomedical and Social Research in rules adopted by the department." The review council was never funded and rules have never been developed.

According to the Department of Health Florida Vital Statistics Annual Report, in 1997 heart disease was the leading cause of death -- almost one of every three deaths. Of the 153,830 deaths in Florida in 1997, 63,536 were related to cardiovascular disease, 37,813 were related to cancer, 9,986 were caused by stroke, and 8,067 were related to pulmonary disease.

Tobacco use is often to blame as the cause of a variety of diseases including cancer, cardiovascular disease, stroke, and pulmonary disease. According to the Florida Coalition on Smoking OR Health, which is a tri-agency made up of the American Cancer Society, the American Heart Association, and the American Lung Association, it is estimated that tobacco use causes up to 37 percent of all cancer deaths, 28 percent of all cardiovascular mortality, and 80 percent of all chronic obstructive pulmonary disease. According to the coalition, collectively, tobacco is estimated to cause one in five deaths in the United States.

Recently the Florida Coalition on Smoking OR Health developed a proposal for a biomedical research endowment. The coalition's proposal suggests that 15 percent of the Tobacco Settlement funds be put into the endowment to support research initiatives that address the health care problems of Floridians in the areas of cancer, cardiovascular diseases, stroke, and pulmonary disease. The long-term goals of the endowment would be to: (1) improve the health of Florida's citizens; (2) expand the foundation of biomedical knowledge related to the diagnosis and treatment of tobacco-related diseases; (3) improve the quality of Florida's academic health centers; (4) increase the amount of federal research dollars that flow into Florida; and (5) stimulate economic activity in the pharmaceutical and biotechnology areas. The coalition believes that because it is estimated that one in five deaths are caused by tobacco use, it is appropriate that some of the money derived from the tobacco settlement be devoted to research to develop better treatments of diseases caused by tobacco use, which include cancer, cardiovascular diseases, stroke, and pulmonary disease.

Chapter 240, F.S., relates to post-secondary education, and it states in s. 240.105, F.S. that the Legislature finds it is in the public interest to provide a system of higher education "which offers selected professional, graduate, and research programs with emphasis on state and national needs." Within ch. 240, F.S., the Cancer Control and Research Act is created under s. 240.5121. This act creates the Florida Cancer Control and Research Fund to provide grants and contracts to qualified nonprofit associations and governmental agencies for cancer control, prevention, education, training, and research. The act provides that the Board of Regents is responsible for awarding grants and contracts to qualified nonprofit associations and governmental agencies in order to plan, establish, or conduct programs in cancer control and prevention, cancer education and training, and cancer research.

B. EFFECT OF PROPOSED CHANGES:

A biomedical research program to support research initiatives that address the health care problems of Floridians in the areas of cancer, cardiovascular disease, stroke, and pulmonary disease will be established within the Department of Health.

Funds will be appropriated from the Tobacco Settlement Trust Fund to the Department of Health for the exclusive purpose of awarding grants and fellowships, under the biomedical research program, for research relating to the diagnosis and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease, and for administrative expenses of the program.

A Biomedical Research Advisory Council consisting of nine members will be created within the Department of Health. The council will advise the Secretary of Health as to the direction and scope of the biomedical research program.

Any university or established research institute in the state may submit applications for biomedical research funding under the program, and grants and fellowships will be awarded by the Secretary of Health, after consultation with the council, on the basis of scientific merit.

An annual progress report on the state of biomedical research in Florida will be submitted by the council to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives.

C. APPLICATION OF PRINCIPLES:

1. Less Government:

a. Does the bill create, increase or reduce, either directly or indirectly:

(1) any authority to make rules or adjudicate disputes?

Yes. The Department of Health is authorized to adopt rules, after consultation with the Biomedical Research Advisory Council, to implement the provisions of the section created in the bill.

(2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

Yes. A biomedical research program will be established within the Department of Health with a list of long-term goals to achieve.

(3) any entitlement to a government service or benefit?

No.

b. If an agency or program is eliminated or reduced:

(1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

N/A

(2) what is the cost of such responsibility at the new level/agency?

N/A

(3) how is the new agency accountable to the people governed?

N/A

2. Lower Taxes:

a. Does the bill increase anyone's taxes?

No.

b. Does the bill require or authorize an increase in any fees?

No.

c. Does the bill reduce total taxes, both rates and revenues?

No.

d. Does the bill reduce total fees, both rates and revenues?

No.

e. Does the bill authorize any fee or tax increase by any local government?

No.

3. Personal Responsibility:

a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

No.

b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

No.

4. Individual Freedom:

a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

No.

b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

No.

5. Family Empowerment:

a. If the bill purports to provide services to families or children:

(1) Who evaluates the family's needs?

N/A

(2) Who makes the decisions?

