Institutional and Legislative Approaches to Medical Futility Disputes in the United States

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President's Council on Bioethics
34th Meeting, Arlington, Virginia
September 12, 2008

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1. What is a futility dispute
2. Causes of futility disputes
3. Resolving intractable disputes
4. Association & institution policies
5. U.S. "safe harbor" statutes
6. Texas pure process

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What is a futility dispute?

3

Emilio Gonzales

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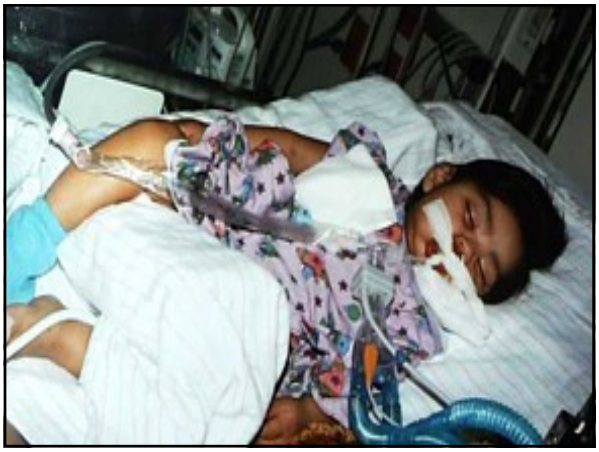

What is a futility dispute?

- Patient
- Advance directive
- Proxy
- Agent
- Surrogate
- Conservator

"Continue to treat"

- Health care provider

"Treatment is inappropriate"

Patient	HCP
Daughter 1	Physician 1
Daughter 2	Physician 2
Parent A	Nurse A
Parent B	

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Table 4. Responses Regarding Demanding Care and Goals of Care for Those in a Persistent Vegetative State

Question and Responses[a]	Public, % (n=1006)	Professionals, % (n=774)	*P* Value
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Yes	72.4	44.3	<.001
No	20.2	44.8	<.001

Can = may

Can = should

Can = must

10

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Table 3. Preferences for Goals of Care and Limited Resources

Question and Responses[a]	Public, % (n=1006)	Professionals, % (n=774)
If doctors believe there is no hope of recovery, which would you prefer?		
Life-sustaining treatments should be stopped and should focus on comfort	72.8	92.6
All efforts should continue indefinitely	20.6	2.5

Causes of Futility Disputes

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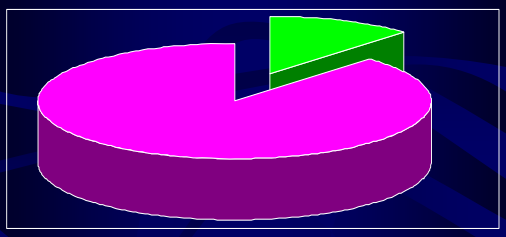
Surrogate demand

Table 5. Responses Regarding Race, Culture, Ethnicity, and Religion

Question and Responses[a]	Public, % (n=1006)	Professionals, % (n=774)	*P* Value
If the doctors treating your family member said futility had been reached, would you believe that divine intervention by God could save your family member?			
Yes	57.4	19.5	<.001
No	35.5	61.1	<.001

Surrogate demand



Zier, Critical Care Med. 2008

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Surrogate demand

Surrogate demand

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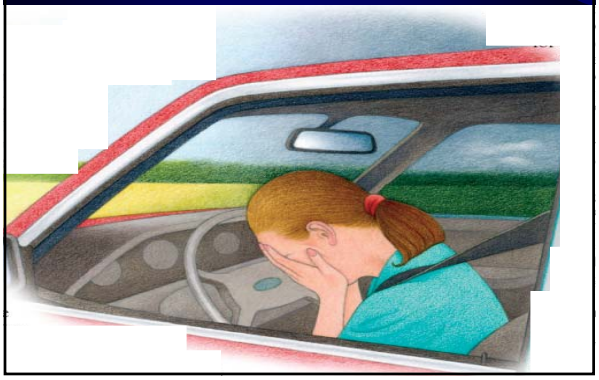
Surrogate demand

