

Regulation and Risk Havens

James Lawford Davies

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Approaches and Rationales

1. Prohibitions/restrictions
2. Regulation/licensing
3. Guidance/self-regulation
4. No regulation or consensus

“The only workable approach found has been the policy of federal neutrality, whereby the federal government does not prohibit embryo research, but also does not officially condone it, encourage it, or support it with public funds”

(President’s Council on Bioethics, 2003)

Approaches and Rationales

Prohibition

Unregulated

Restrictions or prohibitions of certain procedures or techniques

Conditions on licences or authorisations

Restrictions on purposes of permitted research

Requirements re source material

Restrictions on funding

Limitations on duration of research

Governance frameworks

Ethics review

Approaches and Rationales

Contrasts to consider:

Rogue -v- Responsible

Research -v- Therapy

Therapeutic -v- Non-therapeutic

Legitimate forum shopping -v- Ethics dumping

Approaches and Rationales

WE CAN CURE:*

👁️ Diabetes	👁️ Multiple sclerosis
👁️ The effects of ageing	👁️ Parkinson's
👁️ Sporting injuries	👁️ Spinal cord injuries

ARE U TIRED OF SEEKING MEDICAL TREATMENT AND NOTHING IS CHANGING?

IS THE HOSPITAL NOW LIKE YOUR SECOND HOME?

SAD REALITY OF CONTROL MEDICINE
Apparently the best thing for you is control medicine as your last solution. Its like youroxygen. Or worse with all the tests that you have had, the cause of your sickness has not been found

DESPAIR NO MORE THE SOLUTION IS HERE

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➤ Diabetes	➤ Brain Damage
➤ Tumours	➤ Wound Healing
➤ Cancers	➤ Burns
➤ Heart Disease	➤ HIV
➤ Lung Disease	➤ Fibroids
➤ Kidney Failure	➤ Infertility
➤ Visual Imparement	➤ Bone Disease
➤ Deafness	➤ And many more...

SuperLife

STC30 - YOUR PREFERRED CHOICE TO A HEALTHY LIFE

STEM CELL WORKS IN 5 MAIN WAYS:

1. Rejuvenating aged cells.
2. Replicating good cells.
3. Restoring sick cells
4. Replacing dead cells.
5. Repairing damaged cells

BRINGING THE BODY TO NORMAL FUNCTIONALITY

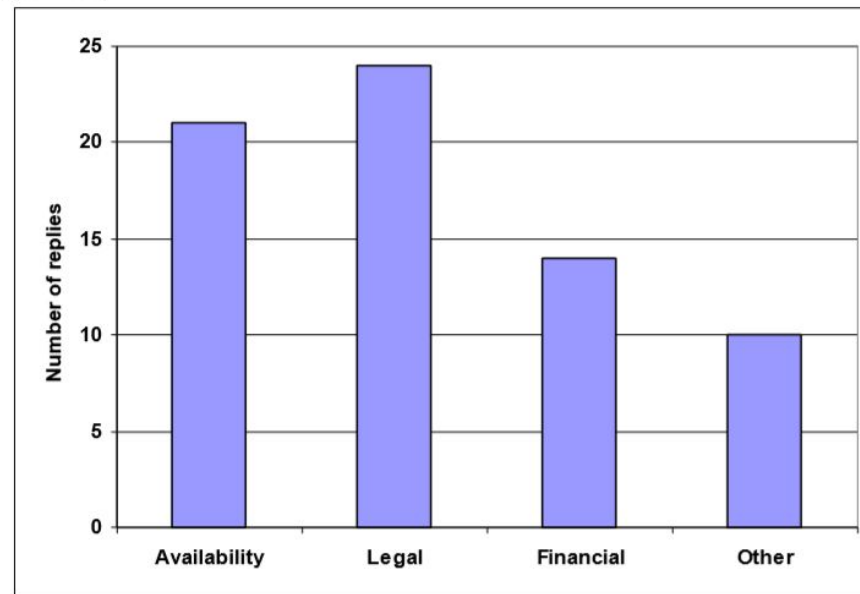
FOR MORE INFORMATION:-

📞 0779 924 311 / 0714 078 063

✉️ sellarchieza@gmail.com

Approaches and Rationales

Figure 17: Patients' reasons for travelling abroad for PGD
(n = 53)



HFEA Regulation: Research (1)

Human Fertilisation and Embryology Act 1990 (as amended in 2008),
Schedule 2(3)(1):

- “A licence under this paragraph may authorise any of the following –
- a) bringing about the creation of embryos *in vitro*, and
 - b) keeping or using embryos, for the purposes of a project of research specified in the licence.”

