Public Confidence & Policy-making for Enhancing Technologies: Lessons from the United Kingdom

CHARLOTTE ELVES*

Abstract

When thinking about how best to make policy in respect of enhancing technologies in the life sciences, there are important lessons to be learnt from the regulation of the life sciences in the United Kingdom. For a range of reasons, public confidence in policy-making is vital to both its efficacy and legitimacy. This is especially true in respect of novel or controversial technologies such as those used for human enhancement. Despite this, the value of public confidence appears to have been overlooked and undermined in policy-making and regulation over the past three decades.

This article takes two legislative case studies to demonstrate that publics might reasonably believe that the prime determinant of policy-making in the life sciences is technological capability — what we can do, rather than what we ought to do. The last section describes two steps that policymakers and legislators might take in order to avoid diminishing public confidence when thinking about regulating enhancing technologies. First, policymakers and legislators ought to address questions of secondary level regulation when promulgating primary level regulation. Secondly, policymakers and legislators ought to prioritise the values of social justice and solidarity over and above the value of individual welfare when deciding on whether any given innovation is permissible.

1 Introduction

When thinking about the role and importance of public perception in the regulation of enhancing technologies, there may be some temptation to ask why the opinions of the affected publics matter. After all, those best placed to determine the legitimacy, efficiency and propriety of any given scheme of regulation must be those scientists, policymakers, and legislators grafting away at the coal-face, who are well informed and well-intended. This view accords with what has become known as the information deficit model of public understanding of science. This model says that public scepticism with regard to scientific or technological progress is primarily attributable to the publics' lack of information or their misunderstanding.[1] This model of public understanding has

* Faculty of Law, University of Oxford. This article reflects the law and technological environment as at the time it passed double-blind peer review at January 2020.

[1] For a useful introduction, see Massimiano Bucchi, 'Of Deficits, Deviations and Dialogues: Theories of Public Communication of Science' in Massimiano Bucchi and Brian Trench (eds), *Handboook of Public Communication of Science and Technology* (Routledge, 2008).

become somewhat unpopular in recent years, and with good reason.[2] Instead, moves have been made toward developing dialogue-based models of public engagement, and these models have been deployed with varying degrees of success across a range of policy-making.[3]

This paper argues that public confidence in the regulation of enhancing technologies is of real importance, but has been undermined over the past three decades in the regulation of reproductive and genetic technologies within the United Kingdom ('UK'). The regularly shifting and sometimes contrary legislative positions explored throughout this paper distort public perceptions of the values identified and weighed in the policymaking process, and to that end, public confidence is undermined. This in turn carries significant implications for future regulatory decision-making in respect of novel or controversial technologies, such as those for human enhancement.

In July 2018, the Nuffield Council on Bioethics published a report on the social and ethical implications of heritable genome editing ('the Report').[4] The Report was a response to the relatively recent development of CRISPR-based gene editing technologies which allow for the precise editing of DNA sequences in living cells. As the Report states, CRISPR-based gene editing technologies make 'deliberately intervening in the human genome for the purposes of selecting traits of future children … a real and distinct possibility.'[5] The Report describes recent technological advances and their potential future uses. In doing so, it suggests that the development of heritable gene editing techniques places parents in a new 'epistemic position', where they have both the knowledge and access to the tools required to shape the lives of their future children.[6]

Interestingly, in describing these technologies as an object of regulation, the Report draws equivalence between them and conventional treatments for infertility. As such, the Report conceptualises these heritable genome editing technologies as technological aides to the exercise of reproductive choice. The decision to frame the technologies this way, while not the primary focus of this paper, is nevertheless interesting. The equivalence that the Report speaks to is perhaps less than obvious when one considers that the reproductive choice that parents exercise when opting for IVF is qualitatively different to that which they exercise when opting for heritable gene editing techniques. The former is done in

2 Brian Wynne, 'Public Understanding of Science' in Jasanoff et al (eds) *Handbook of Science and Technology Studies* (Sage, 1995) 361–89.

3 Jack Stilgoe, Simon J Lock and James Wilsdon, 'Why Should We Promote Public Engagement with Science?' (2014) 23 *Public Understanding of Science* 4.

4 Nuffield Council on Bioethics, *Genome Editing and Human Reproduction: Social and Ethical Issues* (Report, 2018).

5 Ibid vii.

6 Ibid 32.

the hopes of producing a genetically-related child while the latter is done in order to specify the genetic qualities of a future child.

