

Spring 2018

# Pegalis & Erickson Health Law Colloquium

New York Law School

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**WE ARE NEW YORK'S LAW SCHOOL**

**New York Law School—Pegalis & Erickson Health Law Colloquium**

## **EXAMINING THE INTERSECTION OF BIOETHICS AND THE LAW IN 2018**

**Hosted by Trustee and Professor Steven E. Pegalis '65**

**DATE**

April 30, 2018

**TIME**

6:00 p.m.—7:45 p.m.

**LOCATION**

New York Law School  
Auditorium  
185 West Broadway  
New York, NY 10013

**COST**

Free

**CLE**

2 credits in Ethics  
and Professionalism.  
(NY transitional  
and non-transitional)

**RSVP**

[nyls.edu/pegalislecture](http://nyls.edu/pegalislecture)

This CLE will include a focus on clinical decision-making, palliative and end-of-life care, dispute resolution, medical and social science research, and informed consent and decision-making.

**MODERATOR**

**Adam Herbst Esq., M.B.A.**, Chief Legal Officer, Blythedale Children's Hospital and Adjunct Professor, New York Law School

**PANELISTS**

**Joanne T. Haberlin '90, R.N., B.S.N.**, Senior Counsel, NYC Health + Hospitals

**Karen L. Illuzzi Gallinari '88, Esq.**, Health Law, Compliance, and Bioethics Specialist

**Nancy Neveloff Dubler, LL.B.**, Consultant for Ethics, NYC Health + Hospitals and Adjunct Professor, Division of Medical Ethics, NYU Langone Medical Center

**Mary Beth Quaranta Morrissey, Ph.D., M.P.H., J.D.**, Fellow, Fordham University's Global Healthcare Innovation Management Center and Senior Policy Advisor in Health and Ethics, Finger Lakes Geriatric Education Center, University of Rochester Medical Center

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**PEGALIS & ERICKSON HEALTH LAW COLLOQUIUM**  
**AT NEW YORK LAW SCHOOL**  
**EXAMINING THE DYNAMIC INTERSECTION OF**  
**BIOETHICS AND THE LAW IN 2018**

April 30, 2018  
(6:00pm – 7:45pm)

Hosted by Professor Steve Pegalis  
Moderated by Professor Adam Herbst

The American legal system has played a dramatic role in shaping the field of bioethics. The dynamic intersection of law and bioethics is a fruitful area of inquiry for purposes of knowledge generation, policy making and best practices. Reflecting a diversity of perspectives, this CLE will examine the crucial connection between law and matters bioethical in 2018. The program will include a focus on clinical decision making, palliative and end-of-life care, dispute resolution, medical and social science research, and informed consent and decision making.

CLE Details: NYLS is accredited by the State of New York to offer this program with 2 Credits of Ethics and Professionalism Continuing Legal Education. Transitional and Non-Transitional use.

**AGENDA**

6:00pm Welcome – Anthony W. Crowell, Dean and President of New York Law School

6:05pm Introductory Remarks – Steve Pegalis '65, Founding Partner, Pegalis & Erickson, LLC, NYLS Adjunct Professor, NYLS Trustee

6:10 – 7:55pm Panel Discussion Moderated by Adam Herbst, Chief Legal Officer, Blythedale Children's Hospital

## Host and Panelist Bios:

**Steven E. Pegalis** is the founding partner of Pegalis & Erickson, LLC and one of the nation's foremost medical malpractice trial lawyers. In his nearly 50 years practicing law as an advocate for seriously injured victims of negligence he has obtained some of the highest jury verdicts. He is most proud of providing peace of mind, a sense of justice, and financial security to more than 2000 clients to date.

Stacks of photos and thank-you notes from clients' families are among his most prized possessions. He believes his team's personal investments in each case are without peer, and has resulted in consistent success for patients year after year. He and his firm have worked tirelessly with some two thousand injured individuals and their families. For example: in 1998, he obtained a \$116 million jury verdict for a brain injured child, and in 2004 he obtained a \$111.7 million verdict for a brain injured child.

Pegalis is the only lawyer to be named both the 2017 "Lawyer of the Year" on Long Island, for Plaintiffs' Personal Injury Litigation, and the 2016 "Lawyer of the Year," for Plaintiffs' Medical Malpractice lawyer in New York, by *Best Lawyers®* and *Best Lawyers in America®*. The "Lawyer of the Year" distinction reflects the high level of respect a lawyer has earned among other leading lawyers in the region and practice areas for their abilities, professionalism, and integrity. Additionally in 2016, Pegalis was honored with a Lifetime Achievement Award by the New York State Trial Lawyers Association (NYSTLA). In 2015, Pegalis was named co-director with Irwin R. Merkatz, MD, of the Patient Safety Project initiative at New York Law School (NYLS), focused on making significant contributions to medical safety and promoting innovative health law policies for the public good. Also in 2015, Pegalis was honored with the Nassau County Bar Association's *WE CARE* Fund award. Pegalis is the author of *American Law of Medical Malpractice*, Volumes 1-3, now in its 3rd edition. He serves on the NYLS Board of Trustees, was an Adjunct Professor of Law, and was honored with school's Groundbreaker Award for a lifetime commitment to his clients, and successfully pursuing their rights with passion.

Pegalis is an advocate of the American Board of Trial Advocacy, a Dean of the New York State Trial Lawyers Institute, and a member of the American Association for Justice, and the National Board of Trial Advocacy. He is an Associate in Law of the American College of Legal Medicine, and is *AV rated* on Martindale-Hubbell for professional excellence. Each year he is voted to the *Best Lawyers®* List in New York and the *New York Super Lawyers* List. Pegalis has lectured extensively on medical/legal issues, and contributed his experience and viewpoint to numerous articles and publications. He is admitted to practice in New York, the U.S. Court of Appeals, 2nd Circuit, and the U.S. District Courts for the Eastern and Southern Districts of New York. He holds both a Juris Doctor and Bachelor of Law degree from New York Law School, and a Bachelor's Degree from Queens College of the City of New York.

## EDUCATION

New York Law School, JD

Queens College of the City of New York, Bachelor's Degree

## **BAR Admissions/Qualifications**

New York

Southern District of New York

Eastern District of New York

### **Joanne T. Haberlin, R.N., B.S.N., J.D. (NYLS '90)**

Ms. Haberlin is both a registered nurse and an attorney. She is also a graduate of New York Law School. She currently holds the position of Senior Counsel at NYC Health and Hospitals, the nation's largest public health care system. Her area of practice focuses on health care and medical legal issues in the acute, long term care, and ambulatory settings.