Unlicensed research (or research outside the terms of a licence) is a criminal offence

HFEA Regulation: Research (2)

HFEA Licence Committee follows a 'Decision tree':

1. Identify activities to be authorised
2. Is the activity to be licensed permitted?
3. Does the project involve 'hamster test' and creation, use and storage of admixed embryos?
4. Is each activity necessary or desirable for a specified purpose,
or
is it necessary or desirable for the purpose of providing knowledge that may be capable of being applied for increasing knowledge about or developing treatments for serious disease or other serious medical conditions?

HFEA Regulation: Research (3)

- ‘Principal’ permitted research purposes (3A(2) of Sch.2):
 - Increasing knowledge about serious disease or serious medical conditions;
 - Developing treatments for serious disease or other serious medical conditions;
 - Increasing knowledge about causes of any congenital disease or congenital medical condition;
 - Promoting advances in infertility treatments;
 - Increasing knowledge about causes of miscarriages;
 - Developing more effective techniques for contraception;
 - Developing methods for detecting presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation; or
 - Increasing knowledge about the development of embryos

HFEA Regulation: Research (4)

Decision tree (contd):

5. Is the Committee satisfied that the use of embryos (or admixed embryos) is necessary for the purpose of the research?
 6. Has the applicant provided evidence of ethics approval?
 7. Is the Committee satisfied with the patient information and consent forms?
 8. Should licence be granted subject to conditions?
- Condition of all research licences that embryos used/created cannot be used in treatment

HFEA Regulation: Treatment (1)

Section 3ZA(2) and (4):

- A 'permitted egg' is one "whose nuclear or mitochondrial DNA has not been altered"
- An embryo is a 'permitted embryo' if "no nuclear or mitochondrial DNA of any cell of the embryo has been altered"

Section 3ZA(5):

- Regulations may provide that –
 - a) an egg can be a permitted egg, or
 - b) an embryo can be a permitted embryo, even though the egg or embryo has had applied to it in prescribed circumstances a prescribed process designed to prevent the transmission of serious mitochondrial disease.

HFEA Regulation: Treatment (2)

Schedule 2, section 1(4):

A treatment licence “cannot authorise altering the nuclear or mitochondrial DNA of a cell while it forms part of an embryo, except for the purpose of creating something that will by virtue of regulations under section 3ZA(5) be a permitted embryo”.

Unlicensed use of embryos in treatment is a criminal offence

HFEA Regulation

In summary, UK framework:

- Permits basic research but (currently) prohibits clinical use
- Research is subject to
 - licensing
 - regulation and
 - ethical oversight
- Research must be for an approved purpose
- 'Research embryos' cannot be used in treatment
- UK legislation generally objective and unemotional
- Clinical use would require change to primary legislation