After the Report scopes the technical considerations associated with heritable genome editing, Chapter Three moves on to consider the ethical, societal and regulatory implications of heritable genome editing. In its survey of the ethical landscape, the Report considers a range of standpoints: the welfare of the future child, the implications for societies and the implications that these technologies might have for human nature itself. The Report concludes that where a heritable genome editing technique does not adversely affect the welfare of the future person, is not socially divisive, and has been preceded by societal debate, it ought to be considered ethically permissible.[7]

Regarding governance, Chapter Four of the Report outlines the domestic legal position on heritable genome editing techniques, noting the prohibition on their use in the United Kingdom.[8] The legal prohibition follows from the fact that any gamete that is subjected to the techniques used to bring about heritable genome modification would not constitute a 'permitted gamete' for the purposes of section 3ZA of the *Human Fertilization and Embryology Act 2008* (UK).[9] However, the Report notes that there are no prohibitions in international law that would prevent the UK from bringing such gametes into the category of 'permitted gamete', therefore permitting the use of heritable genome editing techniques, provided the ethical pre-conditions described above are satisfied.[10]

The final chapter on Conclusions and Recommendations describes the position that the Council ultimately arrives at regarding the ethical permissibility of heritable genome editing. The Report notes that while at present the necessary conditions do not obtain, the Council can envisage circumstances in which heritable genome editing interventions ought to be permitted. Further, the Report suggests that the ethical and legal permissibility of any instance of heritable genome editing might be ascertained by reference to two principles:[11] first, the welfare of the future person, and second, social justice and solidarity. Therefore, where a proposed use of heritable genome editing does not adversely affect the welfare of the edited individual, and the values of social justice and solidarity are not denigrated, it ought to be permitted by regulation.

In response to the Nuffield Council's report, David Aaronwitch wrote that he supports the use of heritable genetic technologies 'not out of a sense of scientific inevitability but because allowing people to do what I would want to do for my

7 Ibid 96–7.

8 Ibid 100–53.

9 *Human Fertilisation and Embryology Act 2008* (UK).

10 Nuffield Council on Bioethics (n 4) 151.

11 Ibid 157.

children, and to avoid what I would want to avoid, seems the best principle'.[12] This mention of scientific inevitability perhaps reflects a perception by the public that the legal permissibility of genetic technologies in the UK is determined by technological capabilities —what science *can* do — rather than by sustained reflection on the societal and ethical implications of these technologies, or in other words, what science *should* do.

The political and legislative history of two high-profile issues explored below demonstrates that such a belief on behalf of both the public and the media is unsurprising. It is therefore unfortunate that the Nuffield Council's Report does little to disabuse readers of the notion that permissive regulatory frameworks are the inevitable sequelae of technological advancement. On the international stage, this view has perhaps been compounded by the appraisal of the regulatory environment tendered by one controversial CRISPR pioneer. When asked whether he might push ahead with his contentious research plans, Denis Rebikov initially stated that no edited embryos would be implanted without regulatory approval. He then suggested that 'laws are written to change them. As soon as we demonstrate the safety of technology, the rule will change.'[13] While the safety of techniques quite rightly ought to be a determinate of the regulatory position, it is just one among many. This nuance is eclipsed for publics and media alike when statements like Rebikov's, which equate technological capability with regulatory permissibility, appear to bear some truth once we reflect on the political and legislative histories of allied technological developments.

Scientists, policymakers, and legislators have to be aware of the messages that certain regulatory positions or approaches communicate. The latter part of this paper will discuss ways in which policy and legislation regarding enhancing technologies might be debated without exacerbating the harm that has been done to public confidence in regulatory decision making, and how it might move towards ameliorating such harm.

2 *The Importance of Public Confidence in the Regulation of the Life Sciences*

If I am to suggest that previous approaches to legislation in the life sciences have harmed public confidence and that that is a state of affairs to be avoided, I ought to make the case for the importance of public confidence in the first place. There are two different sorts of public confidence that matter when we are thinking

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12 David Aaronovitch, 'Fear of Eugenics Shouldn't Halt Gene Editing', *The Times* (online, 19 July 2018) <https://www.thetimes.co.uk/article/fear-of-eugenics-shouldn-t-halt-gene-editing-fscrzj9qp> last accessed 20 July 2018.

13 David Cyranoski, 'Russian "CRISPR-baby" Scientist Has Started Editing Genes in Human Eggs with Goal of Altering Deaf Gene', *NatureNews* (online, 18 October 2019) <https://www.nature.com/articles/d41586-019-03018-0> last accessed 23 October 2019.

about the regulation of enhancing technologies. The first goes to whether the technology being discussed is morally acceptable. If the public concerned finds the proposed practice morally unacceptable, they would have little reason for confidence in a regulatory scheme that permitted its use. The second aspect of public confidence relates to the public's perception of whether the regulations can avoid consequences that they have prudential reasons to wish to avoid, or whether it can promote other consequences that they have prudential reasons to desire.

Doubtless, there are other barometers of legitimacy and public confidence, particularly measures of input and output legitimacy, and these have been discussed in the literature elsewhere.[14] However, for the most part, when we debate the regulation of enhancing technologies and the role of public perception, it is the former sort of public confidence that we are talking about — it is the moral legitimacy of the regulation that matters.

Past history demonstrates that in the face of meagre public support (or even worse, public opposition) for the moral position adopted by a regulatory scheme, that scheme can fail to operate effectively. The starkest illustration of such a failure can be found in the attempts of the European Union to regulate GMOs in the early 1990s.[15] The implementation of *Council Directive 90/220/EEC* [1990] on the deliberate release of GMOs was met by popular protest, crop burning and the objection of numerous participating Member States.[16] By 1998, the British Press had whipped up a moral panic condemning 'frankenfoods' and the assault on nature that their production allegedly entailed.[17] These factors in turn lead to what many describe as the de facto moratorium on the authorisation of GMOs that ended only with the introduction of a new scheme of regulation, the

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[14] See, eg, Grace Skogstad, 'Legitimacy and/or Policy Effectiveness?: Network Governance and GMO Regulation in the European Union'(2001) 10(3) *Journal of European Public Policy* 321.

