Legal Developments in Clinical Bioethics

HCA Webinar ● February 4, 2014

Thaddeus Mason Pope, J.D., Ph.D.
Hamline University Health Law Institute

1. Mandated disclosures
2. The unbefriended
3. Jahi McMath
4. Marlise Munoz

Mandated Disclosures

Mandated Disclosures:

Introduction to informed consent

Legal duty of informed consent usually **framed** in terms of tort and negligence

Informed consent is **one type** of medical malpractice

What to disclose?

Not everything

You can't send patient to med school

2 main ways to measure MD duty

Material risk

20+ states

Reasonable MD

20+ states

Reasonable physician

- Duty measured by custom
- Like malpractice
- What a prudent **physician** would disclose under circumstances

Material risk

- Duty measured by patient needs
- What a reasonable **patient** would deem significant

Mandated Disclosures:

Problems with informed consent

Not happening

e.g. EOL treatment

At least in material risk jurisdictions, duty to disclose EOL options has existed for **decades**

Health Care Costs in the Last Week of Life

Associations With End-of-Life Conversations

Baohui Zhang, MS; Alexi A. Wright, MD; Haiden A. Huskamp, PhD; Matthew E. Nilsson, BS; Matthew L. Maciejewski, PhD; Craig C. Earle, MD; Susan D. Block, MD; Paul K. Maciejewski, PhD; Holly G. Prigerson, PhD

Only 31% with advanced cancer had EOL discussions

Background: Life-sustaining medical care of patients with advanced cancer at the end of life (EOL) is costly. Patient-physician discussions about EOL wishes are associated with lower rates of intensive interventions.

Methods: Funded by the National Institute of Mental Health and the National Cancer Institute, Coping With Cancer is a longitudinal multi-institutional study of 627 patients with advanced cancer. Patients were interviewed at baseline and were followed up through death. Costs for intensive care unit and hospital stays, hospice care, and life-sustaining procedures (eg, mechanical ventilator use and resuscitation) received in the last week of life were aggregated. Generalized linear models were applied to test for cost differences in EOL care. Propensity score matching was used to reduce selection biases.

Results: Of 603 participants, 188 (31.2%) reported EOL discussions at baseline. After propensity score matching, the remaining 415 patients did not differ in socio- demographic [illegible] illness acknowledgment, or treatment preferences. Further analyses, adjusted by quintiles of propensity scores and significant [illegible] ($177) for patients who reported EOL discussions compared with $2917 ($385) for patients who did not, a cost difference of [illegible]7% lower among patients who reported EOL [illegible] (P=.002). Patients with higher costs had worse quality of death in their final week (Pearson product-moment correlation, partial r = −0.17, P=.006).

Conclusions: Patients with advanced cancer who reported having EOL conversations with physicians had significantly lower health care costs in their final week of life. Higher costs were associated with worse quality of death.

Arch Intern Med. 2009;169(5):480-488

ORIGINAL RESEARCH | IMPROVING PATIENT CARE

End-of-Life Care Discussions Among Patients With Advanced Cancer

A Cohort Study

Jennifer W. Mack, MD, MPH; Angel Cronin, MS; Nathan Taback, PhD; Halden A. Huskamp, PhD; Nancy L. Keating, MD, MPH; Jennifer L. Malin, MD, PhD; Craig C. Earle, MD, MSc; and Jane C. Weeks, MD, MSc

Ann Intern Med. 2012;156:204-210. www.annals.org

Late timing

Table 4. Timing of First End-of-Life Care Discussion for Patients Who Died*

Months Between Diagnosis and Death	Patients, *n*	Median Days Between End-of-Life Care Discussion and Death (IQR)	Patients for Whom Discussion Occurred <1 mo Before Death, %
<1	165	14 (7–23)	NA
1–3	258	34 (14–54)	47
3–6	222	53 (19–97)	34
6–9	126	47 (16–162)	42
9–12	99	54 (15–223)	36
>12	89	69 (23–244)	29
Overall	959	33 (13–75)	NA

JAMA

Online article and related content current as of October 8, 2008.

Associations Between End-of-Life Discussions, Patient Mental Health, Medical Care Near Death, and Caregiver Bereavement Adjustment

Alexi A. Wright; Baohui Zhang; Alaka Ray; et al.

