

Legislation, hESC Research, and Moral Permissibility

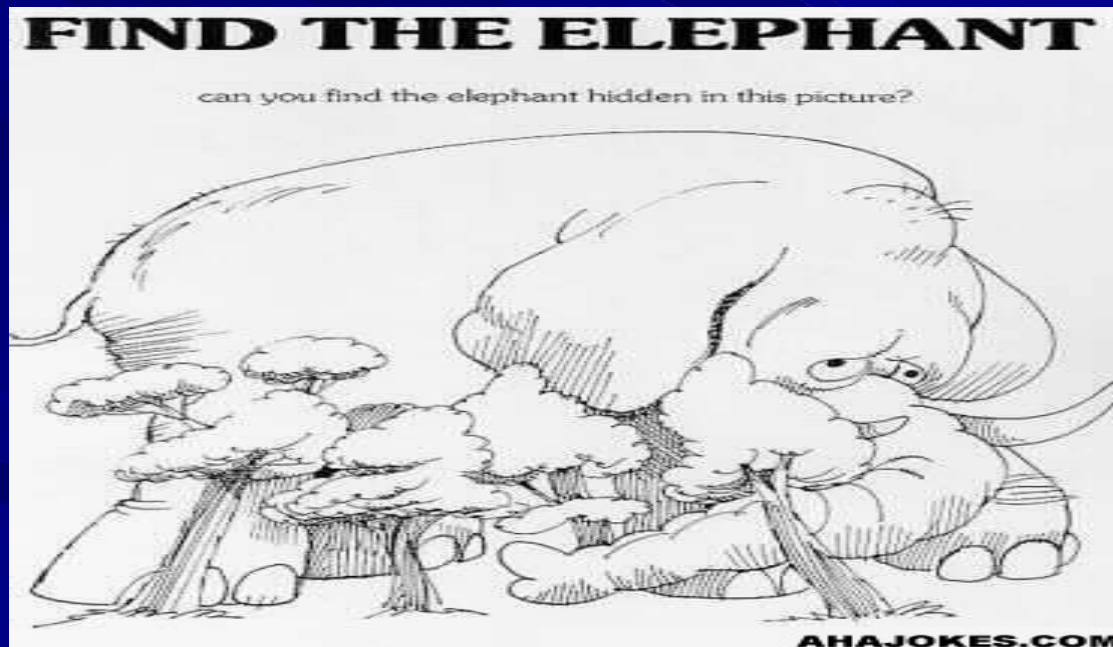
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THE RATE-LIMITING STEP

‘None of the funds made available in this Act may be used for

- (1) the creation of a human embryo or embryos for research purposes; or
- (2) research in which a human embryo or embryos are destroyed’

—*The Dickey Amendment* (‘*DA*’), Pub. L. 108-199, § 510(a), 118 Stat. 3, 277 (2004)



