

Legitimising (the) Experts: Agency Regulation of Emerging Biotechnologies

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Human Fertilisation and Embryology Authority

- Arms length body – delegated responsibility from Parliament to regulate the use of gametes and embryos in research and treatment
- Established in 1990 following extensive debate, consultation and inquiry
- ‘a good example of ethics and pragmatism, scientific expertise combined with public consultation, lobby and parliamentary debates’
- Broad and narrow roles (advisory and executive): ‘schizophrenic’

HFEA Roles

- Reassurance
 - Regulation of new technology
 - Protection of patients and their interests
- Implementing and monitoring safety and quality standards
- Providing information to government
- Facilitating ethical debate
 - Resort to evidence-based decision making esp where contentious subject matter
- Less overt - presiding over achievement of political (social and economic) goals

Health Research Agency

- a central core regulator co-coordinating research regulation
- appropriate medical, scientific and ethical expertise on specialist issues
 - to build confidence in its ability to handle sensitive issues
 - To be knowledgeable and effective.
- Strong leadership and expertise to manage the wide-range of issues within its remit
- must include public and patient involvement to enable the interests of the lay public to be reflected
- a culture that upholds certain values in research

HRA: Recommended Values

- Safeguard the well-being of research participants
- Facilitate high quality health research to the benefit of the public
- Be proportionate, efficient and coordinated
- Maintain and build confidence in the conduct and value of health research through independence, transparency, accountability and consistency

Regulatory Legitimacy

- Public accepts regulatory decisions without coercion
- High level of persuasive power of the arguments made supporting decisions
- Challenging in biotech field: controversial subject matter
- Can be bolstered where decisions are well informed on a scientific basis.
- Regulator needs expertise
 - In the application of its regulatory approach; and
 - In its resort to expert advice on scientific knowledge

Expertise in the Application of the Regulatory Approach: Principles Based Regulation

PBR of Stem Cell Research

- Human Fertilisation and Embryology Authority
- Human gametes and embryos
- s 8(1)(ca) HFE Act 1990 (as amended) HFEA must 'maintain a statement of the general principles which it considers should be followed (i) in the carrying-on of activities governed by this Act, and (ii) in the carrying-out of its functions in relation to such activities'.

The Principles

- HFEA *Code of Conduct* 8th Edition (2009)
- high-level, broadly framed
- Scope for the HFEA to determine whether a new scientific discovery or technique falls within the spirit of the law's aims. e.g.
 - ‘respect for the special status of the embryo when conducting licensed activities’;
 - to ‘give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions’; and
 - to ‘ensure that patients and donors have provided all relevant consents before carrying out any licensed activity.’

PBR is suitable for biotech

- overcomes disadvantages of a system of predominantly primary legislative provisions
- flexibility, within limits
- law will not become outdated
- “future proofing” (Black and Hopper)
- reflect, encompass facilitate innovation
- facilitate effective legal responses
- allows for swift and knowledgeable responses to scientific developments

Expert Application of PBR

- Knowledgeable, expert regulator must be able to swiftly determine whether the actions of scientists fall within the regulatory remit
- Lessons from the financial sector:
 - Communication with regulatees
 - Accurate risk assessment
 - Effective enforcement mechanisms
 - Appropriately qualified employees
 - Understanding regulatees' incentives and influences

Expertise in the Use of Science

Constructed Nature of Science

- Traditional views: Scientific experts present neutral, fact based information free from external political, financial influence
- Constructed nature of science
 - Research paradigms
 - Current standards of evidence and proof
 - Personal and professional goals
 - Wider social attitudes
- Regulators need to caution against a level of influence which avoids the safeguards of appropriate decision-making

Science for Policy

- Reflect influences and biases of advisors
- ‘Transgressive’
 - Science has to be framed to relate to particular context or question
 - Communicated in a way which others can understand
 - May be accompanied by argument/ evidence drawn from other fields
- ?Temptation to minimise uncertainties?

Drawing on Science Advice 1

- Human animal hybrids
- Scientists as subjects of regulation
 - Application to use animal eggs
 - Public declarations of intention to do so
- As science advisors
 - Scientific literature review
- Scientists as policy framers
 - Scientific consultation – ‘are human animal hybrids beneficial to research?’

Drawing on Science Advice 2

- Scientific and Clinical Advances Advisory Committee
 - Advise on scientific and clinical developments (including research) in assisted conception, embryo research and related areas;
 - make recommendations on policy implications
 - Advise on implications for licensing and regulation;
 - where required, to work with the Ethics and Law Advisory Committee to consider the social, ethical and legal implications
 - ‘Necessary and desirable?’

Recommendations

- Rolling group of advisors from differing institutions and/or collaborative groups and funded by different agencies/ organisations
- Take into account the emergent nature of the science
- Place duty on scientists to report licensed work to the Authority
- Require scientists to engage with arguments and opinions of other stakeholders

Legitimising (the) Experts

- Understand constructed nature of science
- Recognising where scientists' input goes beyond the science
- Balance contributions to the regulatory endeavour
- Encourage scientists' reflexivity – what own role is; what is known and what is uncertain
- Ensure that an accurate account of the level of uncertainty is available
- Ensure facilitation of innovation

Conclusion

- Regulating in a polycentric regulatory environment – ceding influence over their decisions to others – experts and lay
- If done properly, it will reinforce the relationship of responsibility and trust which PBR tries to engender
- Expert understanding of
 - relevant regulatory mechanism and
 - nature of information being provided will enhance legitimacy