She provides legal guidance on complex issues both on a real time basis in the clinical setting and in formal training sessions to an array of staff, including physicians, nurses, social workers, bioethics committees and other providers. These issues relate to consent and surrogate decision making involving the acceptance, refusal, or objection, to beneficial treatment; the withholding and withdrawal of treatment; and end of life of issues.

Prior to her current position she held the position of Senior Director of Corporate Risk Management for NYC Health +Hospitals and Senior Director of Risk Management for NYC Health + Hospitals /Elmhurst. Prior to joining NYC Health + Hospitals, she was a litigating attorney at the law firms of Bower and Gardner and Bartlett, McDonough, Bastone and Monaghan. Her practice was focused on medical malpractice litigation. Prior to attaining her law license, she practiced as a registered nurse at New York University Medical Center.

### **Nancy Neveloff Dubler, LL.B.**

Ms. Dubler is a consultant for Bioethics at New York City Health and Hospitals and Adjunct Professor in the Division of Medical Ethics, NYU Langone Medical Center. She is Professor Emerita at the Albert Einstein College of Medicine and former director of the Division of Bioethics at Montefiore Medical Center and the Albert Einstein College of Medicine. She received her B.A. from Barnard College and her LL.B. from the Harvard Law School. She lectures extensively and is the author of numerous articles and books on termination of care, home care and long-term care, geriatrics, AIDS, adolescent medicine, prison and jail health care, Clinical Ethics Consultation, and Bioethics Mediation. Her most recent books are: *Bioethics Mediation: A Guide to Shaping Shared Solutions*, co-author, Carol Liebman, Vanderbilt University Press, 2011; *The Ethics and Regulation of Research with Human Subjects*, Coleman, Menikoff, Goldner and Dubler, Lexis/nexis, 2005, *Supplement 2012*; *Ethics for Health Care Organizations: Theory, Case Studies, and Tools*, with Jeffrey Blustein and Linda Farber Post (2002). She consults often with federal agencies, national working groups and bioethics centers.

### **Mary Beth Quaranta Morrissey, Ph.D., M.P.H., J.D.**

*Converging Perspectives in Bioethical Inquiry and Public Health Ethics: Addressing the Problem of Equity in Palliative and End-of-Life Care*

Dr. Morrissey is a New York health care attorney and a gerontological health and social work researcher. She holds the appointments of Fellow at Fordham University's Global Healthcare Innovation Management Center, and Senior Policy Advisor in Health and Ethics, Finger Lakes Geriatric Education Center (FLGEC), University of Rochester Medical Center. She directs the Aging & Health Workforce Development Institute, a project of the Collaborative for Palliative Care, FLGEC and the Westchester Public Private Partnership for Aging Services. Dr. Morrissey is President-elect and Treasurer of the American Psychological Association Society for Theoretical and Philosophical Psychology, President of the National Committee for the Prevention of Elder Abuse, Founder and President of the Collaborative for Palliative Care, New York, Chair of the New York City Bar Association Bioethical Issues Committee, and Chair of the Westchester County Bar Association Health Law Committee. She is a member of the New York State Bar Association Health Law Section, Ethical Issues Committee and Public Health Committee, and is past president of the State Society on Aging of New York and immediate past president of the Public Health Association of New York City. Morrissey's research and scholarship on pain, suffering and end-of-life inform and guide her practice and advocacy. She has authored numerous publications in law journals and peer-reviewed scientific journals, integrating law, public health and bioethical perspectives. As Chair of the City Bar Bioethical Issues Committee, she led the development and was the leading author of the recently issued City Bar Commentary on Medical Aid in Dying in New York (June 2017).

**Karen L. Illuzzi Gallinari, Esq. (NYLS '88)**

Ms. Gallinari has over 20 years' experience in healthcare law, compliance, medical research and bioethics. Most recently, as a Senior Compliance Officer for NYC Health + Hospitals, Karen assisted NYC Health + Hospitals Office of Corporate Compliance with implementation of NYC Health + Hospitals' Compliance Program. She also is an officer on the Executive Committee of the NYS Bar Association's Health Law Section, a member of the Health Law Section's Biotechnology and Medical Research Committee and is a member of the NY City Bar Associations' Health Law Committee's Bioethical Issues Subcommittee.

Her previous leadership roles include co-chairing a national collaboration of medical research centers through which she facilitated education and dialog on bioethics issues relating to medical research. As Director of Regulatory Affairs for Research at Montefiore Medical Center ("MMC"), Karen was charged with advancing MMC's and the Albert Einstein College of Medicine's DNA Biobank. She also served as MMC's Privacy Officer and Director of Compliance. In that role, she worked on electronic health data security, privacy law and compliance policy training and implementation.

Karen was formerly Vice President of Legal Affairs and General Counsel for Staten Island University Hospital, also served as Vice President for Patient and Family Services for the American Cancer Society, chaired the In-House Counsel Committee for the Health Law Section of the New York State Bar Association and served as NYS Chair of the National Patient Advocate

Foundation. Under Karen's leadership, the NPAF's New York advocacy team was successful in securing a New York State Resolution urging an amendment to Medicare to permit insurance coverage for oral cancer drugs.

Prior to joining SIUH in 1996, she was a litigator with the firm of Anderson Kill Olick & Oshinsky, P.C. Karen applied the firm's insurance coverage expertise to patients and medical institutions seeking to secure insurance coverage for state-of-the-art medical treatments. She also organized a national network of pro-bono attorneys experienced in handling health insurance disputes. Karen is a graduate of New York Law School, Class of 1988.

**Adam S. Herbst, Esq., MBA**

Mr. Herbst is Chief Legal, Planning and Government Relations Officer for Blythedale Children's Hospital. He also serves as the Hospital's Chief Compliance Officer. In this role, Mr. Herbst has legal and compliance oversight for the Hospital and is responsible for developing corporate planning strategies and administering government relations, the ethics program, as well as advocacy and community relations.

Mr. Herbst has devoted a considerable portion of his career specializing at the intersection of where health care law meets with communications, technology and ethical issues. Mr. Herbst has worked on issues related to housing, education, public health, economic development and has trial experience in both federal and state courts, as well as arbitrations throughout the country. He is a frequent speaker on health care access and informed consent.

Mr. Herbst is an Adjunct Professor at New York Law School, teaching Health Law and Policy, and is also the Co-Director of the Health Law Clinic.





