

**Top 10 Legal Developments
in Law and Public Health:
Three re: End-of-Life**

Arthur R. Derse MD JD

Center for Bioethics and Medical Humanities

Medical College of Wisconsin

End of Life

- Advance Care Planning/ Advance Directives/ POLST
- Physician Assisted Suicide
- Pain Medication/Medical Marijuana

Limitation of Treatment: The Consensus

- **Right to refuse any intervention**
 - Ventilators, feeding tubes, blood products
 - Bartling (Cal.App. 1984), Bouvia (Cal.App. 1986)
 - Wons (Fla. 1989), Fosmire (N.Y.1990)
- **All patients have right, even incapacitated**
 - Quinlan (N.J. 1976), Cruzan (U.S. 1990)
- **Withholding / withdrawing**
 - not homicide or suicide
 - Barber (Cal.App. 1983), Cruzan (U.S. 1990)
 - orders to do so are valid Dinnerstein (Mass. 1978)
 - **Courts need not be involved**
 - Meisel A. The consensus about forgoing life-sustaining treatment: Its status and prospects. Kennedy Institute of Ethics Journal. 1993;2:309-345.

Grace Sung Eun Lee 1

- NY, Manhasset LI Northshore
- 28 yo woman
 - Bank mgr., brainstem tumor, rad, chemo, seizure
 - stroke, quadriplegic, “terminally ill,” conscious
 - Request for withdrawal of ventilator
 - Psych eval,: has decisional capacity
- Father, minister, opposed, “suicide,” “sin” “depressed”
 - Says daughter manipulated by doctors, medication
 - Cousin records video, asks “willing to sign...medical proxy to your father?” Patient mouths “yes” twice
- Psychiatrist, SW testify clearly wants w/d of life support

Grace Sung Eun Lee 2

● Courts

- Nassau Cty. Court restraining order from w/d
- Sept. 28, 2012 Lifted State Sup. Ct.
- Oct. 5, 2012 NY Ct. App. – competent and has right to have LSMT removed

● Patient signs HC proxy designating her father as primary decision maker

● Issues = Capacity, influence, proxy responsibility for following patient wishes

- Hartocollis A. Daughter's right to die is weighed against family's wish to keep her alive. New York Times. Oct. 4, 2012. pA17 col. 1
- Newcomb A. Grace SungEun Lee: Terminally ill woman who fought for right to die has change of heart.
 - http://abcnews.go.com/Health/grace-sungeun-lee-terminally-ill-woman-change-heart/story?id=17413456#.UHD_316SNE9

Advance Directives

- **Initially, no evidence that completion changed care**

- Teno JM, Lynn J, Wegner N et al. Advance directives for seriously ill hospitalized patients: Effectiveness with the Patient Self-Determination Act and the SUPPORT Intervention. *J. Am. Geriatr. Soc.* 1997;45:500-507.

- **Subsequently, patients who had prepared advance directives received care that was strongly associated with their preferences**

- 83.2% of subjects who requested limited care and 97.1% who requested comfort care received care consistent with their preferences
 - Silveira MJ, Kim SYH, Langa KM. *N Engl J Med* 2010;362:1211-1218.

Advance Directives

- Advance directives specifying limitations in end of life care were associated with:
 - Significantly lower levels of Medicare spending last 6 months
 - (-\$5585)
 - Lower likelihood of in-hospital death (-9.8%)
 - Higher use of hospice care (17%)
 - In regions characterized by higher levels of end-of-life spending
 - Study: Prospective data from the Health and Retirement Study for 3302 Medicare beneficiaries who dies between 1998-2007 linked to Medicare claims and the National Death Index
 - Hersch Nicholas L, Langa KM, TJ Iwashashnya TJ, Weir DR. JAMA 2011;306(13):1447-1453.