[15] Without wishing to comment on the relationship between moral and prudential reasons, given that prudential concerns regarding risk might also be characterised as moral concerns regarding avoidable harms, we can understand the clear public objection as moral in nature, once combined with other wholly moral concerns about interference with nature and 'playing god'. For an elucidation of the relationship between moral and prudential reasons, see Roger Crisp, 'Prudential and Moral Reasons' in Daniel Star (ed), *The Oxford Handbook of Reasons and Normativity* (Oxford University Press, 2018).

[16] *Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms* [1990] OJ L 117/15. Regarding the nature of the moratorium, see Sarah Lieberman and Tim Gray, 'The So-called "Moratorium" on the Licensing of New Genetically Modified (GM) Products by the European Union 1998–2004: A Study in Ambiguity' (2006) 15 *Environmental Politics* 592.

[17] Editorial, 'Frakenstein Foods', *The Economist* (online, 18 February 1998) <https://www.economist.com/leaders/1999/02/18/frankenstein-foods> last accessed 20 July 2018.

embodiment of which began in *Council Directive 2001/18*.[18] It is notable that this new scheme of regulation focused on public participation in a way that the former scheme had not.[19]

That public perception of the moral legitimacy of a certain technology or its regulation can have such significant impacts on the proper function of regulation is unsurprising given the socio-cultural value it can bear. As Brownsword and Goodwin note:

> Perceptions of the moral legitimacy of the regulatory instruments and regimes go therefore not only to the efficiency of the instruments themselves but to matters of social and political cohesion and ultimately to the (self-) identity of the community itself.[20]

As such, whether or not we subscribe to information deficit-based models of public understanding of science, and whether or not we are skeptical of the utility of public opinion in policymaking, we have good reason to invest in the promotion of public confidence in regulation. Further, following the dominant position within political philosophy, if we are to pay due heed to the democratic ideals of policy-making within liberal societies, we have a duty to ensure that public confidence is promoted in well-informed, well-resourced, and open fora.[21]

3 Life Sciences Legislation and Policy-Making in the UK

In the above section, we scoped the reasons why public confidence in the regulation of enhancing technologies might be important. This section develops a critique of regulatory, legislative, and political changes that have taken place in the United Kingdom, looking at two examples: animal/human hybrid embryos and the 14-day Rule. The argument here is that a diachronic assessment of the regulation of these issues would give publics reason to believe that the regulation of genetic technologies is dictated by technological capabilities, rather than by sustained reflection on the societal and ethical implications of such technologies. To that end, Aaronvitch's comments about scientific inevitability are hardly

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18 *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC* [2001] OJ L 106/1.

19 For this specifically, and a helpful introduction to the regulation of GMOs in Europe prior to the 2001 Directive more generally, see Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Elgar, 2008) 2–11.

20 Roger Brownsword and Morag Goodwin, *Law and the Technologies of the Twenty-First Century* (Cambridge University Press, 2012) 172.

21 For a discussion of the justifications for requiring democracy in political decision making, see Fabienne Peter, 'The Epistemic Circumstances of Democracy' in Michael Brady and Miranda Fricker (eds), *The Epistemic Life of Groups: Essays in the Epistemology of Collectives* (Oxford University Press, 2016).

surprising. For many, the drive behind much regulatory decision-making appears to be what we *can* do (as a matter of scientific possibility or technological capability) rather than what we *should* do.

As Fox notes, in the United Kingdom, this perception is only exacerbated by the real but oftentimes unarticulated desire to maintain the position of the United Kingdom as a world leader in the fields of reproductive technologies and embryology.[22] As time has passed, this previously unarticulated desire to remain at the vanguard of life science innovation has been articulated, and indeed was explicitly referenced in the Government's response to the 2014 consultation on mitochondrial donation.[23] This desire as identified by Fox is only one of a number of political and economic determinants of policy that further militate towards an approach dictated by technological capability rather than sound ethical thinking. Beyond the realm of reproductive technologies, the 2015 House of Lords report on genetic insect technologies referenced economic benefit as a justification for a more permissive regulatory environment in respect of GMO insect production and research.[24]

These various political and economic determinants go some way to explaining why the preferred regulatory or policy approach is one that is seen to favour further innovation, rather than a sustained analysis of the societal, cultural, or ethical desirability of pursuing such innovation. The two examples of legislative development discussed below provide an illustration of the effects that these desires and determinants have in practice.

3.1 Animal/Human Hybrid Embryos

In the UK, the Human Fertilisation and Embryology Authority (the 'Authority') is created under the *Human Fertilisation and Embryology Act 2008* (UK) ('HFEA') as the statutory body responsible for regulating fertility treatment and embryo research in the United Kingdom. Section 4(6) of the Act permits the creation of 'human admixed embryos'.[25] What this means, in both theory and in practice, is that the Authority may, under certain conditions, grant researchers a license to create human/animal hybrid embryos for research. The nature of these human/animal hybrid embryos can vary and much discussion has been given

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22 Marie Fox, 'Legislating Interspecies Embryos' in Stephen W Smith and Ronan Deazley (eds), *The Legal, Medical and Cultural Regulation of the Body: Transformation and Transgression* (Routledge, 2009) 96.

