SURROGATE CONSENT LEGISLATION INITIATIVE

ASSEMBLY BILL 2328

- Author: Assembly Member Howard Wayne
- Principal Co-Author: Assembly Member Dion Aroner
- Senate Co-Author: Gloria Romero
- Sponsored by UC

Where does this legislation fit into the Health and Safety Code?

- Division 20. Misc Health & Safety Provisions
- Chpt 1.3 Human Experimentation (24170-24179.5)
  - 24170: Protection of Human Subjects in Medical Experimentation Act
  - 24171
    - Experimentation on human subjects is vital for the benefit of mankind

Where does this legislation fit into the Health and Safety Code?

- 24171 (con't)
  - Nuremberg Code of Ethics and Declaration of Helsinski are not enforceable by law
  - Therefore, there is a need for protection from unauthorized, needless, hazardous or negligently performed medical experiments on human beings
- 24172: Experimental subject's bill of rights
- 24173: Informed consent requirements

Where does this legislation fit into the Health and Safety Code?

- 24174: Definition of medical experiment
- 24175: Conservatorship permission
- 24176: Fines for medical experiments that do not comply with the law
- 24177: Emergency medical experimentation
- **24178: changed by AB2328**
- 24179: Excludes prescription drugs filled by pharmacist
- 24179.5: Honors advance directives for terminal illness

CONTENT OF THE BILL

- Permits informed consent required for medical experimentation (that relates to the cognitive impairment, lack of capacity, or serious or life threatening diseases and conditions of research participants) be given by surrogate decisionmakers.

AMENDMENTS TAKEN ALONG THE WAY

1. The bill was too broad:

   This bill would provide that these provisions apply only to medical experiments that relate to the cognitive impairment, lack of capacity, or serious or life threatening diseases and conditions of research participants.

AMENDMENTS TAKEN ALONG THE WAY

2. **Remove domestic partner language**

   [Cannot be removed as it is part of current law. Instead the wording was changed.]

   An individual as defined in Section 297 of the Family Code

AMENDMENTS TAKEN ALONG THE WAY

3. **What if there is disagreement among surrogates concerning research participation?**

   Refusal to consent by a person who is a higher priority surrogate shall not be superceded by the consent of a person who is a lower priority surrogate

AMENDMENTS TAKEN ALONG THE WAY

4. **Who can serve as surrogate?**

   A surrogate decisionmaker has reasonable knowledge of the subject

   (note that this stipulation is limited to the non-emergency situation, but does not apply to the emergency condition)

AMENDMENTS TAKEN ALONG THE WAY

5. **What if persons in the same level of the hierarchy disagree on giving permission?**

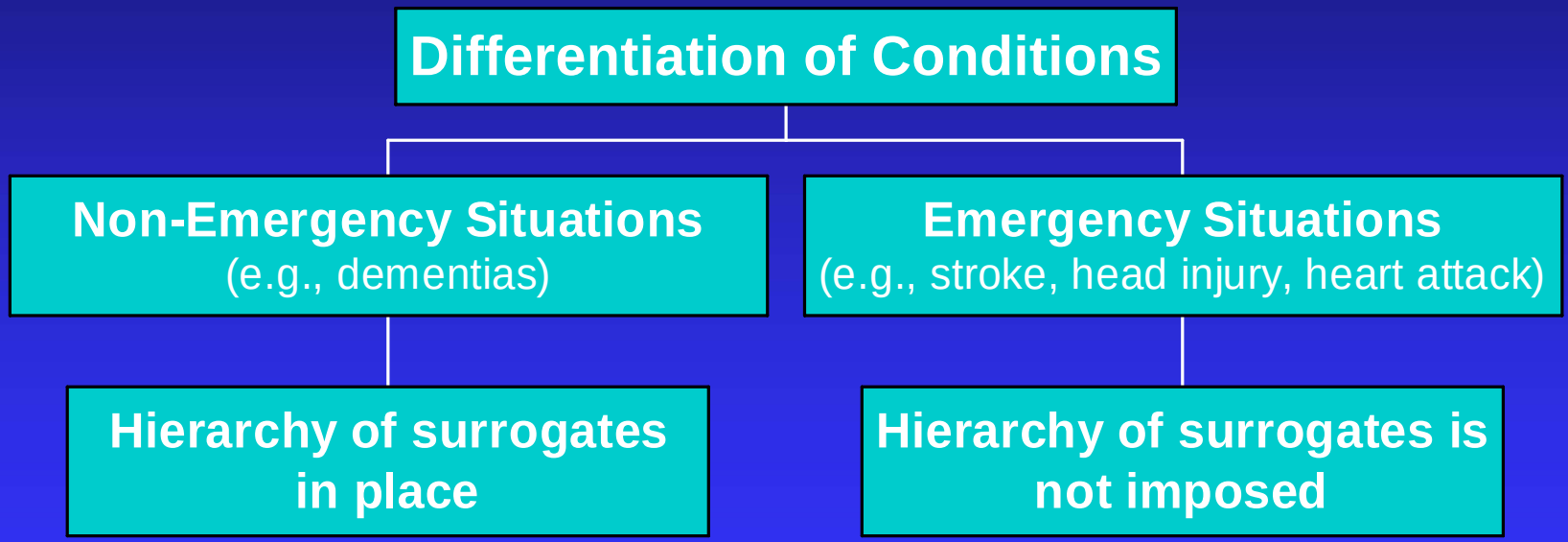
   …in the same order of priority, if any of those persons expresses dissent as to the participation of the person in the medical experiment, consent shall not be considered as having been given