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## Intersection of New York State Laws and Bioethics in the Clinical Setting

*Joanne Haberlin, R.N., B.S.N., Esq.*



# Intersection

## Bioethics and New York State Public Health Laws

The discipline of bioethics potentially interplays in situations in which certain laws are integrated or triggered in the clinical setting:

- Consent (N.Y.S. Public Health Sections 2504; 2803; 2805)
- Health Care Agents and Proxies (N.Y.S. Public Health Law Section 2981;2982)
- Family Health Care Decisions Act ( N.Y.S. Public Health Law Section 2994)

### Common Theme

- Autonomy for health care decisions
- Maintaining control of medical decisions even after the loss of decision making capacity.



# Informed Consent

## Discussion Between Health Care Provider/ Patient or Legally Authorized Representative Risks, Benefits and Alternatives

### N.Y.S. Public Health Law Sections 2803- c; 2504; 2805-d

#### N.Y.S. Public Health Law Section 2504

N.Y.S. Public Health Law Section 2504 delineates in detail those individuals authorized to consent to health care and the limitations related to the consent for treatment

#### Basic premise

Any person who is eighteen years of age or older, or is the parent of a child, or has married, may give effective consent for medical, dental, health and hospital services for himself or herself, and the consent of no other person shall be necessary.

#### Patient's Bill of Rights

N.Y.S. Public Health Law Section 2803(c) states as follows:

Every patient shall have the right to receive adequate and appropriate medical care, to be fully informed of his or her medical condition and proposed treatment, unless medically contraindicated, and to refuse medications and treatment after being fully informed of and understanding the consequences of such actions.

#### N. Y. S. Public Health Law Section 2805 -d)

\_PHL Section 2805 d limits a cause of action for lack of informed consent but also establishes the threshold standard for this cause of action.

It is the failure of the person providing the professional treatment or diagnosis to disclose to the patient such alternatives and the reasonably foreseeable risks and benefits involved as a reasonable medical, dental or podiatric practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation.

#### Case Law

To establish a cause of action to recover damages for malpractice, based on lack of informed consent, a plaintiff must prove that the person providing the professional treatment failed to disclose alternatives, and failed to inform the patient of reasonably foreseeable risks associated with the treatment, and the alternatives, that a reasonable medical practitioner would have disclosed under the same circumstances; and that a reasonable prudent patient in the same position would not have undergone the treatment if he or she had been fully informed; and that the lack of informed consent is a proximate cause of the injury (Zappatta v. Buitriago, 969 N.Y.S.2d 79 2d., Dept. 2013).



# Legally Authorized Representatives and Bioethics

In the context of Bioethics in the clinical setting, these Legally Authorized Representatives often emerge:

- Health Care Agents (N.Y.S. Public Health Law Section 2981)
- Surrogates (N.Y.S. Public Health Law Section 2994-d)

## Comparison:

- Health Care Agent - appointed by the patient.
- Surrogate - appointed by statute.



# Health Care Agents and Proxies

## N.Y.S. Public Health Law Sections 2981; 2982

### Health Care Proxy - N.Y.S Public Health Law Section 2981

- A competent adult has the legal authority to appoint a health care agent to make health care decisions on his or her behalf when he or she is unable to make such decisions due to a lack of capacity.
- The document must be signed by the adult in the presence of two adult witnesses, who shall also sign the proxy. Another person may sign and date the health care proxy for the adult, if the adult is unable to do so, at the adult's direction and in the adult's presence and also in the presence of two adult witnesses who shall sign the proxy.
- The witness shall state that the principle appeared to execute the proxy willingly and free from duress.
- The person appointed as agent shall not act as witness to the execution of the health care proxy.

### Standards for Health Care Agents - N.Y.S. Public Health Law Section 2982

Subject to any express limitations in the proxy, an agent shall have the authority to make any and all health care decisions on the principles' behalf that the principle could make under the law.

- The agent must first consult with a professional before making a decision and must make decisions in accordance with the principle's wishes, or, failing that, in the principle's "best interest" (except for artificial nutrition and hydration if the wishes are not reasonably known or reasonably ascertainable).
- The agent takes priority over other potential surrogates, except the agent does not supersede any authority that the principle may have under law to make or express decisions, wishes, or instructions regarding health care, including life sustaining treatment.
- The authority of the agent commences upon the determination by an attending physician that the principle lacks capacity to make decisions.



# Family Health Care Decisions Act

## N.Y.S. Public Health Law Article 29-CC

The Family Health Care Decision Act has established a procedure to facilitate responsible decision making on behalf of patients who lack capacity, who have not:

- Appointed a Healthcare Agent pursuant to and in accordance with Public Health Law Section 2981.
- Provided clear and convincing evidence of treatment decisions.

**Authorizes a surrogate to make decisions for both beneficial and end of life decisions.**

### Exclusions

- Court appointed guardians under Section 1750(b) of the Surrogate Court Procedure Act.
- Decisions that can be made by a family member or friend under Section 1750(b) of the Surrogate Court Procedure Act.
- Decisions pursuant to New York State Mental Health regulations and OMRDD surrogate decision making regulations.

### Scope /Limitations

- Surrogate's consent is not required if the patient already made decisions about the proposed health care, expressed orally or in writing or, with respect to a decision to withdraw or withhold life sustaining treatment expressed either orally during hospitalization in the presence of two adult witnesses, at least one of whom is a health or social service practitioner affiliated with the hospital, or in writing.
- Mandated clinical criteria must be met in order for the surrogate to withhold or withdraw life sustaining treatment.



# Surrogate List N.Y.S. Public Health Section 2994-d

## List in Order of Priority

- A guardian authorized to decide about health care pursuant to Article 81 of the Mental Hygiene Law
- Spouse or Domestic Partner
- Adult child
- Parent
- Adult Brother or Sister
- Close friend



# Standards for Decisions By Surrogates

## N.Y.S. Public Health Law Section 2994-d

### Beneficial Treatment

Surrogate must decide in accordance with the patients wishes, including the patients religious and moral beliefs, or in accordance with the patient's best interests with a patient centered approach.

### Withholding and Withdrawing of Life Sustaining Treatment –Criteria

Treatment would be an extraordinary burden to the patient and an attending determines, with the independent concurrence of another physician, that to a reasonable degree of medical certainty and in accordance with accepted medical standards that:

- Patient has an illness or injury which can be expected to cause death within six months whether or not treatment is provided, or the patient is permanently unconscious or,
- If the patient is permanently unconscious, the attending physician determines, with the concurrence of another attending physician, that the treatment would be an extraordinary burden to the patient or,
- The provision of treatment would involve such pain and suffering or other burden that it would reasonably be deemed inhumane, or extraordinarily burdensome under the circumstances, and the patient has an irreversible or incurable condition as determined by an attending physician with the concurrence of another attending physician to a reasonable degree of medical certainty and in accordance with accepted medical standards.





