SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/SB 1128

SPONSOR: Health, Aging and Long Term Care Committee and Senator Latvala

SUBJECT: Medical Treatment

DATE: April 20, 2001 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.	Matthews	Johnson	JU	Favorable
3.				
4.				
5.				
6.				

I. Summary:

The bill creates the "Access to Medical Treatment Act" to limit an allopathic or osteopathic physician's exposure to disciplinary and civil liability for treating patients with life-threatening illnesses, diseases, or conditions with investigational medical treatments subject to the patient's informed consent. The bill provides that it does not modify or change the scope or standards of care in such licensee's practice including the prohibition of fraud and exploitation.

The bill creates an undesignated section of law.

II. Present Situation:

The Practice of Medicine

Chapter 458 of the Florida Statutes governs the regulation of the practice of medicine by the Board of Medicine with the Department of Health. The "practice of medicine" is defined to mean the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition. See s. 458.305, F.S. A medical physician is subject to discipline for any act in violation of applicable standards of practice, which include gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment that is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances.[1] A medical physician is also subject to discipline for performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent.[2] In any administrative action against a physician not involving a licensure revocation or suspension, the division (Department of

[1] Section 458.331(1)(t), F.S.
[2] Section 458.331(1)(u), F.S.

Health) has the burden, by the greater weight of the evidence, to establish the existence of grounds for disciplinary action. See s. 458.331(3), F.S. The burden is greater for revocation or suspension of a license, i.e., clear and convincing evidence. A medical physician may also be subject to discipline for aiding, assisting, procuring, or advising any unlicensed person to practice medicine contrary to chapter 458, F.S., or any regulations there under.

The Practice of Osteopathic Medicine

Chapter 459, F.S., the osteopathic medical practice act, similarly provides for the regulation of osteopathic physicians by the Board of Osteopathic Medicine in the Department of Health. The term "practice of osteopathic medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition *See* s. 459.003, F.S. Osteopathic medicine practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health. Chapter 459, F.S., similarly contains provisions relating to the discipline of licensed osteopathic physicians, which are comparable to those in the medical practice act.[3]

Medical Consent Law

Section 766.103, F.S., the Florida Medical Consent Law, provides immunity from civil damages for physicians treating, examining, or operating on patients without the patient's informed consent under non-emergency circumstances, subject to two conditions. The first condition is that the physician attempt to obtain consent from the patient or from a person authorized to give consent on behalf of the patient by applying accepted standards of medical practice among members of the medical profession or community that would be sufficient to give a reasonable person a general understanding of the procedure, acceptable alternative treatments, and the substantial risks and hazards inherent in the proposed treatment that have been recognized by members of the profession. The second condition is that the patient could reasonably be anticipated, under all the surrounding circumstances, to have consented to the treatment had he been advised by the physician as required under the first condition.

Medical Research

There are federal regulations governing medical research including the regulation of human subjects participating in such research. This regulation applies to all research involving human subjects conducted by the Department of Health and Human Services (HHS) or research that is partially or fully federally funded. Several research activities are exempted from requirements contained in these regulations. *See* 45 CFR, Part 46. These regulations do not supersede any federal, state, or local law. Institutions engaged in research covered by these regulations must designate one or more Institutional Review Boards (IRBs). IRBs function in hospitals, other facilities, universities, and governmental agencies to safeguard the rights and welfare of human subjects.[4]

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[3] See s. 459.015 (1)(x), F.S., An osteopathic physician is subject to discipline for any act in violation of applicable standards of practice, which include gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment that is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances. Under s. 459.015(1)(y), F.S., an osteopathic physician is also subject to discipline for performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent.

[4] The composition of the IRBs is specifically provided for in the regulations to the extent that they:

Federal Food and Drug Administration

The United States Food and Drug Administration (FDA) does not regulate medical practice which regulation has historically been left to the states. However, the FDA does regulate devices and drugs, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.

Consequently, the FDA has adopted regulations to cover all clinical investigations that support applications for research or marketing permits for products regulated by the FDA, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.[5] A clinical investigation (clinical trial) is a research study to answer specific questions about vaccines or new therapies or new ways of using *known* treatments. All clinical trials are based on a set of rules called a protocol that describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. Clinic trial participants are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment. There are strict federal guidelines and safeguards for these participants. Every clinical trial must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits and to protect the rights of the participants, particularly those representative of the vulnerable population (i.e., children, prisoners, persons with mental disabilities, and persons who are educationally or economically disadvantaged.)