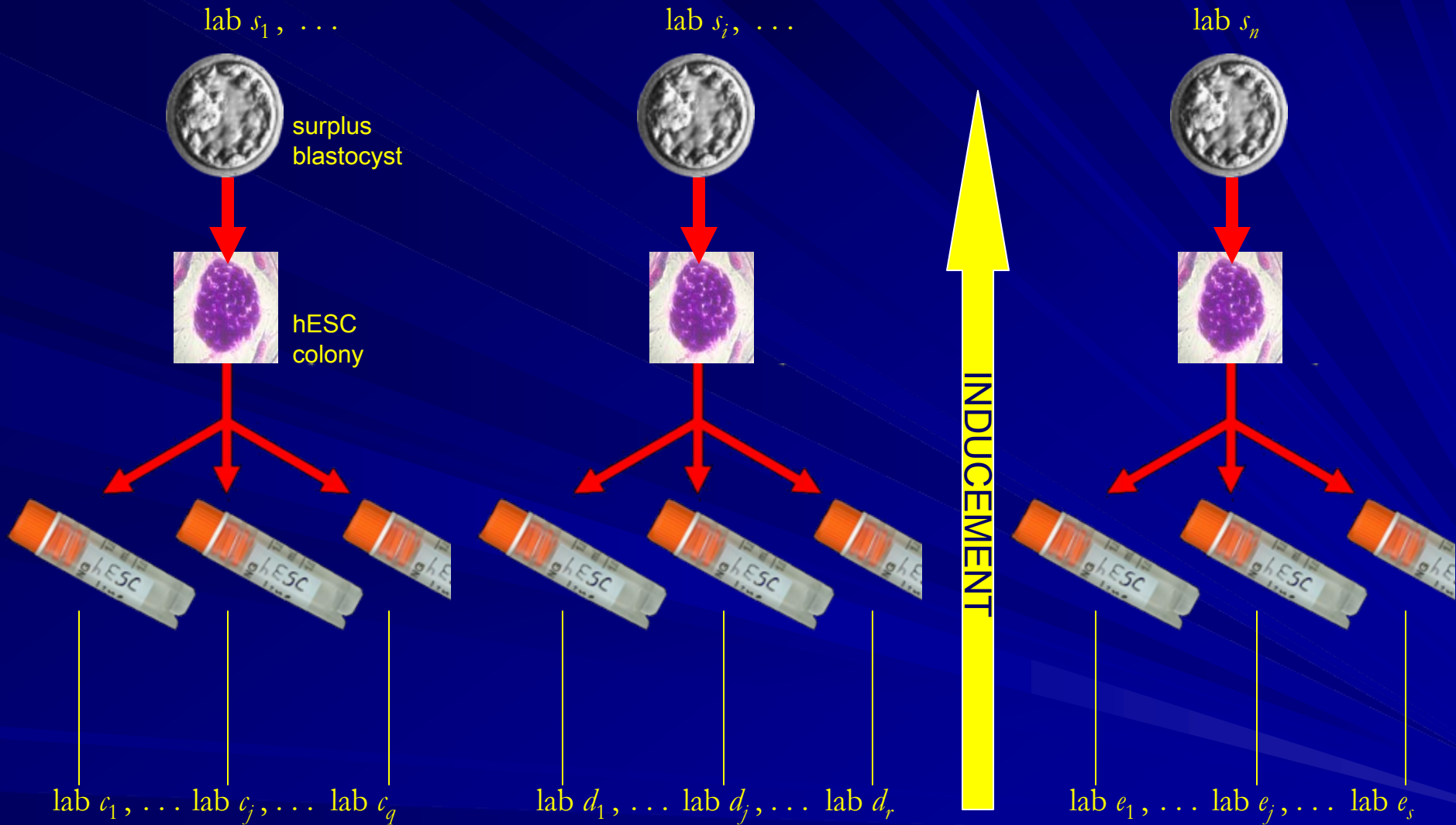
TRYING TO DODGE THE ELEPHANT

‘Studies utilizing pluripotent stem cells derived from human embryos may be conducted using NIH funds only if the cells were derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment.’

—*National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells*, 65 Fed. Reg. 51976 (2000)

- NIH distinction between *deriving* and *using derivatives*
 - Said to avert *DA*
- Differently put, grantees may use lines obtained in unfunded derivations by others, or *other-derived* lines, but may not perform *self-derivation*

SUPPLY OF OTHER-DERIVED CELL LINES



Observation: demand for hESC induces supply by two means

- One-to-one interactions between consumers and suppliers
- Aggregate demand by invisible hand effect of consumers acting independently

FUNDING USE OF *OTHER-DERIVED* LINES

No Escape from DA's Maw

Legal Analysis

1. In *DA's* ban on *research in which a human embryo or embryos are destroyed*, how do we read *research in which*?
 - a. Might *research in which* capture only directly funded acts?
 - i. Congenial to NIH plan
 - ii. Would thwart legislative intent
 - Intent to avoid taxpayer complicity in embryo destruction
 - Supporters did not want government to come within country mile of embryo destruction
 - b. Suggests that *research in which* captures any project of which embryo destruction is direct, collaborative, or induced stage
 - i. This the interpretation most faithful to legislative intent
 - ii. Conflates derivation and downstream studies that induce derivation
2. On most faithful interpretation
 - a. Funding use of other-derived lines violates *DA*
 - i. Republicans vociferously so alleged against NIH
 - Threatened suit, for which compelling case
 - Obviated when new administration withdrew NIH policy[†]

[†]NIH, 66 Fed. Reg. 57107 (2001)

FUNDING USE OF *OTHER-DERIVED* LINES

No Escape from DA's Maw

Legal Analysis (cont.)

