

**STORAGE NAME:** h1871z.hcs

**DATE:** June 23, 1999

**\*\*FINAL ACTION\*\***

**\*\*SEE FINAL ACTION STATUS SECTION\*\***

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

**BILL #:** HB 1871 (Passed as sections 61 and 62 of HB 2125)

**RELATING TO:** Autism/Secretin Research

**SPONSOR(S):** Rep. Tullis

**COMPANION BILL(S):** SB 976 (i), HB 1467 (c), HB 2125 (c), SB 2220 (c)

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

- (1) HEALTH CARE SERVICES
- (2) HEALTH & HUMAN SERVICES APPROPRIATIONS
- (3)
- (4)
- (5)

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I. FINAL ACTION STATUS:

06/18/99 Approved by Governor; Chapter No. 99-397

II. SUMMARY:

HB 1871, which was adopted as sections 61 and 62 of HB 2125, requires the Division of Children's Medical Services of the Department of Health to contract with a private nonprofit provider that is affiliated with a teaching hospital to conduct clinical trials, approved by a federally-sanctioned institutional review board within the teaching hospital, on the use of the drug Secretin to treat autism. The bill requires the private nonprofit provider conducting the clinical trials to report its findings to the Division of Children's Medical Services, the President of the Senate, the Speaker of the House of Representatives, and other appropriate bodies.

The bill provides an appropriation of \$50,000 to the Division of Children Medical Services of the Department of Health from the General Revenue Fund for implementing the bill.

The effective date of this provision is July 1, 1999.

III. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

**Autism**

Autism is a complex neurodevelopmental disability affecting communication, social functioning, and adaptive behavior. It is estimated that autism occurs in about 15 of every 10,000 births nationwide. The Center for Autism and Related Disabilities in Florida notes that autism occurs by itself, with mental retardation, or with other health problems such as epilepsy, viral infections, or changes in a person's growth rate or metabolism. According to the National Institute of Child Health and Human Development, autism is a major pediatric health issue in the United States, with associated health care costs exceeding \$13 billion per year. The cause of autism is unknown. According to the National Institute of Mental Health, it is generally accepted that autism is caused by abnormalities in brain structures or functions.

Section 393.063(3), F.S., 1999 Supplement, defines autism as "a pervasive, neurologically based developmental disability of extended duration which causes severe learning, communication, and behavior disorders with age of onset during infancy or childhood. Individuals with autism exhibit impairment in reciprocal social interaction, impairment in verbal and nonverbal communication and imaginative ability, and a markedly restricted repertoire of activities and interests." Individuals with autism, regardless of severity of impairments and the presence of coexisting conditions, do share some common needs. Difficulties with speech and language necessitate varying degrees of speech therapy. Occupational and physical therapy may also be helpful in improving social and functional abilities. Intensive behavioral programs, varying in intensity and structure based on individual need, are universally recognized as essential in assisting people with autism with developing critical social and functional skills. Finally, early intervention is important for children. Interventions that occur during this critical period in a child's development have been documented to significantly increase a child's skills and capacities for life-long learning.

According to the National Institute of Mental Health (NIMH), a number of treatment approaches have evolved in the decades since autism was first identified, including developmental and behaviorist approaches. Developmental approaches provide consistency and structure along with appropriate levels of stimulation. Behaviorist training involves time-intensive, highly structured, repetitive sequences in which a child is given a command and rewarded each time he responds correctly. By using this approach for up to 40 hours a week, some children may be brought to the point of near-normal behavior. Others are much less responsive to the treatment. However, some researchers and therapists believe that less intensive treatments, particularly those begun early in a child's life, may be more efficient and just as effective. Presently, NIMH is funding several types of behaviorist treatment approaches to help determine the best time for treatment to start, the optimum treatment intensity and duration, and the most effective methods to reach both high and low functioning children.

**Secretin**

According to the National Institutes of Health, Secretin is a gastrointestinal peptide hormone that controls digestion. The primary action of secretin is to increase the volume and bicarbonate content of secreted pancreatic juices. The United States Food and Drug Administration has approved Secretin for single dose use in diagnosing gastrointestinal problems such as impaired pancreatic function or gastric problems such as ulcers in adults. The use of Secretin for any other purpose may be considered a use for which the United States Food and Drug Administration has not issued formal approval; such use is commonly referred to as "off-label" use of a drug.

Little research has been published on the use of Secretin as a treatment for children with autism. A recent study of three children with autism and gastro-intestinal problems titled "Improved social and language skills after Secretin administration in patients with autistic spectrum disorders" (Horvath K, et al. published in the *Journal of the Association for Academic Minority Physicians* 1998; 9: 9-15) indicated that after Secretin infusion, the children's gastro-intestinal problems improved and the children became more sociable and communicative. On October 7, 1998, *Dateline NBC* reported that an autistic child, Parker Beck, who had suffered constant diarrhea and vomiting for almost two years and who was given Secretin while being treated for the gastro-intestinal problems, had improved communicative skills. According to the director of the Autism Research Institute, unofficially, about 200 children have received Secretin and more than half of the children have shown some positive response. The Autism Research Institute preliminary survey on the use of Secretin to treat autism

indicated that there is little data as to what is the best dosage and optimal schedule of administration of Secretin for treatment of autism.