In addition, the FDA has adopted regulations[6] that authorize the use of investigational new drugs (INDs) for patients who are not participants in any research or clinical study. The use of INDs have allowed physicians greater flexibility to use unapproved drugs to treat seriously ill patients rather than waiting for formal approval on the safety or effectiveness of the drug. A treatment IND is a mechanism for providing eligible subjects with investigational drugs for the treatment

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- must have a minimum of 5 members with varying backgrounds, including consideration of racial and cultural diversity;
- may not ever consist entirely of men or women or members of only one profession;
- at least one member must have a nonscientific focus such as lawyers, ethicists, or clergy; at least one member must not be affiliated with the institution or be an immediate family member of a person affiliated with the institution;
- members may not participate in initial or continued review of research that results in a conflict of interest for them; and
- members may request assistance or persons with special expertise to review complex issues, which require expertise beyond or in addition to that available among members.

Members of IRBs are charged with ascertaining the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB may approve, require modification in (to secure approval), or disapprove all research activities covered by the these regulations; it may specify what information must be given to subjects as a part of informed consent; it must require documentation of informed consent or may waive the documentation requirement; it must notify the researcher and the institution in writing of its decision to approve or disapprove a research proposal; and it must conduct continuing review of research covered by the regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

[5] The Protection of Human Subjects provisions under 21 C.F.R. 50, although specialized to support new product applications regulated by the Food and Drug Administration, are comparable to those found in 45 C.F.R. 46, with some exceptions.
[6] 21 C.F.R. 312.34 and 312.35

of serious and life-threatening[7] illnesses for which there are no satisfactory alternative treatments. A treatment IND may be granted after sufficient data has been collected in support of a new drug application to show that the drug may be effective and does not have unreasonable risks. Before a treatment IND may be used, four requirements must be met: 1) the drug is intended to treat a serious or immediately life-threatening disease; 2) there is no satisfactory alternative treatment available; 3) the drug is already under investigation, or trials have been completed; and 4) the trial sponsor is actively pursuing marketing approval. Treatment IND studies require prospective IRB review and informed consent.

In addition, the FDA has established a "Parallel Track"[8] policy that allows wider access to promising new drugs for AIDS/HIV related diseases under a separate "expanded access" protocol that parallels the controlled clinical trials that are essential to establish the safety and effectiveness of new drugs. These "Parallel Track" studies require prospective review by the Institutional Review Board and informed consent.

The use of a test article (drug, biological product, or device) without prior IRB review is permitted when a life-threatening condition exists; when no standard acceptable treatment is available; and when there is not time for IRB approval. In a life-threatening emergency, an investigator may use a device or administer one course of treatment to a subject without prospective IRB review. The FDA has established procedures to allow the use of investigational drugs in an emergency situation that does not allow time for submission of an IND application in the usual manner; however, a prospective IRB review and informed consent would still be required.[9]

If the drug, biologic or medical device is approved and marketed but used by an allopathic or osteopathic physician in a manner not listed in the approved labeling, it is called "off-label" or investigation use of the product. In such cases the allopathic or osteopathic physician must use her or his professional judgment about the product and is ultimately accountable to her or his regulatory board and the appropriate standards of care in the "off-label" or investigational use of a product. "Investigational use" of approved, marketed products includes the use of an approved product in the context of a clinical study protocol. When the principal intent of the investigational use of a test article is to develop information about the product's safety or efficacy, submission of an IND application, an investigational device exemption application, or review by an IRB may be required with certain specified exceptions.[10]

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[7] Under 21 C.F.R. 312.80- 312.88 (Subpart E) at 312.81 (a), the term "life-threatening" is defined to mean: (1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and (2) Diseases or conditions with potentially fatal outcomes, where the endpoint of clinic trial analysis is survival.

[8] 57 Federal Register 13250

[9] 21 C.F.R. 312.36. Further the emergency use provision in FDA regulations [21 CFR 56.104(c)] is an exemption from prior review and approval by the IRB. The subject must be in a life-threatening situation requiring intervention before review at a convened meeting of an IRB is feasible. The exemption, which may not be used unless all of the conditions described in 21 C.F.R. 56.102(d) exist, allows for one emergency use of a test article without prospective IRB review. Any subsequent use of the investigational product at the institution must have prospective IRB approval and review.