- b. Funding the use of presidential lines violates *DA*
 - i. To this Republicans now turn blind eye, as transgressor is administration of own party
 - ii. But elephant remains in the room
- 3. Opinion of DHHS General Counsel (1999) provides no shelter
 - a. Does not develop distinction between deriving and using derivatives
 - i. That gloss applied by NIH
 - Curious history of interpretation of interpretation
 - b. Does state that pluripotent stem cell is not embryo
 - i. A tautology in construing *embryo*
 - c. Opinion does not discuss *research in which*
- 4. In general, hESC studies constitute immediately downstream stages of projects that destroy embryos
 - a. Funding of hESC research contravenes *DA*
 - b. For Congress to authorize NIH-funded hESC research without contradicting itself, it must override, let lapse, or repeal *DA*
 - i. Castle-DeGette, Specter bills override *DA*

FUNDING USE OF *OTHER-DERIVED* LINES

Noncomplicity Infeasible

Moral Analysis

1. NIH distinction between *deriving* and *using derivatives*
 - a. Killing vis-à-vis using remains
 - i. Donee who did not perform or induce killing may use remains (*e.g.*, organ transplant) without complicity in killing
2. Demand for hESC induces supply
 - a. Would supplying labs $s_1, \dots, s_p \dots s_n$ derive cell lines anyway?
 - i. Doubtless some, but not all that external demand induces
 - b. Inducement renders consumers, and funding source, complicit in embryo destruction
 - i. Users of other-derived lines ride in the same boat of moral responsibility with the others deriving them. Furrier example.
3. No practical scheme for delivering hESC to investigators in which demand does not induce supply
 - a. Noncomplicitous government support for hESC research an illusion
 - b. The moral defense of hESC lies elsewhere, as we shall shortly see
 - c. No compelling moral rationale for hampering science[†]
in futile quest for noncomplicity

[†]Daley, *N Engl J Med* 351:627–628 (2004)

IMPLICATIONS FOR EXPANDING RESEARCH

1. If inducing derivation is to be moral, so must derivation be (contrapositive of ‘If derivation is immoral, inducing derivation is immoral’)
2. hESC research justified not because use and derivation distinguishable, but because both permissible
3. Permissible because donor exercised discretion to forbid intrauterine transfer—a stronger condition than informed consent.¹ A gift.
4. Decision bounds the donated embryos’ developmental potential
 - a. No possible persons correspond; no moral gain for any being from foregoing research
 - i. Entails permissibility of using embryos barred from womb in fulfillment of duty of mutual aid
 - Embryos donated as such
 - Hence ban on destroying embryos in research disserves morality
 - Embryos formed from donated cells²
 - Hence ban on creating embryos in research disserves morality
5. Suggests public policy allowing research use of embryos barred from womb

¹Guenin, *Science* 292:1659–1660 (2001)

²Guenin, *Nature Biotech* 21:482–3 (2003)

THE CASTLE-DEGETTE, SPECTER BILLS†

1. Replicate NIH policy
 - a. Allow use only of other-derived lines
2. Achieve this by overriding *DA* to extent of authorizing downstream use of other-derived lines notwithstanding that embryos are destroyed
 - a. **‘Notwithstanding any other provision of law** (including any regulation or guidance), the Secretary shall conduct and support research that utilizes human embryonic stem cells in accordance with this section (regardless of the date on which the stem cells were derived from a human embryo)’ [emphasis added]
 - i. ‘Notwithstanding’ clause assumes ‘research in which’ captures projects of which embryo destruction is induced stage
3. Do not otherwise disturb *DA* ban on destroying embryos
4. Do not disallow self-derivation of lines
 - a. Sponsors evidently assume that bills allow use but not self-derivation
 - b. Texts do not disallow self-derivation
5. Do not in any way affect *DA* ban on creating embryos
 - a. Hence nonprocreative cloning remains barred
6. Elephant not untouchable, but only partly ejected from the arena

†H. R. 10 (Castle, DeGette et al.), S. 471 (Specter et al.), 109th Cong., 1st Sess. (2005)