JAMA. 2008;300(14):1665-1673 (doi:10.1001/jama.300.14.1665)

EOL discussion

less

aggressive

medicine

17

JAMA

Online article and related content current as of October 8, 2008.

Associations Between End-of-Life Discussions, Patient Mental Health, Medical Care Near Death, and Caregiver Bereavement Adjustment

Alexi A. Wright; Baohui Zhang; Alaka Ray; et al.

JAMA. 2008;300(14):1665-1673 (doi:10.1001/jama.300.14.1665)

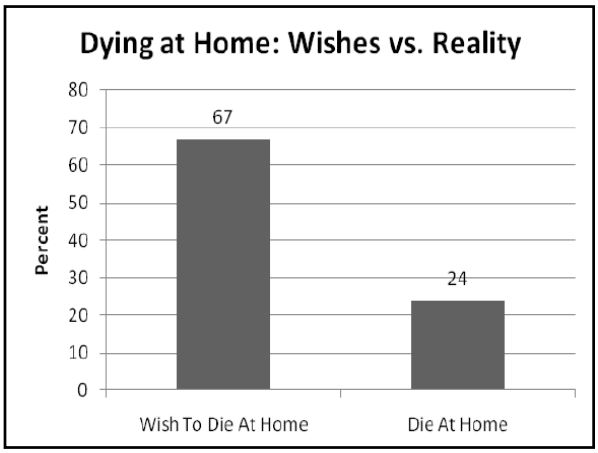
EOL discussion

Earlier hospice referral

Better patient QOL

Better family bereavement

18



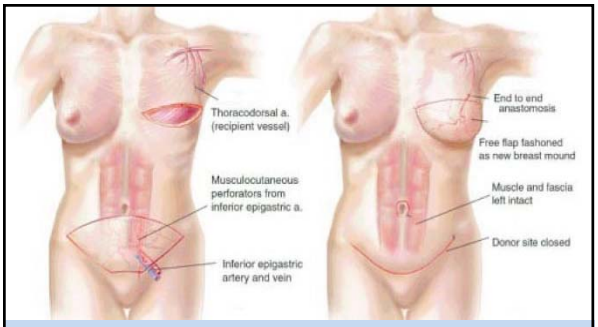
Legislative Finding:

"patients with reduced life expectancy due to advanced illnesses . . . are often **unaware** of their legal rights, particularly with regard to controlling end-of-life decisions."

Not just EOL

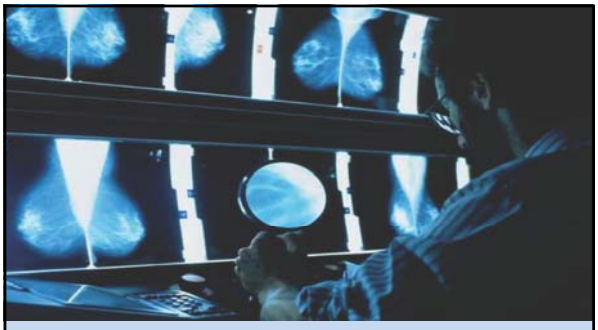
Other gaps

Other mandates



Breast reconstruction coverage

N.Y. A.B. 10094, S.B. 6993 (2010)



Breast density

Cal. S.B. 1538 (2013)

Mandated Disclosures:

Statutory mandates

1991

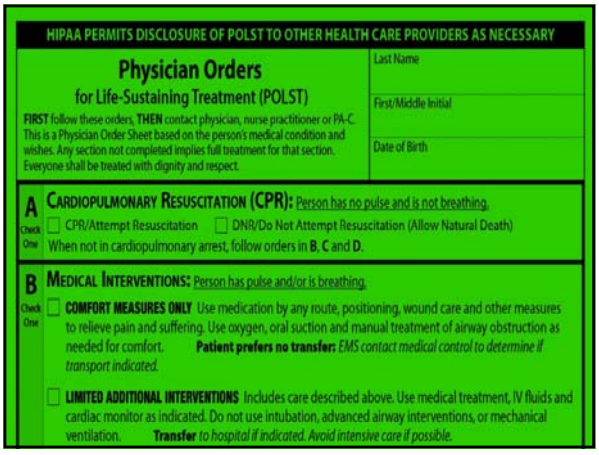
Patient Self Determination Act

Duty on facilities

Upon admission

Apprise of AD rights under state law

Last 5 years at state level



HIPAA PERMITS DISCLOSURE OF POLST TO OTHER HEALTH CARE PROVIDERS AS NECESSARY

Physician Orders for Life-Sustaining Treatment (POLST)

FIRST follow these orders, **THEN** contact physician, nurse practitioner or PA-C. This is a Physician Order Sheet based on the person's medical condition and wishes. Any section not completed implies full treatment for that section. Everyone shall be treated with dignity and respect.