CMS final rule re: Advance Care Planning

- **Centers for Medicare and Medicaid Services (CMS) final rule**
 - **Re: payment**
 - **Advise patients re: advance care planning during annual exam**
 - **Effective Jan. 1, 2011**
 - **Rescinded Jan. 5, 2011**
 - **Physicians not restricted from discussing end of life without payment**

POLST Paradigm

- **Physician Orders on Life-sustaining Treatment**
- **Translation of patient wishes into portable pre-hospital physician orders**
 - **Resuscitation, Intubation, Artificial nutrition and hydration, Antibiotics, Dialysis**
- **Widespread adoption**
 - Also known by different acronyms depending upon the state in which it has been adopted. New York Medical Orders for Life Sustaining Treatment (MOLST), North Carolina Medical Orders for Scope of Treatment (MOST), West Virginia and Idaho Physicians Orders for Scope of Treatment (POST), and Vermont Clinician Orders for Life-Sustaining Treatment (COLST).
 - Schmidt TA, Hickman SE, Tolle SW, Brooks HS. The physician orders for life-sustaining treatment (POLST) program: Oregon emergency medical technicians' practical experiences and attitudes. *J Am Geriatrics Soc.* 2004; 52:1430-1434.

NJ POLST

- **POLST Act signed by Gov. Christie**
 - Dec. 21, 2011
 - Sponsored by GOP Assemblywoman Nancy Munoz, RN, CNS (Essex)
 - Administered by Commissioner of Health and Senior Services
 - Instructions must be adhered to
 - Unless patient gives physician or healthcare proxy power to override

Allegation of Failure to Comply with POLST directions

DeArmond Case 1

- **Calif.**
- **Emily DeArmond, 18 yo**
 - Brain Cancer, dependent adult, mother = decision maker
 - Calif. POLST completed by primary care physician with mother, includes Do Not Intubate (DNI) Order
 - Unresponsive, brought to Kaiser Anaheim ED, Nov. 6, 2011
 - Claims ED physician told of POLST & DNI
 - Intubates despite POLST & admits
 - Transferred to another Kaiser facility, Lakeview
 - Comfort measures, extubated
 - Died Nov. 7
- **Suit filed by family for Damages and Injunctive relief**
 - ED physician new or should have known @ POLST and violated order
 - Kaiser failed to educate or establish policies and procedures to follow POLST
 - DeArmond v. Kaiser Health Group, Superior Ct. Ca., Orange Cty. Filed Nov. 3, 2011

Allegation of Failure to Comply with POLST directions

DeArmond Case 2

- **Calif. Physician Orders for Life Sustaining Treatment**
 - Sec. 4781.2.
 - (a) A health care provider shall treat an individual in accordance with a [POLST] form.
 - (b) Subdivision (a) does not apply if the [POLST] form requires medically ineffective health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.
 - (c) A physician may conduct an evaluation of the individual and, if possible, in consultation with the individual, or the individual's legally recognized health care decisionmaker, issue a new order consistent with the most current information available about the individual's health status and goals of care.
 - California State POLST Legislation (AB 3000 [Statutes 2008, Chapter 266], January 1, 2009.

WI Catholic Bishops on POLST 1

- **“A POLST form presents options for treatments as if they were morally neutral. In fact, they are not...”**
- **“A POLST oversimplifies these decisions and bears the real risk that an indication may be made on it to withhold a treatment that, in particular circumstances, might be an act of euthanasia. Despite the possible benefits of these documents, this risk is too grave to be acceptable.”**
- **Other concerns**
 - the lack of a patient signature acknowledging that the form truly represents a person’s choices;
 - potential conflict with current Wisconsin law and/or other advance care directives (for example, use by minors or their guardians, or use during pregnancy);
 - the absence of a conscience clause that protects facilities or practitioners, which cannot follow a POLST treatment order due to the institution’s or person’s moral, ethical, or medical concerns; and
 - the immediate effect of the document, even when a person is receiving non-emergency treatment.

WI Catholic Bishops on POLST 2

- **“Due to the serious and real threats to the dignity of human life that POLST and all similar documents present, we encourage all Catholics to avoid using all such documents, programs, and materials...”**
 - **Upholding the Dignity of Human Life. A Pastoral Statement on Physician Orders for Life-Sustaining Treatment (POLST) from the Catholic Bishops of Wisconsin. Wisconsin Catholic Conference . July 25, 2012.**
 - <http://www.wisconsinatholic.org/WCC%20Upholding%20Dignity%20POLST%20Statement%20FINAL%207-23.pdf>

Physician Assisted Suicide [PAS]

- Physician Assisted Death
- Physician Assisted Aid-in-Dying

Physician Assisted Suicide

- **No constitutional right**
 - **Glucksberg, Vacco**
 - **US S.Ct. 1997**
- **States free to develop laws**
- **Oregon & Washington (referenda),
Montana (Sup. Ct.)**
 - **Failed efforts: NH, HI, NY, CT**

