

**ETHICAL AND LEGAL ISSUES
OF THE TERMINALLY ILL PATIENT**

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**END OF LIFE ISSUES
Outline**

- Framing the Issues
- Termination of Life Support
Competency and Decisional Authority
- The Patient Self-Determination Act
- Physician-Assisted Suicide/Patient-Directed Death
- Access to Unapproved Drugs

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END OF LIFE ISSUES

Framing the Issues

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END OF LIFE ISSUES
Termination of Life Support

- In re Quinlan
- Cruzan v. Director, Missouri Department of Health
- In re Schiavo

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END OF LIFE ISSUES
Termination of Life Support

- In re Quinlan, 355 A 2d 647 (N.J. 1976)
 - Facts: Karen Ann Quinlan ceased breathing, became comatose, then developed symptoms of a Persistent Vegetative State (PVS). She was intubated and fed via a nasogastric tube.
 - Procedural History: Quinlan's father asked to be appointed guardian of his adult unmarried daughter. He stated his intent to cease all extraordinary medical procedures. The Trial Court refused. N.J. Supreme Court reversed.

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END OF LIFE ISSUES
Termination of Life Support

- Holding: A competent adult has a constitutional right to privacy that allows him/her to refuse life-sustaining medical care and a guardian can assert that right on his/her behalf. Quinlan's father was an appropriate guardian.
- Analysis: The court relied on the substituted judgment of a surrogate decision-maker. No civil or criminal liability if guardian agreed to the withdrawal and a hospital ethics committee confirmed there is no reasonable possibility of her recovering a cognitive, sapient state.

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END OF LIFE ISSUES
Termination of Life Support

- Cruzan v Director, Missouri Dept. of Health 497 U.S. 261 (1990)
 - Facts: Nancy Cruzan had an auto accident that led to transient cessation of cardiac and respiratory functions and cerebral contusions. She became comatose and evolved to a PVS. Nutrition and hydration were provided via a nasogastric tube.

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END OF LIFE ISSUES
Termination of Life Support

- Procedural History: Cruzan's parents asked the hospital to terminate food and water. The hospital refused without a court order. The parents obtained such approval from a state trial court.
- Trial court held: Substantive due process gives a competent person a federal constitutional right to refuse "death-prolonging procedures." Also Cruzan had effectively exercised that right when she told a friend years earlier that "if sick or injured, she would not want to continue her life unless she could live at least half way normally."

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END OF LIFE ISSUES
Termination of Life Support

- The Missouri Supreme Court reversed: 760 SW.2d 408 (Mo.1988). It held "no person can assume that choice for an incompetent in the absence of the formalities required under Missouri's Living Will statutes or the 'clear and convincing inherently reliable evidence absent here'. The Supreme Court granted certiorari to decide whether the U.S. Constitution grants what is in common parlance referred to as "a right to die."

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Termination of Life Support

- The Court recognized a substantive due process liberty interest under the 14th Amendment to refuse medical treatment including refusing nutrition and hydration in the manner Cruzan received them. But, in all substantive due process cases, the exercise of the liberty interest must be balanced against the state's relevant interests – here Missouri's in the protection and preservation of human life. Missouri's choice to advance that interest by requiring clear and convincing evidence before allowing refusal on behalf of an incompetent was not an unconstitutional infringement of the liberty interest.

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END OF LIFE ISSUES
Termination of Life Support

- In re Schiavo 851 So. 2d 182 (Fla App.2003)
Facts: In 1990, Terri Schiavo had a cardiac arrest and fell into a PVS. A state court appointed her husband as guardian.

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Termination of Life Support

- Procedural History: In 1998, he petitioned the court to decide whether to discontinue the tube feeding. A conflict arose between the husband and Schiavo's parents – the latter objected to ceasing nutritional and hydration support. In 2003, a Florida state judge found that there was clear and convincing evidence that Schiavo was in a PVS and that, if she could make her own decision she would choose to discontinue life-prolonging procedures. An appeals court affirmed the lower court's decision and the Florida Supreme Court declined to review it.

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Termination of Life Support

- The parents sought and obtained state legislative authority to require reinsertion of the feeding tube. The law (2003-418) known as "Terri's Law" was signed by Governor Bush. Its constitutionality was challenged and in 2004, the Florida Supreme Court ruled it was unconstitutional since it violated the separation of powers. A law that permits the executive to interfere with the final judicial interpretation in a case is an invasion of the authority of the judicial branch.

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Termination of Life Support

In re Schiavo – cont'd

- In 2005, The U.S. Supreme Court refused to hear an appeal brought by Governor Bush. The trial judge again ordered the tube removed. The parents again sought further judicial review. The trial and appellate courts refused to reopen the case. New legislation was passed by the Florida House but the Senate refused to agree noting it would again be found to be unconstitutional.

