

# Regulation in Practice: Understanding Regulatory Bodies

Neil Stephens



## Overview of the paper:

- Introduction: Understanding Regulatory Bodies?
- Two empirical case studies
- Understanding regulatory bodies in practice
- Making sense of uncertainty: Regulatory Regress
- Conclusion

## Understanding Regulatory Bodies

- Report on how laboratories make sense of UK stem cell regulation
- Focus upon the uncertainties faced by laboratories
- Make explicit the role of laboratories in *producing*, as well as being subject to, regulatory texts and regulatory practice

# Interim UK Regulatory Route Map for Stem Cell Research & Manufacture

Version: 12.03.09

Start Here

Q1. Are the stem cells intended for Human Application?  
*Discuss with HTA*

NO

YES

Q2. Will the stem cells be derived from Human Embryo?

NO

YES

Possible application for HTA Licence  
*Discuss with HTA*

Submissions to:  
(i) HFEA, (ii) REC, &  
(iii) NHS R&D Office

Generation of Stem Cell Line

Generation of Stem Cell Line

*In vitro* Stem Cell Research

Deposition in UK Stem Cell Bank via Steering Committee

Q3. Will the cells be Genetically Modified?

NO

YES

HSE Notification may be needed

*In vitro* Stem Cell Research

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*In vitro* Stem Cell Research

Q6. Is animal *in vivo* work required?

NO

YES

Home Office Approval

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Stem Cell Research in Animals

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Q4. Will the stem cells be manufactured into a Medicinal Product or Investigational Medicinal Product? If yes, they will be regulated as an ATMP. *Discuss with MHRA/EMA*

Q6. Is animal *in vivo* work required?

NO

YES

Home Office Approval

Stem Cell Research in Animals

Key:

Regulatory Question	Research or Manufacturing Activity
Statutory Regulatory Process	Non-Statutory Good Practice

Serious Adverse Event & Reactions Reporting to HTA

Clinical Stem Cell Research

Submissions to NHS R&D Office & REC

(Non-statutory good practice for studies outside the NHS)

Stem Cell Research in Animals

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Post-marketing Surveillance of Stem Cell ATMP

Positive Opinion of EMA: Marketing Authorisation Granted

Submission to EMA

Preparation of Regulatory Dossier for EMA

Quality, Safety & Efficacy Data Generated

Safety reporting to Regulatory Agencies

Stem Cell Clinical Trial

NO

YES

Q7. Will the clinical research involve gene therapy?

Submissions to:  
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Preparation of Clinical Trial documentation & obtain EudraCT number

Manufacture unlicensed product

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## Two empirical case studies

- **The UK Stem Cell Bank:** storage and distribution of hESC lines
  - Interviews and observations conducted 2005-2009, focus upon 2007/2008

Conducted by Neil Stephens

- **‘Headlab’:** Anonymous UK laboratory working on Huntington’s & Parkinson’s disease
  - Interviews and observations conducted 2007-2008