N/A

(3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

N/A

(5) Are families penalized for not participating in a program?

N/A

b. Does the bill directly affect the legal rights and obligations between family members?

No.

c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

(1) parents and guardians?

N/A

(2) service providers?

N/A

(3) government employees/agencies?

N/A

D. STATUTE(S) AFFECTED:

Section 240.5125, F.S., is created.

E. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates s. 240.5125, F.S., relating to biomedical research. The following subsections are created:

Subsection (1) creates within the Department of Health a biomedical research program to support research initiatives that address the health care problems of Floridians in the areas of cancer, cardiovascular disease, stroke, and pulmonary disease. The long-term goals of the program are to: improve the health of Florida's citizens by researching better treatments for cancer, cardiovascular disease, stroke, and pulmonary disease; expand the foundation of biomedical knowledge relating to these diseases; improve the quality of Florida's academic health centers; increase the state's per capita funding for biomedical research; and stimulate economic activity in the state in areas related to biomedical research.

Subsection (2) provides that funds appropriated from the Tobacco Settlement Trust Fund to the Department of Health for the purposes of this section are to be used exclusively for the award of grants and fellowships, under the biomedical research program, for research relating to the diagnosis and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease, and for expenses incurred in the administration of this section.

Subsection (3) creates within the Department of Health the Biomedical Research Advisory Council to consist of nine members. Membership and appointment requirements are established and the council shall adopt internal organizational procedures as necessary for its efficient organization. The Department of Health is to provide staff, information, and assistance as is reasonably necessary to assist the council in carrying out its responsibilities.

Subsection (4) provides that the council shall advise the Secretary of Health as to the direction and scope of the biomedical research program, and possible responsibilities of the council are listed.

Subsection (5) provides that applications for biomedical research funding under the program may be submitted from any university or established research institute in the state, and all qualified investigators will have equal access and opportunity to compete for the research funding. Grants and fellowships will be awarded by the Secretary of Health after consultation with the council. Types of applications to be considered for funding shall include: investigator-initiated research grants, institutional research grants; and predoctoral and postdoctoral research fellowships.

Subsection (6) provides for the appointment of a peer review panel to ensure that all proposals for research funding are appropriate and evaluated fairly on the basis of scientific merit. Subsection (7) provides that the council and peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to strict policy with regard to conflict of interest. Meetings of the council and the peer review panel are subject to the provisions of ch. 119, F.S., s. 286.011, F.S., and s. 24, Art. I of the State Constitution.

Subsection (8) authorizes the department to contract on a competitive bid basis with an appropriate entity to administer the program. Administrative expenses are not to exceed 15 percent of the total funds available to the program in any given year.

Subsection (9) authorizes the department, after consultation with the council, to adopt rules as necessary to implement the provisions of this section.

Subsection (10) provides that the council shall submit an annual progress report on the state of biomedical research in Florida to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives.

Section 2. Provides for an appropriation from the Tobacco Settlement Trust Fund to the Department of Health of \$150 million for fiscal year 1999-2000 to fund the biomedical research program as provided in s. 240.5125, F.S.

Section 3. Provides for an effective date of July 1, 1999.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

An appropriation of \$150 million from the Tobacco Settlement Trust Fund will be provided to the Department of Health for fiscal year 1999-2000 to fund the biomedical research program.

According to the Department of Health, necessary non-recurring funds for the administration of the program are set out below.

	<u>Year 1</u>	<u>Year 2</u>
First-Year Start-Up Effect:		
EXPENSE:		
Professional Package (furniture, software) 4@ \$2,855 & 1@ \$2,387	\$ 13,807	
OCO: 5@ \$4,177	\$ 20,885	
Total Non-Recurring Expenses	\$ 34, 692	

2. Recurring Effects:

According to the Department of Health, necessary recurring funds for the administration of the program are set out below.

	<u>Year 1</u>	<u>Year 2</u>
SALARIES/BENEFITS:		
1 Senior Epidemiologist	\$ 58,585	\$ 78,113
1 Biological Scientist IV	\$ 40,567	\$ 54,089
1 Biological Scientist III	\$ 34,261	\$ 45,681
1 Operations & Management Consultant II	\$ 36,236	\$ 48,315
1 Administrative Assistant I	\$ 24,357	\$ 32,476
(Lapsed 25% first year)		
EXPENSES:		
Professional Package Senior Epidemiologist (medium travel)	\$ 15,733	\$ 15,733
Biological Scientist IV (medium travel)	\$ 15,733	\$ 15,733
Biological Scientist III (medium travel)	\$ 15,733	\$ 15,733
Operations & Management Consultant II	\$ 9,019	\$ 9,019
Administrative Assistant I	\$ 4,115	\$ 4,115
Travel to Council Meetings to Tallahassee	\$ 7,356	\$ 7,356
Travel to Peer Review Committee Members	\$ 24,520	\$ 24,520
Printing Report	\$ 6,000	\$ 6,000
Total Recurring Expenses	\$292,215	\$356,883

3. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

According to the Department of Health, total expenditures for administration of the program would be \$326,907 for Year 1 and \$356,883 for Year 2. These amounts constitute just over 2

tenths of one percent of the total appropriated amount, and as such are far below the allowed 15 percent administrative rate.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

None.