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Termination of Life Support

- The parents (and the Right to Life Lobby) then sought congressional relief. Congress passed P.L. 109-3. This gave the Middle District of Florida jurisdiction to hear, determine, and render judgment on a suit or claim by or on behalf of Schiavo for the alleged violation of any right of Schiavo under the Constitution or laws of the U.S. relating to the withholding or withdrawal of food, fluids, or medical treatment necessary to sustain her life.

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END OF LIFE ISSUES
Termination of Life Support

- The parents filed a lawsuit under PL109-3 asking for a TRO requiring resumption of nutrition and hydration. The District Court denied the TRO. It also found no basis to sustain the parents substantive or procedural due process claims under the 14th Amendment.

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END OF LIFE ISSUES
Termination of Life Support

In re Schiavo – cont'd

Held: The Eleventh Circuit agreed the P.L.109-3 did not alter the established rules under the Federal Rule for Civil Procedure 65 for granting a TRO.

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END OF LIFE ISSUES
Termination of Life Support

Putting Principle into Practice
Issues

- Execution of an advanced directive in conformity with State laws.
- Willingness of other family members to agree with the decision of the surrogate decision-maker.
- Role and action of the Institution and other caregivers in the care of the patient.

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**UNITED STATES LAWS AND THE RIGHTS
OF THE TERMINALLY ILL**

THE PATIENT SELF-DETERMINATION ACT OF 1991

- Federal (U.S.) Law
- Requires providers of services to Medicare and Medicaid beneficiaries:
 - To give adult individuals at time of admission or enrollment to healthcare institutions or programs information regarding their rights under State laws concerning advance directives.
- These rights include:
 - Right to direct own health care decisions
 - Right to accept or refuse medical or surgical treatment
 - Right to prepare an advance directive
 - Receipt of institutional policies that govern the utilization of these rights.

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**END OF LIFE ISSUES
Physician-Assisted Suicide**

Cases

- Washington v Glucksberg, 521 U.S.702 (1997)
- Vacco v Quill 521 U.S. 793 (1997)
- Gonzales v Oregon 126 S.Ct. 904 (2006)

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**END OF LIFE ISSUES
Physician-Assisted Suicide**

Washington v Glucksberg, 521 U.S. 702 (1997)

- Facts: The Washington State Legislature passed a law stating that one is guilty of promoting a suicide attempt when one knowingly causes or aids another person to attempt suicide.

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**END OF LIFE ISSUES
Physician-Assisted Suicide**

- Procedural History: H. Glucksberg, M.D. and other physicians along with some mentally competent, terminally ill patients sued asserting the law unconstitutionally infringed on patients' substantive due process liberty interests in committing suicide with the assistance of their physicians.
 - The District Court found the law unconstitutional on the basis of equal protection clause.

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**END OF LIFE ISSUES
Physician-Assisted Suicide**

- The Ninth Circuit Panel reversed finding no constitutional right to assistance in committing suicide.
- The Ninth Circuit en banc disagreed and affirmed the District Court's holding of unconstitutionality.
- The U.S. Supreme Court granted cert.

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**END OF LIFE ISSUES
Physician-Assisted Suicide**

- Holding: Assisted suicide is not a fundamental liberty interest even if refusing life-sustaining treatment is. The ban on assisted suicide is rationally related to several state interests including preserving life and preventing suicide
- Concurrence: Several concurring opinions expressed interest in deferring to state legislative resolution of the matter.
- Analysis: Physician-assisted suicide is not a federal constitutional matter. There is a preference for state legislative action to resolve the issue.

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**END OF LIFE ISSUES
Physician-Assisted Suicide**

Vacco v Quill 521 U.S. 793 (1997)

Facts: Similar to Glucksberg – New York criminalized assisted suicide

Procedural History: Several terminally ill patients sued alleging a violation of the equal protection clause of the 14th amendment

- The District Court rejected the claim stating there is a difference between refusing treatment and hastening death.
- The Second Circuit reviewed and stated there was no meaningful difference between what New York permitted and what it criminalized.

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**END OF LIFE ISSUES
Physician-Assisted Suicide**

The U.S. Supreme Court granted cert.

Holding: The Court reversed the Second Circuit finding there was a meaningful difference between declining treatment and hastening death and New York could constitutionally criminalize only the latter.

Analysis: The Glucksberg plaintiffs relied on substantive due process.

The Vacco plaintiffs relied on an equal protection argument, but the basis for their contention was the same as in Glucksberg

The Court in both cases disagreed with the core contention that there is no difference between refusing treatment and seeking assistance to commit suicide.

