By the Committee on Health Care; and Senators Saunders, Fasano, King, Smith, Rich, Dockery and Wise

587-1813A-05

1	A bill to be entitled
2	An act relating to biomedical research;
3	providing legislative intent; amending s.
4	561.121, F.S.; redistributing certain funds
5	collected from taxes on alcoholic beverages;
6	amending s. 381.855, F.S.; revising the purpose
7	of the Florida Center for Universal Research to
8	Eradicate Disease; requiring the center to
9	provide grants for cancer research and
10	Alzheimer's disease research; revising
11	membership of the center's advisory council;
12	providing procedures for the awarding of grants
13	for cancer research and Alzheimer's disease
14	research; amending s. 381.921, F.S.; revising a
15	goal of the Florida Cancer Council; amending s.
16	1004.445, F.S.; renaming the Johnnie B. Byrd,
17	Sr., Alzheimer's Center and Research Institute
18	as the "Ronald Reagan Alzheimer's Center and
19	Research Institute"; providing an effective
20	date.
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22	Be It Enacted by the Legislature of the State of Florida:
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24	Section 1. It is the intent of the Legislature to
25	provide increased funding to support grants for biomedical
26	research in this state with the anticipation that sustained
27	funding for biomedical research over a period of years will
28	lead to an alleviation of human suffering from diseases such
29	as cancer and Alzheimer's disease. It is the intent of the
30	Legislature to dramatically reduce this state's inordinately

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31 high cancer burden, reducing both cancer incidence and

CODING: Words stricken are deletions; words underlined are additions.

mortality, while advancing scientific endeavors in this state, 2 making this state a world-class leader in cancer research and treatment. Further, it is the intent of the Legislature to 3 4 support Alzheimer's disease research statewide through the 5 awarding of research grants on a competitive basis. Additionally, it is the intent of the Legislature to stimulate dramatic economic development, particularly in the biotech industry, through investment in this state's biomedical 8 9 research. 10 Section 2. Subsection (1) of section 561.121, Florida Statutes, is amended to read: 11 12 561.121 Deposit of revenue.--13 (1) All state funds collected pursuant to ss. 563.05, 564.06, and 565.12 shall be paid into the State Treasury and 14 disbursed in the following manner: 15 (a)1. Two percent of monthly collections of the excise 16 taxes on alcoholic beverages established in ss. 563.05, 564.06, and 565.12 shall be deposited into the Alcoholic 18 Beverage and Tobacco Trust Fund to meet the division's 19 appropriation for the state fiscal year. 2.0 21 2. Beginning July 1, 2004, there is annually 2.2 distributed \$15 million to the Grants and Donations Trust Fund 23 within the Department of Elderly Affairs, and these funds are 2.4 annually appropriated to support a contract with the Johnnie 2.5 B. Byrd, Sr., Alzheimer's Center and Research Institute at the 26 University of South Florida for the purposes of conducting 27 research, developing and operating integrated data projects, 2.8 and providing assistance to memory disorder clinics as established in s. 430.502. 29 2.3. Beginning July 1, 2004, there is annually 30 distributed \$6 million to the Biomedical Research Trust Fund

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program.

within the Department of Health, and these funds are annually appropriated to the James and Esther King Biomedical Research Program. From these funds, up to \$250,000 shall be available annually for the operating costs of the Florida Center for Universal Research to Eradicate Disease.

3. Beginning July 1, 2005, there is annually distributed \$9 million to the Department of Health, and these funds are annually appropriated to the Florida Center for Universal Research to Eradicate Disease to provide grants to researchers seeking cures for cancer, with emphasis given to the qoals enumerated in s. 381.921 as those goals inure to the advancement of such cures. From these funds, up to \$200,000 shall be available annually for administration of the grant

4. Beginning July 1, 2005, there is annually distributed \$15 million to the Department of Health, and these funds are annually appropriated to the Florida Center for Universal Research to Eradicate Disease to provide grants to researchers seeking cures for Alzheimer's disease. From these funds, up to \$200,000 shall be available annually for administration of the grant program and up to \$250,000 shall be available annually for the operating costs of the Florida Center for Universal Research to Eradicate Disease.

4. Beginning July 1, 2004, there is annually distributed \$9 million to be paid by warrant drawn by the Chief Financial Officer upon the State Treasury to Florida State University for the School of Chiropractic Medicine.

Notwithstanding the provisions of chapter 216, until the School of Chiropractic Medicine is completely staffed and fully operational, these funds may be used for any purpose by the university.

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(b) The remainder of collection shall be credited to the General Revenue Fund.

