EPEC
Education for Physicians on End-of-life Care
Participant’s Handbook

Plenary 2
Legal Issues
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Abstract

A broad legal consensus has developed around issues of end-of-life care in the United States. The clear and consistent legal principles directing treatment limitation, decision making for patients who lack capacity, the use of opioids, physician-assisted suicide, and futility are discussed. Some of these and related points are provided in a summary of “pearls” and potential “pitfalls.”

Key words

advance directives, capacity, confidentiality, decision-making capacity, ethics, futility, guardianship, informed consent, law, legal counsel, limitation of treatment, opioids, physician-assisted suicide, proxy, surrogate

Cautionary note

This session is intended to present the broad legal consensus in end-of-life care with the understanding that neither the authors nor the American Medical Association nor the Robert Wood Johnson Foundation are rendering specific legal advice to physicians in so doing. Individual state laws can and do vary on many points, and may change. It is the individual physician’s responsibility to be familiar with current laws governing his or her practice and to seek legal counsel if a specific situation requires it.

Objectives

The objectives of this plenary are to:

- describe the broad legal consensus that has developed around issues of end-of-life care
- list the common legal myths and pitfalls that can interfere with quality care

Introduction

Traditionally, questions of end-of-life care were resolved through decision making by physicians in conjunction with patients and families. If the dying patient was a child, such questions were resolved with parents. However, as technologic breakthroughs advanced medical interventions, new questions arose concerning the appropriate use or discontinuation of these interventions. In the absence of other guidance, many of these questions have been brought to courts for resolution. Landmark bioethics cases have acted as important benchmarks of the evolving societal consensus within the United States, and case names often act as a shorthand regarding the principles for which they have come to stand.

Many physicians are unfamiliar with these benchmark cases and so tend to be more cautious than necessary about decision making at the end of life. Generally, legal precedent
follows medical ethical principles in end-of-life care. For instance, physicians are not required to provide treatment that would be ineffective. Nor are physicians required to provide treatment when a patient with the capacity to make health care decisions (or an authorized health care agent) has refused such treatment. In fact, it may be more legally perilous for a physician to continue to treat against patient or surrogate wishes.

**Law and ethics**

In the United States, law is created in 1 of 2 systems—federal and state—and is made by judges (common law), legislatures (statutory law), and executive agencies empowered by legislatures (regulatory law). Enforcement is either through the administrative system (licensure suspension or revocation), the civil system (most commonly, monetary judgments, but in the medical context, often an order to take an action or to stop treatment, known as “declaratory or injunctive relief”), or the criminal system (fines and/or prison). End-of-life issues are generally addressed through civil common law (federal or state) or statutory law (usually state). Although many important legal principles in end-of-life decision making are widely accepted among the states, it is important for physicians to become familiar with their state’s specific statutes and cases.

**Resolving difficult cases: role of law and ethics**

In any discussion of ethical issues in medicine, legal issues may arise. Both ethics and the law set norms or standards for conduct. The law often expresses a kind of minimal ethical societal consensus—one that society is willing to enforce through civil judgments or criminal sanctions. However, there are areas of conduct that the law does not and cannot address. Moreover, going to court as a means of dispute resolution is often a slow and expensive process and, in end-of-life cases, rarely necessary. Clinicians facing difficult decisions concerning patients near the end of life may be aided by consultation with ethics consultants and ethics committees. Health care institutions are mandated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to have a mechanism to resolve ethical issues, and most health care institutions have ethics consultants or have established ethics committees. These consultants or committees usually have developed processes to allow clinicians, patients, and families a forum for the discussion of end-of-life decision making and a mechanism to provide recommendations regarding ethically appropriate choices in a given situation (see Module 9: Medical Futility).

**Informed consent**

Informed consent in end-of-life care is important for 2 reasons beyond the fact that it is a basic legal and ethical requirement for all medical interventions. First, many patients and families (or parents if the patient is a child) who are facing treatment withdrawal may not have been fully informed of the risks and benefits of the therapy at the time it was begun, nor, often, were they told that treatment would be withdrawn if the treatment was no longer effective. Knowing the burdens of continued treatment, the fully informed patient
or surrogate may not elect further treatment. Second, patients and families who refuse further treatment should be told the consequences of the discontinuation of treatment, just as they are told the benefits and risks of other interventions.