# Standards for Decisions Without Surrogate

## N.Y.S. Public Health Law Section 2994-g

FHCDA establishes a procedure for making health care decisions for patients who lack decisional capacity with no available surrogate.

### Routine Medical Care and Treatment

An attending physician shall be authorized to decide about routine medical treatment .

### Major Medical Care and Treatment:

#### General Hospital

With respect to a decision to provide major medical treatment, the attending physician shall make a recommendation in consultation with hospital staff directly responsible for the patient's care.

At least one other physician designated by the hospital must independently determine that he or she concurs that the recommendation is appropriate.

#### Residential Health Care Facility and Hospice

In a residential health care facility, and for a hospice patient not in a general hospital, the medical director of the facility or hospice must independently determine that that he or she concurs that the recommendation is appropriate, the second physician must be designated by the residential health care facility or hospice.

Any health or social service practitioner employed or affiliated with the facility or hospice may provide a second opinion for decisions about physical restraints.



# Standards- Patients Without a Surrogate

## Withholding and Withdrawal of Life Sustaining Treatment

### Judicial Determination

Court may determine the case based on statutory standards.

### Attending Physician with the Concurrence of a Second Physician

The attending physician with the independent concurrence of a second physician designated by the hospital, must determine to a reasonable degree of medical certainty:

- Life sustaining treatment offers the patient no medical benefit because the patient will die imminently even if the treatment is provided; and
- The provision of life sustaining treatment would violate accepted medical standards.

### Judicial Intervention

Court approval is not required.

However, this provision does not apply to any treatment necessary to alleviate pain or discomfort.



# Formal Recognition of Bioethics

## N.Y.S. Public Health Law Section 2994-m

The FHODA requires each hospital to establish an Ethics Review Committee.

### Functions of the Committee:

- Consider and respond to any health care matter presented to it by a person connected with a case.
- May include advice and making recommendations about proposed health care.
- Provide assistance in resolving disputes about proposed health care on ethical aspects of proposed health care.

### Membership

- Committee must be interdisciplinary and include at least five members who have demonstrated an interest in, or commitment to, patient's rights or to the medical, public health, or social needs of those who are ill.
- At least three ethics review committee members must be health or social services practitioners, at least one of whom must be a registered nurse and one of whom must be a physician.
- At least one member must be a person without any governance, employment or contractual relationship with the hospital.

### Residential Healthcare Facility

- In a residential health care facility the facility must offer the residents' council of the facility (or of another facility that participates in the committee) the opportunity to appoint up to two persons to the ethics review committee, none of whom may be a resident of or a family member of a resident of such facility, and both of whom shall be persons who have expertise in or a demonstrated commitment to patient rights or to the care and treatment of the elderly or nursing home residents through professional or community activities, other than activities performed as a health care provider.

### Person Connected with the Case

A person connected with the case may not participate as an ethics review committee member in the consideration of that case.



# Ethics Review Committee Interventions

## General Hospital with a Surrogate

In a general hospital, if the attending physician objects to a surrogate's decision to withdraw or withhold nutrition and hydration provided by means of medical treatment, in that the provision of treatment would involve such pain, suffering or other burden that it would be reasonably inhumane or extraordinarily burdensome under the circumstances, and the patient has an irreversible condition or incurable condition as determined by an attending physician with the concurrence of another physician to a reasonable degree of medical certainty.

The decision shall not be implemented until an Ethics Review Committee including one physician not directly responsible for the care or a Court reviews the decision and determination.

## Emancipated Minor Patients

If the attending physician determines that a patient is an emancipated minor with decisional capacity, the patient shall have the authority to decide about life sustaining treatment.

Such authority shall include a decision to withhold or withdraw life sustaining treatment if an attending physician and the ethics review committee determine that the decision accords with the decision for surrogate decision making for adults and the ethics review committee approves the decision.

## Residential Health Care Facility with a Surrogate -Review of a Life Sustaining Treatment Determination

Surrogate shall have authority to refuse life sustaining treatment if the patient has an irreversible or incurable condition as determined by the attending physician, with the concurrence of another attending physician, that the provision of treatment would involve such pain and suffering or other burden that it would be reasonably deemed inhumane or extraordinarily burdensome under the circumstances.

However, an Ethics review is required including one physician who is not directly responsible for the care, or a Court reviews the decision.

Does not apply to decisions to withhold cardio pulmonary resuscitation.



# Ethics Review Committee Interventions

## Concurring Physician Objection for Health Care Decisions for Adult Patients Without Surrogates

If a physician consulted for a concurring opinion objects to an attending physician's recommendation or determination or a member of the hospital staff directly responsible for the patient's care objects to an attending physician's recommendation about major medical treatment or treatment without medical benefit, the matter shall be referred to the ethics review committee if it can not otherwise be resolved.

## Request by a Person Connected to the Case

A person connected with the case requests the ethics review committee to provide assistance in resolving a dispute about proposed care:

- Patient
- Any person on the surrogate list
- Parent or guardian of a minor patient
- Hospital administrator
- Attending physician
- Any other health or social service provider who is or has been directly involved in patient care.
- Any duly authorized state agency including the facility director or regional director for a patient transferred from a mental hygiene facility.
- The facility director for a patient transferred from a correctional facility.



# Procedural Highlights

## Ethics Review Committee

### Response

The ethics review committee shall respond promptly, as required by the circumstances. The committee shall permit persons connected with the case to present their views to the committee, and to have the option of being accompanied by an advisor when participating in a committee meeting.

### Notice

The ethics review committee shall provide the patient, when there is an indication of the patient's ability to comprehend the information, the surrogate and other persons directly involved in the decision or dispute regarding the patient's care, or any parent or guardian of a minor directly involved in the decision or dispute, an attending physician, and other persons the committee deems appropriate with the following :

- Notice of any pending case consideration concerning the patient, information about the ethics committee's procedures, composition and function and the committee's response to the case following an ethics review concerning the withdrawal or withholding of life sustaining treatment.
- Treatment shall not be withdrawn or withheld until persons identified above have been informed of the committee's decision.

### Hospice

When an ethics review committee is convened to review decisions regarding hospice care for a patient in a general hospital or residential health care facility, the responsibilities shall be carried out by the ethics review committee of the hospital or residential facility provided that such a committee shall invite a representative from hospice to participate.





