Nanomedicine: An Exceptional Regulatory and Ethical Challenge?

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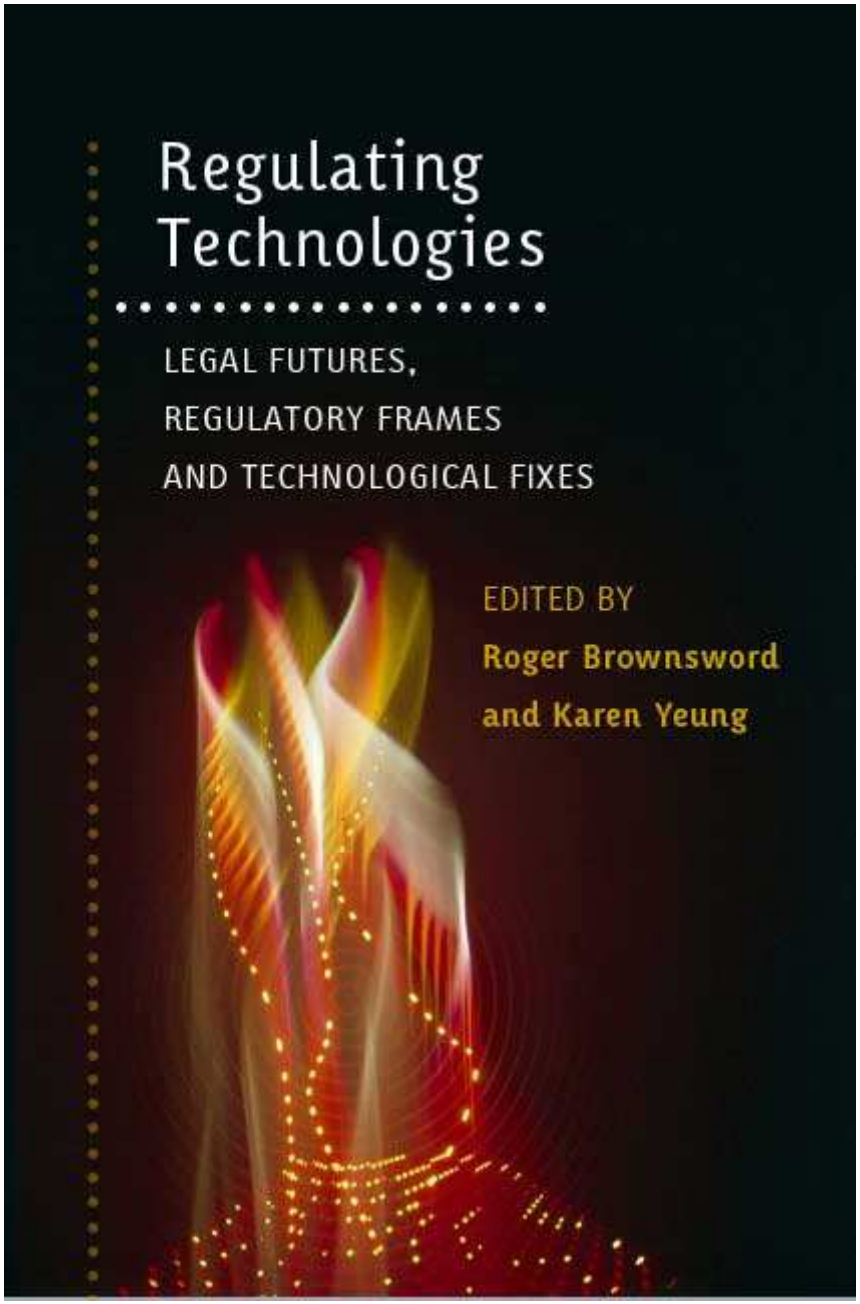
Regulating
Technologies
LEGAL FUTURES,
REGULATORY FRAMES
AND TECHNOLOGICAL FIXES
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Is there a problem?

- In the Ministerial Foreword to *UK Nanotechnologies Strategy: Small Technologies, Great Opportunities* (London, March 2010), we read that the government is determined “to develop the nanotechnologies industry while protecting the health of consumers and employees and avoiding damage to the environment.”