23 Health Science and Bioethics Division, Department of Health (UK), *Mitochondrial Donation* (Paper, 2014) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/332881/Consultation_response.pdf> last accessed 15 October 2019.

24 Science and Technology Committee, *GM Insects* (House of Lords Paper No 68, Session 2015–16) 30.

25 *Human Fertilisation and Embryology Act 2008* (UK) s 4(6).

over the distinction between 'cytoplasmic hybrids' and 'true hybrids'. [26] 'Cytoplasmic hybrid' refers to embryos created by combining nuclei from human cells with enucleated animal eggs, while 'true hybrid' refers to those embryos created by the combination of human and animal gametes.[27] The fact that this piece of legislation permits the creation and use of both techniques for creating human/animal hybrids is perhaps somewhat surprising, given the recorded public and governmental opinion that preceded the Act.

The technological capacity to create human/animal hybrid embryos was developed in 2005 and discussions about the permissibility of the practice began in earnest in 2006 when the Authority received two applications seeking a license to create hybrid embryos.[28] In November of the same year, the Government published a White Paper proposing a blanket ban on the creation and use of human/animal hybrid embryos, thus prohibiting the creation of both cytoplasmic hybrids and true hybrids.[29]

Having sought legal advice, and following the purposive interpretation of 'human embryo' favoured by the House of Lords in *Regina v Secretary of State for Health ex parte Quintavalle (on behalf of Pro-Life Alliance)*, the Authority announced that the issuing of licenses with respect to the creation and use of human/animal hybrid embryos fell within their remit.[30] For the time being, however, the Authority reserved deliberation on the applications and launched a public consultation. Two of the five questions posed were as follows:

- Q3. Do you think that the law should in future permit the creation of true hybrid embryos for licensed research purposes?
- Q4. Do you think that the HFEA should in future issue licenses to allow research using human chimera embryos?

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26 Fox (n 22).

27 For an interesting analysis of the way this distinction was presented to the public, see Nicole Zeegers, 'Devolved Regulation as a Two-Stage Rocket to Public Acceptance of Experiments with Human Gametes and Embryos: A UK Example to be Followed by the Netherlands' (2014) 1(1) *European Journal of Comparative Law and Governance* 10.

28 For details regarding the specifics of these applications and their proposed research purposes, see Human Fertilisation and Embryology Authority, 'HFEA Statement on Licensing of Applications to Carry Out Research Using Human-Animal Cytoplasmic Hybrid Embryos' (Statement, 2007) <https://www.hfea.gov.uk/en/377.html> last accessed 21 July 2018.

29 Department of Health (UK), *Review of the Human Fertilisation and Embryology Act: Proposals for Revised Legislation (Including Establishment of the Regulatory Authority for Tissue and Embryos)* (Cm 6989, 2006) 25.

30 *Regina v Secretary of State for Health ex parte Quintavalle (on behalf of Pro-Life Alliance)* [2003] UKHL 13.

Francoise Baylis has noted the numerous flaws of this consultation and suggested that its primary purpose was not a genuine engagement with public opinion but rather a cynical effort to fend off the possibility of future legal challenge.[31] For our purposes here, it is pertinent that the response of a number of legal academics and ethicists to questions three and four above were framed not by reference to ethical or legal principles, but instead by reference to the technological capabilities (or lack thereof) of the time.[32]

Ultimately, the Authority's public consultation reaffirmed its own policy preference for a permissive regulatory response to human/animal hybrids without having provided the public with an impartial assessment of the possible policy positions. The conclusion of their consultation supported the grant of licenses to create cytoplasmic hybrids. However, in recognition of public anxiety with regard to true hybrids, as well as the lack of current technological capability for their creation, the Authority rejected the possibility of granting licenses for the research using true hybrids.[33] This compromise appeared to reconcile the wants of the research community with anxieties of the public. However, not only was this a lost opportunity for impartial and meaningful public engagement on an issue that was, at the time, high profile, it might also have served to reinforce the notion that the regulation of science and technology is predicated on technological capability, rather than rigorous reflection on ethical, societal, or cultural values.

At roughly the same time, the Science and Technology Select Committee articulated their disagreement with the Government's proposed blanket ban on the creation of human/animal hybrid embryos.[34] Foreshadowing the conclusions of the Authority, the Government's draft of the Human Tissue and Embryo Bill met the Science and Technology Committee halfway. It proposed a permissive approach to the use and creation of cytoplasmic hybrid embryos, but reaffirmed their proposed prohibition on the creation and use of true hybrid embryos, which in any case could not yet be created by technology.[35] However, all semblance of compromise was undone when the Joint Committee of both Parliamentary Houses recommended a permissive regulatory approach with regard to the use

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31 Francoise Baylis, 'The HFEA Public Consultation Process on Hybrids and Chimeras: Informed, Effective, and Meaningful?' (2009) 19(1) *Kennedy Institute Ethics Journal* 41, 59.