Reasonable information giving is judged partly by the standards of what any good professional would give and what any reasonable person would want in the same circumstances. Though not legally required, an important ethical goal would go beyond this to a standard that takes into account what this particular patient would want under the circumstances.

Information must include the nature of the procedure, the risks, the benefits, and the alternatives to it. In deciding which of the many risks of any intervention to identify in particular, choose the common ones and the serious ones even if rare.

Consent is as important as information giving, or more so. It must involve proper understanding (for instance, does the patient understand that the consequence of declining life-prolonging intervention is probably an earlier death?). Consent must also be voluntary and free of coercion.

Informed consent may be documented. Usually, health care facilities have a predrafted form that can be used. However, documentation is of no risk management benefit if the process was absent or ineffective. The informed consent process is one of discussion and shared decision making. Ideally it is woven into regular clinical interaction and reflects a deliberative relationship in which the physician fosters and advocates for the well-being of the patient, the health care values, and the goals and specific wishes, as reflected in the shared decisions. To attain this, the physician should bring news and information to the patient (or parents if the dying patient is a child) about his or her disease and its management in as timely and sensitive a fashion as possible, bringing it all into focus before settling on a specific decision together (see Module 2: Communicating Bad News, and Module 7: Goals for Care).

Whereas, traditionally, analysis of decision making considers the patient, family, and physician viewpoints, actually decisions are significantly determined by external constraints. Constraints are placed, for instance, by the insurance carriers, and most recently by the managed care organization's coverage and reimbursement policies. Physicians must be aware that nonetheless the direct responsibility for informed consent falls to them. Even with the recent trend of holding plans liable for patient care decisions, the physician remains most directly available to and responsible for patient and surrogate decisions.
Treatment limitation at the end of life—legal consensus

In the past 2 decades, federal and state courts have decided a number of cases that have established a consensus of important legal principles in end-of-life care. Though these principles have not been unanimously adopted by all federal and state courts and legislatures, the consensus that has emerged has been broadly accepted with a distinct minority of exceptions, as follows:

1. Patients may refuse unwanted treatment: The most important of these principles is that patients with decision-making capacity may refuse unwanted medical treatment, even if this may result in their death.\(^1\)\(^2\)\(^3\) This is based on both the common-law respect for bodily integrity and the liberty interest articulated in the 14th Amendment to the Constitution. The most important expression of this principle was enunciated by the United States Supreme Court in the Cruzan case, where a key question was whether an individual has a constitutional right to refuse treatment. Other courts have affirmed this principle; it applies even in cases where the patient does not have a life-threatening illness.\(^4\)\(^-\)\(^6\)

2. Surrogate decision making: Patients who lack capacity to make the decisions at hand have the same rights as those who have capacity. However, the manner in which these rights are exercised is different. Authorized surrogate decision makers may make decisions to limit treatment for patients who lack decision-making capacity using standards as discussed below.

3. Withdrawing or withholding treatment: Withholding or withdrawing life-sustaining medical treatment is considered neither homicide\(^7\) nor suicide.\(^8\) Courts have drawn a distinction between intentionally causing a patient’s death and allowing a patient to die as a result of the withdrawal of life-sustaining treatment. In addition, there is a legal consensus that both withdrawing and withholding treatment, if not wanted by the patient or ineffective, can be justifiable.

Courts have also upheld the validity of DNR (do-not-resuscitate) and other treatment limitation orders.\(^9\) There are no limitations on the type of treatment that may be withheld or withdrawn—courts have rejected distinctions between “ordinary” and “extraordinary” treatment. Thus, ventilator withdrawal that may result in death is permissible,\(^10\)\(^11\) and even parenteral nutrition and hydration may be withheld or withdrawn under the same conditions as any other form of medical treatment.\(^12\) Physicians should provide the patient (or parents if the patient is a child) with information about his or her situation, offer choices about all treatments, assist with decision making, and not automatically assume that ventilators, feeding tubes, or other life-prolonging treatments are required.
These principles are established in legal doctrine, and physicians should feel comfortable applying them. There are few situations that cannot be resolved by the physician in collaboration with the patient and family. Only rarely does limitation of life-prolonging treatment at the end of life require court intervention.\textsuperscript{13}

**Deciding for the patient without decision-making capacity—legal devices**

Few patients with life-threatening illnesses retain decision-making capacity until the moment of their death. Most patients endure some period of incapacity at the end of their lives. Limitation of life-sustaining treatment is possible for patients who lack capacity to make medical decisions. However, it is necessary to first determine incapacity and have arrangements for proxy decision making.

