

# SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based only on the provisions contained in the legislation as of the latest date listed below.)

BILL: SB 976

SPONSOR: Senator Myers

SUBJECT: Autism

DATE: March 18, 1999

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HC</u>	<u>Fav/1 amendment</u>
2.	<u>Peters</u>	<u>Hadi</u>	<u>FP</u>	<u>Favorable</u>
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____

## I. Summary:

The bill 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 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.

This bill creates two sections which have not been designated to a section of the Florida Statutes.

## II. 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(2), Florida Statutes, defines autism to mean 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 develop 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. These approaches include developmental and behaviorist. 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.

### **State-funded Coverage for the Treatment of Autism**

#### ***Medicaid State Plan***

Physical therapy, speech-language therapy, and occupational therapy are available, subject to certain eligibility requirements and coverage limits, under Florida's Medicaid Program. These services are not specifically provided for the treatment of people with autism, but for people with indicators for the particular service.

The Medicaid therapy program provides therapy services to Medicaid recipients under the age of 21 when the service is determined to be medically necessary. The Medicaid behavioral health program provides services to individuals with a diagnosed mental illness. Autism and other developmental disabilities (i.e., mental retardation) are not included in the list of diagnoses covered by the Community Mental Health Program. However, if an individual is diagnosed with mental illness and autism, the individual would be eligible for behavioral interventions.

#### ***Developmental Services***

As of January 1, 1999, the Developmental Services Program of the Department of Children and Family Services was providing services to 1,148 individuals with a primary or secondary diagnosis of autism. Of these 1,148 individuals, 779 are enrolled in Medicaid.

The Developmental Services Home and Community-Based Waiver programs (the DS waiver) provide services to eligible individuals with developmental disabilities, including autism. In order to participate, individuals must be Medicaid eligible and meet the Intermediate Care Facility for the Developmentally Disabled level of care requirements. The greatest expenditures for wavier

services for individuals with autism are residential habilitation and adult day training. Both services provide intensive supports for extended periods of time. The waiver programs are funded at a set level each year by the Legislature. Individuals with the most severe needs have priority for services.

The Developmental Services Program also provides services to individuals with a developmental disability through its general revenue-funded programs. General revenue expenditures for individuals with autism are greater for behavior services, respite care, and long-term residential care. Service provision is subject to availability of funding and services are allocated based on severity of need.

***Department of Education, Exceptional Student Program***

According to the Department of Education (DOE), if a student meets certain eligibility criteria (including, but not limited to early onset of disorder at birth or during the first 3 years of life and evidence of severely delayed or absent speech and language skills), a student is eligible to participate in the exceptional student program for autistic children. The program provides services for children, ages 0-21.

For school year 1997-98, the total full-time equivalent cost allocation for students with autism was \$42,239,888. During school year 1997-98, DOE reported 2,704 children participating in the autism program or 0.12 percent of the total public school population or 0.064 percent of the Florida population between the ages of 0 -21. The autism category may include children with Rett's Syndrome and Asperger's Syndrome. The department serves students with a wide range of needs for services. In addition to academic instruction, students may also be receiving services for health care (administration and monitoring of medication), behavioral support, communication, and independent functioning.

The number of children whose primary exceptionality is autism who are also receiving occupational therapy, physical therapy, and speech therapy is: occupational therapy 876, physical therapy 102, and speech therapy 437. The department indicated that this is a duplicated count, not a child count. (Students could be served in more than one program.)

***Centers for Autism and Related Disabilities***

Section 228.055, F.S., establishes five regional autism centers to provide nonresidential resources and training services for persons of all ages and of all levels of intellectual functioning who have autism. Each center is operationally and fiscally independent and provides services within a geographical region of Florida. Each center coordinates services within and between state and local agencies and school districts, but may not duplicate services provided by those agencies or school districts. Each center must provide: a staff that has expertise in autism and autistic-like behaviors, and sensory impairments; individual and family assistance; technical and consultation services; professional training programs; and public education programs to increase awareness regarding autism and sensory impairments.

The five centers for autism and related disabilities are: The Department of Communication Disorders at Florida State University; The College of Medicine at the University of Florida; The University of Florida Health Science Center at Jacksonville; The Florida Mental Health Institute at the University of South Florida; and The Mailman Center for Child Development at the University

of Miami. A constituency board works collaboratively with each center to provide advice on policies, priorities, and activities. The centers hold annual meetings to promote statewide planning for issues relating to autism and facilitate coordination, networking, training, and feedback among the center's staff and constituencies. The Department of Education, in cooperation with the regional autism centers must adopt administrative rules to carry out their programs to coordinate services for persons with autism.

### **Private Sector Coverage**

Many insurance carriers specifically exclude autism spectrum disorder from being covered for speech and language therapy and occupational therapy, even though the defining symptoms are ones of neurologically-based communication, movement, and sensory integration problems. However, these same symptoms in an individual who has received specific traumatic injury to the brain (e.g., car accident, blow to the head, stroke) may be covered.

Some insurance carriers have indicated that coverage is provided for prescription drugs; however, other types of benefits (i.e., physical therapy, occupational therapy) may or may not be covered, contingent upon the symptoms of the patient. Other plans exclude developmental disorders (autism and mental retardation).

### **Florida State Employees' Group Health Insurance**

The Florida State Employees' Preferred Provider Organization (PPO) and the Health Maintenance Organizations (HMO) provide coverage for the diagnosis and medical treatment (including prescription drugs) of autism, Asperger's Syndrome, Rett's Syndrome, and pervasive developmental disorder. However, the PPO specifically excludes coverage for speech and occupational therapies and the HMOs exclude occupational therapy. Also, the PPO and the HMOs generally exclude coverage for experimental or investigational treatments, custodial care, non-prescription drugs, and training and educational services.

### **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 may 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.

### **III. Effect of Proposed Changes:**

The bill 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 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's Medical Services of the Department of Health from the General Revenue Fund for implementing the bill.

The bill provides an effective date of July 1, 1999.

### **IV. Constitutional Issues:**

#### **A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

#### **B. Public Records/Open Meetings Issues:**

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Subsections 24(a) and (b) of the Florida Constitution.

#### **C. Trust Funds Restrictions:**

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

### **V. Economic Impact and Fiscal Note:**

#### **A. Tax/Fee Issues:**

None.

#### **B. Private Sector Impact:**

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.

#### **C. Government Sector Impact:**

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. 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.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

The bill should clarify that the clinical trials to be conducted by a private nonprofit provider affiliated with a teaching hospital should be approved by a federally sanctioned institutional review board within the teaching hospital.

**VIII. Amendments:**

#1 by Health, Aging and Long-Term Care:

Clarifies that the clinical trials for the evaluation of the use of secretin to treat autism must be approved by a federally-sanctioned institutional review board within the affiliated teaching hospital.