Section 3. Section 381.855, Florida Statutes, is amended to read:

381.855 Florida Center for Universal Research to Eradicate Disease.--

- million Americans suffer from acute, chronic, and degenerative diseases and that biomedical research is the key to finding cures for these diseases that negatively affect all Floridians. The Legislature further finds that, while there is much research being conducted throughout this state and throughout the world, there is a lack of coordination of efforts among researchers. The Legislature, therefore, finds that there is a significant need for a coordinated effort if the goal of curing disease is to be achieved. Moreover, the Legislature finds that the biomedical technology sector meets the criteria of a high-impact sector, pursuant to s. 288.108, having a high importance to this state's economy with a significant potential for growth and contribution to our universities and quality of life.
- (2) It is the intent of the Legislature that Florida strive to become the nation's leader in biomedical research and commit itself to being the state to find cures for the most deadly and widespread diseases. It is further the intent of the Legislature that there be a coordinated effort among the state's public and private universities and the biomedical industry to discover such cures. Moreover, it is the intent of the Legislature to expand the state economy by attracting biomedical researchers and research companies to this state.

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- (3) There is established within the Department of Health the Florida Center for Universal Research to Eradicate Disease, which shall be known as "CURED."
- (a) The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, provide grants for cancer research and Alzheimer's disease research, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use.
- (b) 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.
- (c) The center shall 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. Summit attendees shall cover the costs of such attendance or obtain sponsorship for such attendance.
- (d) The center shall encourage clinical trials in this state on research that holds promise of curing a disease or condition. The center shall 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, or cord blood.

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- (e) The center shall facilitate the formation of partnerships between researchers in this state and institutions in other states and countries where research with rare plants or animals could lead to cures.
- (f) The center shall encourage agricultural colleges and agricultural businesses in this state to be active in the search for cures and in providing information to the public about disease prevention.
- (g) The center shall facilitate partnerships among researchers working to cure all types of diseases, including those that are prevalent in developed countries and those that occur mainly in developing countries.
- (h) The center shall also encourage the discovery and production in Florida of vaccines that prevent disease.
- (i) The center shall monitor the supply and demand needs of researchers relating to stem cell research and other types of human tissue research. If the center determines that there is a need for increased donation of human tissue, it shall notify hospitals licensed pursuant to chapter 395 which 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. Such hospitals shall implement programs that encourage voluntary donations of cord blood or other needed adult tissue.
- (j) The center shall be funded through private, state, and federal sources.
- (k) The center shall serve as a registry of all known opportunities for biomedical grants and may assist any public or private biomedical research program in this state in preparing grant requests.

1	(1) The center shall provide grants for cancer
2	research and Alzheimer's disease research to further the
3	search for cures for those diseases.
4	(m)(1) The center shall maintain a website with links
5	to peer-reviewed biomedical research. The website shall also
6	contain a list of all known biomedical research being
7	conducted in Florida and shall facilitate communication among
8	researchers and other interested parties.
9	$\frac{(n)(m)}{m}$ The center shall submit an annual report to the
10	Governor, the President of the Senate, and the Speaker of the
11	House of Representatives no later than January 15 which
12	contains recommendations for legislative change necessary to
13	foster a positive climate for biomedical research in this
14	state.
15	(4) The Department of Health may outsource the duties
16	of the center to a private entity or state university.
17	(5) There is established within the center an advisory
18	council that shall meet at least annually.
19	(a) The council shall consist of the members of the
20	board of directors of the Florida Research Consortium and at
21	least one representative from:
22	1. The Emerging Technology Commission.
23	2. Enterprise Florida, Inc.
24	3. BioFlorida.
25	4. The Biomedical Research Advisory Council.
26	5. The Florida Medical Foundation.
27	6. Pharmaceutical Research and Manufacturers of
28	America.
29	7. The Florida Tri-Agency Coalition on Smoking OR
30	Health.

31 8. The Florida Cancer Council.

The American Cancer Society, Florida Division, Inc. 2 The American Heart Association. 10. The American Lung Association of Florida. 3 11. 4 The American Diabetes Association, South Coastal 12. 5 Region. 6 13. The Alzheimer's Association. 7 14. The Epilepsy Foundation. The National Parkinson Foundation. 8 15. 9 The Florida Public Health Foundation, Inc. 16. 10 Scripps Florida or the entity formed in this state 17. by The Scripps Research Institute. 11 12 18. The Florida Research Consortium. 13 (b) Members of the council shall serve without compensation, and each organization represented shall cover 14 all expenses of its representative. 15 16 (6)(a) Applications for cancer research funding may be submitted from any university or established research 18 institute in the state. All qualified investigators in the state, regardless of institution affiliation, shall have equal 19 access and opportunity to compete for the research funding. 2.0 21 Grants shall be awarded by the Secretary of Health, after consultation with the council, on the basis of scientific 22 23 merit, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high 2.4 quality. The following types of applications shall be 2.5 considered for funding: 26 27 1. Investigator-initiated research grants. 2.8 2. Institutional research grants. (b) To ensure that all proposals for research funding 29 are appropriate and are evaluated fairly on the basis of 30