AMENDMENTS TAKEN ALONG THE WAY

6. **Surrogates should not receive compensation for giving permission**

   Any person who provides surrogate consent pursuant to subdivisions (c) and (f) may not receive financial compensation for providing the consent

CONTENT OF THE BILL



CONTENT OF THE BILL

- Section 24178 (C)

  For medical experiments in a **“nonemergency” room environment**, if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a surrogate decisionmaker with **reasonable knowledge of the subject,** who shall include any of the following persons, in the following descending order of priority:

ORDER OF PRIORITY FOR NON-EMERGENCY SITUATIONS

- a. Agents identified by an advance health care directive
- b. Conservator or guardian with authority to make health care decisions
- c. Spouse
- d. Individual as defined in Section 297 of the Family code: the declared domestic partner
- e. Adult son or daughter
- f. Custodial parent
- g. Adult brother or sister
- h. Adult grandchild
- i. An available adult relative with the closest degree of kinship to the person

CONTENT OF THE BILL

- States that if two or more available surrogates in the same order of priority disagree, consent is considered not to have been given.

CONTENT OF THE BILL

- States that if two or more available persons who are in different orders of priority disagree, the higher priority person shall not be superceded by the lower priority person.

CONTENT OF THE BILL

- Section 24178 (F)

  For medical experiments in an **“emergency” room environment**, if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a surrogate decisionmaker who is **any** of the following persons:

Surrogate DecisionMakers for Emergency Situations (ASA, AHA)

- a. Agents identified by an advance health care directive
- b. Conservator or guardian with authority to make health care decisions
- c. Spouse
- d. Individual as defined in Section 297 of the Family code: the declared domestic partner
- e. Adult son or daughter
- f. Custodial parent
- g. Adult brother or sister

CONTENT OF THE BILL

- When there are two or more available persons described in the list of surrogate decisionmakers, refusal to consent by one person shall not be superceded by any other of those persons.

CONTENT OF THE BILL

- Exempts from this section individuals who have been involuntarily committed pursuant to the Lanterman-Petris-Short Act and persons voluntarily committed or committed by a conservator to mental hospitals or institutions.

CONTENT OF THE BILL

- Any person who provides surrogate consent pursuant to subdivisions (C) and (F) may not receive financial compensation **for providing the consent**

TRACKING OF THE BILL

- Assembly Health Committee (4/16/02): Vote 15:1:3
- Assembly Judiciary Committee (5/7/02): Vote 9:2:2
- Assembly Floor (5/20/02): Vote 46:23:11
- Senate Health Committee (6/12 & 19/02): Vote 7:2
- Senate Floor (passed 8/22/02): Vote 25:13
- Assembly Floor (concurrence with Senate amendments; passed 8/26/02): Vote 56:11
- To enrollment 8/27/02
- **Governor's signature on 9/11/02**
- **Chaptered by the Sec'y of State on 9/12/02**

SPECIAL THANKS

- UCOP Sponsors (Joanna Beam, Sandy Fried, Jeff Hall)
- Leon Thal and Bill Jagust (testimony time)
- ARCCs (Alzheimer's Disease Research Centers of California)
- HHS Advisory Committee
- California Council of the Alzheimer's Association
- American Stroke Association / American Heart Association
- Lola Crosswhite and daughter Diana Shaw
- All the support letter writers

UC's Policies / Practices After the Governor Signs AB 2328

- How should UC IRBs and researchers proceed in regard to proxy consent between the Governor's signing date and the effective date of January 1, 2003?
- Courts scrutinize consent for clinical trials
- Weaknesses in surrogate consent law have been publicized
- Assess your willingness to assume the potential risk

UC's Policies / Practices After January 1, 2003

Potential issues to consider:

- Assessing capacity to consent
- Determining the relationship of research to the condition of the subject
- Assessing expressions of dissent/resistance to participation
- Determining the availability of surrogates; notice to members of surrogate classes; disputes among surrogates
- Assessing the surrogate's "reasonable knowledge" of the subject
- Distinguishing between compensation and reimbursement of the surrogate
- Data safety & monitoring boards
- Identifying & disclosing non-financial conflicts of interest
- Other issues? (jeff.hall@ucop.edu)