

Regulating Stem Cell Research: New Science and New Policy Challenges

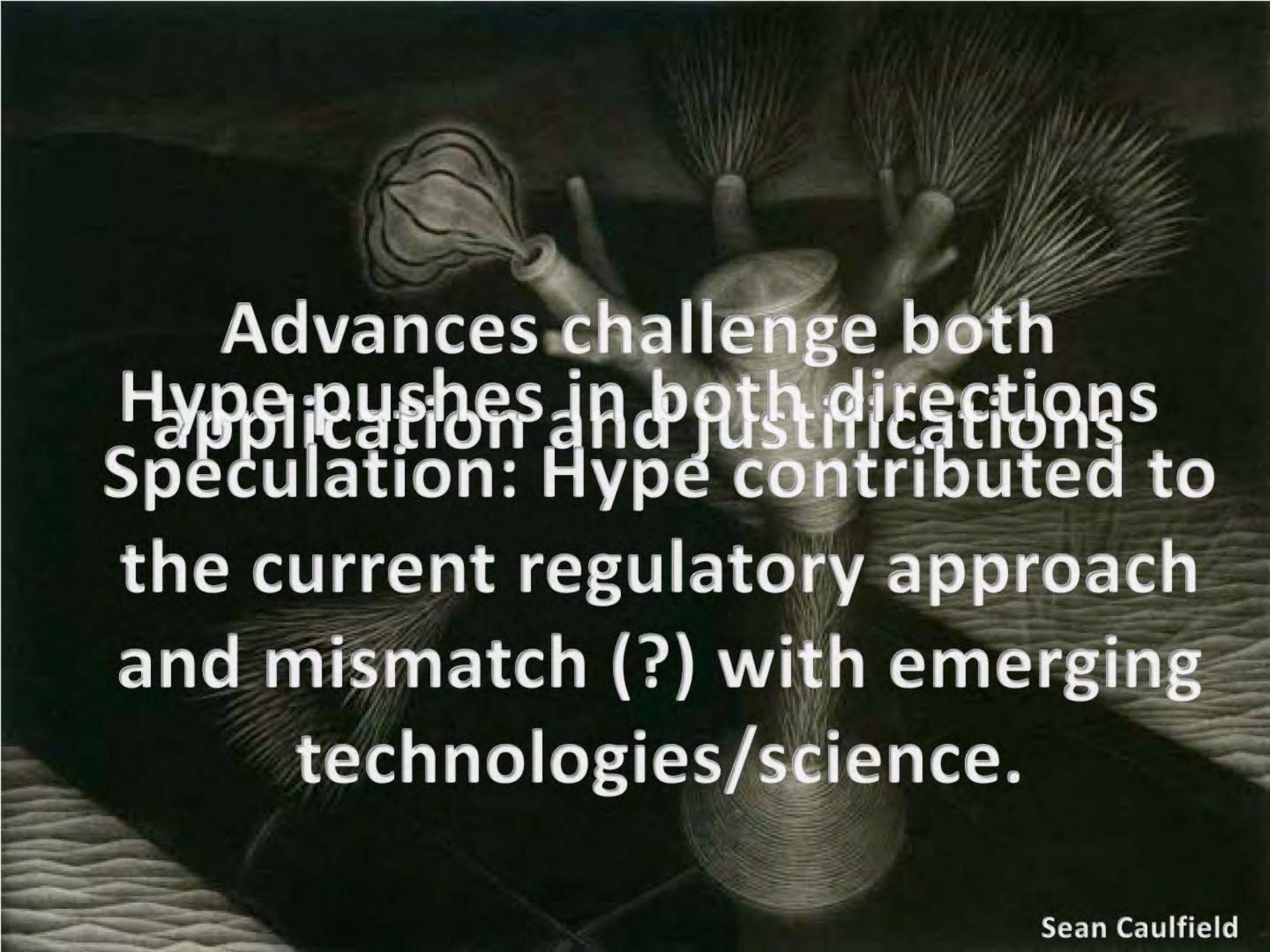
Timothy Caulfield

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Toronto



UNIVERSITY OF ALBERTA
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**Advances challenge both
Hype pushes in both directions
application and justifications
Speculation: Hype contributed to
the current regulatory approach
and mismatch (?) with emerging
technologies/science.**



Law lagging behind ...