2. Direct Private Sector Benefits:

None.

3. Effects on Competition, Private Enterprise and Employment Markets:

None.

D. FISCAL COMMENTS:

The original proposal by the Tri-Agency Coalition on Smoking OR Health provided for the establishment of an endowment of \$150 million to be spent on biomedical research to develop better treatments of diseases caused by tobacco use. The bill, however, does not describe an endowment mechanism, and as written appears to provide \$150 million for biomedical research for only Fiscal Year 1999-2000. Language specifying how the funds are to be managed within state government, what percentage of the principal can be spent each year, and how unspent funds are to be used would help to clarify the intent of the use for the \$150 million. The Department of Health has noted that it cannot support this bill unless amendments are included to address these appropriation concerns.

According to the Department of Health, the provision of up to 15 percent of funds to be spent on administration of the project is more than sufficient, and 10 percent might be adequate.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require counties or municipalities to expend funds nor does it require them to take an action requiring the expenditures of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

According to the Department of Health, the intent of the advocates of the bill was to support research in the prevention of tobacco-related diseases, as well as diagnosis and treatment. The department believes this intent is suggested by the inclusion of a member with expertise in the field of behavioral or social research on the advisory council. As written, the goals of the program appear to relate only to the diagnosis and treatment of diseases relating to tobacco use, not to prevention. (See page 2, lines 4, 7, and 25.) The department has noted that it cannot support the bill unless amendments are made to address these concerns.

It is unclear why the Biomedical Research Program is created within Chapter 240, F.S., relating to post-secondary education. Because the program is established within the Department of Health, it would be more appropriate for the program to be created within ch. 381, F.S., relating to public health, or ch. 385, F.S., relating to chronic diseases.

The bill requires the Advisory Council to submit an annual progress report on the state of biomedical research in Florida. The Board of Regents has expressed concern that the term "biomedical research" is subject to many definitions and is much broader than the purposes defined starting on page 2, line 21 of the bill. Therefore, the Board of Regents recommends that the annual report required on page 6, line 12 be limited to biomedical research relating to the diagnosis and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

Subsection (7) of s. 240.5125, F.S., of the bill provides that no member of the Biomedical Research Council or any peer review panel established to advise the council, may participate in any discussion or decision relating to a research proposal submitted by any firm, entity, or agency with which the member is associated as a member of the governing board, or as an employee, or with which the member has entered into a contractual arrangement. This provision is intended to prohibit conflicts of interest by members of the council or peer review panels. The Board of Regents, however, feels this provision is problematic and has expressed the following concerns. First, it could be construed to effectively prohibit anyone associated with the state research university represented by the Advisory Council member provided for in subsection (3)(a)1 of the proposed section, from submitting any research proposal for consideration/decision by the council. Second, it will make it extremely difficult to find qualified individuals to serve on peer review panels. According to the Board of Regents, the same objective of prohibiting conflicts of interest could be achieved more effectively by: (a) requiring that the peer review panels adhere to the National Institute of Health peer review process, which provides for peer review panel members to abstain from voting under prescribed circumstances that would constitute a conflict of interest; and (b) requiring that advisory council members acknowledge potential conflicts of interest, and abstain from voting on specific research proposals recommended for funding as part of peer review panels.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On April 12, 1999, the Committee on Health Care Services passed a strike-everything amendment sponsored by Representative Fasano. This amendment does the following:

- Names the biomedical research program the Connie Mack Biomedical Research Program and includes the program within the Lawton Chiles Endowment Fund.
- Provides for specific appropriations from the Lawton Chiles Endowment Fund to be distributed on a competitive-project basis for biomedical research funding and to eight institutions. These eight institutions include:
 - University of Florida Cancer Center;
 - University of Miami Medical Center;
 - H. Lee Moffitt Cancer Center and Research Institute;

STORAGE NAME: h1985a.hcs

DATE: April 13, 1999

PAGE 10

- Florida State University, Biomedical Research;
 - Florida Agricultural and Mechanical University, Pharmacy Research;
 - Mayo Clinic;
 - University of South Florida, Biomedical Research; and
 - Walt Disney Memorial Cancer and Research Institute.
- Clarifies that research funded by this bill should include the *prevention* of tobacco-related diseases as well as the *diagnosis and treatment* of such diseases.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

Prepared by:

Staff Director:

Amy K. Guinan

Phil E. Williams