Last Name

First/Middle Initial

Date of Birth

A Check One — **CARDIOPULMONARY RESUSCITATION (CPR):** Person has no pulse and is not breathing.
☐ CPR/Attempt Resuscitation ☐ DNR/Do Not Attempt Resuscitation (Allow Natural Death)
When not in cardiopulmonary arrest, follow orders in **B**, **C** and **D**.

B Check One — **MEDICAL INTERVENTIONS:** Person has pulse and/or is breathing.
☐ **COMFORT MEASURES ONLY** Use medication by any route, positioning, wound care and other measures to relieve pain and suffering. Use oxygen, oral suction and manual treatment of airway obstruction as needed for comfort. **Patient prefers no transfer:** *EMS contact medical control to determine if transport indicated.*
☐ **LIMITED ADDITIONAL INTERVENTIONS** Includes care described above. Use medical treatment, IV fluids and cardiac monitor as indicated. Do not use intubation, advanced airway interventions, or mechanical ventilation. **Transfer** *to hospital if indicated. Avoid intensive care if possible.*

healthcare facilities must determine "which of those individuals who do not have a [POLST] should be offered the opportunity to complete [one]."

Utah Admin. R. 432-31 (2011)

1996

Michigan Dignified Death Act
Mich. Comp. Laws 333.5651

2008

Right to Know End-of-Life Options Act
Cal. H&S Code 442.5

When . . . provider diagnoses . . . terminal illness, . . . shall, **upon the patient's request**, provide . . . comprehensive information and counseling regarding legal end-of-life options.

Prognosis with or without disease-targeted treatment

Right to accept **disease-targeted treatment**, with or without palliative care

Right to refuse or withdraw from **life-sustaining treatment**

Right to have comprehensive **pain** and symptom management

Meaning and availability of **hospice** care

Right to give individual health care **instruction** (POLST; AD)

Attend to emotional cues, ability to absorb…

2009

Patient's Bill of Rights for Palliative Care & Pain Management (Vt. Stat. tit. 18 § 1871)

Maryland S.B. 546, H.B. 30

Ariz. S.B. 1304

2010

Palliative Care Information Act
NY Pub. Health L. 2997c

Similar to CA

But better

CA: "upon the patient's request"

NY: "shall offer to provide"

2011

Palliative Care Access Act
NY Pub. Health L. 2997d

2012

Massachusetts Act Improving the Quality of Health Care & Reducing Costs through Increased Transparency, Efficiency & Innovation

2014

Hospital Licensure Regulations

105 CMR. 130.1900

Mandated Disclosures:

Enforcement

New York

$2000 civil penalty

$5000, if repeat violations

1 year prison, if willful

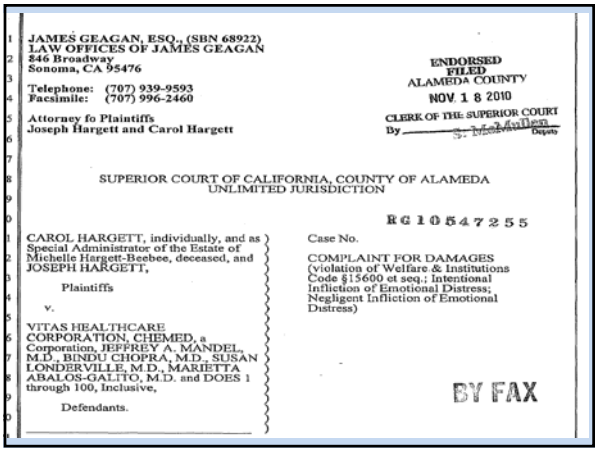
California

No separate penalties

But **defines** duties under common law

Michelle Hargett

terminal pancreatic cancer



JAMES GEAGAN, ESQ., (SBN 68922)
LAW OFFICES OF JAMES GEAGAN
846 Broadway
Sonoma, CA 95476

Telephone: (707) 939-9593
Facsimile: (707) 996-2460

Attorney fo Plaintiffs
Joseph Hargett and Carol Hargett

ENDORSED
FILED
ALAMEDA COUNTY
NOV 1 8 2010
CLERK OF THE SUPERIOR COURT
By S. Mullen Deputy

SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA
UNLIMITED JURISDICTION

RG 10547255

CAROL HARGETT, individually, and as Special Administrator of the Estate of Michelle Hargett-Beebee, deceased, and JOSEPH HARGETT,

Plaintiffs

v.