**Determining and declaring decision-making incapacity**

Though a court of law may determine a patient to be incompetent and appoint a guardian to make important decisions, including those concerning health care, for the patient, many patients who have not been declared incompetent by a court may nonetheless have problems with their capacity to make health care decisions.

In assessing a patient’s ability to make a decision regarding health care, one must evaluate 3 elements of the capacity to make health care decisions.

First, the patient must possess the ability to comprehend the information about the medical problem as well as to appreciate the impact of the disease and the consequences of various options for treatment, including forgoing treatment. Second, the patient must possess the ability to evaluate the options by comparing risks and benefits of each option, to deliberate in accord with the patient’s own values, and to make choices that are not irrational. The patient should also be able to maintain a consistent choice over time. Third, the patient should be able to communicate his or her choice.

Generally, determination of the capacity to decide on a course of treatment must relate to the individual abilities of the patient, the requirements of the task at hand, and the consequences likely to flow from the decision. Thus, when the consequences for well-being are substantial, there is a greater need to be certain that the patient possesses the necessary level of capacity.\textsuperscript{14}

A lack of decision-making capacity may be caused by any break in the chain of decision making: the ability to understand, to reason and evaluate, and to communicate a decision. Obviously, patients in a coma, infants, young children, and the profoundly mentally disabled lack decision-making capacity for all medical decisions. Some other patients, such as those at the end of life with significant metabolic abnormalities, some disorientation, or early dementia, may retain some degree of decision-making capacity. Physicians taking care of patients at the end of life should make a determination of the patient’s decision-making capacity before each significant health care decision.
Evaluating decision-making capacity can be summarized as follows:

- **Ability to understand:**
  - Does the patient have the ability to understand the basic information needed to make a decision?

- **Ability to evaluate:**
  - Can the patient reason and weigh the consequences of the decision?
  - Does the patient make a decision?
  - Is the decision reasonably consistent over time?

- **Ability to communicate:**
  - Can the patient communicate the decision?

Declarations of incapacity can be done by a formal, legal statement, but more usually are done by simply recording the evaluation of the primary physician or a psychiatrist in the medical record. The recorded evaluation should document the basis for declaring the patient incapacitated. A record of the patient’s lack of decision-making capacity as determined by 2 physicians may be required before a power of attorney for health care can be activated. Most declarations of incapacity should be for the limited scope of the decision at hand, and the record should so indicate. Subsequent decisions will require reevaluation.

Once incapacity is determined, physicians should use 1 of 2 criteria or tests that courts have generally used to decide life-sustaining medical treatment. The first test requires determination that treatment would not be in the best interests of the patient. For example, one court applying the test determined that for a patient in a persistent vegetative state, it is not in the patient’s best interest to continue treatment. The second test applies the proxy’s substituted judgment to determine whether the patient would have wanted treatment withheld if he or she had been competent. This test takes into account the patient’s subjective wishes. Decision making that involves the application of advance directives uses the substituted judgment criterion.

**Guardianship**

Traditionally, if the patient has made no other provisions, the mechanism for making both medical and nonmedical decisions for incapacitated patients has been to establish a legal guardian, that is, a person with legal guardianship. End-of-life decision making for patients who have never had decision-making capacity (eg, infants and young children, or developmentally disabled adults) generally requires an individual who is legally able to act in the patient’s best interest, such as a parent or guardian. Additionally, federal regulations (so-called Baby Doe regulations) apply to end-of-life decisions made for infants and newborns. But this mechanism has a number of disadvantages for the average life-threateningly ill patient. The guardianship process is often slow and costly for the patient...
or family. Moreover, the guardian is normally expected to make decisions using the traditional best interest standard, which does not always rely on the patient’s previously expressed preferences. For the parent/guardian of a mature adolescent patient, the conversations eliciting the patient’s wishes are difficult. Consequently, they may not have taken place. For most adult patients at the end of life, legal guardianship is an option of last resort for making health care decisions. It may, for instance, be used if the proxy is clearly acting against the patient’s interests and needs to be replaced.