Provider resistance

Avoid patient suffering

Provider resistance



Category: futile care		
1. Follow the family's wishes for the patient's care when I do not agree with them but do so because hospital administration fears a lawsuit	41 (93)	29 (66)
2. Follow the family's wishes to continue life support even though it is not in the best interest of the patient	42 (95)	39 (89)
3. Carry out a physician's order for unnecessary tests and treatment	43 (98)	32 (73)
5. Initiate extensive life-saving actions when I think it only prolongs death	44 (100)	38 (86)
12. Carry out the physician's orders for necessary tests and treatments for terminally ill patients	43 (97)	30 (68)
19. Prepare an elderly man for surgery to have a gastrostomy tube put in, who is severely demented and a "No Code"	42 (95)	18 (41)

ORIGINAL ARTICLE

The relationship between moral distress and perception of futile care in the critical care unit☆

Melinda J. Mobley*, Mohamed Y. Rady*,*, Joseph L. Verheijde*, Bhavesh Patel*, Joel S. Larson*

Provider resistance

Provider resistance

Table 2. Predictive Accuracy of Surrogates Versus a Preliminary Population-Based Treatment Indicator

	Accuracy	(95% CI)
Overall[a]		
Surrogates	78.4%	(73, 84)
Treatment indicator	78.5%	(72, 85)

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Resolution of Futility Disputes through Consensus

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Prendergast (1998)

- 57% surrogates immediately agree
- 90% agree within 5 days
- 4% continue to insist on LSMT

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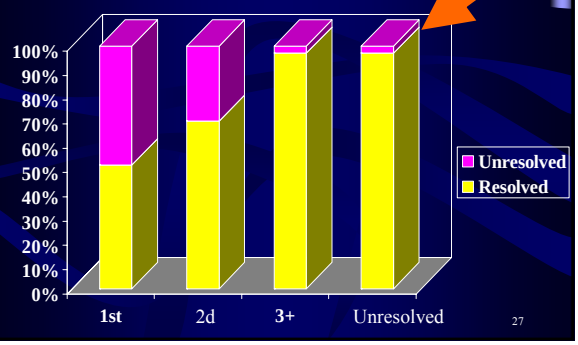
Garros et al. (2003)



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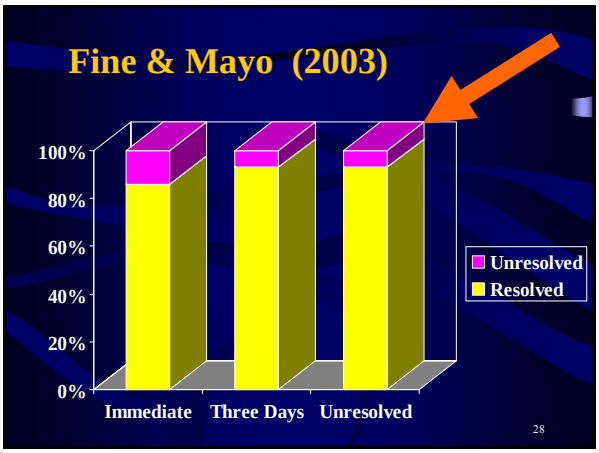
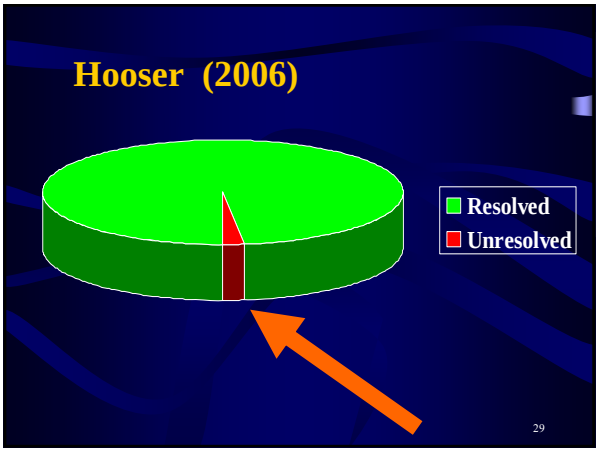
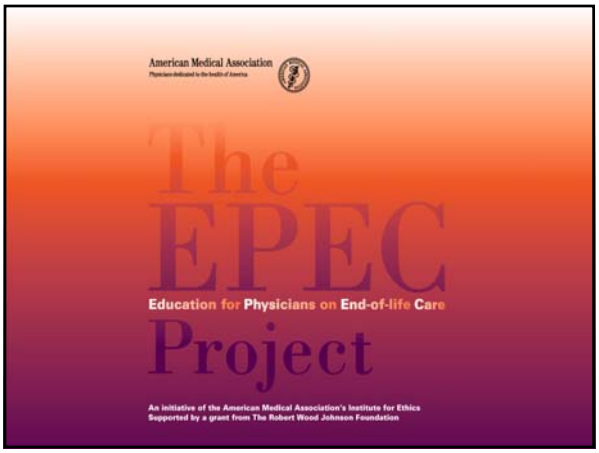