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# Bioethics in Medical Research

Karen L. Illuzzi Gallinari, Esq.

Healthcare Law, Compliance and Bioethics Specialist



# Milestones in Research Ethics

- 1979 Belmont Report\*, heavily influenced the “Common Rule”
- 1991 Federal Policy for the Protection of Human Subjects (the “Common Rule”) was published.  
(Adopted by 15 Federal departments and agencies)
- 2000 Further publicized ethical abuses prompting establishment of the Office of Human Research Protections
- Full title is the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Issued 30 September 1978, published FR 18 April 1979. Named for Belmont Conference Center, where the document was drafted in part.



# Belmont Report

- 3 basic principles for ethical research
  1. Respect for persons / individual autonomy  
Risks involved and informed consent
  2. Beneficence, benefit to the participant
  3. Justice, risks and benefits equitably distributed



# Final Amendment of The Common Rule

- Federal Policy for the Protection of Human Subjects
- Originally published in 1991 and codified in by other Fed. depts/agencies
- Final amendment published January 19, 2017
- Implementation delayed at least until July 19, 2018, possibly Jan. 2019
- Comments regarding additional 6 month delay due by May 21, 2018.



# Research Ethics and Biobanking

- A biobank is a collection of:
  - health information linked to
  - human specimens
    - blood
    - urine
    - tissue samples
  - available for Institutional Review Board (IRB) approved research



# Future Advances in Medicine

- Personalized medicine is:
  - Health care tailored to the biological traits of individuals
- Has potential to improve:
  - Prevention of disease
  - Effectiveness of treatments
  - Reactions to medication
- Requires:
  - Large numbers of specimens
  - Diverse races and ethnicities
  - Linkage to computerized patient information



# Legal and Ethical Requirements

## FEDERAL

- Federal Common Rule to Ensure Protection of Human Subjects ("The Common Rule")
- Health Insurance Portability and Accountability Act ("HIPAA/HITECH") Final Omnibus Rule Jan. 2013
- Federal Genome-wide Association Studies Guidelines
- Food and Drug Administration Requirements



# Legal and Ethical Requirements

## NYS

- NY Pub. Hlth Law 24-A, Protection of Human Subjects\*
- NY Civil Rights Law § 79-L.  
Confidentiality of records of genetic tests  
Addresses clinical and research testing
- 10 NYCRR Part 58-1, Section 1.8: Results of tests to be reported only to physicians or other authorized persons

\*NYSBA, Hlth Law Section, Medical Research/Biotech Committee proposal to NYSDOH to permit research institutions which comply with the Common Rule to be in compliance with NYS research requirements.





# Risks of Biobank Participation

- Minimal
- Small privacy risk
- Rare chance of anxiety, if meaningful individual results become available
  - If so, private life, long-term care or disability insurance may be affected
  - Genetic counseling would be offered to help address risks of learning individual genetic results



# “Benefits” of Participation

- No direct benefit to individual patient
- Participation may help people in the future
- No payment of any kind for:
  - Tests
  - Treatments
  - Products
  - Other things of value which may result from the research



# Other Important Issues

- Rare possibility of actionable patient specific results \*
- Pediatric samples
- Adults who lack capacity

\*NYSBA, Hlth Law Section, Medical Research/Biotech Committee proposal to NYSDOH to amend 10 NYCRR Part 58-1, Section 1.8 To Permit research investigators to report research findings which represent significant health risks to subject's physician.



# Key provisions of the Final Common Rule

- Does not expand the definition of “human subjects research” to include research using anonymous or de-identified specimens
- Allows the use of “broad consent” for storage of and research on identifiable biospecimens
- States intent to simplify informed consent documents, but includes element on commercial gain
- Expands research that is “exempt” from regulation because of low-risk, but requires limited review by an IRB

\*See E.g., John Conley, Some Thoughts on the New Common Rule for Human Subjects Research, Genomics Law Report, March 29, 2017.



# National Biobank Initiatives

- Nat'l Instit. Of Hlth, "All of Us" <https://allofus.nih.gov/>
  - One million participants
  - 2017 budget \$230 million, \$40 million from the 21st Century Cures Act. Congress authorized \$1.455 billion over 10 years
  - The Struggle to Build a Massive 'Biobank' of Patient Data, NY Times, Gina Kolata, March 19, 2018
  - 17,000 volunteers, "beta testers", supplied blood and urine samples, measurements taken, and surveys
  - Geisinger and Kaiser Permanente, backed away from grants to participate due to programs complexity
- Private ventures, EG. Regeneron, 300 Participants



# EXAMINING THE INTERSECTION OF BIOETHICS AND THE LAW IN 2018

## Bioethics Mediation: A Guide to Shaping Shared Solutions New York Law School April 30, 2018

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# Why Mediation

- new player introduces “neutral turf”
- identifies styles/patterns of communication
- no “stake” in previous treatment decisions—  
*impartial to this situation*
- less politically vulnerable (residents and fellows)
- committed to empowering patients and family



# STADA

- Sit
- Tell me about Mama
- Admire
- Discuss
- Ask

# Mediation

- It is a private, voluntary, informal process in which an impartial third person facilitates a negotiation between people in conflict and assists them to find solutions that meet their interests and needs.
- The mediator works with the parties, helping them identify their goals and priorities, generate and explore options, and exchange information that may be necessary in formulating a solution.
- Mediators are optimists who work to “LEVEL THE PLAYING FIELD”.

# Medical Facts

*“Medical facts” can be defined as consensus agreements among the staff regarding the meaning of the medical narrative, the present data, and the observations of staff regarding the patient’s improvement or deterioration. For the purposes of mediation, a medical fact is an interpretation of data in a moment of time by the most powerful player in the discussion.*

# Mediation in Health Care Settings

Bioethics mediation combines the clinical substance and perspective of bioethics consultation with the tools of the mediation process, using the techniques of mediation and dispute resolution in order to:

- identify the parties to the conflict and seek consensus

- Deciding Not to Reach a Resolution Is Not an Option
- The Playing Field Is Usually Uneven for Patients and Their Families
- Confidentiality Is Limited to Information Not Relevant to Patient Care
- Time Is of the Essence

## Additional Roles of the Consultant/Mediator

- teacher
- reference point for new literature
- mentor in the politics of medicine

## Conclusion



**WE ARE NEW YORK'S LAW SCHOOL**



# Directions in Bioethics and Public Health: Converging Perspectives

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*Fordham University*

# Background and Work: *Interdisciplinary*

Interdisciplinary focus:

