ESRC Innovative Health Technologies Final Conference

Policy and Regulation: International Investigations

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Pharmaceutical Regulation and Innovation

(John Abraham, Courtney Davis, Alison Kraft, Paul Martin)

Cultural Politics and Negotiated Regulatory Policy for Embryonic Stem Cell Research (Brian Salter)

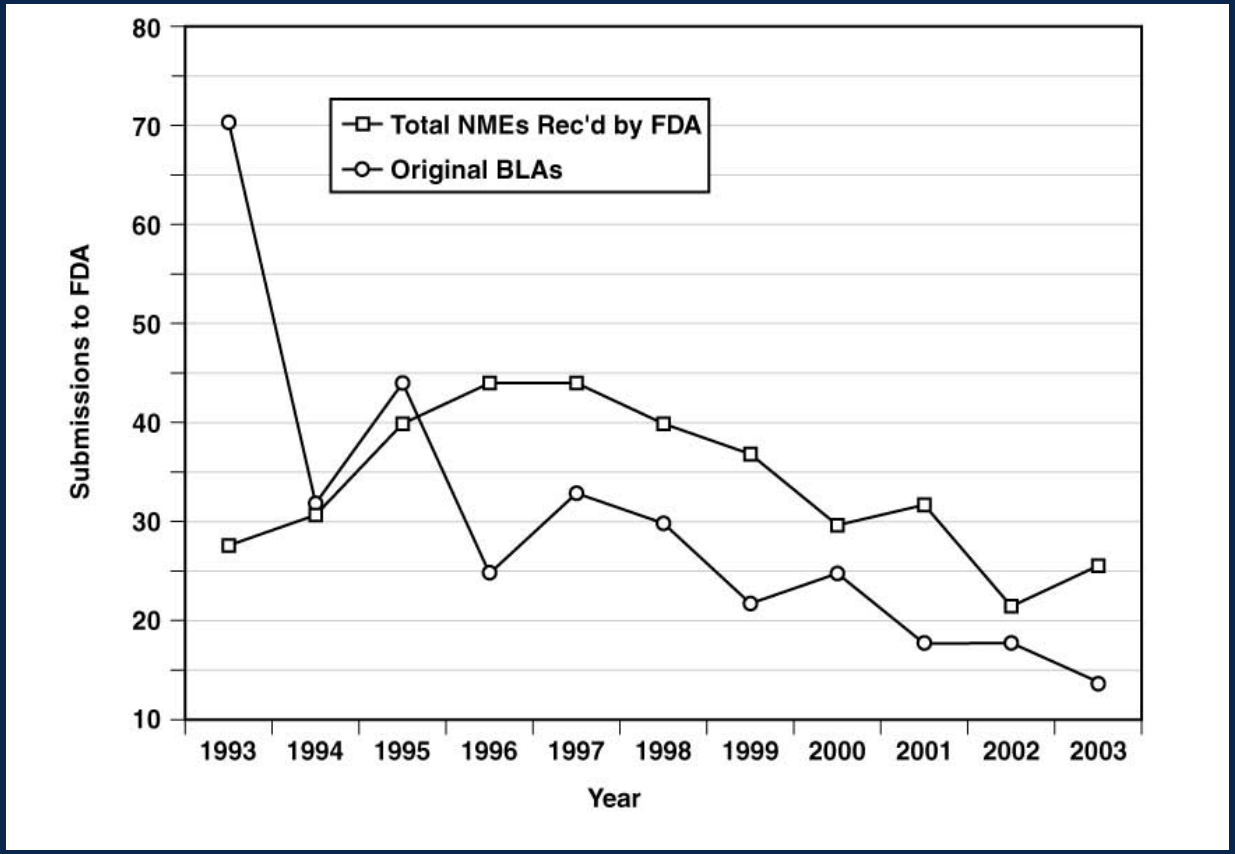
Emergence of Hybridity in Regulation of Tissue Engineering and Transpecies Transplantation (Nik Brown, Alex Faulkner, Julie Kent, Mike Michael)

Pharmaceutical Regulation and Innovation in the EU and US

- The Productivity ‘crisis’
- Could there be over-regulation?
- Is it due to the changing structure of innovation?

‘Productivity Crisis’

EU figures tell a similar story



Streamlining of Regulation

- Since 1980s Governments accepted pharmaceutical industry's demands for accelerated review of new drugs
- Regulators streamlined scientific standards and increased consultation with companies to foster innovation
- Median FDA review times reduced from 14 months in 1993 to 6 months in 2004. Similar reductions in Europe from 1990

Changing structure of innovation

1950s 60s & early 70s heavy R&D investment and search for drugs related to antibiotics

Random screening paradigm discovered steroids, contraceptive pill, antipsychotics, benzos, calcium antagonists and B-blockers

1980s shift to rational drug design combined with focus on chronic conditions created ‘block-buster’ culture whose sales belie the underlying productivity decline

Pharma - In Conclusion

"Regarding the current 'productivity crisis', the evidence suggests that 'over-regulation' is not a factor.