Fine & Mayo (2003)
100%
80%
60%
40%
20%
0%
Immediate
Three Days
Unresolved
Unresolved
Resolved
28


Hooser (2006)
Resolved
Unresolved
29


American Medical Association
The
EPEC
Education for Physicians on End-of-life Care
Project
An initiative of the American Medical Association's Institute for Ethics
Supported by a grant from The Robert Wood Johnson Foundation

Consensus

Intractable

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Professional Medical Associations

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Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association
Learn and Live

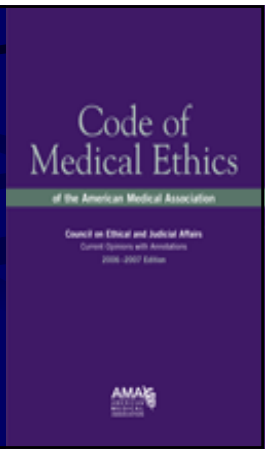
AMA
HELPING DOCTORS HELP PATIENTS

ACOG The American College of Obstetricians and Gynecologists

MSNJ
MEDICAL SOCIETY OF NEW JERSEY

AMA Code 2.037

When further intervention . . . becomes futile, physicians have an obligation to shift . . . toward comfort and closure



1. Earnest attempts should be made in advance to **deliberate over and negotiate** prior understandings between patient, proxy, and physician on what constitutes futile care for the patient, and what falls within acceptable limits . . . .

2. Joint decision-making should occur between patient or proxy and physician to the maximum extent possible.

3. Attempts should be made to **negotiate** disagreements if they arise, and to **reach resolution** within all parties' acceptable limits, **with the assistance of consultants** as appropriate.

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4. Involvement of an institutional committee such as the **ethics committee** should be requested if disagreements are irresolvable.
5. . . . .
6. If the process supports the physician's position and the patient/proxy remains un-persuaded, **transfer** to another institution . . . .
7. If transfer is not possible, the **intervention need not be offered**.

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Chill from Legal Fear

38

- Barber (Cal. 1983)
- Manning (Idaho 1992)
- Rideout (Pa. 1995)
- Bland (Tex. 1995)
- Wendland (Iowa 1998)
- Causey (La. 1998)

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Liability Exposure

- Grossly overstated risks
- But **some** real exposure

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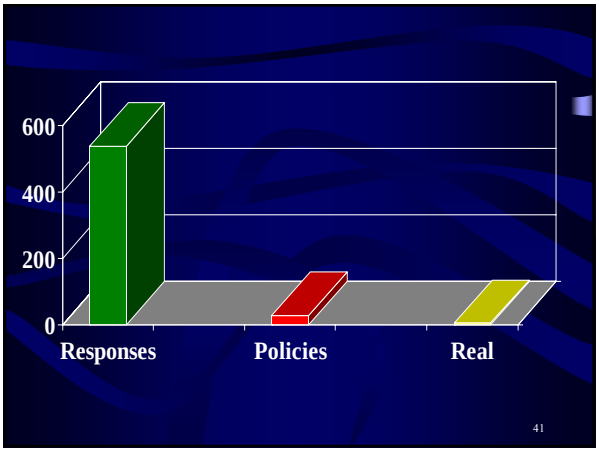

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Statutory Safe Harbors

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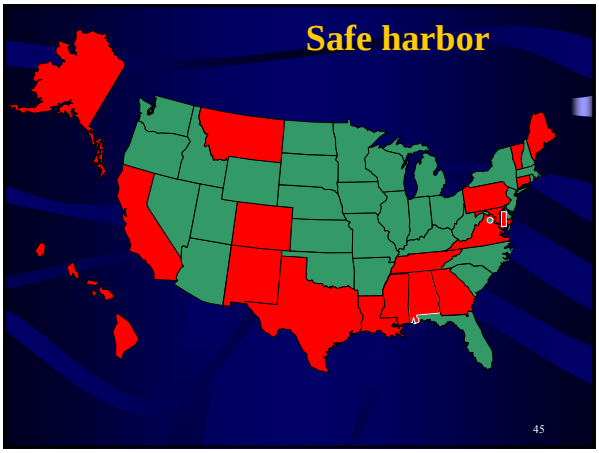

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New Mexico (1995)
Maine (1995)
Delaware (1996)
Alabama (1997)
Mississippi (1998)
California (1999)
Hawaii (1999)
Tennessee (2004)
Alaska (2004)
Wyoming (2005)

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N.M.S.A. 24-7A-7(D)

Except as provided in Subsections E and F of this section, a health-care provider . . . **shall comply** . . .with an individual instruction of the patient . . . .