VITAS HEALTHCARE CORPORATION, CHEMED, a Corporation, JEFFREY A. MANDEL, M.D., BINDU CHOPRA, M.D., SUSAN LONDERVILLE, M.D., MARIETTA ABALOS-GALITO, M.D. and DOES 1 through 100, Inclusive,

Defendants.

Case No.

COMPLAINT FOR DAMAGES (violation of Welfare & Institutions Code §15600 et seq.; Intentional Infliction of Emotional Distress; Negligent Infliction of Emotional Distress)

BY FAX

Mandated Disclosures:

Opposition

4 types of opposition to mandated disclosures

Mandated Disclosures:

Opposition 1

June 6, 2011

Law on End-of-Life Care Rankles Doctors

By JANE E. BRODY

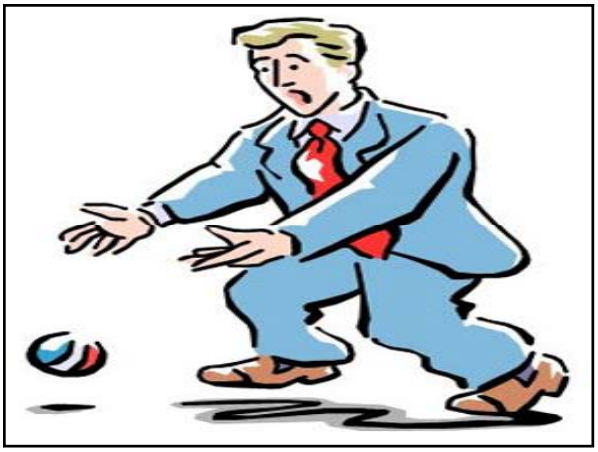
ACP

American College of Physicians

Statement of Principles on the Role of Governments in Regulating the Patient-Physician Relationship

A Statement of Principles of the American College of Physicians
July 2012

"Laws . . . should not mandate . . . provision . . . of information . . . that, in the physician's clinical judgment and based on clinical evidence and the norms of the profession, are not necessary or appropriate . . . ."



Mandated Disclosures:

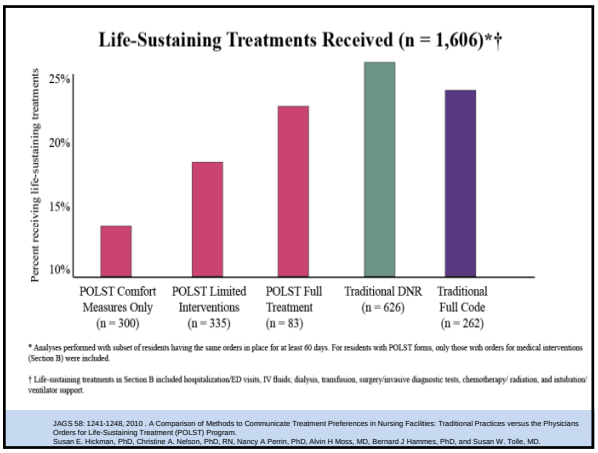
Opposition 2

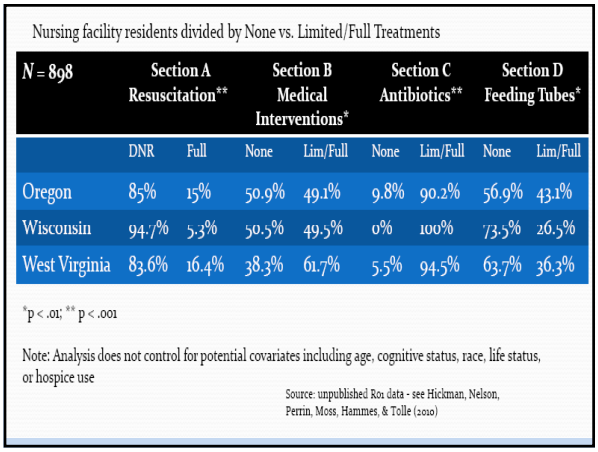
The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Physicians and the (Woman's) Body Politic