[10] 21 C.F.R. 312.3 (b)(1)

III. Effect of Proposed Changes:

Section 1. The "Access to Medical Treatment Act" is created to allow an allopathic or osteopathic physician to treat an individual for a life-threatening illness, disease, or condition by means of an investigational medical treatment subject to the individual's or the individual's legal representative's authorization, provided the following steps are followed:

- The physician examines the individual;
- There is no reasonable basis on which to conclude that the treatment itself when used as directed, poses an unreasonable and significant risk of danger to the individual;
- The physician provides an oral explanation and a written statement disclosing the facts regarding the nature of the treatment, that the treatment is experimental and not approved by the FDA for such indication, any available alternative treatments, and the risks of side effects which are generally recognized by reasonably prudent physicians.
- The individual acknowledges in writing receipt of such oral explanation and written statement.

If these steps are followed, the physician's investigational treatment cannot constitute *unprofessional conduct* by the physician on that basis alone. The bill provides that this provision is not intended to modify or change the scope of practice of any licensees of the Department of Health or alter in any way the provisions including the standard of care within the respective physician's practice act and the prohibition against fraud and exploitation.

Section 2. The bill provides an effective date of July 1, 2001.

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 Art. VII, s. 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 Art. I, s. 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 Art. III, s. 19(f) of the *Florida Constitution*.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

This bill may lift the chilling effect upon the medical profession regarding the use of alternative or investigational medical treatment for individuals with life-threatening conditions, illnesses or diseases, provided the individual requests and authorizes such treatment.

This bill may facilitate an individual's access to alternative or non-conventional forms of medical treatment when circumstances are life-threatening.

C. Government Sector Impact:

Indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The term "life-threatening" is undefined in the bill, which may raise an issue as to what diseases, illnesses or conditions constitute life-threatening for purposes of investigational medical treatment. As noted earlier, under federal regulations for purposes of authorizing the use of investigational new drugs (i.e., unapproved drugs), the term "life-threatening" is defined to mean: (1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and (2) Diseases or conditions with potentially fatal outcomes, where the endpoint of clinic trial analysis is survival. Under 21 C.F.R. 312.80- 312.88 (Subpart E) at 312.81(a).

One of the conditions for the use of an investigational medical treatment is that there is no reasonable basis on which to conclude that the treatment itself, when used as directed, poses an unreasonable and significant risk of danger to the patient. Since the safety and effectiveness may not have been conclusively evaluated, it will be the physician's judgment call as to the reasonableness of the treatment without the benefit of no or insufficient scientific evidence to support his or her findings regarding the treatment. This standard would not comport to federal standards currently used in expedited IND treatment which at a minimum requires that: 1) the drug is intended to treat a serious or immediately life-threatening disease; 2) there is no satisfactory alternative treatment available; 3) the drug is already under investigation, or trials have been completed; and 4) the trial sponsor is actively pursuing marketing approval. Treatment IND studies require prospective IRB review and informed consent. A treatment IND may be granted by the FDA only after sufficient data has been collected in support of a new drug application to show that the drug may be effective and does not have unreasonable risks.

The bill does not afford patients with similar safeguards currently provided by IRBs against subsequent *unprofessional conduct* resulting from the investigational medical treatment authorized under the bill. Unprofessional conduct is not a standard recognized within the Osteopathic Medical Practice Act although the Medical Practice Act refers to unprofessional conduct for purposes of disciplinary action as that conduct which the division determines that the

physician is unable to practice with reasonable skill and safety and presents a danger to patients. *See* s. 458.331(8), F.S. One ground for disciplinary action under the Osteopathic Medical Practice Act is whether the physician failed to practice osteopathic medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similarly osteopathic physician as being acceptable under similar conditions and circumstances. *See* s. 459.015(x), F.S. Under current law, this would be established on case-by-case basis.

The bill uses the term "investigational" and "experimental" interchangeably for describing the medical treatments. According to the Department of Health, the term "investigational" is a medical term of art over which the medical community disagrees. Generally, investigational treatments are those that have been studied and determined to be no longer experimental but for which further study is needed. Experimental relates to a treatment, drug or device for which no conclusions have been reached regarding the safety and efficacy, but about which there is reasonable theoretical basis to believe in the safety and efficacy. Experimental treatments are subjected to appropriate clinical trials prior to acceptance as standard of care.

VIII. Amendments:

None.