Four illustrative cases

- the development of nanofluids that can be used, with energy-saving effects, in motor car cooling systems
- the use of a hand-held nanosensoring device that will help asthma sufferers to monitor their condition
- the application of nanoscience to reduce the fat content in ice cream
- the use of titanium dioxide nanoparticles in third generation solar cells.

So, what is the question?

Is there any sense in which the (unknown and unpredictable) characteristics of materials on the nanoscale call for an exceptional regulatory and ethical response? In particular, is such a response called for where nanomaterials are used in medical products and devices?

Three possible exceptions

- (1) beyond current regulation: need a dedicated regulatory regime for nanomedicine
- (2) beyond ‘precaution’: current approach not an adequate safeguard for patient health and safety
- (3) beyond ‘informed consent’: need new ethic to govern the nanomedical relationship between doctors and patients.

Regulatory environment for nanomedicine needs to meet four desiderata (see Brownsword and Goodwin, *Law and the Technologies of the Twenty-First Century* (CUP)):

Regulatory prudence: risks to HSE should be acceptable

Regulatory legitimacy

Regulatory effectiveness(in protecting patients and values, but also in allowing for innovation)

Regulatory connection and sustainability.

Regulatory Prudence

- Many questions raised about nanoparticles in cosmetics and sunscreens. Should we allow nanoproducts into circulation without being confident that they are safe?
- House of Lords Science and Technology Committee, *Nanotechnologies and Food*. 1st Report of Session 2009-2010, HL Paper 22-I, January 8, 2010.

What is the responsibility of regulators?

To ensure that individuals are in a position to make their own informed self-interested choices (above a safety threshold?) (nanomedicines in clinical practice)

To ensure that the (background) risks to which individuals are exposed (without this being the outcome of their own prudential choice) are ‘acceptable’ (nanomedicines in clinical trials?)

Standard risk assessment.

In the context of limited uncertainty, precautionary reasoning might be invoked.

Does nanomedicine go beyond this paradigm?

Extreme uncertainty: where the question is whether X might cause Z, the risk assessors will advise regulators that they cannot say that X certainly will cause Z, nor that it certainly will not; all that they can say is that this is a possibility with a likelihood in the range > 0 < 1.

Rational to make a precautionary intervention without having a figure for the likelihood of Z eventuating?

Exceptional principle?

If the choice is between

(a) (possibly unnecessary) regulatory intervention (with loss of benefit); and

(b) (possibly harmful) non-intervention,

then, rational (and prudent) regulators will take whichever option, in the event of error (of getting it wrong), avoids the least acceptable outcome.

Regulatory legitimacy

Do we need to reinvent ethics?

Our ethical thinking is driven *formally* by a focus on:

- (good) Consequences
- Individual rights
- Individual duties

ORIGINAL PAPER

Nanoethics: Old Wine, New Bottles?

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Keywords Nanoethics · Nanoproducts · Nanomedicine · Precaution · Product liability

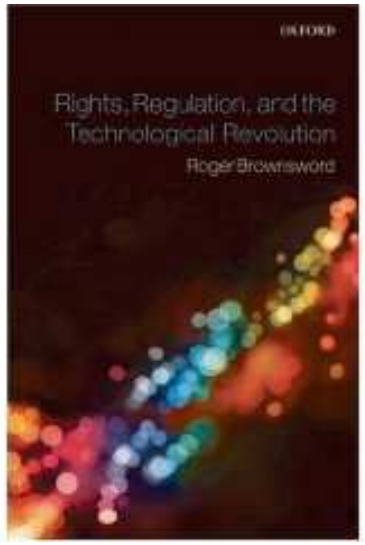
These are substantively articulated in many different ways but, in Europe, the leading articulations are:

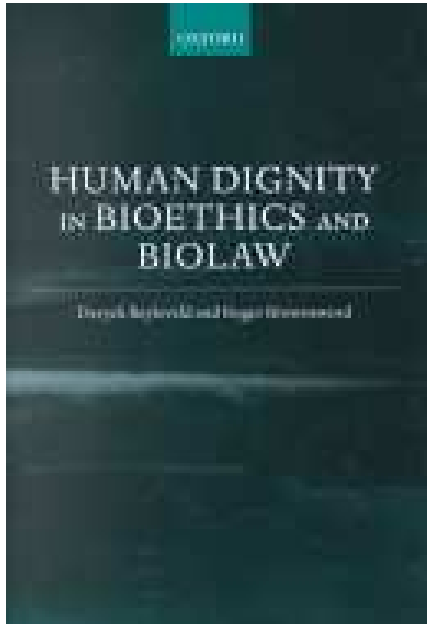
Utilitarianism

Human rights

Human dignity

From a rights perspective, the main justification rests on informed consent, but how can consent be informed where the negatives and risks are unknown?