R. Alta Charo, J.D.





Nursing facility residents divided by None vs. Limited/Full Treatments

N = 898	Section A Resuscitation**		Section B Medical Interventions*		Section C Antibiotics**		Section D Feeding Tubes*	
	DNR	Full	None	Lim/Full	None	Lim/Full	None	Lim/Full
Oregon	85%	15%	50.9%	49.1%	9.8%	90.2%	56.9%	43.1%
Wisconsin	94.7%	5.3%	50.5%	49.5%	0%	100%	73.5%	26.5%
West Virginia	83.6%	16.4%	38.3%	61.7%	5.5%	94.5%	63.7%	36.3%

*p < .01; ** p < .001

Note: Analysis does not control for potential covariates including age, cognitive status, race, life status, or hospice use

Source: unpublished R01 data - see Hickman, Nelson, Perrin, Moss, Hammes, & Tolle (2010)

Mandated Disclosures:

Opposition 3

PRINCETON UNIVERSITY PRESS

More Than You Wanted to Know: The Failure of Mandated Disclosure

Omri Ben-Shahar & Carl E. Schneider
(April 2014)

"most common and **least successful** regulatory technique in American law"

VOLUME 31 · NUMBER 6 · FEBRUARY 20 2013

JOURNAL OF CLINICAL ONCOLOGY ORIGINAL REPORT

Electronic Prompt to Improve Outpatient Code Status Documentation for Patients With Advanced Lung Cancer

Jennifer S. Temel, Joseph A. Greer, Emily R. Gallagher, Vicki A. Jackson, Inga T. Lennes, Alona Muzikansky, Elyse R. Park, and William F. Pirl

See accompanying editorial on page 663

Conclusion

e-mail prompts may improve the rate and timing of code status documentation in the EHR and warrant further investigation.

Ongoing process

NOT a one-time event

Arch Intern Med. 2009;169(5):480-488

Variable	Discussed EOL Care Preferences With Physician: Yes (n=75)	No (n=70)
Medical care received during the last week of life, No. (%)		
Intensive care unit stay	2 (2.7)	10 (14.3)
Ventilator use	1 (1.3)	10 (14.3)
Resuscitation	1 (1.3)	6 (8.6)
Chemotherapy	4 (5.3)	7 (10.0)
Inpatient hospice used	8 (10.7)	5 (7.1)
Inpatient hospice stay ≥1 wk	4 (5.3)	2 (2.9)
Outpatient hospice used	58 (77.3)	40 (57.1)
Outpatient hospice stay ≥1 wk	52 (69.3)	34 (48.6)
Place of death, No. (%)[b]		
Intensive care unit	2 (2.9)	9 (13.2)
Hospital	15 (21.7)	18 (26.5)
Inpatient hospice	5 (7.2)	3 (4.4)
Home	47 (68.1)	38 (55.9)

Mandated Disclosures:

Opposition 4

Focus on information **content** than on **manner** of delivery

Must incorporate lessons from **PtDA**

Next 5 years:

Safe harbor for using "certified" PtDA

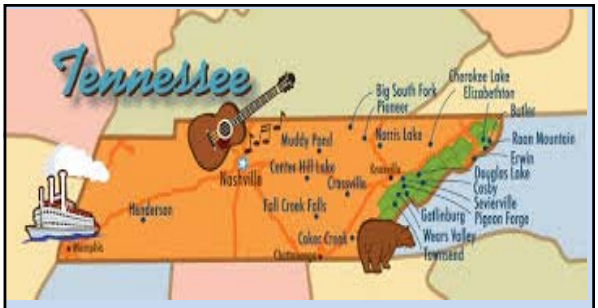
Decision Making for Patients without Surrogates

Incapacitated

No agent (DPAHC)

No guardian

No surrogate



Wider & more flexible
e.g. "close friend"

4% of 1.3 million in nursing homes

5% of 500,000/year who die in ICU

Most jurisdictions:
only mechanism is
court-appointed **guardian**

BUT Slow
Expensive
Unavailable

In entire USA, **only a few** mechanisms that are accessible, quick, convenient, and cost-effective

SENATE, No. 1233

STATE OF NEW JERSEY

216th LEGISLATURE

INTRODUCED JANUARY 30, 2014

Sponsored by:
Senator LORETTA WEINBERG
District 37 (Bergen)

SYNOPSIS

Provides for designation of surrogates to make health care decisions for certain patients; establishes demonstration program for transition of isolated patients from inpatient care to post-acute care.