Physician Assisted Suicide: Oregon Experience

- **14 year experience (1998-2011)**
 - 596 deaths (≈0.3% of deaths)
- **Top reasons**
 - Loss of autonomy (91%)
 - Loss of activities enjoyed (88%)
 - Loss of dignity (83%)
 - Loss of bodily functions (54%)
 - Burden for family, friends, caregivers (36%)
 - Not pain, finances, out of state
 - Characteristics and end-of-life care of DWDA patients who died after ingesting a lethal dose of medication as of February 29, 2012, by year, Oregon, 1998-2011. Oregon DHS 2012.
 - <http://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Documents/year14-tbl-1.pdf>

Physician Assisted Suicide: Washington & Montana

- **Washington**

- Referendum I-1000 similar to Oregon law
- Passed 59% (Nov. 2008)

- **Montana**

- No statutory or public policy basis for prohibition of physician-assisted suicide, effectively permitting the procedure
 - (Baxter, Montana 2009)
- No regulation

Physician Assisted Suicide: Washington Experience

- 2 year experience (2009-2011)
 - 240 deaths
- Top reasons (2009-2011)
 - Loss of autonomy (90/100/87%)
 - Loss of activities enjoyed (87/91/89%)
 - Loss of dignity (64/82/79%)
 - Loss of bodily functions (52/41/%)
 - Burden for family, friends, caregivers (28/23%/–)
 - Inadequate pain control or concern (36/25%/–)
 - Not finances
 - Characteristics and end-of-life care of DWDA patients who died after ingesting a lethal dose of medication as of February 29, 2012, by year, Washington, 2009-2011. Washington DOH 2012.
 - <http://www.doh.wa.gov/portals/1/Documents/5300/DWDA2011.pdf>

Georgia 1

- **Georgia Supreme Court struck down assisted suicide law**
 - Feb. 2012
 - Dismissal of charges against a physician and three other members of the Final Exit Network
 - accused of assisting in the suicide of John Celmer, a 58-year-old man with oral cancer
 - speech acts of advertising or offering assisted suicide services
 - 1994 Georgia law OCGA § 16-5-5 (b) provides that any person “who publicly advertises, offers, or holds himself or herself out as offering that he or she will intentionally and actively assist another person in the commission of suicide and commits any overt act to further that purpose is guilty of a felony.”
 - Violation of the statute is punishable by imprisonment for not less than one nor more than five years.

Georgia 2

- **Legislature outlaws physician-assisted suicide**

- **May 2012**

- **“Any person with actual knowledge that a person intends to commit suicide who knowingly and willfully assists such person in the commission of such person's suicide shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not less than one nor more than ten years.”**

- **Excludes palliative care measures delivered with the sole intent of alleviating pain rather than causing death**

- <http://www.legis.ga.gov/legislation/20112012/127675.pdf>

Massachusetts DWDA 1

- **Massachusetts Death with Dignity Act**
- **November 6, 2012 Ballot Question 2**
 - “An adult Massachusetts resident who has the capacity to make health care decisions and who has been determined by his or her attending and consulting physicians to be suffering from a terminal disease that will cause death within six months may obtain medication that the patient may self administer to end his or her life in a humane and dignified manner.”

Massachusetts DWDA 2

- Adult MA resident, terminal illness \leq 6 mo
- 2 physicians verify competence & voluntary
- Must be informed of option of palliative care
- 3 requests by pt. (2 oral, 1 written); 15 d waiting period b/w 1st oral & physician writing Rx
- Written request must be independently witnessed by 2 persons
- 48 hr period b/w written request by pt. and physician writing Rx
- Physician participation voluntary

Massachusetts DWDA 3

- Signatures exceeded minimum for ballot
 - and to bypass need for legislative approval
- Poll
 - 60% support
 - 29% oppose
 - 11% no opinion or declined
 - Western New England University Polling Institute survey of 504 voters, May 2012.
 - O'Reilly KB. Push for “death with dignity” in Massachusetts picks up steam. *amednews*. Jul. 16, 2012.
 - <http://www.ama-assn.org/amednews/2012/07/16/prsc0716.htm>
 - Angell M. May doctors help you die? *New York Review of Books*.
 - <http://www.nybooks.com/articles/archives/2012/oct/11/may-doctors-help-you-die/?pagination=false>