scientific merit, the Secretary of Health, in consultation

with the council, shall appoint a peer review panel of 2 independent, scientifically qualified individuals to review the scientific content of each proposal and establish its 3 4 scientific priority score. The priority scores shall be forwarded to the council and must be considered in determining 5 6 which proposals shall be recommended for funding. 7 (c) The council and the peer review panel shall 8 establish and follow rigorous quidelines for ethical conduct and adhere to a strict policy with regard to conflict of 9 10 interest. A member of the council or panel may not participate in any discussion or decision with respect to a research 11 12 proposal by any firm, entity, or agency with which the member 13 is associated as a member of the governing body or as an employee, or with which the member has entered into a 14 contractual arrangement. Meetings of the council and the peer 15 review panels are subject to chapter 119, s. 286.011, and s. 16 17 24, Art. I of the State Constitution. 18 (7)(a) Applications for Alzheimer's disease research funding may be submitted from any university or established 19 2.0 research institute in the state. All qualified investigators 21 in the state, regardless of institution affiliation, shall 2.2 have equal access and opportunity to compete for the research 23 funding. Grants shall be awarded by the Secretary of Health, after consultation with the council, on the basis of 2.4 scientific merit, as determined by an open, competitive peer 2.5 review process that ensures objectivity, consistency, and high 26 2.7 quality. The following types of applications shall be 2.8 considered for funding: 29 1. Investigator-initiated research grants. 30 2. Institutional research grants.

1	(b) To ensure that all proposals for research funding
2	are appropriate and are evaluated fairly on the basis of
3	scientific merit, the Secretary of Health, in consultation
4	with the council, shall appoint a peer review panel of
5	independent, scientifically qualified individuals to review
6	the scientific content of each proposal and establish its
7	scientific priority score. The priority scores shall be
8	forwarded to the council and must be considered in determining
9	which proposals shall be recommended for funding.
10	(c) The council and the peer review panel shall
11	establish and follow rigorous quidelines for ethical conduct
12	and adhere to a strict policy with regard to conflict of
13	interest. A member of the council or panel may not participate
14	in any discussion or decision with respect to a research
15	proposal by any firm, entity, or agency with which the member
16	is associated as a member of the governing body or as an
17	employee, or with which the member has entered into a
18	contractual arrangement. Meetings of the council and the peer
19	review panels are subject to chapter 119, s. 286.011, and s.
20	24, Art. I of the State Constitution.
21	Section 4. Section 381.921, Florida Statutes, is
22	amended to read:
23	381.921 Florida Cancer Council mission and
24	dutiesThe council, which shall work in concert with the
25	Florida Center for Universal Research to Eradicate Disease to
26	ensure that the goals of the center are advanced, shall
27	endeavor to dramatically improve cancer research and treatment
28	in this state through:
29	(1) Efforts to significantly expand cancer research
30	capacity in the state by:
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- (a) Identifying ways to attract new research talent and attendant national grant-producing researchers to Florida based cancer research facilities in this state;
- (b) Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;
- (c) Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
- (d) Encouraging the employment of bioinformatics in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;
- (e) Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and
- (f) Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research.
- (2) Efforts to improve both research and treatment through greater participation in clinical trials networks by:
- (a) Identifying ways to increase adult enrollment in cancer clinical trials;
- (b) Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials;
- 28 (c) Providing tools to cancer patients and
 29 community-based oncologists to aid in the identification of
 30 cancer clinical trials available in the state; and

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- (d) Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks.
- $\hbox{(3)} \quad \hbox{Efforts to reduce the impact of cancer on} \\$ disparate groups by:
- (a) Identifying those cancers that disproportionately impact certain demographic groups; and
- (b) Building collaborations designed to reduce health disparities as they relate to cancer.
- Section 5. Section 1004.445, Florida Statutes, is amended to read:
- 12 1004.445 Ronald Reagan Johnnie B. Byrd, Sr.,
 13 Alzheimer's Center and Research Institute.--
 - (1) The <u>Ronald Reagan</u> Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute is established at the University of South Florida.
 - an agreement for the utilization of the facilities on the campus of the University of South Florida to be known as the Ronald Reagan Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, including all furnishings, equipment, and other chattels used in the operation of those facilities, with a Florida not-for-profit corporation organized solely for the purpose of governing and operating the Ronald Reagan Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute. This not-for-profit corporation, acting as an instrumentality of the state, shall govern and operate the Ronald Reagan Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute in accordance with the terms of the agreement between the State Board of Education and the not-for-profit corporation. The not-for-profit corporation may, with the prior approval of the