32 For responses, see, eg, Centre for Law, Gender and Sexuality, University of Kent (Document, 2007) <https://www.kent.ac.uk/clgs/documents/pdfs/CentreResponceToHFEA07_000.pdf> 21 July 2018.

33 Human Fertilisation and Embryology Authority, 'Statement on Licensing Applications to Carry Out Research Using Human-Animal Cytoplasmic Hybrid Embryos' (Press Release, 17 January 2007).

34 *Science and Technology Select Committee, Government Proposals for the Regulation of Hybrid and Chimera Embryos* (House of Commons Paper No 272-1, Session 2006–07)

35 Human Tissue and Embryos (Draft) Bill 2007 (UK).

and creation of both types of human/animal hybrid embryos.[36] On 13 November 2008, the HFEA was enacted, with section 4(6) providing for the creation of both types of human/animal hybrid embryo.[37] Thus, within 18 months of the technological possibility of creating human/animal hybrid embryos being realised, the proposed regulatory position as it had played out in the public arena shifted from total prohibition, in line with public and governmental opinion, to a permissive licensed-based approach allowing for the creation of both cytoplasmic and true hybrid embryos.

3.2 14-day Rule

In 1984, the report of the Committee on the Inquiry into Human Fertilisation, chaired by Baroness Warnock, recommended that a 14-day limit be imposed on *in vitro* embryo research.[38] That is, no research should be conducted on human embryos past the fourteenth day following fertilisation. Some years later, this recommendation became enshrined in English and Welsh law by virtue of s 3(3)a of the *Human Fertilisation and Embryology Act 1990* (UK).[39]

Until relatively recently, the 14-day rule posed few barriers to research given our inability to maintain human embryos in culture beyond 7–9 days.[40] However, this changed in 2016 when two separate research teams, one at the University of Cambridge and another at Rockefeller University in New York, developed a protocol for the culturing of human embryos *in vitro* up until the 14-day mark.[41] Both the Cambridge and the Rockefeller lab were able to maintain at least one human embryo in culture for 14 days, at which point the embryos were destroyed in accordance with English and Welsh law[42] and, in the case of the Rockefeller lab, in accordance with United States' national guidelines.[43] This technological advancement rapidly raised questions about the continuing utility of and

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36 Joint Committee on the Human Tissue and Embryos (Draft) Bill, *Human Tissue and Embryos (Draft) Bill* (House of Commons Paper No 630-I, House of Lords Paper No 169-I, Session 2006–07).

37 *Human Fertilisation and Embryology Act 2008* (UK).

38 Department of Health and Social Security (UK), *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (Cm 9314, 1984).

39 *Human Fertilisation and Embryology Act 1990* (UK) s 3(3)(a).

40 Insoo Hyun, Amy Wilkerson and Josephine Johnston, 'Embryology Policy: Revisit the 14-day Rule' (2016) 533 *Nature* 169.

41 A Deglincerti et al 'Self-Organization of the *In Vitro* Attached Human Embryo' (2016) 533 *Nature* 251; M N Shahbazi et al, 'Self-Organization of the Human Embryo in the Absence of Maternal Tissues' (2016) 18 *Nature Cell Biology* 700.

42 *Human Fertilisation and Embryology Act 1990* (UK) s 3(3)(a).

43 National Institute of Health (UK), *Report of the Human Embryo Research Panel* (National Influence of Health Report, 1994).

justification for the 14-day rule. It sparked numerous calls to reopen the debate with a view to abolishing, or at least amending the rule.[44]

The majority of those calls justified the desired extension to the 14-day rule on the basis of ethical claims rooted in beneficence — that to fail to allow research beyond 14-days eschews a moral imperative to pursue the valuable therapeutic and/or humanitarian benefits that such research would surely yield.[45] Others pointed to the idea that the 14-day rule recommended by the Warnock report did not reflect a principled ethical position, but was rather a pragmatic approach, brokered to avoid a stand-off between parties with irreconcilable views.[46] As such, amending the rule would not offend against any identifiable principle. Those opposed to the extension argued that the 14-day rule represented a principled moral position vis a vis the moral status of embryos or, even if it did not (because moral status is instantiated prior to the fourteenth day), any relaxation of the rule would cause further moral harm.[47]

Much has been said about the pragmatic character of the compromise that the 14-day rule reflects.[48] However, for our purposes, it is more important to think about the communicative value of the rule and public perception of it.[49] Within many related debates regarding the regulation of reproductive or genetic technologies, the 14-day rule has acted as a gate keeper, inducing confidence and allaying concerns by imposing constraints on the seemingly controversial research practice in question. In the context of the human/animal hybrid embryo debate

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44 Giula Cavaliere, 'A 14-day limit for Bioethics: The Debate over Human Embryo Research' (2017) 18 *BMC Medical Ethics* 38; Patrick Foong, 'Destroying Research Embryos within 14 Days Limits Chance of Medical Breakthroughs', *The Conversation* (online, 29 January 2017) <https://theconversation.com/destroying-research-embryos-within-14-days-limits-chance-of-medical-breakthroughs-71986> last accessed 18 July 2018; John Harris, 'It's Time to Extend the 14-Day Limit for Embryo Research', *The Guardian* (online, 6 May 2016) <https://www.theguardian.com/commentisfree/2016/may/06/extend-14-day-limit-embryo-research> last accessed 18 July 2018.