Hawaii

- **Hawaii doctors offer to write Rxs for PAS**
 - To test HI law re: assistance in suicide
- **Poll HI adults**
 - 77% favor PAS
 - 76% physicians favor PAS
 - Dec. 2011 Compassion & Choices poll
- **Physician Advisory Council for Aid in Dying**
 - **Guidelines based on OR, WA**
 - 2 physicians diagnose, evaluation
 - No 15 day waiting period
 - **Dr. Robert Nathanson**
 - Wrote Rx for secobarbital to help terminally ill patient “hasten death.”
 - **Hotline**
 - O'Reilly KB, 5 Hawaii doctors offer assisted suicide to terminally ill patients. *amednews* Apr. 17, 2012
 - <http://www.ama-assn.org/amednews/2012/04/16/prsd0417.htm>

Carter v. Canada

- **Gloria Taylor 63yo ALS petitions for PAS**
 - Along with British Columbia Civil Liberty Ass'n
- **BC Supreme Court**
 - Strikes down Canadian Criminal Code Sec. 241 ban on AS as unconstitutional
 - Order for Canadian Gov't to draft legislation consistent with Constitution
 - Taylor granted constitutional exemption to obtain PAS with conditions:
 - including written request and physician attestation re: dx, prog, risks, results, pall care option, right to change mind
 - Jun. 2012
 - Carter v. Canada (Attorney General),. 2012 BCSC 886. Date: 20120615. Docket: S112688. Registry: Vancouver.
- **Taylor did not exercise right before died Oct. 4, 2012**
- **Mar. 2013 hearing scheduled**

Pain Relief & Medical Boards

● Board actions vs. physicians

– Perception of risk >> actions

- Martino A. In search of a new ethics for treating patients with chronic pain: What can medical boards do? *Journal of Law, Med. & Ethics* 1998:332-349.
- Hoffman DE, Tarzian AJ. Achieving the right balance in oversight of physician prescribing for pain: The role of state medical boards. *Journal of Law, Med. & Ethics* 2003:21-40. (survey of 38 boards)
- Ziegler SJ, Lovrich NP. Pain relief, prescription drugs, and prosecution: A four-state survey of chief prosecutors. *Journal of Law, Med. & Ethics* 2003:75-100.

Opioid Undertreatment

- **Oregon Medical Board v. Bilder**
 - Discipline of practitioner for multiple cases of undertreatment of pain
 - Oregon Medical Board Re: Dr. Paul Bilder 1999, 2002
- **Bergman v. Chin**
 - (liability for elder abuse and recklessness for undertreatment of pain)
 - award \$1.5 million, reduced by judge to \$250,000
 - (Calif. Trial Court verdict Jun. 13, 2001)

Prescription Drug Abuse

- **Narcotics = most widely prescribed drugs in the United States**
- **1998 → 2008**
 - = 400% increase in prescription drug abuse
- **1994 → 2003**
 - **Rxs for “Controlled Substances” = 22M → 354M**
 - **ED visits for misuse prescribed & OTC 500K → 1M**
 - **Admissions for misuse = 40K → 300K**
 - **Deaths ≈ 5K → 14K**
 - **Substance Abuse Treatment Admissions Involving Abuse of Pain Relievers: 1998-2008. Substance Abuse and Mental Health Services Administration (SAMHSA). July 15, 2010. <http://www.whitehousedrugpolicy.gov/news/press10/071510.html>**
 - **2008 Deaths = 15K**
 - **2009 Deaths = 16K**
 - Mahoney D. FDA Approves REMS for Long-Acting Opioids. NY Times. July 11, 2012
 - **Methadone accounts for almost a third of deaths**
 - **31.4% OD deaths; 1.7% of 257M Rx**
 - Bakalar N. Many Fatal Overdoses Linked to Methadone. NY Times. July 9, 2012.