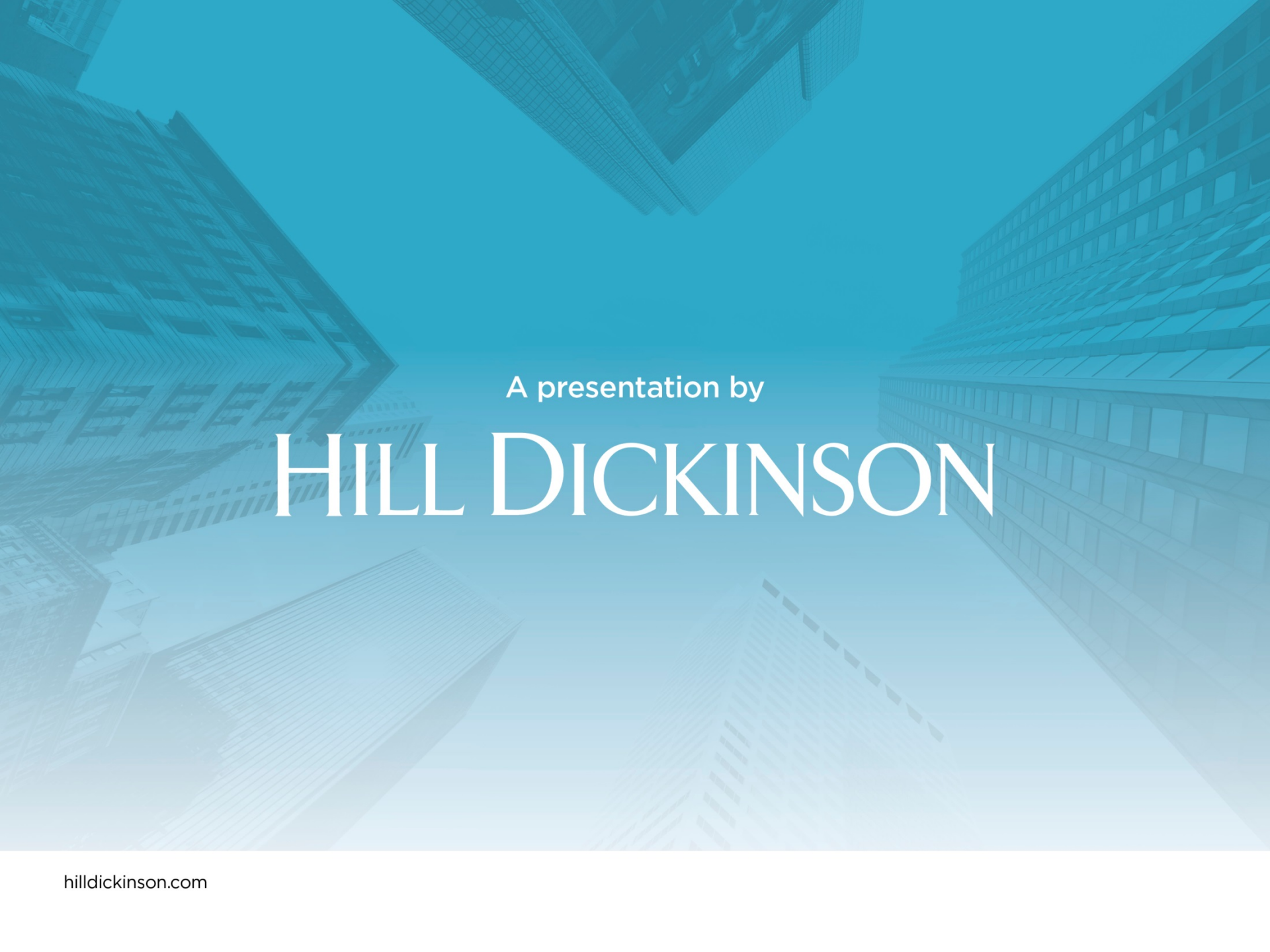
mtDNA

History of mtDNA donation (2004-2017):

- Research licence application (including legal challenge)
- Ethical scrutiny of research
- 2008 Act provided for future regulations allowing potential use in treatment
- 4 HFEA scientific reviews and reports
- 2 public consultations
- 2 Parliamentary debates, resulting in new regulations
- Extensive media and public engagement
- Enormous support and commitment from patient groups
- Treatment licence application

Conclusions

- No quick fix
- UK model offers a stable, flexible and potentially permissive regulatory framework:
 - Protects patients
 - Allays public concerns
 - Protects researchers
 - Provides an environment within which scientific innovation and progress may flourish
- No basis for a moratorium in UK
- PGD and mtDNA offer a useful model for robust regulation of therapeutic applications
- Need for transparency and open dialogue between researchers and policy makers, both nationally and internationally



A presentation by

HILL DICKINSON