45 Insoo Hyun, Amy Wilkerson and Josephine Johnston, 'Embryology Policy: Revisit the 14-day Rule', *NatureNews* (online, 4 May 2016) <https://www.nature.com/news/embryology-policy-revisit-the-14-day-rule-1.19838>.

46 M Brazier, 'Embryos' Rights: Abortion and Research' in Michael Freeman (ed), *Medicine Ethics and Law: Current Legal Problems* (London Stevens, 1988)16.

47 See the contribution of Professor David Jones in Nuffield Council on Bioethics, *Human Embryo Culture: Discussion Concerning the Statutory Time Limit for Maintaining Human Embryos in Culture in Light of Some Recent Scientific Developments* (Report, 2017) 69–72.

48 Duncan Wilson, *The Making of British Bioethics* (Manchester University Press, 2014) 161–6.

49 R M Hare, '*In Vitro* Fertilisation and the Warnock Report' in Ruth Chadwick (ed), *Ethics, Reproduction and Genetic Control* (Croom Helm, 1987); M Lockwood, 'The Warnock Report: A Philosophical Appraisal' in M Lockwood (ed), *Moral Dilemmas in Modern Medicine* (Oxford University Press, 1985) 155–86.

discussed above, much store was placed in the idea that if the use of these hybrids were allowed, it would be constrained by the 14-day rule.

This was reflected in some of the assurances made during the Authority's 2007 public consultation process.[50] Further, regular reference to the 14-day rule as a safeguard or as a chock, blocking the otherwise inevitable slide down an ethical slippery slope, has been made during the course of various Parliamentary debates. In the House of Lords debates regarding the possibility of broadening the criteria upon which licenses might be granted for embryonic research, Lord Hunt, among others, pointed to the 14-day rule as an assurance in support of such a move.[51] During the second reading of the Human Reproductive Cloning Bill, Members of Parliament once again referred explicitly to the safeguarding function of the 14-day rule.[52] More recently, in the House of Commons during debates on mitochondrial replacement, Jane Ellison was not alone in making similar reference to the role of the 14-day rule as a safeguard.[53]

As such, whether or not we believe the 14-day rule reflects a principled ethical position regarding the moral status of the embryo, it has come to be offered up as a stop against ethical folly and has consequently taken on further function and value. Across a range of genetic technologies or biotechnological innovations, the 14-day rule has been presented in policy-making as a threshold beyond which policy will not push, and beneath which any activity is considered, prima facie, ethical. Given this, it would appear unfortunate if the first point at which the continued propriety of the 14-day rule was called into question was at the very time that it might, realistically, be breached. The opportunity costs associated with reopening this debate have been discussed elsewhere, most often in the context of abortion debates.[54]

I suggest here, however, that an otherwise overlooked opportunity cost exists in the guise of harm to public confidence and the reinforcement of the notion that the primary driver in debates of this nature is the current technological capability, rather than considered reflection on societal and ethical implications. With that in mind, the next section will offer some suggestions as to how we might engage

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50 Human Fertilisation and Embryology Authority, *Hybrids and Chimeras: A Consultation on the Ethical and Social Implications of Creating Human/Animal Embryos in Research* (Report, 2007).

51 United Kingdom, *Parliamentary Debates*, House of Lords, 22 January 2001, vol 621, col 117 (Lord Hunt of Kings Heath).

52 United Kingdom, *Parliamentary Debates*, House of Commons, 29 November 2001, vol 375, col 1180 (Dr. Evan Harris).

53 United Kingdom, *Parliamentary Debates*, House of Commons, 1 September 2014, vol 585, col 122 (Jane Ellison).

54 Nuffield Council on Bioethics, *Human Embryo Culture: Discussion Concerning the Statutory Time Limit for Maintaining Human Embryos in Culture in Light of Some Recent Scientific Developments* (Report, 2017).

in public debates and policy-making with regard to enhancing technologies, without giving publics the impression that policy decisions are predicated upon scientific inevitability.

3 Future Directions for Debating and Presenting Policy-making for Enhancing Technologies

Where then, does this leave us when thinking about how best to promulgate policy for enhancing technologies? There may be some temptation to think that the conclusion of the Nuffield Council's Report might be chalked up as a continuation in the worrying trend of life sciences policy being dictated by the scientific inevitability described above. However, the outlook need not be quite so bleak, as the Report itself contains some of the means by which such impressions might be avoided.

Writing in the midst of a series of technological advances that yielded novel dilemmas, Roger Brownsword noted the difference between primary and secondary level regulation.[55] Primary level regulation, he suggests, seeks to 'control, confine and channel *ex ante* the particular aspect of genetic practice that is its target'.[56] By contrast, secondary level regulation 'operates *ex post*, endeavouring to compensate for, or adjust in response to, the consequences of a genetic practice that cannot be controlled by primary level legislation'.[57] Thinking about enhancing technologies, the questions we would ask in the context of primary level regulation would revolve around permitting or prohibiting a certain practice. On the other hand, questions around secondary level regulation might ask how we could prevent the practice from exacerbating pre-existing social inequalities. It is argued here that the distinction Brownsword draws ought to be afforded greater prominence, not only in terms of shaping debates regarding the regulation of enhancing technologies, but also in supplying the substantive content of such regulation.

