Pegasus and the Chimera
Ethical Issues in Stem Cell-Based Animal Research

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The Road to the Clinical Translation of Stem Cells

Stem-Cell-Based Therapies

Stem-Cell-Based Clinical Trials

Phase I

Phase II

Phase III

Phase IV

FDA Regulations Regarding Biologic Products
The Road to the Clinical Translation of Stem Cells

- FDA Regulations Regarding Biologic Products
  - Determinations of Cell or Tissue Type, Purity, and Potency
    - Human-Animal Chimera Studies
  - Quality Control Standards for Cell or Tissue Processing
    - Risk of Transmitting Infectious and Genetic Diseases
  - Safety and Efficacy in vivo
    - Proof of Concept in (at Least) Two Animal Models
  - Human-Animal Chimera Studies
The Chimera Myth
What Does It Mean For a Chimera Study To Be *Unethical*?

- Building on current ethical standards for basic science research and animal research.
  - Scientific and humanitarian importance of study.
  - Animal welfare.
  - Informed consent of human materials donors.

- What else is left?
The Public’s Commonly-Held Concerns (and Assumptions)
The Public’s Commonly-Held Concerns (and Assumptions)

- Human/animal chimera research *per se* violates human dignity.

- Neuroscientific chimera studies involving the CNS could produce human-animal chimeras with *uniquely-human psychological characteristics*, thus creating “morally-ambiguous” creatures.
The “Limit” Case

- Acute neurological chimerism of non-human primates.

- Examine the limit case and then reason back down to chimerism in other, “lesser” species.
Searching for “Factor X”

- What morally relevant characteristics do non-human primates lack that chimerism could imbue?
  - Human-like mental faculties?
  - Human-like cognitive faculties?
  - Human-like beliefs?
  - Self-consciousness?
The “Limit” Case

- Methodological and philosophical challenges to addressing the limit case.

- What does the limit case teach us?
“Man might be described fairly adequately, if simply, as a two-legged paradox. He has never become accustomed to the tragic miracle of consciousness. Perhaps, as has been suggested, his species is not set, has not jelled, but is still in a state of becoming, bound by his physical memories of a past of struggle and survival, limited in his futures by the uneasiness of thought and consciousness.” - Steinbeck and Ricketts
Thank You

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