Drug Enforcement Administration (DEA)

- Federal agency charged with oversight of controlled substances
 - Harrison Narcotic Act 1914
 - Controlled Substances Act 1970
- 2006 actions re: physicians
 - 735 investigations of physicians opened ($\approx 1/1,000$)
 - 71 physicians arrested for crimes related to “diversion” ($\approx 1/10,000$)
 - 735,000 physicians in active practice (est. 2000)

DEA & Pain Relief (1)

- **Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act**
 - Pain relief vs. fear of prosecution
 - Twenty-one Health Organization and DEA, 2001
 - Undertreatment = serious problem
 - Guidelines = safety unless “knowingly and intentionally” prescribed drugs for illegitimate reasons; quantity not
 - Incorporated into FAQs posted on DEA website

DEA & Pain Relief (2)

- **2004 - DEA removal of FAQs**
 - Concerns by pain medicine experts and 30 attorneys general
- **2005 - DEA Clarification**
 - More concerns
- **2006 - DEA Notice of Rule Making**
 - No definitive guidelines for prescribing controlled substances
 - Cannot modify or expand through endorsement of guidelines
 - DEA does have authority to determine whether prescription issued for a legit medical purpose within CSA and DEA regs.
 - Pain & Policy Studies Group
 - <http://www.painpolicy.wisc.edu/DEA/index.htm>

DEA & Pain Relief (3)

- 2006 - DEA & physician reluctance re: pain relief
 - ”The longstanding requirement...that physicians may prescribe controlled substances only for legitimate medical purposes in the usual course of professional practice should in no way...cause any physician to be reluctant to provide legitimate pain relief.”
 - Dispensing of controlled substances for the treatment of pain. *Fed Reg* 69 2004 67170–67171; Policy statement: Dispensing of controlled substances for the treatment of pain *Fed Reg* 71 2006 52715–52723.

DEA – The New Approach

- In the past decade, “the [DEA] has tried a variety of tactics with limited success, from arresting hundreds of doctors to closing scores of pharmacies.”
- Now putting pressure on distributors [intermediaries between drug makers and pharmacies].
- “In response, the distributors are scrambling to limit their liability by more closely monitoring their distribution pipelines and cutting off some customers.”
 - Meier B. A new painkiller crackdown distributors. New York Times. Oct. 18, 2012.

REMS for Long-Acting Opioids

- **Risk Evaluation and Mitigation Strategy (REMS)**
 - **Approved July 2012; Available by March 31, 2013**
 - **FDA-approved educational materials for providers & patients**
 - **Dangers (& Signs) of abuse & addiction**
 - **>70% of those who abuse Rx pain meds obtain from friends or relatives (usu. with permission & free)**
 - **Morgan D. Prescription drug abuse abetted by family, friends: study. Reuters Apr. 25, 2012.**
 - **Applies to approx. 30 meds**
 - **Hydromorphone, oxycodone, morphine, oxymorphone, methadone, fentanyl (transdermal) and buprenorphine (transdermal)**
 - **Participation in educational program NOT mandatory**
 - **Mahoney D. FDA Approves REMS for Long-Acting Opioids. NY Times. July 11, 2012**

Doctors Petition FDA to Change Labeling of Narcotics

- **Physicians for Responsible Opioid Prescribing**
- **For long-term, non-cancer pain**
 - Cleveland Clinic, Mayo Clinic, Public Citizen
- **Risks = addiction, overdose, resp. suppression, falls, fxs, sleep apnea, cognitive impairment**
- **Limit of 100mg/day MS & 90 days for non-cancer pain**
 - 14 tabs Vicodin, 13 tabs of Percocet
 - Fauber J. Doctors petition FDA to change labeling of pain-killers. Journal Sentinel. July 25, 2012

Medical Marijuana

● Montana

- Legislature passed bill to repeal medical marijuana, governor vetoed.
- Legislature passed new Montana Medical Marijuana Act with more restrictions
- State restrictions on medical marijuana do not violate constitutional rights
 - Montana Cannabis Industry Assn. v. State of Montana (Mont. 2012)
- Nov. 2012 Montana Medical Marijuana Veto Referendum, IR-124 (2012)
 - Gallegos A. Patients have no constitutional rights to medical marijuana, state court rules. amednews Sep. 24, 2012.
 - <http://www.ama-assn.org/amednews/2012/09/24/gvsc0924.htm>

● Sixteen states have medical marijuana laws

- Calif. - Federal/DEA prosecutions/warning– 650/1400 dispensaries close, Oct. 2011-Jun 2012

● Non-medical marijuana referenda, Nov. 2012

- WA, OR, CO – legalization, regulation, licensing, intoxication

End of Life

- Advance Care Planning/ Advance Directives/ POLST
- Physician Assisted Suicide
- Pain Medication/Medical Marijuana