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**END OF LIFE ISSUES
Physician-Assisted Suicide**

Gonzales v Oregon 126 S.Ct. 904(2006)

Facts: Oregon enacted the Oregon Death With Dignity Act (ODWDA). The Act exempts from civil or criminal liability state-licensed physicians who, in compliance with the ODWDA, dispense or prescribe a lethal dose of drugs upon the request of a terminally ill patient.

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**END OF LIFE ISSUES
Physician-Assisted Suicide**

Procedural History: In 2001, Attorney General Ashcroft issued a directive stating that the use of a controlled substance under the ODWDA was not a "legitimate medical purpose" under the Controlled Substances Act of 1970 as codified at 21 CFR §1306.04. This stated that a controlled substance had to be issued for a legitimate medical purpose by an individual acting in the course of his professional practice.

The District Court enjoined enforcement of the Ashcroft Directive but transferred the case to the Ninth Circuit. The Ninth Circuit claimed original jurisdiction.

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**END OF LIFE ISSUES
Physician-Assisted Suicide**

Holding: Congress did not authorize the A.G. to decide that physician assisted suicide violates the Controlled Substances Act. The Ashcroft Directive criminalizes medical practices specifically authorized by the ODWDA and interferes with Oregon's authority to regulate medical care within its borders.

Supreme Court accepted cert and held that the CSA manifests no intent to regulate the practice of medicine generally. It upheld the opinion of the Ninth Circuit.

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**END OF LIFE ISSUES
Access to Unapproved Drugs**

Case: Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach

Facts: The Abigail Alliance was founded in 2001 by the father of a patient with a cancer of the head and neck who sought and was denied access to a drug that at the time was experimental. The purpose of the Alliance was to advocate for greater access by patients with advanced cancer for whom there were no effective drugs or pharmaceuticals in early stages of development and testing.

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Access to Unapproved Drugs

Drug development occurs in 3 stages with a 4th post-marketing stage. Ordinarily, investigational drugs may be used only within a controlled trial. The FDA instituted a compassionate use policy in the 90s under which it may approve the use of an investigational drug outside of clinical trials for life-threatening disease when:

- there is no comparable treatment alternative
- clinical trials of the drug are underway, and
- formal FDA approval for the drug is being sought.

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END OF LIFE ISSUES
Access to Unapproved Drugs

The FDA may deny compassionate use if:

- The scientific evidence does not provide a reasonable basis to conclude that the drug may be effective for its intended use, or
- If it would add an unreasonable and significant risk of illness.

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END OF LIFE ISSUES
Access to Unapproved Drugs

Procedural History: In 2003, the Alliance submitted a citizen's petition to the FDA requesting broader availability of investigational drugs for terminally ill patients. Before the FDA acted formally on the petition, the Alliance sued in federal court. It alleged that the failure of the FDA to permit the sale of investigational drugs to terminally ill patients violated patients' rights to privacy and due process under the Fifth Amendment.

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Access to Unapproved Drugs

In August 2004, the district court granted FDA's motion to dismiss. It ruled that there is no fundamental right of access to investigational drugs.

The Alliance appealed. In May, 2006, a 3-judge panel of the U.S. Court of Appeals for the District of Columbia reversed the district court and ruled that terminally ill patients have a constitutional right to purchase unapproved drugs that have successfully completed Phase I testing. 445 F.3d.470(DC Cir.2006).

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Access to Unapproved Drugs

The panel's majority relied on the Supreme Court's analysis in Washington v Glucksberg where, in ruling there is no fundamental right to physician assisted suicide, the Court articulated a relatively restrictive test requiring courts to balance the claimed right against the nation's history and legal traditions for evidence of whether the right is fundamental. It relied also on Cruzan wherein the Court held that competent individuals have a constitutionally protected right to reject life-sustaining medical treatment.

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END OF LIFE ISSUES
Access to Unapproved Drugs

The FDA requested a rehearing before the full DC Circuit Court of Appeals. The petition was granted and the panel's opinion was vacated.

On August 7, 2007, the DC Circuit Court of Appeals decided. The specific question before the court was whether terminally ill patients have a fundamental right to experimental drugs that have passed Phase I testing.

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END OF LIFE ISSUES
Access to Unapproved Drugs

Holding: There is no constitutionally protected fundamental right by terminally ill patients to experimental drugs. There is "no constitutional right of access to unapproved drugs."

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END OF LIFE ISSUES
Questions

- What are the goals of therapy for terminally ill patients?
- How can individuals promote or assert their self-determination and ability to direct their end-of-life care?
- What is the proper balance between an individual's rights and the role of States to safeguard the health, safety, and welfare of its citizens? How is this balance achieved?
- How can these competing interests be resolved without going to court?

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