... or leaping ahead?

Role of pop hype in early debates.

Two recent technological developments.

Lessons learned?

Anti-abortion
march focuses
on stem cell bill

Jewish, Islamic faiths
support controversial
stem cell research

Science a big theme in the

political/public/parliamentary debates

Cloning
of embryos
considered

CANADA
Stem-cell research opponents hold up anti-cloning bill

Embryonic stem cells held in laboratory bottles.

Fears

By Arthur Caplan, Ph.D.

Despite a lot of claims by con artists, frauds and nuts, no one in over 15 years has been able to clone a human embryo, much less make a cloned human being. Even though a slew of magazine and Internet articles have long hinted that human cloning is just around the corner, the corner has proven to be more like a chain of mountains.

Jim Bronskill.

1999. p. A3

outraged

“There is a group of people, the Raelians, running around. We have heard that name mentioned a few times today. The Raelians are a cult and they work through their company called Clonaid. Their vision is to perpetuate human life by creating a clone.” James Lunney, Canadian Alliance 27/02/2003

nations need
applications,
and shortsigt

but provides no evidence

is sobering, and
constitutes acceptable military
to do so would be both irresponsible

REASONS FOR JUDGMENT:
(paras. 1 to 156)

McLachlin C.J. (Binnie, Fish and Charron JJ. concurring)

artificial creation of human life in clandestine laboratories, on shoddy operating tables, and in shuttered basements

commodification of reproductive materials

public health evil.

The genetic make-up of offspring, may now be artificially altered through genetic manipulation and germ cell line intervention.

permit artificially-created newborns to die

“dehumanize motherhood”

considered inappropriate commodification

replication technique of cloning.

“baby farms”

discrimination based on ethnicity or genetic status

cross-species hybrids:

devaluation of persons with disabilities

The production of human life in clandestine facilities

criminal law to control transgenic research

Social
Used
religious

These myths are still present in today's public debate on cloning and stem-cell research. Because these old stories have established themselves in the cultural imagination, they are used by the mass media independently of their validity to describe the current problems. Knowledge of these associations can be important for biology and medicine today, because it helps us to better understand the anxieties in the population about advanced biomedical research.

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Cloning in the media and popular culture

An analysis of German documentaries reveals beliefs and prejudices that are common elsewhere

Giovanni Maio

Magnetised stem cells could treat arthritis

20 April 2009 by Andy Coghlan
Magazine issue 2704
Four stories



Stem Cells Hold Promise for Injured Athletes, But Questions Remain

By Erik Malinowski May 24, 2011 | 7:00 am | Categories: [Medicine, health](#)



Preemie twins fight for breath

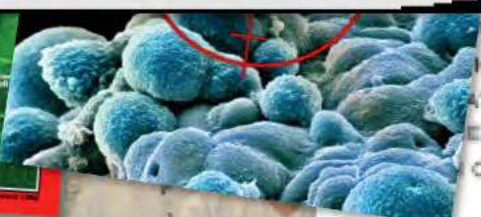
Stem-cell research holds promise for tiny, damaged lungs
<http://www.edmontonjournal.com/health/Preemie+twins+>

BY SHEILA PRATT, EDMONTONJOURNAL.COM MAY 24, 2011



The sooner it gets from the lab to the bedside, the better for thousands of premature babies, he says.

"These parents (Luis and Julie) are watching, of course. I hope to treat their babies in five years' time" if all goes well.



FEATURE HEALTH NATIVE MED HEALTH CLUB

Stem Cell Cures or Incremental Advances?