- Health law & policy
- Public health
- Bioethics
- Gerontological social work and psychological research
- Medical and psychological humanities





# Part I. Goals and contexts

- Paradigm shifts
- Key influences
- Convergences and directions



# Paradigm Shifts

- Individual needs and interests understood in relation to *the other* and in social and ecological contexts
- Critique of neoliberalism as sociopolitical movement and implications for bioethics (Morrissey, Lang & Newman, in press, 2018; Sugarman, 2015)



# Influence of Public Health

- Reframing obligation: obligation to individual *and* community



# Influence of Human Science Research and Phenomenology

- Heightened focus on lived experience from first-person perspective of experiencing individual and individual's life-world
- Transcendence of consciousness: consciousness always directed to objects outside itself - *intentionality*
- Role of reflection in understanding human experience and intentionalities



# Law and Bioethics

- Law as lived social practice
- Humanistic foundations of law (Vining, 2008)
- Understanding therapeutic benefits of law from perspective of beneficiaries (Morrissey & Jennings, 2006)



# Convergences of Bioethics and Public Health: *Directions*

- Fostering a palliative ethic of care (Fins, 2006) through relief of pain and suffering
- Moving away from technical rationality and rigid principlism (Morrissey & Barber, 2014)
- Gaining deeper access to first-person experience and life-historical narratives as person-in-environment, embedded in social context and community
- Democratizing knowledge through participatory processes of deliberation and debate
- Making allocation of resource decisions explicit



Part II. The Role of Politics and Values in Research:  
*The Case of Medical Aid-in-Dying and Implications for  
Bioethics and Public Health*



# Objectives: *Ethics and Equity*

- Frame --- and reframe --- the problem and narrative of terminal illness and suffering, and give voice to those who are marginalized and invisible – *multiple stories*
- Describe practice of Medical Aid in Dying and its implications for interdisciplinary sciences – *moving beyond medical to ethical*
- Interpret available existing data
- Discuss relationship between values and research – focus on *Equity: Is Medical Aid in Dying a colonizing activity of non-Hispanic white people? Are the social structures coercive?*
- Call for more robust participatory action research designs





# Framing of Social Problem

- High suffering burden in serious and terminal illness across diverse populations and groups in United States and in New York
- Social and structural determinants of health, mental health and well-being, such as income, education, housing, neighborhood and food security
- Forms of structural discrimination that perpetuate inequities in access to basic health care, hospice and palliative care, and essential medicines
- Voices and stories that have not been heard
- Public Policy Goal: *Attaining health care justice for all persons by eliminating inequities*



# Key Issue: *Equity*

- Equity is fundamentally about fairness and just distribution of resources.
- A central issue in Medical Aid in Dying is that of equitable access to care and the social determinants of health that influence equitable access to care.
- Call for more robust research about lived experiences of persons with serious and terminal illness across racially, ethnically and socioeconomically diverse groups, and what they want at end of life.



# What is Medical Aid in Dying?

- Medical Aid in Dying is a medical practice that would allow a physician to prescribe a lethal medication to a mentally competent, terminally ill individual who requests and consents to such lethal medication for the purpose of ending her/his own life.
- The term “physician aid in dying” has also been used to describe physician-aided dying practice, which proponents seek to differentiate from “physician assisted suicide.”
- The language of “hastening death” or “wish to hasten death” has also been used in these contexts (Balaguer et al., 2016).



# NY Court of Appeals Decision and NY Bill

- *Myers v. Schneiderman* NY Court of Appeals Decision (2017 N.Y. slip Op. 06412, 30 N.Y.3d (2017) – suit sought recognition of a right to make autonomous decision to end one’s life (choosing aid in dying) under NYS Constitution. HELD no constitutional right to aid in dying in New York.
- Bill introduced in NYS Legislature: A.2383/S.3151-A, 241<sup>st</sup> N.Y Leg. Sess. (2018), amending A.2383 / S.3151 (2017).
- Public Policy Issues:
  - Beneficiaries: The bill appears to apply to all possible beneficiaries and therefore as presently written would have universal application. For example, there are no residency requirements. (The six states and the District of Columbia that have legalized aid in dying all have residency requirements.) There are also no safeguards for institutionalized persons such as nursing home residents or inmates.
  - Financing and Delivery Systems: No information.



# Alternative to Palliative Care: *Allocation of Resources?*

- Alternative Option: The proposed bill would position Medical Aid in Dying as an alternative to palliative care. Practically, it is unclear what this would mean and how it would be operationalized.
- Would New York now require that Medical Aid in Dying be included in palliative and end-of-life options offered to patients under the NY Palliative Care Information Act and Palliative Care Access Act?
- What are the public policy choices and decisions that need to be debated and made about allocation of resources to palliative care and Medical Aid in Dying if they are structured as care alternatives?

Palliative Care Patient Information Act, N.Y. Public Health Law § 2997-c(2) (PHL);  
Palliative Care Access Act, PHL § 2997-d



# Dearth of Research

- **Dearth of Research:** Few investigations of the personal, social and cultural meanings associated with desires to end one's own life, especially among racially and ethnically diverse groups.
- **Public Health Data:** Oregon and Washington (based on information collected from After Death Forms and Physician Compliance Forms); data from other states not available (California, Montana, Vermont, Colorado and DC)
- **Types of studies:** retrospective using public health data; cross-sectional; studies of Oregonians interested in DWD
- **Limitations:** public health data collected from physician and other records; aid in dying advocacy organizations may introduce bias into recruitment of study participants; constraints on interviews with very sick people



# Oregon Data: *Twenty Year Picture*

- Over 20 years, 1,975 persons obtained prescriptions and 1,275 died from ingestion (under two thirds)
- 99.7% of population did not take advantage of the law
- Oregon's population is not as racially and ethnically diverse or economically segregated as New York.