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N.M.S.A. 24-7A-7(F)

A health-care provider or health-care institution **may decline** to comply with an individual instruction or health-care decision that requires **medically ineffective** health care or health care contrary to **generally accepted health-care standards** applicable to the health-care provider or health-care institution.

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N.M.S.A. § 24-7A-9

A health-care provider . . . is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(4) declining to comply . . . as permitted by Subsection E or F of Section 24-7A-7 NMSA . . .

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Illusory Safe Harbors

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Safe harbors NOT navigable

"Bad" safe harbor language

"generally accepted health care standards"

"significant benefit"

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Effect of bad safe harbor

- Uncertainty
- Few futility policies
- Little "full" implementation of futility policies

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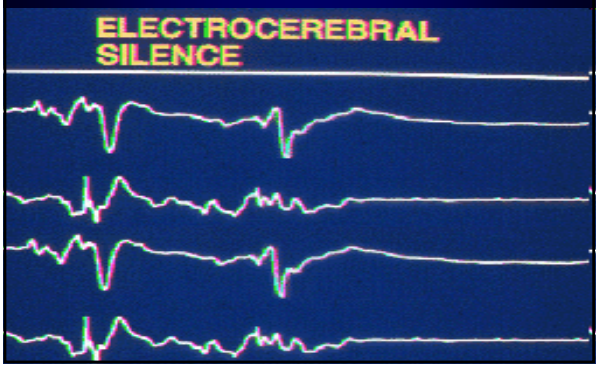
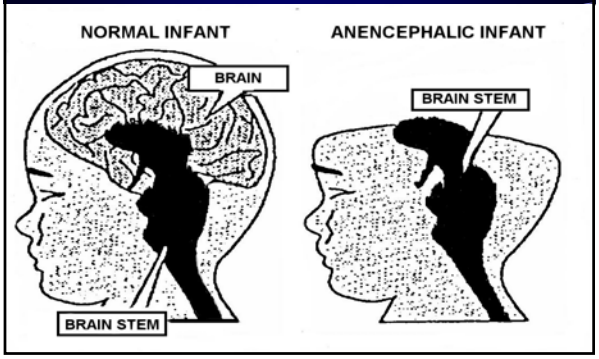
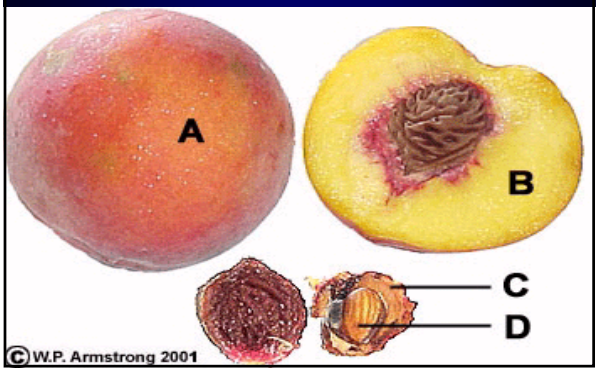
Brain death



Anencephaly



Physiological futility



- ***In re Cho Fook Cheng*** (Suffolk Fam. & Prob. Ct., Mass. 2006).

- ***Cecilia Cole v. Univ. Kansas Med. Ctr.,*** (Wyandotte Cty. Dist. Ct., Kan. 2006).

- ***Daisy M. Conner v. Memorial Hermann Baptist Beaumont,*** (172d Dist. Ct., Tex. 2006).

- ***Teron Francis v. Montefiore Med. Ctr.,*** (12th Jud. Dist., N.Y. Sup. Ct. 2005).

- ***Jesse Koochin v. Primary Children's Medical Center,*** (3d Dist. Ct., Utah 2004).