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State Board of Education, create either for-profit or not-for-profit corporate subsidiaries, or both, to fulfill its mission. The not-for-profit corporation and its subsidiaries are 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 practice activities of the institute, for the benefit of the institute and the fulfillment of its mission.

- (b)1. The affairs of the not-for-profit corporation shall be managed by a board of directors who shall serve without compensation. The board of directors shall consist of the President of the University of South Florida and the chair of the State Board of Education, or their designees, 5 representatives of the state universities, and no fewer than 9 nor more than 14 representatives of the public who are neither medical doctors nor state employees. Each director who is a representative of a state university or of the public shall be appointed to serve a term of 3 years. The chair of the board of directors shall be selected by a majority vote of the directors. Each director shall have only one vote.
- 2. The initial board of directors shall consist of the President of the University of South Florida and the chair of the State Board of Education, or their designees; the five university representatives, of whom one shall be appointed by the Governor, two by the President of the Senate, and two by the Speaker of the House of Representatives; and nine public representatives, of whom three shall be appointed by the Governor, three by the President of the Senate, and three by the Speaker of the House of Representatives. Upon the expiration of the terms of the initial appointed directors,

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all directors subject to 3-year terms of office under this
paragraph shall be appointed by a majority vote of the
directors and the board may be expanded to include additional
public representative directors up to the maximum number
allowed. Any vacancy in office shall be filled for the
remainder of the term by majority vote of the directors. Any
director may be reappointed.

- (3) The State Board of Education shall provide in the agreement with the not-for-profit corporation for the following:
- (a) Approval by the State Board of Education of the articles of incorporation of the not-for-profit corporation.
- (b) Approval by the State Board of Education of the articles of incorporation of any not-for-profit corporate subsidiary created by the not-for-profit corporation.
- (c) Utilization of lands, facilities, and personnel by the not-for-profit corporation and its subsidiaries for research, education, treatment, prevention, and the early detection of Alzheimer's disease and for mutually approved teaching and research programs conducted by the University of South Florida or other accredited medical schools or research institutes.
- (d) Preparation of an annual financial audit pursuant to s. 11.45 of the not-for-profit corporation's accounts and the accounts of any subsidiaries to be conducted by an independent certified public accountant. The annual audit report shall include management letters and shall be submitted to the Auditor General and the State Board of Education for review. The State Board of Education, the Auditor General, and the Office of Program Policy Analysis and Government Accountability shall have the authority to require and receive

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from the not-for-profit corporation and any subsidiaries, or from their independent auditor, any detail or supplemental data relative to the operation of the not-for-profit corporation or subsidiary.

- (e) Provision by the not-for-profit corporation and its subsidiaries of equal employment opportunities for all persons regardless of race, color, religion, gender, age, or national origin.
- (4) The State Board of Education is authorized to secure comprehensive general liability protection, including professional liability protection, for the not-for-profit corporation and its subsidiaries, pursuant to s. 1004.24. The not-for-profit corporation and its subsidiaries shall be exempt from any participation in any property insurance trust fund established by law, including any property insurance trust fund established pursuant to chapter 284, so long as the not-for-profit corporation and its subsidiaries maintain property insurance protection with comparable or greater coverage limits.
- (5) In the event that the agreement between the not-for-profit corporation and the State Board of Education is terminated for any reason, the State Board of Education shall assume governance and operation of the facilities.
- (6) The institute shall be administered by a chief executive officer, who shall be appointed by and serve at the pleasure of the board of directors of the not-for-profit corporation, and who shall exercise the following powers and duties, subject to the approval of the board of directors:
- (a) The chief executive officer shall establish programs that fulfill the mission of the institute in research, education, treatment, prevention, and early

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detection of Alzheimer's disease; however, the chief executive officer may not establish academic programs for which academic credit is awarded and which culminate in the conferring of a degree, without prior approval of the State Board of Education.