**Terminology of advance directives**

Over the past 2 decades, courts and legislatures have recognized legal tools called “advance directives” as valid indicators of patients’ previously expressed desires. Terminology in this area may be confusing. The process of discussion, documentation, and implementation of wishes is termed *advance care planning*. The most common of the advance directives are the living will (a form of instructional directive to limit life-sustaining medical treatment in the face of a life-threatening illness) and the durable power of attorney for health care (an appointment of a health care agent or proxy to make decisions according to the incapacitated patient’s preference). Other types of instructional directive include personal letters, a values history, and a medical directive.

Advance directives give immunity from successful prosecution to physicians who, in good faith, follow the directive. Though advance directives are, for the most part, statutory documents created by state legislatures, they can also be an advisory document that acts as evidence of patient wishes, and this is binding under common law beyond state borders. Moreover, state legislatures may direct that health care providers honor other states’ advance directives. As a result of the Patient Self-determination Act, states are required to recognize at least 1 form of advance directive, and hospitals are required to inform patients of their right to refuse medical treatment and to make advance directives18 (see Module 1: Advance Care Planning).

**Choosing a surrogate**

Despite the availability of these documents, the majority of individuals do not complete advance directives. As a result, a number of states have enacted surrogacy laws (eg, Illinois19). Under these laws, patients without advance directives who become incapacitated may have a decision maker appointed from a list of eligible individuals, including a spouse, family member, or others as prescribed by statute. The hierarchy of the individual’s eligibility may vary from state to state. Surrogacy laws give legal recognition to a process that many physicians used in the past when no one had been appointed as guardian—namely, turning to the person most likely to be recognized as the appropriate representative of the patient.20 In states that do not have surrogacy laws, physicians often continue to rely informally on the next-of-kin hierarchy from which the surrogacy statutes are adapted.
Approaches to surrogate decision making

Once a surrogate is identified, he or she must determine the patient’s wishes regarding end-of-life treatment. Where the patient has an advance directive specifying treatment choices, this may only entail interpreting the directive. Most states require that a surrogate determine that it is more likely than not that the patient would have made a particular health care decision (this standard is known as the preponderance of evidence standard, expressed as “more probable than not”). Some states require a higher degree of certainty (clear and convincing evidence, a higher standard than preponderance of the evidence) that the patient would have chosen a particular course of action. The difficulty in determining whether verbal expressions of health care preferences meet these standards reinforces the importance of written advance directives. For example, a general comment made by the patient that he or she “would never want to live as a vegetable” does not give a great deal of guidance as to whether to discontinue life support after an accident that leaves the individual with significant brain damage, but not in a persistent vegetative state (see Module 1: Advance Care Planning).

The appropriate use of opioids in end-of-life care—developing consensus

The concepts of palliative care and hospice have developed in response to the ethical mandate that patients and families should receive care that relieves suffering and improves the quality of their lives. Both depend on the appropriate use of opioids to relieve pain, shortness of breath, and other symptoms. The federal Drug Enforcement Agency and state licensure and drug regulation agencies are charged with enforcing the laws concerning controlled medical substances, such as opioids. Traditionally, these agencies have monitored physicians’ prescriptions for opioid use. In the past, many physicians and regulators have been overly concerned about the problems associated with substance abuse and addiction. Today, there is a growing awareness by regulatory bodies of the role of opioids in medical practice. The result is a lessening of concerns about addiction when physicians are prescribing opioids.

The principle of double effect recognizes the difference between the provision of adequate treatment that unintentionally hastens death, and the provision of medication that intentionally causes a patient’s death (see physician-assisted suicide below and Module 5: Physician-Assisted Suicide). Physicians have a responsibility to be aware of the realistic risks associated with the treatments they offer (eg, the minimal risk of death associated with opioids when prescribed appropriately for pain relief). Physicians should feel comfortable providing medication, including opioids, using accepted dosing guidelines to alleviate a patient’s pain and suffering, even if an unintended secondary effect might risk hastening the patient’s death (see also Module 10: Common Physical Symptoms).
Physician-assisted suicide—a matter of individual state law

Perhaps no other end-of-life ethical issue has generated as much controversy as that of physician-assisted suicide. Although there is an ethical and legal consensus that patient refusal of life-sustaining medical treatment is not suicide, provision of medication with the intent to produce death is considered to be assisting suicide. All states except Oregon have laws that make assisting a suicide by anyone (including physicians) a criminal offense.