Many of the problems noted above are, to some extent, a result of incrementalism in the arena of science and technology regulation. At times, incrementalism is justifiable — there are certain instances in which legislators must act in a sufficiently timely and moderate fashion in order to avoid something like the Collingridge dilemma.[58] In these circumstances, policymakers and legislators

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55 Roger Brownsword, 'Regulating Human Genetics: New Dilemmas for a New Millennium' (2004) 12(1) *Medical Law Review* 14, 16.

56 Ibid 16.

57 Ibid.

58 David Collingridge, *The Social Control of Technology* (St Martin's Press, 1980). The dilemma lies in the difficulty between regulating a technology early when it is young, or late after it is better developed and more widely used. When it is still young, regulation is easier but the technology's undesirable impacts are likely yet to be known. On the other hand, later regulation will be more well-informed, but there is

might openly and fully anticipate that further data about the technology could militate in favour of a different regulatory position and demonstrate a willingness to act accordingly if, and when, such a time comes. The more pernicious form of incrementalism, however, trades on a series of bargains and promises driven by the scientific imperative. Arguably, it is this incrementalism that we saw in the legislative process for human/animal hybrid embryos. Such incrementalism is made possible by focusing on narrow issues and putting off patently inevitable questions regarding allied technologies or likely future directions of travel. This was the state of affairs we witnessed in the setting and answering of questions in the Human Fertilisation and Embryology Authority's public consultation. It is incrementalism of this sort that entrenches regulatory positions once the technology in question has become established and reinforces the view that the utility of the technology is the primary regulatory determinant.

These arguments might appear as though they are claiming to observe slippery slopes in action throughout and across the legislative process effecting the regulation of reproductive and genetic technologies in the United Kingdom. After all, what else can undesirable incrementalism be, but the real-time slide down the slippery slopes of which we are so often warned? However, the arguments here intend to assert no such thing. I do not wish to suggest that the regulation of reproductive and genetic technology over the past twenty years vindicates concerns with regard to slippery slopes, because I do not claim to offer a position on the ethical or empirical actualities of the legislation. Rather, what I am concerned about demonstrating is that appearances of the incrementalism described above can do real harm to public confidence in policy-making and regulation and to public understanding of science.

Requiring policymakers, public debates and legislators to address questions associated with the secondary level of regulation might serve as a helpful tool to avoid such incrementalism. The very process of considering our options from the perspective of secondary level regulation requires us to look further and more critically into the future, compared to that required when taking the primary level approach. Further, taking into account our possible secondary level regulatory options (even in the promulgation of primary level regulation) might serve to highlight the bases on which debates might, in the future, be reopened. Paying proper attention to the reasons for which we might revisit certain legislative positions and articulating them clearly is important if we are to demonstrate that not all forward movement is a result of advancing technological capability. Instead, by debating the reasons for which regulation might be reopened in the future, it demonstrates that increasingly permissive policy might be justified on the basis of changing social, political and cultural values or circumstances, rather than because of technological capability alone.

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the risk that technology will have already developed to a stage where one loses control over its regulation.

We can, for example, imagine a situation in which we should favour primary level regulation prohibiting a technology that, if unavailable to all, would exacerbate existing social inequalities. However, if we turned our minds to possible secondary level regulatory solutions, we might recognise that state-funded provision of the technology might be a feasible way to overcome the reasons supporting prohibition. Thus, if in the future the technology became sufficiently affordable such that state-funded provision could be established, we would recognise the existence of legitimate reasons for re-visiting the question of prohibition. Of course, if, despite the technology's affordability, the state decided against providing public funding for the technology in question, we would have no reason to revisit our primary level regulation. Thus, I suggest that discussion of secondary level regulatory options ought to be prominent within public debates and policy-making in the context of enhancing technologies.

Impressions of incrementalism might also be avoided in a further way. The second recommendation I make here relates to the priorities between the values that we articulate and weigh within public debates and policy-making. In the development of policy for the regulation of enhancing technologies and in the communication of that policy to the public, priority should be given to the values of justice and fairness, over and above the results of the utilitarian calculus. That both of these sets of considerations enter into, and even compete with one and other, in policy-making was reflected by Baroness Warnock.