NATURE BIOTECHNOLOGY | NEWS

South Korea's stem cell approval

Heiko Yang

"6% is not terrible. You're getting a modest improvement, and that might be the best they ever do" says University of Michigan cardiologist Mark Russell. For Hearticellgram-AMI, a price tag of 20-million Won (\$19,000) may be overly optimistic," says Russell.

On July 1, the Korea Food and Drug Administration approved a stem cell treatment for myocardial infarction developed by FCB-Pharmicell of Seongnam. Locals view the regulatory go-ahead as a world first and also a vote of confidence for the nation's scientific expertise following the cloning scandal that found stem cell scientist Woo Suk Hwang guilty of fraud (*Nat. Biotechnol.* **24**, 745–747, 2006). The treatment, Hearticellgram-AMI, is an autologous stem cell transplant of mesenchymal stem cells, cultured from a patient's own bone marrow, injected into the coronary arteries. The approval comes after six years of clinical trials; as yet, the company has not published results in a peer-reviewed journal. Another major caveat is clinical efficacy: patients showed a 6% improvement in the left ventricular ejection fraction used as measure of heart function six months after one dose of Hearticellgram-AMI. "6% is not terrible. You're getting a modest improvement, and that might be the best they ever do" says University of Michigan cardiologist Mark Russell. For Hearticellgram-AMI, a price tag of 20-million Won (\$19,000) may be overly optimistic," says Russell.

Hype fueled debate...