EGE Opinion No 21 (2007) para 5.7

The requirement for informed consent is of crucial importance in both medical research and health care. But both the lack of knowledge and the uncertainties that exist [with regard to the biomedical applications of nanotechnology] create problems for the attempts to provide adequate and understandable information and [to] obtain consent….

But, much confusion about what information is required for consent and more generally!

An ‘informed’ (valid) consent

Where A consents to act x by B, the consent will be informed provided that the rights-holder, A, understands that:

(i) A has the particular right in question;

(ii) A has the option of giving or withholding consent;

(iii) if consent is withheld, there is no penalty;

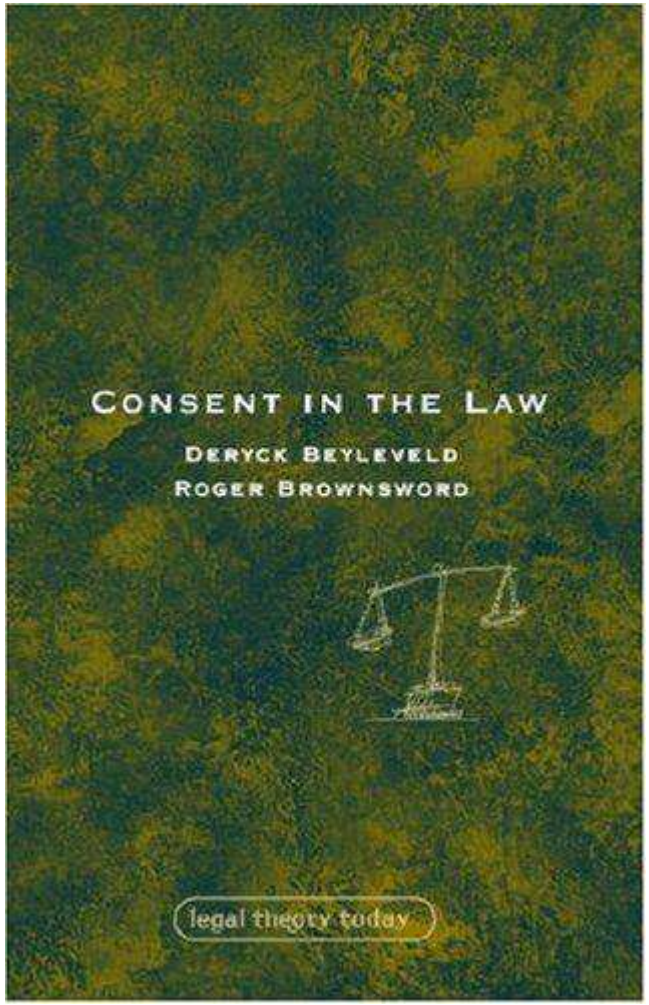
(iv) if consent is given, an act, x, is being authorised that, without the consent, would involve a violation of the right;

(v) if consent is given to B, then provided that B acts within the scope of the authorisation, B (by doing x) does no wrong to A—that is, A understands that he or she is precluded (by the consent) from complaining about B’s doing of x.

Informational rights

- Negative rights relating to privacy, confidentiality, data processing
- Positive rights to know (for information to be disclosed)

What is the relationship between breach of a positive right to be informed and an otherwise informed consent given by the right-holder?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legal theory today

Regulatory effectiveness

- Regulatory interventions often are ineffective (corruption, capture, resources, avoidance, evasion, external factors).
- Often there are unintended negative effects.
- Concern that precautionary intervention might stifle nano-innovation.
- However, where the legitimacy limits are driven by HR or HD, there can be no relaxation for the sake of innovation (compare criticisms of the *Brüstle* decision at the ECJ).