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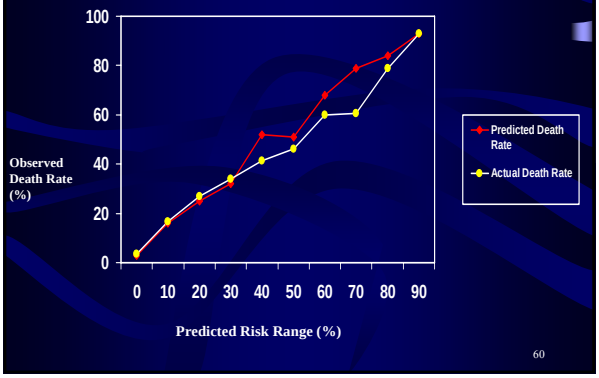
APACHE Scores and Mortality



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Qualitative Futility

- Benefit burden
- QOL
- Cost per QALY

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Goals of Medicine

- Cure disease
- Alleviate pain & suffering
- Restore function
- Prevent disease
- Prolong corporeal existence

?

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Growing Intractable Conflict

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Consensus

Intractable

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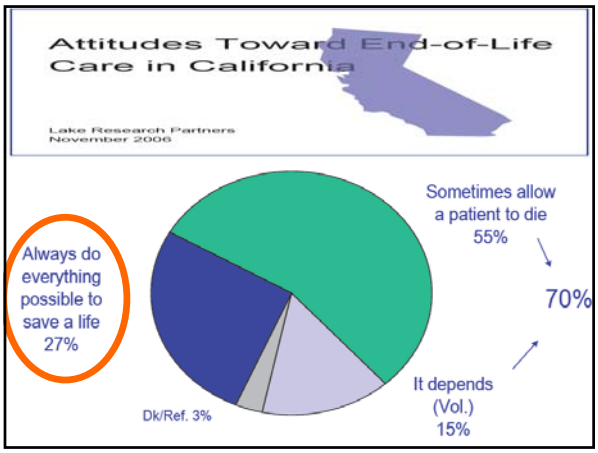
TREND: DO EVERYTHING TO SAVE LIFE, OR SOMETIMES LET PATIENT DIE?

	May 1990			November 2005		
	Do everything to save life	Sometimes let a patient die	It depends / DK / Ref	Do everything to save life	Sometimes let a patient die	DK/ Ref
	%	%	%	%	%	%
	15	73	12=100	22	70	8=100



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If a patient demands such care			

- More palliative care
- More EOL training
- Provider rights
- Financial incentives

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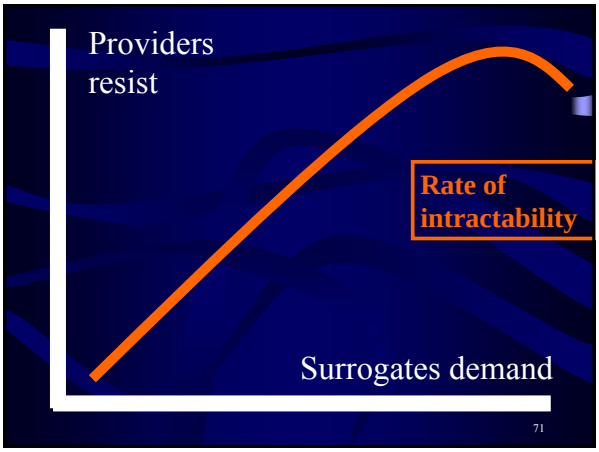

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Exception 1: Replace the Surrogate

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NO	YES
▪ *Wanglie* (Minn. 1991)	▪ *Baby Terry* (Mich. 1994)
▪ *Baby Ryan* (Wash. 1994)	▪ *Mason* (Mass. 1996)
	▪ *Howe* (Mass. 2005)

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Exception 2: Underground Refusals

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TABLE 5

PROPORTION OF PHYSICIANS (n = 726) WHO WITHHELD LIFE-SUSTAINING TREATMENT ON THE BASIS OF MEDICAL FUTILITY

Consent Status	n (%)
Without the written or oral consent of the patient or family	219 (25%)
Without the knowledge of the patient or family	120 (14%)
Despite the objections of the patient or family	28 (3%)

D. Asch, *Am. J. Resp. Crit. Care Med.* (1995)

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- Slow Code
- Show Code
- Hollywood code

Way Forward?

Texas pure process

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Tex. H&S Code 166.046

- 48hr notice
- Ethics committee meeting
- Written decision
- 10 days
- No judicial review

Tex. H&S Code 166.045

A physician . . . is not civilly or criminally liable or subject to review or disciplinary action . . . if the person has complied with the **procedures** outlined in Section 166.046

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TX safe harbor

- Measurable procedures
- Safe harbor protection certain

NM safe harbor

- Vague substantive standards
- Safe harbor protection uncertain

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April 14, 2006

Ms. ~~Gonzales~~ Gonzales
407 Neches St.
Lockhart, Texas 78644

SETON MEDICAL CENTER
A member of the

Dear Ms. Gonzales;

We, the physicians and other members of the healthcare team, appreciate you taking your time to attend the patient care conferences regarding your son.