- (b) The chief executive officer shall have control over the budget and the moneys appropriated or donated to the institute from private, local, state, and federal sources, as well as technical and professional income generated or derived from practice activities of the institute. However, professional income generated by university faculty from practice activities at the institute shall be shared between the institute and the university as determined by the chief executive officer and the appropriate university dean or vice president.
- (c) The chief executive officer shall appoint representatives of the institute to carry out the research, patient care, and educational activities of the institute and establish the compensation, benefits, and terms of service of such representatives. Representatives of the institute shall be eligible to hold concurrent appointments at affiliated academic institutions. University faculty shall be eligible to hold concurrent appointments at the institute.
- (d) The chief executive officer shall have control over the use and assignment of space and equipment within the facilities.
- (e) The chief executive officer shall have the power to create the administrative structure necessary to carry out the mission of the institute.
- (f) The chief executive officer shall have a reporting relationship to the Commissioner of Education.

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- (g) The chief executive officer shall provide a copy of the institute's annual report to the Governor and Cabinet, the President of the Senate, the Speaker of the House of Representatives, and the chair of the State Board of Education.
- (7) The board of directors of the not-for-profit corporation shall create a council of scientific advisers to the chief executive officer comprised of leading researchers, physicians, and scientists. The council shall review programs and recommend research priorities and initiatives to maximize the state's investment in the institute. The members of the council shall be appointed by the board of directors of the not-for-profit corporation. Each member of the council shall be appointed to serve a 2-year term and may be reappointed to the council.
- (8) In carrying out the provisions of this section, the not-for-profit corporation and its subsidiaries are not agencies within the meaning of s. 20.03(11).
- (9) The following information is confidential and exempt from the provisions of s. 119.07(1) and s. 24, Art. I of the State Constitution:
- (a) Personal identifying information relating to clients of programs created or funded through the <u>Ronald</u>

 <u>Reagan Johnnie B. Byrd, Sr.</u>, Alzheimer's Center and Research

 Institute which is held by the institute, University of South

 Florida, or State Board of Education or by persons who provide services to clients of programs created or funded through contracts with the <u>Ronald Reagan Johnnie B. Byrd, Sr.</u>,

 Alzheimer's Center and Research Institute;
- (b) Any medical or health records relating to patients which may be created or received by the institute;

- (c) Materials that relate to methods of manufacture or production, potential trade secrets, potentially patentable material, actual trade secrets as defined in s. 688.002, or proprietary information received, generated, ascertained, or discovered during the course of research conducted by or through the institute and business transactions resulting from such research;
 - (d) The identity of a donor or prospective donor to the Ronald Reagan Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute who wishes to remain anonymous, and all information identifying such donor or prospective donor;
 - (e) Any information received by the institute in the performance of its duties and responsibilities which is otherwise confidential and exempt by law; and
 - (f) Any information received by the institute from a person from another state or nation or the Federal Government which is otherwise confidential or exempt pursuant to that state's or nation's laws or pursuant to federal law.

Any governmental entity that demonstrates a need to access such confidential and exempt information in order to perform

its duties and responsibilities shall have access to such

information and shall otherwise keep such information
confidential and exempt. This section is subject to the Open

25 Government Sunset Review Act of 1995 in accordance with s.

119.15 and shall stand repealed on October 2, 2006, unless reviewed and saved from repeal through reenactment by the

Legislature.

(10) Any appropriation to the institute provided in a general appropriations act shall be paid directly to the board

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1	of directors of the not-for-profit corporation by warrant
2	drawn by the Chief Financial Officer from the State Treasury.
3	Section 6. This act shall take effect July 1, 2005.
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5	STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
6	COMMITTEE SUBSTITUTE FOR SBs 1872 and 2378
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8	The Committee Substitute differs from SBs 1872 and 2378 in the
9	following ways:
10	The bill provides funding for biomedical research by redistributing funds that are deposited in the Alcoholic
11	Beverage and Tobacco Trust Fund. The bill deletes the \$15 million that currently funds the Johnnie B. Byrd, Sr.,
12	Alzheimer's Center and Research Institute and designates instead that \$15 million be directed annually to the
13	Department of Health for the Florida Center for Universal Research to Eradicate Disease to provide grants for
14	Alzheimer's disease research. The bill deletes the \$9 million that is annually distributed to the Florida State University
15	School of Chiropractic Medicine and instead directs \$9 million annually to the Department of Health for the Florida Center
16	for Universal Research to Eradicate Disease for grants for cancer research.
17	The bill does not allocate tobacco settlement funds or
18	cigarette tax proceeds for cancer research and does not require the Florida Cancer Council to provide grants for cancer research.
19	The bill renames the Johnnie B. Byrd, Sr., Alzheimer's Center
20	and Research Institute as the Ronald Reagan Alzheimer's Center and Research Institute.
21	and Research Institute.
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