An alternative and more convincing explanation would instead centre on the decreasing returns that arose from the industry's 'lock in' around a paradigm based on incremental innovation based on a limited number of established drug targets".

Cultural Politics and Negotiated Regulatory Policy for Embryonic Stem Cell (ESC) Research in the EU

- Conflict between science and civil society
- The integration of cultural values and politics into regulation of science
- The trans-mutation of polarised cultural politics into negotiated compromise in regulation

Conflict between science and civil society

- ESC scientists claim research promises therapies for irreversible organ/tissue failure
- Human ESC research problematic because manipulates part of cultural identity: human embryo
- UK permits use of embryos (medical research) regardless of source, but Irish constitution defends the ‘right to life of the unborn’ at other end of continuum

The integration of cultural values and politics into regulation of science

- Conflict consigned to ‘ethics’ as legitimate vehicle for continuing political bargaining
- European Group on Ethics (EGE) directed by EU Parliament and Council to evaluate ethics of biotech research - regulation of ESC science no longer a ‘technocratic preserve’.
- Ethical objects, such as embryo source or age and ESC line origin or research purpose, used in negotiation

The trans-mutation of polarised cultural politics into negotiated compromise in regulation

- The EGE changed political debate from static opposing ethical positions to their refinement and negotiation
- For example, EU would not fund human cloning for reproduction but would fund research on human embryos created from infertility treatment but no longer needed for that purpose

ESC - In Conclusion

- In the EU “the search for political utility has necessitated the development of rules and procedures that can contribute to a practical outcome. Cultural politics is therefore operating at two levels in order to accommodate the otherwise incompatible requirements of (a) unchanging legitimacy of particular value positions and (b) the need for those positions to be negotiable”.

Emergence of Hybridity in Regulation of Tissue Engineering and Transpecies Transplantation in UK, US and Europe

- Xenotransplantation - challenges of IHT to regulatory definitions and their institutional representations
- Tissue engineering - institutional viability

Xenotransplantation – definitional challenges

- New technical procedures alter boundaries of regulation, e.g. previous defn of Xeno did not account for production methods involving ex-vivo contact of human and animal tissues
- amended FDA defn of Xeno: ‘any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source, or (b) human body fluids, cells, tissues or organs that have had ex vivo contact with live nonhuman animal cells, tissues or organs (FDA 2001).

Xenotransplantation – definitional challenges

- Previous focus on use of whole organs, such as pigs' livers, distracted from xeno hybrids such as human skins cultured on living cells of dead mice
- UK regulatory structures separate animal health from human-medical governance which may undermine efficiency or regulators to assess risk and effectiveness hybrid Xenos

Xenotransplantation – definitional challenges

- In this case the capacity of regulatory bodies to move smoothly across long established institutional structures in response to material hybridity is limited.
- This reflects institutional representations of boundaries that are seen to exist in nature, but boundaries that are traversed or innovated in biotechnology.

Xeno - In Conclusion

"The messy material hybridity of biomedical regulatory objects highlights societal attempts to introduce stable regulatory orders in highly complex socio-political zones. To understand the variability of governance in different innovative technological fields, it is necessary to bring into view the detailed social, cultural and material shaping that produce regulatory orderings".

Tissue Engineering – institutional viability

- TE includes cultured cell implants for cartilage repair, bone substitutes, ‘living’ skin tissues; and future developments expected to include vascular prostheses, organ-assist devices (liver, kidney), whole organs, structures (heart valves, joints), neurological tissues and stem cell therapies
- the boundaries between pharmaceuticals, medical devices and TE are crucial areas of negotiation in re-ordering regulation. Some TE products have already been regulated as pharmaceuticals or as medical devices.

Tissue Engineering – institutional viability

- As tissue and cell therapy is a field in which an intensive worldwide exchange is taking place, there have been commercial and public health regulatory interests in developing clear world-wide standards.
- Regulatory efforts have been directed at distancing TE and human tissues/cells from the allied worlds of XT.
- However, the distinction of two regulatory jurisdictions will no longer be tenable, with both defined as XT.

Tissue Engineering – institutional viability

"The leakiness of distinctions between types of human tissue and their methods of 'production' means that the isolation or segregation of particular zones of a regulatory order is difficult to achieve. Hybrids have the potential to overwhelm purification because rhetorical and material connections constantly reference new associations. The XT/device divide could not be sustained, nor could the cell therapy/medicines divide, nor could the TE/medicines/devices divides as overarching distinctions".

TE -In Conclusion

"Like XT we see attempts to construct and align pure regulatable fields across the hybrid materiality of human tissue-derived therapies in order to control various politico-material risks. Also, we see these attempts at partitioning undermined by changes in the sociotechnical definition of regulatable therapeutic materials. So we also see tensions between different organisational and ontological claims at the heart of the social constitution of human therapeutic materials".