Oregon Public Health Division, *Oregon Death with Dignity Act: 2017 Data Summary*. Oregon Health Authority (February 9, 2018),



# Snapshot of Oregon Data

**Table 1. Characteristics and end-of-life care of 1,127 DWDA patients who have died from ingesting a lethal dose of medication as of January 23, 2016, by year, Oregon, 1998–2016**

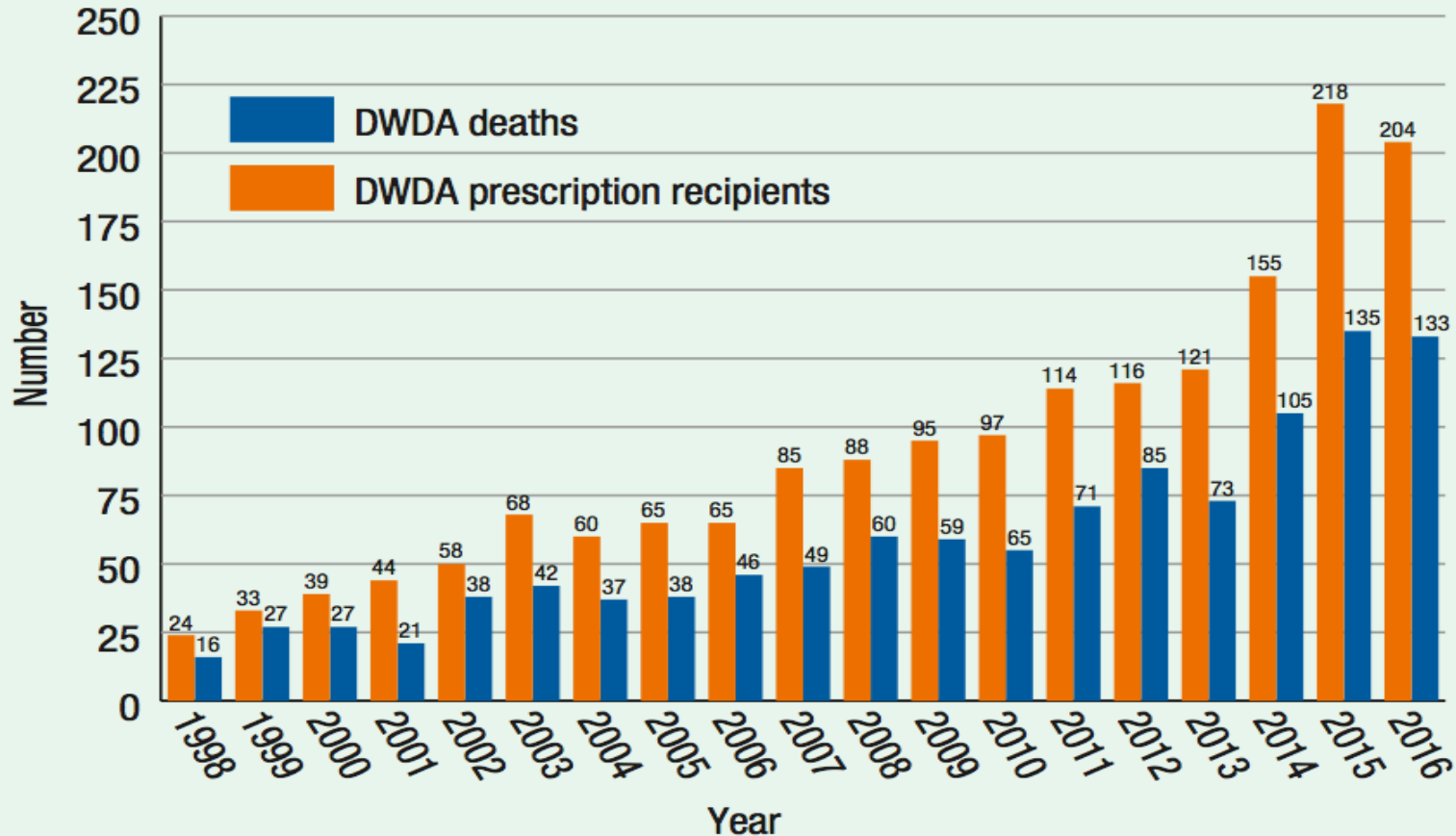
Characteristics	2016		1998–2015		Total	
	(N=133)		(N=994)		(N=1,127)	
<b>Sex</b>	<b>N (%)<sup>1</sup></b>		<b>N (%)<sup>1</sup></b>		<b>N (%)<sup>1</sup></b>	
Male (%)	72	(54.1)	510	(51.3)	582	(51.6)
Female (%)	61	(45.9)	484	(48.7)	545	(48.4)
<b>Age</b>						
18–34 (%)	1	(0.8)	8	(0.8)	9	(0.8)
35–44 (%)	1	(0.8)	23	(2.3)	24	(2.1)
45–54 (%)	6	(4.5)	64	(6.4)	70	(6.2)
55–64 (%)	18	(13.5)	206	(20.7)	224	(19.9)
65–74 (%)	52	(39.1)	289	(29.1)	341	(30.3)
75–84 (%)	31	(23.3)	259	(26.1)	290	(25.7)
85+ (%)	24	(18.0)	145	(14.6)	169	(15.0)
Median years (range)	73	(32–97)	71	(25–102)	71	(25–102)
<b>Race</b>						
White (%)	127	(96.2)	956	(96.6)	1,083	(96.5)
African American (%)	0	(0.0)	1	(0.1)	1	(0.1)
American Indian (%)	0	(0.0)	2	(0.2)	2	(0.2)
Asian (%)	2	(1.5)	13	(1.3)	15	(1.3)
Pacific Islander (%)	0	(0.0)	1	(0.1)	1	(0.1)
Other (%)	0	(0.0)	3	(0.3)	3	(0.3)
Two or more races (%)	1	(0.8)	4	(0.4)	5	(0.4)
Hispanic (%)	2	(1.5)	10	(1.0)	12	(1.1)
<i>Unknown</i>	1		4		5	
<b>Marital status</b>						
Married (including Registered Domestic Partner) (%)	62	(47.0)	449	(45.4)	511	(45.5)
Widowed (%)	26	(19.7)	232	(23.4)	258	(23.0)
Never married (%)	8	(6.1)	78	(7.9)	86	(7.7)
Divorced (%)	36	(27.3)	231	(23.3)	267	(23.8)
<i>Unknown</i>	1		4		5	
<b>Education</b>						
Less than high school (%)	5	(3.8)	58	(5.9)	63	(5.6)
High school graduate (%)	23	(17.4)	218	(22.1)	241	(21.5)
Some college (%)	38	(28.8)	261	(26.4)	299	(26.7)
Baccalaureate or higher (%)	66	(50.0)	450	(45.6)	516	(46.1)
<i>Unknown</i>	1		7		8	