Safety

Regulation

Tourism

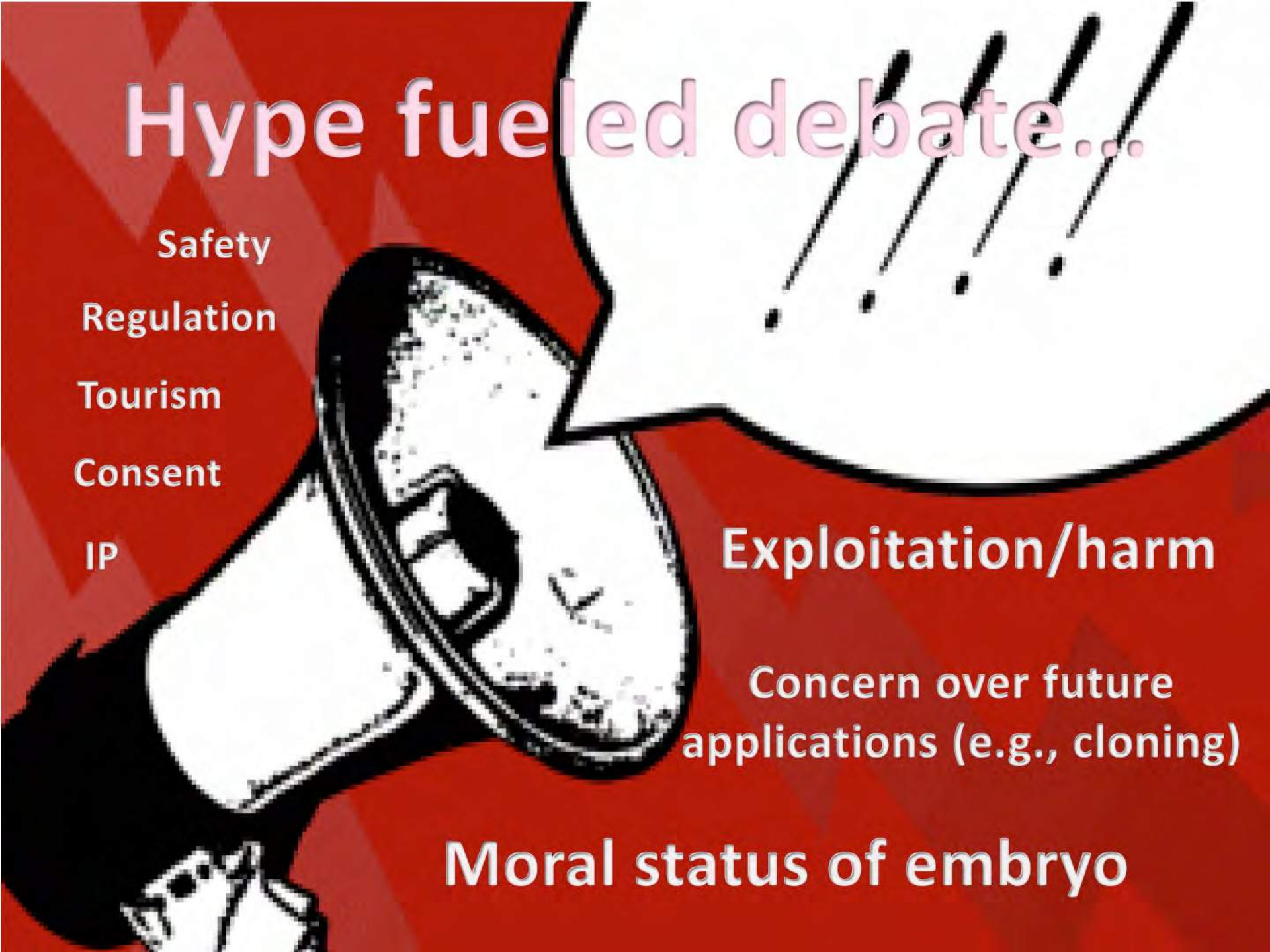
Consent

IP

Exploitation/harm

Concern over future applications (e.g., cloning)

Moral status of embryo



iPS example...

Simplistic to say current
policy solely result of
cultural portrayals of
benefit/risk...

... but key to the story and
contributed to a confused
policy debate about the
applications of the
emerging technologies.

International Stem Cell Corporation's Human Parthenogenetic Stem Cell Development Of Treatments For Liver Disease

19 May 2008

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Human Embryonic Stem Cell Lines Created Without The Destruction Of Embryos

ScienceDaily (Jan. 12, 2008) — Advanced Cell Technology, Inc. together with colleagues announced the development of five human embryonic stem cell (hESC) lines without the destruction of embryos. These new results have the potential to end the ethical debate surrounding the use of embryos to derive



Skin cell breakthrough

By Fiona MacRae
Science Correspondent

STEM cells taken from ordinary skin have been used to ease the effects of Parkinson's

'Ethical' treatment could ease the pain of Parkinson's

want to make it as safe as possible. But as long as we quantify the risks, the choice should be there.'
Dr Marita Pohlshöfer
Muscular Dystrophy

Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors

HYBRID

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Human Embryonic Stem Cell Lines Generated without Embryo Destruction

Young Chung,^{1,6} Irina Klimanskaya,^{1,6} Sandy Becker,¹ Tong Li,¹ Marc Maserati,¹ Shi-Jiang Lu,¹ Tamara Zdravkovic,² Dusko Ilic,³ Olga Genbacev,² Susan Fisher,^{2,4} Ana Krtolica,³ and Robert Lanza^{1,5,*}

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The New York Times
nytimes.com

May 20, 2008

WORLD BRIEF | EUROPE

Britain: Hybrid Embryo Ban Is Defeated

By SARAH LYALL

The House of Commons has defeated a bill that would have banned the creation of so-called hybrid embryos — part human and part animal — for medical research. That means scientists who obtain proper licenses will be allowed to create hybrid embryos by transferring DNA from human cells into animal eggs that have had most of

EMBRYO IN ITS TRUE SENSE'

PROFESSOR John Burn, the head of Newcastle University's Institute of Human Genetics, last week confirmed the creation of Europe's first part-human, part-animal embryo. Scientists succeeded in transferring a human nucleus, derived from skin cells, into an animal egg.
Prof Burn said: "This is a hybrid embryo in its true sense — it is full of human DNA and will be used for research."

