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: March 28, 2001 REVISED: _____ _____ _____ _____

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

I. Summary:

The bill creates the "Access to Medical Treatment Act," which authorizes an allopathic or osteopathic physician to treat an individual for a life-threatening illness, disease, or condition by means of an investigational medical treatment authorized by the individual or the individual's legal representative if: 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; and 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 Food and Drug Administration for such indication, any available alternative treatments, and the risks of side effects which are generally recognized by reasonably prudent physicians. Under these circumstances, such medical treatment does not constitute, by itself, *unprofessional conduct* by the physician. The bill provides that it does not modify or change the scope of practice of any licensees of the Department of Health or alter in any way the provisions of the individual practice acts for those licensees, which require licensees to practice within their respective standards of care and which prohibit fraud and exploitation.

The bill creates an undesignated section of law.

II. Present Situation:

The Practice of Medicine

Chapter 458, Florida Statutes governs the regulation of the practice of medicine by the Board of Medicine. Section 458.305, F.S., defines the "practice of medicine" to mean the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other

physical or mental condition. The Board of Medicine within the Department of Health regulates the practice of medical physicians.

Section 458.331, F.S., specifies grounds for which a medical physician may be subject to discipline by the Board of Medicine. 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] Pursuant to subsection 458.331(3), F.S., in any administrative action against a physician which does not involve revocation or suspension of his or her license, the division (Department of Health) shall have the burden, by the greater weight of the evidence, to establish the existence of grounds for disciplinary action. The division shall establish grounds for revocation or suspension of a license by clear and convincing evidence. A medical physician may be subject to discipline for aiding, assisting, procuring, or advising any unlicensed person to practice medicine contrary to the medical practice act or to any administrative rule adopted by the Department of Health or the Board of Medicine.

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. Section 459.003, F.S., defines the "practice of osteopathic medicine" to mean the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which 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., contains provisions relating to the definition of practice and 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

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

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

The Federal government has adopted several administrative regulations governing medical research. One such regulation is protection of human subjects, 45 Code of Federal Regulation (CFR), Part 46, (regulations) which apply to all research involving human subjects conducted by the Department of Health and Human Services (HHS) or research that is funded in whole or in part by a grant, contract, cooperative agreement, or fellowship provided by HHS. Several research activities are exempted from requirements contained in these regulations. These regulations do not supersede any federal, state, or local law.

Institutional Review Boards

Institutions engaged in research covered by these regulations must designate one or more Institutional Review Boards (IRBs). Institutional Review Boards function in hospitals, other facilities, universities, and governmental agencies to safeguard the rights and welfare of human subjects. The composition of the IRBs is specifically provided for in the regulations to the extent that they: 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.

Investigational New Drugs

The United States Food and Drug Administration has adopted 21 Code of Federal Regulations, Part 50, 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.[4] 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. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

The federal government has strict guidelines and safeguards to protect people who choose to participate in clinical trials. Every clinical trial in the United States 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. Institutional Review Boards ensure that appropriate additional safeguards are in place to protect the rights and welfare of vulnerable populations, such as children, prisoners, persons with mental disabilities, and persons who are educationally or economically disadvantaged.

The United States Food and Drug Administration has adopted regulations[5] that authorize the use of investigational new drugs (INDs). The use of INDs have allowed a wider use of unapproved agents for physicians to treat seriously ill patients rather than focus on the safety or effectiveness of the drug. A treatment IND is a mechanism for providing eligible subjects with investigational drugs for the treatment of serious and life-threatening[6] 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"[7] 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 IRB review 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

[4] 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.
[5] 21 C.F.R. 312.34 and 312.35
[6] 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.
[7] 57 Federal Register 13250

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.[8]

"Off-Label" and Investigational Use of Marketed Drugs, Biologics and Medical Devices

The FDA does not regulate the practice of medicine. The FDA has consistently taken the position that the practice of medicine is a state regulatory issue. Products regulated by the FDA include food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. "Off-Label" use of a marketed drug, biologic, or medical device occurs when an allopathic or osteopathic physician uses a product for an indication not in the approved labeling. 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" use of a product.

"Investigational use" of approved, marketed products include 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.[9]

III. Effect of Proposed Changes:

Section 1. The "Access to Medical Treatment Act" is created, which allows an allopathic or osteopathic physician to treat an individual for a life-threatening illness, disease, or condition by means of an investigational medical treatment authorized by the individual or the individual's legal representative if: 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; and 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. Under these circumstances, such medical treatment does not constitute, by itself, *unprofessional conduct* by the physician. The bill provides that it does not modify or change the scope of practice of any licensees of the Department of Health or alter in any way the provisions of the individual practice acts for those licensees, which require licensees to practice within their respective standards of care and which prohibit fraud and exploitation.

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

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[8] 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.

[9] 21 C.F.R. 312.3 (b)(1)

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:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill authorizes an allopathic or osteopathic physician to treat her or his patient for any life-threatening illness, disease, or condition by means of an investigational medical treatment authorized by the patient or her or his legal representative, under specified circumstances. As used in the bill, the term, “life-threatening” is undefined. Some diseases and conditions may be life threatening for some patients and not necessarily life-threatening for others.

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. The term, *reasonable* is vague. If the “medical treatment” is investigational as provided in the bill, then it is not clear whether its safety or effectiveness has been conclusively evaluated. Therefore, the physician making a determination as to the reasonableness of the treatment has no scientific evidence to support her

or his 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 safeguards currently provided by IRBs against subsequent *unprofessional conduct* resulting from the investigational medical treatment authorized under the bill.

Institutions and hospitals sponsoring clinical trials may be hindered in their ability to enforce compliance with protocols established by IRBs to protect patients.

VIII. Amendments:

None.