# Oregon DWD Historical Data

Figure 1: DWDA prescription recipients and deaths\*, by year, Oregon, 1998–2016



\*As of January 23, 2017



# Washington: Death with Dignity Data 2015 and 2014 (Sex, Age, Race and Ethnicity, Marital Status)

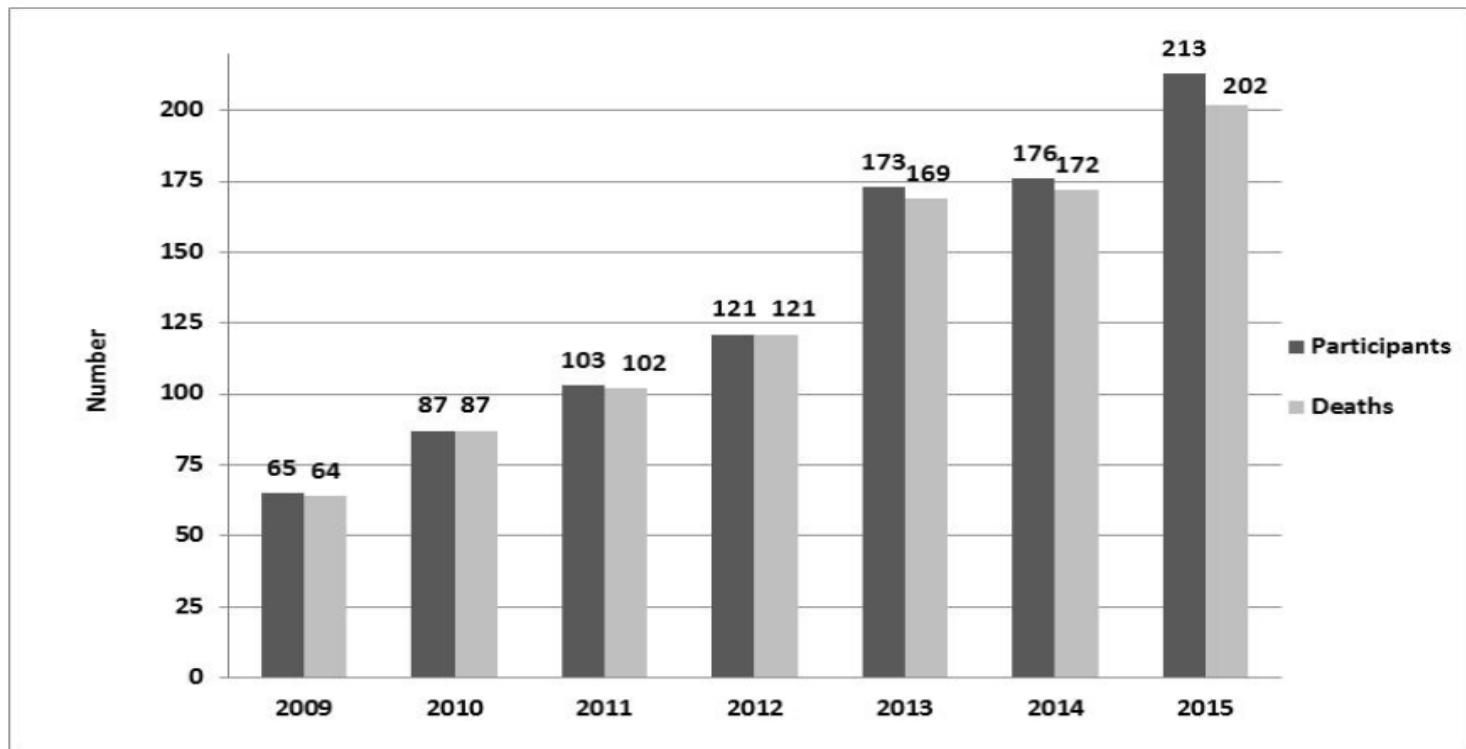
**Table 1. Characteristics of the participants of the Death with Dignity Act who have died**

	2015		2014 <sup>1</sup>	
	Number	%	Number	%
<b>Sex<sup>3</sup></b>				
Male	106	53	75	44
Female	93	47	97	56
<b>Age (years)<sup>2</sup></b>				
18-44	5	2	7	4
45-54	12	6	10	6
55-64	38	19	33	19
65-74	63	31	53	31
75-84	42	21	40	23
85+	42	21	29	17
Range (min-max)	20-97		21-101	
<b>Race and Ethnicity<sup>3</sup></b>				
Non-Hispanic White	194	98	159	92
Hispanic and/or Non-White	5	2	12	7
Unknown			1	1
<b>Marital Status<sup>3</sup></b>				
Married	93	47	81	47
Widowed	41	20	34	20
Divorced	53	27	37	21
Domestic partner (state-registered)	0	0	18	10
Never married	12	6	1	1
Unknown			1	1



# Washington DWD Historical Data

**Figure 2. Number of Death with Dignity Participants and Known Deaths, 2009-2015**



	Oregon	Washington
	(N = 132)	N= (199)
<b>Sex</b>		
Male	(56) 42.4%	(106) 53%
Female	(76) 57.6%	(93) 47%
<b>Age (years)</b>		
18-44	(6) 4.5%	(5) 2%
45-54	(2) 1.5%	(12) 6%
55-64	(21) 15.9%	(38) 19%
65-74	(41) 31.1%	(63) 31%
75-84	(30) 22.7%	(42) 21%
85+	(32) 24.2%	(42) 21%



# Comparison Data Oregon & Washington 2015

	Oregon	Washington
	(N = 132)	N= (199)
<b>Race and Ethnicity</b>		
Non-Hispanic White	(122) 93.1%	(194) 98%
Hispanic and or Non-White	(4) 3.1%	(5) 2%
Unknown	(1) 0.76%	



# Comparison Data Oregon & Washington 2015

	Oregon	Washington
	<b>(N = 132)</b>	<b>N= (199)</b>
<b>Education</b>		
Less than high school	(7) 5.4%	(8) 4%
High School Graduate	(31) 23.8%	(42) 21%
Some College	(36) 27.7%	(55) 27%
Baccalaureate or higher	(56) 43.1%	(93) 47%
Unknown	(2)	(1)



# Schoepfer Study: *Role of Social Support*

- Mixed method study of competent, terminally ill older adults (50 and over)
- Purposive sampling across care settings (N=96)
- 84% White
- Findings: relationship between consideration to hasten death and "social support"
- *"Poor or conflictual social support was experienced by 33.3% of the respondents who considered a hastened death but only 2.6% of those not considering one."*  
(Schroepfer, 2008, p. 616)



# Call for Debate and deliberation and Well-designed research

- City Bar Commentary (June 2017)
- Hearings in NY – May 3, 2018, NYC
- More public debate and deliberation
- Well-designed research studies