EXPANSION of hESC RESEARCH

Stem Cell Research Enhancement Act of 2005

USE OF OTHER-DERIVED LINES

- Authorizes research using other-derived hESC lines
 - To that extent overrides *DA* ban on projects of which embryo destruction an induced stage ('research in which . . . embryos are destroyed')
 - Only as to surplus embryos
 - Regardless when derivation occurs
- Leaves *DA* otherwise undisturbed
- Yield in research



Studies of other-derived hESC
from surplus embryos

My Proposal

USE OF DONATED EMBRYOS

- *Rule:* 'The government shall support biomedical research using human embryos that, before or after formation, have been donated to medicine under donor instructions forbidding intrauterine transfer.'
- Yield in research



- Derivation of hESC
- Studies of hESC
- Somatic cell nuclear transfer
- Parthenogenesis
- Fertilization (including fertility research)

ADVANTAGES OF RULE ALLOWING DONATED EMBRYO USE

- Optimizes scope of research
 - Note: companion Hatch-Feinstein bill, though excluding nonreproductive cloning from crime, does not authorize any research

- Makes the publicly-supported and the morally permissible coincide
 - Defines eligible research by conditions that confer moral permissibility
 - Thus manifests its moral justification
 - This avails in presenting policy to those unclear why donated embryos should be research subjects

HOW TO CONVINCe MEMBERS OF CONGRESS?

Suppose a legislator supportive of expanding hESC research, but disinclined to disturb *DA*



- **Three reasons to give for overriding ban on embryo destruction to extent of donated embryo use**
 1. To approve hESC use is to approve derivation
 - a. Given that one practice induces the other, cannot fund use of hESC without complicity in destruction of donated embryos
 - b. To approve former but not latter would be inconsistent
 2. Effect of *DA* ban on embryo destruction in research
 - a. Hinders research
 - b. Achieves no moral gain, as noncomplicity an illusion

HOW TO CONVINCING MEMBERS OF CONGRESS? (cont.)

3. Get in step with voters

- a. A voter either approves the sacrifice of donated embryos or does not
 - i. Those who do not approve put no store in use of other- instead of self-derived lines; complicity in others' derivation is apparent
 - ii. Those who approve put no store in the distinction because they assume that funded investigators sacrifice embryos
 - Distinction between other- and self-derived cell lines is a bureaucratic invention introduced to avoid *DA*
 - Distinction not current in moral views
 - Few press reports on Castle-DeGette mention distinction
 - Not found in state policies such as California Prop 71
 - A mere appropriations rider, *DA* unknown to most of public

■ **Argument for overriding ban on embryo creation to extent of donated embryo use**

1. Donor instructions against intrauterine transfer are justification of all donated embryo use; intent to initiate pregnancy plays no role
2. Hence use of surplus embryos does not rest on morally higher ground than creating embryos in research

LEGISLATIVE MOVES

■ Rule Allowing Donated Embryo Use

‘The government shall support and conduct biomedical research that uses and consumes all and only those human embryos donated as such, or formed from donated cells, as to which the donor instructions forbid intrauterine embryo transfer’

or

■ Revise Castle-DeGette, Specter

- To provide for ‘research that *derives and utilizes* human embryonic stem cells, *and that otherwise uses embryos donated as such or formed from donated cells*’
- Make clear that qualifying condition is decision against intrauterine transfer taken by donor alone and embodied in instructions to donee
- Expand ‘Secretary’ to include National Science Foundation, Department of Energy
 - To them, *DA* has never applied

FDA'S EFFECTIVE INTERDICTION OF REPRODUCTIVE CLONING†

ACTION

- Pronouncement of reproductive cloning as unsafe
- Refusal to allow any attempt

JURISDICTION

- Four-fold statutory authority
- Compliance with Administrative Procedure Act (21 C.F.R. Part 1271 eff. 1-21-04)

PENALTY FOR VIOLATION

- Imprisonment
- For a physician, probable loss of license



EFFECT

- Not a single reported attempt at reproductive cloning in U.S.
- Probable future incidence of reproductive cloning in U. S.: nil
- Anticlone legislation —at best redundant, at worst a platform for banning SCNT in research