1992

California

Cal. H&S Code 1418.8

"IDT"

"Epple Committee"

The **interdisciplinary team** shall oversee the care of the resident utilizing a team approach . . .

- the resident's attending physician
- a registered professional nurse with responsibility for the resident
- other appropriate staff in disciplines as determined by the resident's needs
- where practicable, a patient representative

Celebrating 30 CANHR 30 Years of Advocacy

SUPERIOR COURT OF CALIFORNIA,
COUNTY OF ALAMEDA

CALIFORNIA ADVOCATES FOR NURSING HOME REFORM (CANHR); and GLORIA A.; Petitioners vs. RONALD CHAPMAN, MD., as Director of the California Department of Public health Respondent.	No. VERIFIED PETITION FOR WRIT OF MANDATE, DECLARATORY RELIEF AND INJUNCTION Date: Time: Dept: Judge: Action filed: Trial Date: None Set

COI

patient representative only "where practicable"

Early

Litigation just getting started

More external oversight =

- Slow, cumbersome, expensive
- Risks of under-treatment & over-treatment

Jahi McMath

Jahi McMath:

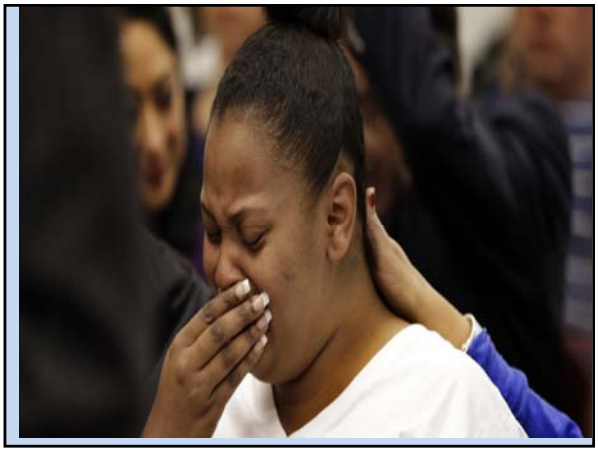
Case History

"An individual . . . . . **is dead** . . . who has sustained **either**

(1) irreversible cessation of circulatory and respiratory functions, **or**

(2) irreversible cessation of all functions of the entire brain."

Cal. H&S Code 7180-81

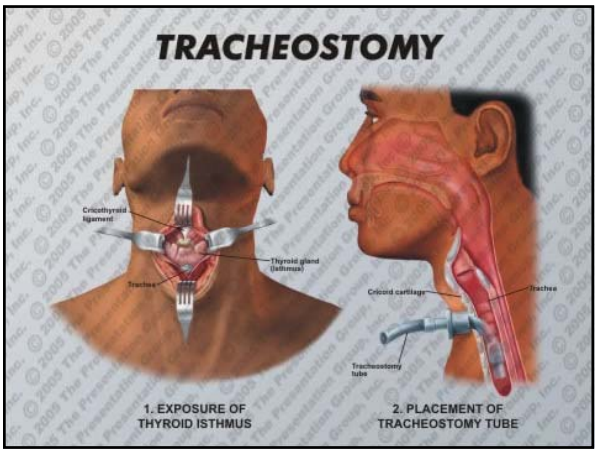


"When an individual is pronounced [brain] dead . . ., there shall be **independent confirmation** by another physician."

"independent . . . physician"

Paul Fisher

Stanford Child Neurology



Jahi McMath:

Lawsuits

Claim:

CA should be like NJ

"Death . . . **shall not be declared** upon the basis of neurological criteria . . . when the licensed physician . . ., has reason to believe, . . . would violate the personal **religious beliefs** of the individual."

N.J. Stat. 26:6A-5

". . . hospital shall [provide] next of kin with a **reasonably brief period of accommodation** . . . . continue only previously ordered cardiopulmonary support. No other medical intervention is required."

Cal. H&S Code 1254.4

"**Reasonably brief period** . . . amount of time afforded to gather family or next of kin at the patient's bedside."