> Technology has made all kinds of things possible that were impossible, or unimaginable in an earlier age. Ought all these things be carried into practice? This is the most general ethical question to be asked about genetic engineering, whether of plants, animals, or humans. The question may itself take two forms: first, we may ask whether the benefits promised by the practice are outweighed by its possible harms. This is an ethical question posed in strictly utilitarian form … It entails looking into the future, calculating probabilities, and of course evaluating outcomes. 'Benefits' and 'harm' are not self-evidently identifiable values. Secondly we may ask whether, even if the benefits of the practice seem to outweigh the dangers, it nevertheless so outrages our sense of justice or of rights or of human decency that it should be prohibited whatever the advantages. [59]

The benefit of privileging assessments of justice and fairness when thinking about the regulation of enhancing technologies is that it enables us to insulate policy-making from the ever swinging and fast changing utilitarian calculus. The latter is more profoundly altered by advancing technological capabilities than considerations of justice and fairness. Insulating policy-making from the rapid cycling of the utilitarian calculus might well avoid providing publics with the

[59] Baroness Mary Warnock, 'Philosophy and Ethics' in C Cookson, G Nowak and D Thierbach (eds), *Genetic Engineering: The New Challenge* (European Patent Office, 1993) 67.

impression that technological capability is the primary determinant of the regulation of enhancing technologies.

The Nuffield Council's Report discussed above concludes that heritable genome alteration would be permissible where two criterion are satisfied:

1. The alteration made is not contrary to the welfare of the individual in receipt of the genetic intervention; and

2. The use of gametes or embryos that have been subject to genome editing procedures cannot reasonably be expected to produce or exacerbate social division or the unmitigated marginalisation or disadvantage of groups within society.[60]

While there might be the temptation to consider the Report's conclusion a further demonstration of incrementalism in policy-making, as was suggested earlier, this need not be the case. Following from the championing of fairness- and justice-based assessments of enhancing technologies, I argue that in the context of Nuffield's timely contribution, we have good reasons to prioritise the second principle they offer up: evaluations of the social justice and solidarity implications of a technology. Such approach can abate concerns that policy-making in accordance with the Nuffield's Council's guidance ultimately produces policy determined by technological capability. Assessments of how a technology impacts the welfare of individuals are often more intimately connected to the realities of technological capability than assessments of social justice or fairness. As such, prioritising the latter avoids making policy that appears to be determined by technological capability alone.

Borrowing from a recent example in the scientific literature, we can see this effect in practice. Discussions regarding the permissibility of heritable genome editing have been fuelled by the development in 2015 of CRISPR-based gene editing technologies.[61] In their report, the Nuffield Council refer explicitly to the development of CRISPR as the impetus for convening the working group.[62] On the basis of data examining the technological capabilities, many have argued that its use should be allowed by reference to the ethical principle of beneficence and the ability of the technology to improve the welfare of individuals.[63] Taking into account evidence of the potential benefit of CRISPR-based genome editing for individuals, the utilitarian calculus weighs in favour of a permissive regulatory approach. However, data recently published in *Nature* demonstrates that the

60 Nuffield Council on Bioethics (n 4).

61 Martin Jinek et al, 'A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity' (2012) 337 *Science* 816.

62 Nuffield (n 4) vii.

63 Christopher Gyngell, Hilary Bowman-Smart and Julian Savulescu, 'Moral Reasons to Edit the Human Genome: Picking Up from the Nuffield Report' (2019) 45 *Journal of Medical Ethics* 514.

deleterious effects of CRISPR-editing causes far more damage to the human genome than had previously been anticipated and therefore should not be used for human applications.[64] In this instance, taking account the potential harm (or at least, lack of benefit) that CRISPR-editing might cause the individual, the utilitarian calculus would not weigh in favour of a permissive regulatory approach. This example illustrates the ways in which issues of technological capability and utilitarian calculations might confound one another in the process of policy-making. In contrast, an assessment of concerns based on social justice or solidarity would likely weigh against a permissive regulatory approach in both cases, given the societal inequalities that such a technology might exacerbate, regardless of its safety for individuals.

In this paper, I have sought to argue that legislative positions adopted in the United Kingdom over the last two decades have paid little heed to, and may in fact have reduced, public confidence in the life sciences regulation. We have good reasons to seek out and promote public confidence in the regulation of emerging technologies. These range from the democratic to those focused on the operational effectiveness of regulation. Arguably, they will only become stronger and more numerous as enhancing technologies continue to advance and we begin to develop enhancement technologies capable of affecting not just individuals but our commonly-held social and cultural experiences, positions, and values. If we are to promulgate effective, future proof, and ethically sound policy for enhancing technologies, we would do well to reflect on some of the flaws of policy-making in the life sciences over the last three decades.

It is incumbent on policymakers and legislators to ensure that policy-making in the arena of enhancing technologies is not determined by scientific imperative and current technological capabilities. However, it is just as important that policy decisions or legislative positions are communicated in a way that avoids leaving publics with the impression that it is technological capability (or 'scientific inevitability', as Aaronvitch put it) that determines how decisions are made.

There are a number of ways that we might avoid misleading publics as to the primary bases of our decision-making. Among those, two are of particular importance. The first involves engaging in discussions about what we think secondary level regulation should look like if primary level regulation were to permit the practice in question. This helps us to articulate the circumstances under which any given regulatory position might be revisited or even reversed in the future. The second involves prioritising questions of society over and above those of the individual when both promulgating and communicating policy with regard to enhancing technologies. Only in these ways can we avoid impressions of cynical incrementalism.

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64 Michael Kosicki, Kart Tomberg and Allan Bradley, 'Repair of Double-Strand Breaks Induced by CRISPR-Cas9 Leads to Large Deletions and Complex Rearrangements' (2018) 36 *Nature* 765.