Recently, some patients and physicians have argued that suicide with the assistance of a physician should be available for patients who have advanced life-threatening illnesses and have decision-making capacity. In 1997, the United States Supreme Court held that there is no federal Constitutional right to assisted suicide. In doing so, it reaffirmed the distinction between withholding or withdrawing life-sustaining treatment and assisted suicide. The decision leaves open the possibility that state supreme courts will find a state constitutional right, or, more likely, that states will develop a statutory right. Oregon has followed the latter route and has legalized physician-assisted suicide (see Module 5: Physician-Assisted Suicide).

Futility—lack of consensus

Another controversial issue in end-of-life care is the process for determining when medical interventions are no longer effective, especially when medical personnel and the patient or surrogate disagree about the decision. A number of cases suggest that this issue is still undergoing development in judicial analysis. To guide the process, some general principles can be drawn from medical practice and case law:

1. Physicians should be careful when thinking that a treatment may be “futile.” In medical decision making when a treatment under consideration may seem to be futile, the physician should ask, “futile for what goal?” That goal should be defined by the patient or surrogate (or parents if the patient is a child) in conjunction with the physician.

2. Physicians’ recommendations for limiting treatment should be based as much as possible on objective determination of ineffectiveness, for the accepted goal rather than subjective opinions about the worth of the intervention or of the patient’s continued life. Where there is concern or question, a second clinical opinion about the potential effectiveness of treatment may be both beneficial and necessary.

3. Where the patient or family disagrees with the physician’s judgment, ethics consultation or committee review may be advisable.

4. If there is continued disagreement, facilitate transfer of the patient when feasible to another health care practitioner or health care facility willing to continue or cease treatment (see Module 9: Medical Futility).
5. If transfer to another physician or institution is not possible, the intervention need not be offered.

In cases where futility comes up, there is very commonly a major component of unsuccessful communication and strained relationships. Try to keep communication good, listen well, convey information effectively, and keep an empathic approach. In several studies a correlation exists between quality relationships and reduced malpractice rates, not only in futility cases but in general.

Confidentiality

Confidentiality concerns are not usually different for patients facing the end of life. There are no major legal differences. In general, confidentiality should be broken if the absence of information puts an identifiable third party at risk of major damage. Reporting requirements demand that certain infectious disease diagnoses be reported to public health authorities.

Legal counsel and risk

Physicians have a responsibility to make ethical decisions in the care of patients at the end of life within the law that governs their medical practice. While ethics committees and consultation may consider legal aspects, they do not act as a legal advisor to the physician and should not be mistaken as such.

Though there is broad legal consensus on much of end-of-life treatment, some state variations remain (eg, standards of certainty that surrogates must demonstrate in making decisions) and some difficult legal issues remain unresolved (eg, futility).

In addition, if the physician works in a managed care organization that has set limits on care that the patient or family disagrees with, the physician may have to choose to advocate for one party over the other. The physician may also face incentives and disincentives to make decisions that run counter to the patient’s wishes. But, although there is a duty to the institution, including possibly a contractual one, the physician carries the direct responsibility for patient care and may have more legal risk than the institution if the patient’s care is compromised.

When physicians are uncertain as to the approaches to resolving a given case, legal counsel may be sought. However, it is important for the physician to recognize that hospital counsel represents the health care institution, and may not focus on the needs of the individual physician. In addition, legal counsel’s primary duty is to protect the client from legal liability, not necessarily to facilitate ethical practice.
Summary

For physicians, the management of patients at the end of their lives may give rise to legal considerations. However, many of these legal issues have been resolved and a broad legal consensus of the appropriate treatment and limitation of treatment in end-of-life care has emerged. It is important for physicians who are caring for patients at the end of life to understand the ethical and legal consensus, noting where their jurisdiction’s laws may differ. Most importantly, physicians should remember that the best risk-reduction strategy, from both an ethical and a legal perspective, is effective communication with the patient and family. Many of the points in this session can be summarized in the “take-home” list of pearls and pitfalls that follows the list of resources/references.

Key take-home points

1. The law is an important factor to take into account in the care of patients at the end of life. However, the law does not always prescribe the ethically appropriate medical decision.