The National Institutes of Health encourages human and animal research including genetic, neuroanatomic, neurophysiologic, immunologic, neurochemical, and neuropsychologic studies to shed light on the etiology and pathophysiology of autism and studies of effective behavioral and psychopharmacologic interventions. The National Institutes of Health does not currently have a formal position on the therapeutic use of Secretin in the treatment of autism. The National Institute of Child Health and Human Development invites qualified applicants to submit applications for research funding to explore the safety, efficacy, and mechanism of action of Secretin as an effective treatment for autism or gastro-intestinal disorders associated with autism.

#### **Protection of Human Subjects**

The United States Department of Health and Human Services has established regulations (Protection of Human Subjects, 45 Code of Federal Regulations part 46) to establish a federal policy for the protection of human subjects. The federal policy for the protection of human subjects applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency which takes appropriate action to make the policy applicable to such research. Under the federal regulation for the protection of human subjects, institutional review boards must review and have authority to approve, require modifications in, or disapprove all research activities. Federally sanctioned institutional review boards use the following criteria for approval of research: risks to subjects are minimized by the use of procedures which are consistent with sound research design; risks to subjects are reasonable in relation to anticipated benefits; selection of subjects is equitable; informed consent will be sought from each prospective subject or the subject's legally authorized representative; informed consent is appropriately documented; when appropriate, the research plan makes adequate provision for monitoring data to ensure the safety of subjects; and when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

#### **Children's Medical Services**

Under the authority of chapters 383 and 391, F.S., the Children's Medical Services (CMS) Office of the Department of Health provides a comprehensive system of care ranging from prevention services to long-term care services for financially-eligible high-risk pregnant women, sick or low birthweight newborns, and children with chronically handicapping or potentially handicapping conditions. Prevention services are available through statewide programs such as infant metabolic screening, infant hearing screening, and poison control centers. Prevention services also include the statewide Regional Perinatal Intensive Care Centers (RPICC) Program, which provides specialized services to high-risk pregnant women and newborns. Early intervention services are available throughout the state for infants and toddlers who are at risk for developmental delay. These services are provided by local agencies and Developmental Evaluation and Intervention programs. To administer the Children's Medical Services Program, the Department of Health has among its powers, duties, and responsibilities the charge "to sponsor or promote grants for projects, programs, education, or research in the field of medical needs of children, with an emphasis on early diagnosis and treatment" (s. 391.026(7), F.S., 1998 Supplement).

#### **B. EFFECT OF PROPOSED CHANGES:**

The bill will require the Division of Children's Medical Services of the Department of Health to contract with a private nonprofit provider that is affiliated with a teaching hospital to conduct clinical trials, approved by a federally-sanctioned institutional review board within the teaching hospital, on the use of the drug Secretin to treat autism. The bill will require the private nonprofit provider conducting the clinical trials to report its findings to the Division of Children's Medical Services, the President of the Senate, the Speaker of the House of Representatives, and other appropriate bodies.

The bill will provide an appropriation of \$50,000 to the Division of Children's Medical Services of the Department of Health from the General Revenue Fund for implementing the research initiative.

The effective date of this provision is July 1, 1999.

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?

N/A

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

Yes. The bill directs the Division of Children's Medical Services of the Department of Health to enter a contract for specific research purposes.

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

N/A

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?

N/A

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

N/A

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

N/A

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

N/A

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

N/A

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?

N/A

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

N/A

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?

N/A

- 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:**

None.

**E. SECTION-BY-SECTION ANALYSIS:**

See EFFECT OF PROPOSED CHANGES above.

**IV. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:**

**A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:**

1. Non-recurring Effects:

The bill provides an appropriation of \$50,000 to the Division of Children's Medical Services of the Department of Health from the General Revenue Fund for implementing the bill's requirements to contract with a private nonprofit provider to conduct clinical trials on the use of the drug Secretin to treat autism.

2. Recurring Effects:

N/A

3. Long Run Effects Other Than Normal Growth:

A favorable outcome of the clinical trials evaluating the use of Secretin to treat autism could potentially reduce state and federal expenditures for autism services.

4. Total Revenues and Expenditures:

N/A

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:**

1. Non-recurring Effects:

N/A

2. Recurring Effects:

N/A

3. Long Run Effects Other Than Normal Growth:

N/A

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

N/A

2. Direct Private Sector Benefits:

A favorable outcome of the clinical trials evaluating the use of Secretin to treat autism has the potential to benefit a significant number of autistic children and their families in Florida.

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

N/A

D. FISCAL COMMENTS:

None.

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

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require counties or municipalities to spend funds or to take action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

The bill does not reduce the authority that counties and municipalities have to raise revenue in the aggregate.

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

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

VI. COMMENTS:

As previously indicated, the bill requires the private nonprofit provider conducting the clinical trials to report its findings to the Division of Children's Medical Services, the President of the Senate, the Speaker of the House of Representatives, and other appropriate bodies. No time frame is indicated for such reporting.

VII. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

HB 1871 was never heard in a House committee. When the identical companion measure, SB 976, was heard in the Senate Committee on Health, Aging and Long-Term Care on March 3, 1999, the committee adopted an amendment which specified that the research conducted must be approved by a federally-sanctioned institutional review board within the teaching hospital conducting the research. This modified version of the bill was adopted as part of HB 2125.

VIII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

Prepared by:

Phil E. Williams

Staff Director:

Phil E. Williams

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**FINAL ANALYSIS PREPARED BY THE COMMITTEE ON HEALTH CARE SERVICES:**

Prepared by:

Staff Director:

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