Regulatory connection

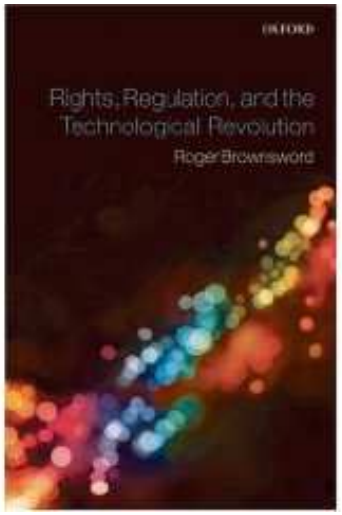
- The problem of making the initial connection (Collingridge dilemma).
- The problem of staying connected.
- Much written about regulatory gaps, tracks (drugs/devices) and disjunctures (ex ante/ex post liability).
- Emerging technologies present a connection challenge but nano is not exceptional.

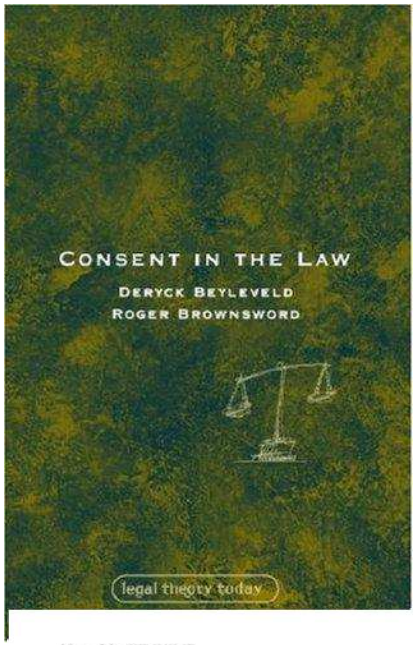
Gregory N. Mandel, “Regulating Emerging Technologies” (2009) 1 *Law, Innovation and Technology* 75 arguing for a governance approach that focuses on six areas: (1) improving data gathering and sharing in the face of limited resources; (2) filling newly exposed or created regulatory gaps; (3) incentivizing strong corporate stewardship beyond regulatory requirements; (4) enhancing agency expertise and coordination; (5) providing for regulatory adaptability and flexibility; and, (6) achieving substantial, diverse stakeholder involvement.

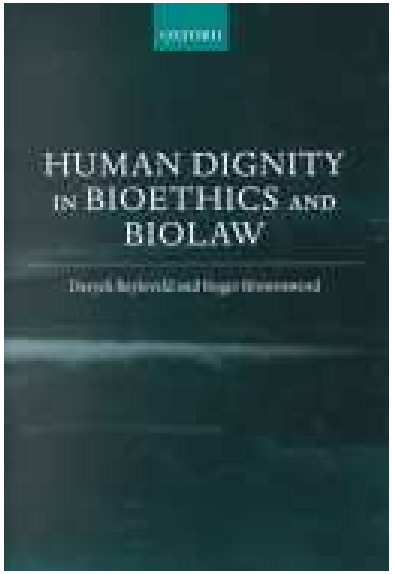
The result of these proposals would be a system that is more protective of human health and the environment, more efficient for industry and taxpayers, and better geared for responsible technology development.

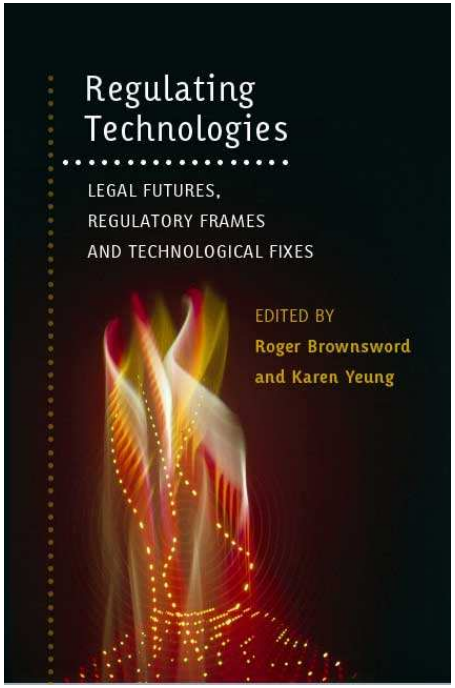
Conclusion

- Nanomedicine, like any emerging technology, does present serious regulatory challenges---concerning regulatory prudence, legitimacy, effectiveness, and connection. Getting the regulatory environment right is complex.
- However, we do not need to make exceptional provision for nanomedicine. We have the regulatory resources to handle it in a rational way.









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