2. State laws can vary from the prevailing legal consensus on end-of-life care (e.g., in the degree of certainty that a surrogate should have about a patient’s wishes). It is important for physicians to become familiar with the laws of their state on end-of-life care.

3. Listen carefully and empathically, and communicate clearly. A quality professional relationship may be your greatest protection against legal action.

Informed consent

4. The informed consent process is one of discussion, shared decision making, and documentation of the process and the decisions. The patient must be informed and free of coercion.

5. Even though reimbursement and incentive issues may exert considerable pressure, physicians remain both ethically and legally responsible for providing patients with accurate information (in the manner in which they request to receive it), for offering appropriate therapies, and for the decisions they make.

Treatment limitation at the end of life

6. Patients with decision-making capacity may refuse unwanted medical treatment even if this may result in their death, and even in cases where the patient does not have a life-threatening illness.

7. Continuing treatment in violation of patient or surrogate wishes can be both ethically inappropriate and legally perilous.
Surrogate decision making

8. Patients who lack capacity to make the decisions at hand have the same rights as those who have capacity. Only the process in which these rights are exercised is different.

9. If a patient is determined to be incapacitated to make a health care decision, the physician should document the basis for that determination (inability to understand, evaluate, and communicate). Unless a patient is permanently incapacitated, a patient’s decision-making capacity should be reevaluated for each major medical decision.

10. Authorized surrogate decision makers may make decisions to limit treatment for patients who lack decision-making capacity. Surrogate decision makers may make decisions by using the substituted judgment standard (what the patient would want under the circumstances, if known) or the best interest standard. The approach will depend in part on whether the patient has executed an advance directive.

Withholding or withdrawing treatment

11. Decisions to withhold or withdraw life-sustaining medical treatment under appropriate circumstances are not considered either homicide or suicide (see Module 11: Withholding /Withdrawing Treatment).

12. There are no limitations to the type of treatment that may be withheld or withdrawn.

13. Most decisions to limit treatment may be made without going to court.

Appropriate use of opioids

14. Physicians have a responsibility to be aware of the realistic risks associated with the treatments they offer.

15. It is ethically inappropriate to provide inadequate treatment of pain and symptoms for patients at the end of life because of fears of unintentionally hastening death.

16. Physicians should feel comfortable providing medication, including opioids, using accepted dosing guidelines to alleviate a patient’s pain and suffering, even if the unintended secondary effect of the administration of medication might be to shorten the patient’s life (see Module 4: Pain Management, and Module 10: Common Physical Symptoms).

Physician-assisted suicide

17. Provision of medication with the intent to produce death is considered to be assisting suicide, a criminal offense in most states.

18. When the US Supreme Court ruled that there was no constitutional right to assisted suicide, it also reaffirmed the difference between withholding or withdrawing life-sustaining treatment and assisted suicide.
Futility

19. Physicians’ recommendations regarding limitation of treatment should be based on objective determination of ineffectiveness, rather than subjective opinions about the worth of the intervention or of the patient’s continued life.

Confidentiality

20. Confidentiality concerns are not usually different for patients facing the end of life.

Role of counsel

21. Ethics committees and consultants can be helpful in resolving ethical issues in end-of-life care.

22. An institutional legal counsel’s primary duty is to protect the client-institution from legal liability, not necessarily to facilitate ethical practice. Physicians have a separate responsibility to make ethical decisions in the care of patients at the end of life.

Pearls

1. A quality professional relationship may be your greatest protection against legal action.

2. A general comment made by the patient that he or she “would not ever want to live as a vegetable” does not give a great deal of guidance to discontinue life support. Probe for more elucidation.

3. Where there is concern, seek a second opinion.

Potential pitfalls

1. Forgetting that patients who cannot communicate or who have some mental incapacity may still make some valid decisions.

2. Turning to ethics committees for legal advice. They are not legal advisors.

Resources/references


1. Meisel A. The legal consensus about forgoing life-sustaining treatment: its status and prospects. Kennedy Inst Ethics. 1993;2:309-345. The summary of consensus has been adapted from Meisel with some of those points of consensus omitted from this list, but discussed in this article infra.

6. Wons v Public Health Trust of Dade County, 500 So2d 679 (FlaApp 3 Dist 1987).
15. Wis Sup Ct Case No 89-1197 4/1/92.
17. 45 CFR § 1340.15(b)(1)-(2).