No

adjudication

on the merits

TRO only

stopgap to preserve status quo pending hearing

Challenge to what is **settled**

Brain death laws: early **1980s**

Prognostic mistrust

Racial mistrust

Religious pluralism

BUT - with changed societal attitudes, time to **reevaluate ??**

PewResearchCenter

NUMBERS, FACTS AND TRENDS SHAPING THE WORLD

NOV. 21, 2013

Views on End-of-Life Medical Treatments

Growing Minority of Americans Say Doctors Should Do Everything Possible to Keep Patients Alive

Views About End-of-Life Treatment Over Time

% of U.S. adults

	1990	2005	2013	Diff. 90-13
Which comes closer to your view?				
There are circumstances in which a patient should be allowed to die	73	70	66	-7
Doctors and nurses should do everything possible to save the life of a patient in all circumstances	15	22	31	+16
Don't know	12	8	3	-9
	100	100	100	

Marlise Munoz

Marlise Munoz: Case History

"A person **may not** withdraw or withhold life-sustaining treatment under this subchapter from a **pregnant** patient."

Tex. H&S Code 166.049

Marlise Munoz: Lawsuit

017-270080-14

CAUSE NO. _____

ERICK MUNOZ, AN INDIVIDUAL AND HUSBAND, NEXT FRIEND, OF MARLISE MUNOZ, DECEASED	§	IN THE DISTRICT COURT
v.	§	____ JUDICIAL DISTRICT
JOHN PETER SMITH HOSPITAL, AND DOES 1 THROUGH 10, INCLUSIVE	§	TARRANT COUNTY, TEXAS

PLAINTIFF'S ORIGINAL PETITION FOR DECLARATORY JUDGMENT AND APPLICATION FOR UNOPPOSED EXPEDITED RELIEF

"Life-sustaining treatment . . . **sustains the life** of a patient and without which the patient will die."

Tex. H&S Code 166.001

Contrast *McMath*:

Here, there **was** an adjudication on the merits

CAUSE NO. 096-270080-14

ERICK MUÑOZ, AN INDIVIDUAL AND HUSBAND, NEXT FRIEND OF MARLISE MUÑOZ, DECEASED	§	IN THE DISTRICT COURT
	§	TARRANT COUNTY, TEXAS
VS.	§	
JOHN PETER SMITH HOSPITAL, AND DOES 1 THROUGH 10, INCLUSIVE	§	96TH JUDICIAL DISTRICT

JUDGMENT

All relief not expressly granted herein is denied.

SIGNED this _24th_ day of January 2014.

R. H. WALLACE, JR., JUDGE PRESIDING

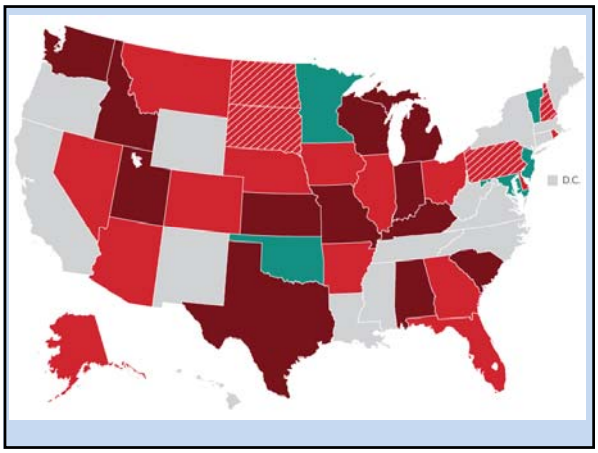
Having considered those matters, the Court finds:

1. The provisions of § 166.049 of the Texas HEALTH AND SAFETY CODE do not apply to Marlise Muñoz because, applying the standards used in determining death set forth in § 671.001 of the Texas HEALTH AND SAFETY CODE, Mrs. Muñoz is dead.

2. In light of that ruling, the Court makes no rulings on the Plaintiff's constitutional challenges to § 166.049.

Judgment **not** novel

But **stirred** dormant controversies



Other AD **limitations** ripe for reexamination

EXAMPLE:

Oral food & fluid

Thaddeus Mason Pope
Director, Health Law Institute
Hamline University School of Law
1536 Hewitt Avenue
Saint Paul, Minnesota 55104
T 651-523-2519
F 901-202-7549
E Tpope01@hamline.edu
W www.thaddeuspope.com
B medicalfutility.blogspot.com

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