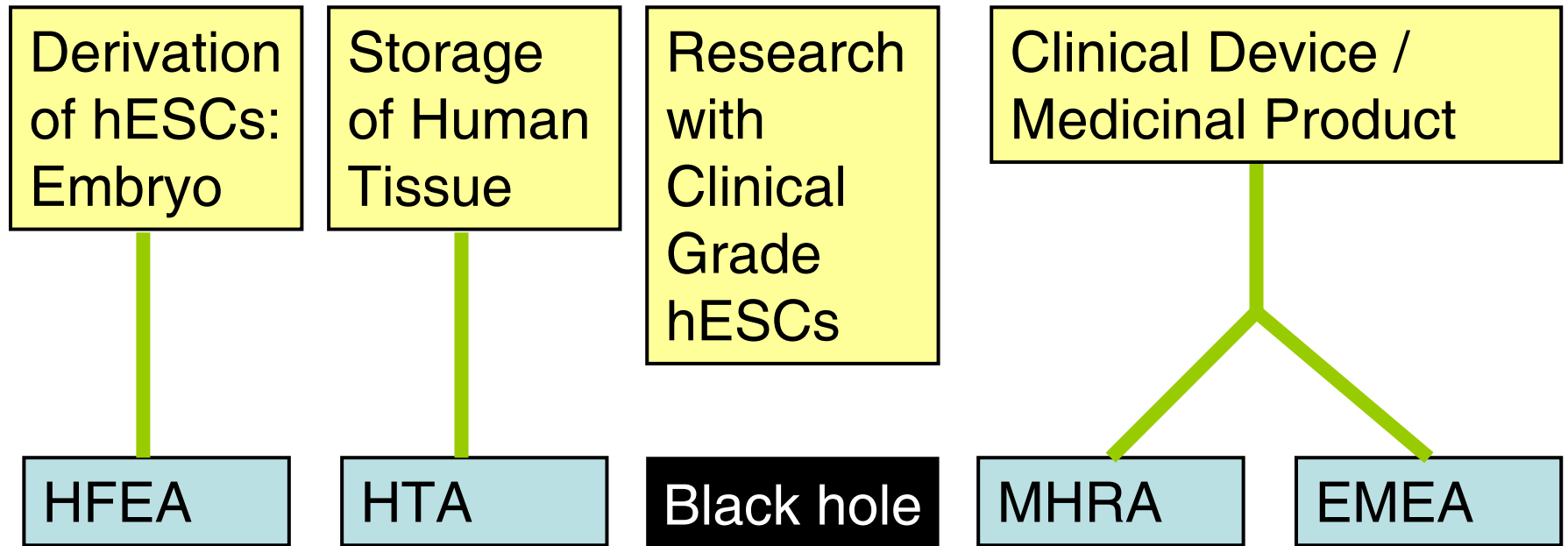
Conducted by Jamie Lewis

Focus on two locations of discussion around these issues:

Quality Forum at the UK Stem Cell Bank, Oct 2007

UK National Stem Cell Network annual meeting, Edinburgh, April 2008

## Regulatory bodies present in debates about the UK stem Cell Bank



- Human Fertilization & Embryology Authority

- Human Tissue Authority

- Medicines & Healthcare products Regulatory Agency

- European Medicines Agency

# UK Stem Cell Bank Interim Quality Assurance Programme

Ran 2006-2007



## **Ambiguity & Definitional issues**

Medicinal product *or* raw material?

Unclear what the exact definitions of 'raw material' and 'medicinal product' will be in relation to hESCs.

Furthermore the form eventual therapeutic applications might take is unknown.

## Problem of competing imagined futures and multiple expectations.

Hope & promise are important for enrolling resources to a scientific program and framing stakeholder engagement with an emerging technology.

Will hESC lines be used in therapy? Will they be disease models? What form might any of these take? Raw materials of medicinal products?

Imagined futures introduce uncertainties to the present.

## Making sense of uncertainty: Regulatory Regress

Starting with Wittgenstein, as interpreted by Winch:

*Rules do not include the rules of their own application.*

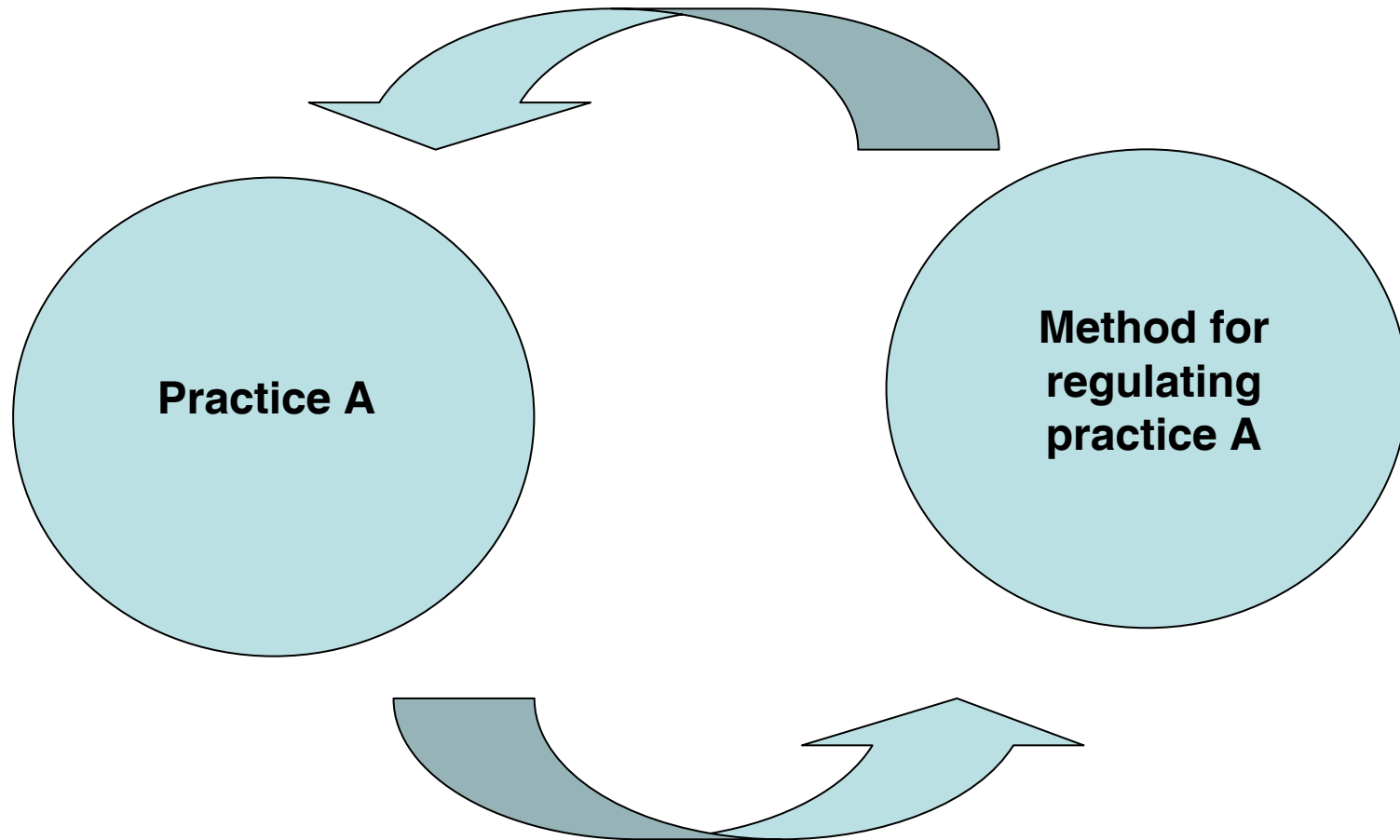
We want to argue that we have empirical evidence to suggest that:

*Regulations do not include the rules of their own application.*

In the case of the **Regulatory Regress**, we want to argue that:

Individuals can not know the correct interpretation of a regulation until the wider networks shaping its meaning are settled, yet these wider networks can not be settled until a correct interpretation is agreed.

# Regulatory Regress



However, under Regulatory Regress **the circularity can be broken**; through micro-level social interaction and wider social shaping.

# Signs of closing Regulatory Regress: Establishment of the Quality Forum

The UK Stem Cell Bank, working with the laboratories with a HFEA license to derive hESCs, have formed the 'Quality Forum'

## Aim to:

Write a Code of Practice for hESC GMP to be ratified by the HTA & MHRA

possibility of self-auditing

possibly introduce the Stem Cell History File

## Who makes regulation?

In a traditional concept of regulation there are two clearly defined actors: the 'regulator' and the 'regulated'. The difference between the two is one of power, scrutiny and accountability.

However, our empirical work demonstrates a spreading of autonomy between the two groups at these early stages of regulatory development, before the wider networks are settled.

Subsequently we want to introduce the concept of the '**regulatory actor**': to encapsulate the shared roles and anxieties of those who are involved in the processes before the role of 'regulator' and 'regulated' have been settled.



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Home Office approval & safety study under GLP

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## Conclusion

Competing imagined futures introduce uncertainty into the regulatory process

The circularity of needing the regulation before you can produce the science, but need the science before you can produce the regulation, can be termed **Regulatory Regress**

Under these circumstances of uncertainty the division between regulators and regulated is less distinct as both sets of regulatory actors engage with closing uncertainty.

The support of the Economic and Social Research Council (ESRC) is gratefully acknowledged. The work presented forms part of the programme of the ESRC Genomics Network at Cesagen.

