

**Title:** Huperzine

**Author:** Angela Dunn and James M. DuBois

**Description:** While in the early stages of Alzheimer's disease, Bernadette enrolls in an experimental drug study that will not begin until she is in the late stages of the disease. Once Bernadette reaches the advanced stages of Alzheimer's and her cognitive capacities are impaired, her family members learn of the study and file a complaint with the hospital's IRB, claiming that Bernadette never would have agreed to participate in this study.

**Headings:** Decision-making Capacity, Assent, and Surrogate Permission; Decision-making capacity (competence), determination of; Mental health disorders, participants with (including addictive disorders and developmental disabilities)

**Case Type:** Decision making

### Huperzine

Bernadette is a 78-year-old woman who was recently diagnosed with Alzheimer's disease. Prior to her diagnosis, she had retired from a 40-year career as psychiatric researcher at a prestigious university. Her work primarily focused on dementia related disorders of the elderly, including Alzheimer's.

Her doctor has submitted a research proposal, which would investigate the effects of an experimental drug, Huperzine, on persons with late-stage Alzheimer's. This drug inhibits the breakdown of specific neurotransmitters and stimulates neurotransmitter regeneration. In Phase II of the drug trial, 40% of the research subjects experienced seizures with temporary but prolonged motor function loss.

Bernadette's doctor would like to enroll her into the study. Although treatment will begin in late stage Alzheimer's, Bernadette is at an early stage in the disease so is apparently able to express her wishes for treatment. Having been a psychiatric researcher for many years, she certainly exhibits an understanding and appreciation of her disorder. When the benefits and side effects of Huperzine are presented to her she shrugs and says, "If I couldn't find a cure for Alzheimer's then I might as well help someone else find it." So Bernadette signs the informed consent form, allowing the researchers to administer Huperzine to her long after her cognitive capacities have been seriously impaired.

Once Bernadette reaches the advanced stages of the disease, Huperzine is administered and she experiences the described side effects. Her distraught family members learn of the study and immediately file a grievance with the hospital's Institutional Review Board. Her family questions her capacity to make decisions about her future when she initially signed the consent form. They contend that Bernadette would never have wanted to be subjected to such treatment.

**As a member of the hospital's IRB, how would you respond to the grievance? What would you do?**