At the last conference, your son's physician discussed his brain condition and the poor prognosis for any further neurological improvement. As you know, the physicians involved in the care of your son believe that his condition is irreversible and that to continue certain treatments will serve to prolong his suffering without the possibility of cure. We understand that you do not agree with this position and want the hospital to continue to provide all current treatments for your son.

When disagreements of this nature arise, Texas law allows hospitals to call the hospital ethics committee meeting to review whether certain treatments are medically appropriate. A meeting has been called for the Seton Family of Hospitals Pediatric Ethics Committee to consider Emilio Gonzales's care. This meeting will be held on February 16, 2007 at 09:00 a.m. in the 3rd floor boardroom at Brackenridge Hospital of Austin. The physicians providing care for your son, as well as the ethics committee members will attend the meeting. Under Texas law you have the right to attend and participate in this meeting. While that is not legally required, we strongly encourage you to be present for this discussion. You will be given the opportunity to ask questions regarding your son's care and to provide input into the committee's decision-making process.

Step 2: HEC Meeting

Step 3: HEC Decision

The Ethics Committee further recommends that

- **The treatment plan for the patient be modified to allow only comfort measures (such as hydration, pain control and other interventions designed to decrease the patient's suffering).**
- **New complications that develop should not be treated, except with additional palliative measures, as appropriate.**
- **The patient's code status be changed to a DNR.**
- **Appropriate spiritual and pastoral care resources should be provided to Emilio's mother and family members.**

In summary, the consulted members of the Ethics Committee concur with the recommendation by the Attending Physician and patient care team to withdraw aggressive care measures, including use of the ventilator, and to allow palliative care only. The Attending Physician, with the help of the Children's Hospital of Austin, will continue to assist the patient's family in trying to find a physician and facility willing to provide the requested treatment. The family may wish to contact providers of their choice to get help in arranging a transfer.

Step 5: Unilateral Withdrawal

No transfer → Can withdraw on the 11th day after HEC written decision given to surrogate

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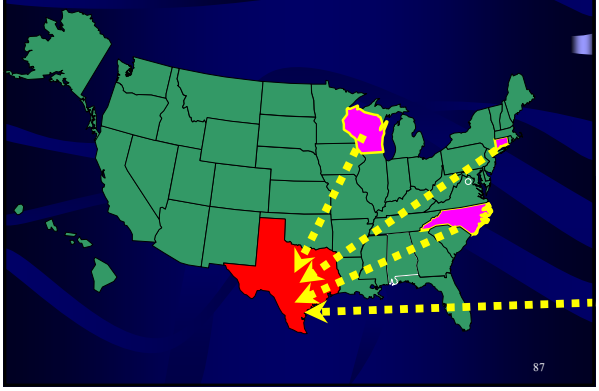
Texas is a model



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Due Process

- Notice
- Opportunity to present
- Opportunity to confront
- Assistance of counsel
- Independent, neutral decision maker
- Statement of decision with reasons
- Judicial review (after exhaustion)

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Tex. SB 439 (2007)

- More notice
- Get to "participate" not just "attend"
- Access to medical records
- More time to prepare
- Get to bring 5 or more helpers

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Thank you

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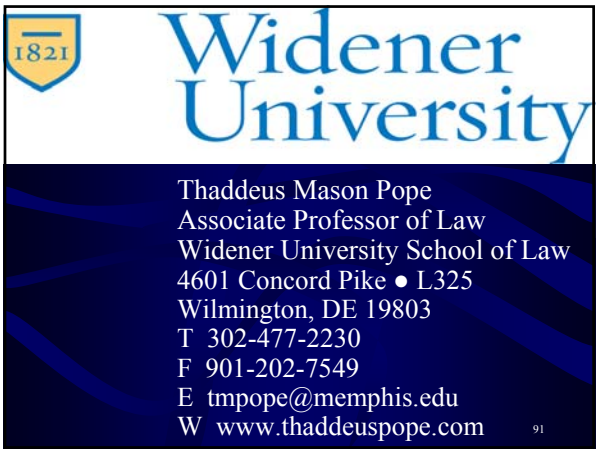
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