What’s law got to do with human germline editing?

Ilke Turkmendag
Senior Lecturer in Law, Innovation, & Society, Newcastle University

Thérèse Murphy
Professor of Law, Queen’s University Belfast

Our co-authored (Fox, Murphy, Thompson, and Turkmendag) Debate & Dialogue was published in the June 2019 print issue of Social & Legal Studies. Entitled ‘What’s Law got to do with Good Science?’, it was an engagement with Charis Thompson’s book, Good Science: The Ethical Choreography of Stem Cell Research (MIT, 2013). As the title suggests, in the article we addressed the relationship between law and science, focusing on three areas taken up in Thompson’s monograph, which we selected based on our research interests, namely:

1. the place of human rights in the regulation of science and technology
2. the regulatory aspects of mitochondrial donation, and
3. the politics of animal research and animal rights.

In writing the Debate & Dialogue, our aim was to contribute to the ongoing conversation about science and its relationship to law, ethics and society, to which Charis Thompson provided a thoughtful response. In the same spirit, in the following we provide some reflections on how the law relates to the current debates on an emergent technique, human germline editing (HGE).

Recent attempts at altering embryos

Around the time our Debate & Dialogue was accepted, there was an uproar about a controversial clinical application of an emergent biomedical technology. In November 2018, a Chinese researcher, He Jiankui, announced that he had used CRISPR/Cas9 to create embryos resistant to HIV, and implanted them into a woman, culminating in the birth of a set of twins. He Jiankui claimed to have altered a gene called CCR5, with the hope of offering people living with HIV a chance to have a genetically related child without HIV. There is not enough evidence to confirm whether He’s alteration worked. Moreover, some scientists contend that people with altered CCR5 genes may be more susceptible to certain diseases. In any case, the fact that germline interventions are banned in 30 countries (Araki and Ishii 2014), and prohibited by a number of international human rights instruments, did not stop He going ahead and creating the world’s first-reported genetically edited babies.

However, once it was reported, He’s action met with widespread condemnation, including from the Chinese government, which issued draft regulations in February 2019 to restrict the use of gene editing in humans. Furthermore, 18 scientists and ethicists from seven countries called for a moratorium on all clinical uses of HGE (Lander 2015). However, just a few months later, in both June and July 2019, a molecular biologist from Russia, Denis Rebrikov,

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1 Genome editing technology CRISPR/Cas9 enables deliberate alterations to be made in the DNA of living organisms. There has been a great deal of controversy about the possibility of using genome editing for human germline intervention in which human embryos, sperms or eggs are modified to influence the characteristics of a future person. This process, Heritable Genome Editing (HGE), can be potentially used both to prevent transmission of a genetic disorder and to enhance human traits (https://www.liebertpub.com/doi/10.1089/crispr.2018.0040).

2 See eg the Universal Declaration on the Human Genome and Human Rights (UNESCO 1997).
announced that he too intends to edit human embryos. Previously in June, Rebrikov had announced plans to create HIV-resistant embryos by disabling their CCR5 gene and implanting them to mothers with HIV. Responding to Rebrikov’s initial claim, the Association for Responsible Research and Innovation in Genome Editing, the Genome Writers Guild and the Japanese Society for Genome Editing published a joint statement. Referring to clinical applications as ‘irresponsible experiments’, they have called for a comprehensive framework for the international regulation of human germline editing activities and to prevent clinical applications leading to live births before they are deemed safe.

**Self-governance**

HGE has previously seen attempts at self-governance, with international Gene Editing Summits held first in 2015 (Washington DC) and then in 2018 (Hong Kong), convened by the US National Academy of Sciences and the US National Academy of Medicine, the Royal Society of the United Kingdom, and the Academy of Sciences of Hong Kong. The 2015 summit accepted that HGE would be ‘irresponsible’ until safety issues were addressed. It was during the second summit that He presented his work. Two statements published in its aftermath emphasised that clinical use of germline editing remains irresponsible at this time. However, these statements have no binding authority, and it seems as though the message is not strong enough to stop scientists trying the techniques to create gene edited babies.

There have also been some mixed signals. Take the UK as an example. In 2015, with the coming into effect of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations, genetic modification enabling the conception of children without mitochondrial disease was permitted. In 2016, the Human Fertilisation and Embryology Authority, the UK’s independent regulator overseeing fertility treatment and research, granted its first licence permitting CRISPR/Cas9 on human embryos for research purposes. And 2018 brought perhaps the clearest sign of an emerging permissive approach with the publication of a report from an independent but influential body, the Nuffield Council on Bioethics, which concluded that modifying eggs, sperm and embryos destined for the womb to avoid disease, could be morally permissible under certain conditions. Four conditions were listed: the techniques (1) must be in the best interest of the resulting child, (2) must not increase discrimination, (3) must be safe, and (4) well-regulated.

**A discourse of hope**

Arguably, the main force behind the pressure for more permissive regulation of HGE is a ‘discourse of hope’. This is akin to what the sociologist Michael Mulkay observed during the embryo debates in the UK in 1990s, which led to the regulation of human embryo research and IVF treatment (see also Jacob and Prainsack 2010). In the context of HGE, there are two main features of the discourse of hope:

1. enhancing reproductive autonomy: Giving people who have transmittable or inheritable disease and disorders a choice to have a healthy genetically-related baby.

In this context, new reproductive technologies and repro-genetic interventions are seen as tools, which will protect not only the right to respect for private and family life but also a ‘right to have a healthy child’, a framing that the UK public became familiar with during the Mitochondrial Replacement Techniques debate (Turkmendag 2017). The framing of HGE as a reproductive tool also demonstrates the perceived importance of having a genetically related baby to some couples and individuals, a desire that has to be taken into account in the HGE debate rather than ignored or condemned.
2. not falling behind: As Brian Salter and Alex Faulkner argue, ‘innovation in biomedicine is a global enterprise’ and the global players in the life sciences do not want to fall behind.

Creating a permissive but well-regulated environment for basic research and potential clinical applications will avoid scientists moving to more permissive or unregulated jurisdictions. In this context, strict regulations are seen as an obstacle to innovation and scientific progress.

In our Debate & Dialogue, we emphasised that ‘good science’ should be ‘safe and fair’. In the discourse of hope, which focuses on enhancing reproductive autonomy and supporting scientific progress, safety and fairness are often underplayed. Publics are supposed to trust that HGE is ‘good science’, and that clinical applications will be performed in a responsible manner. However, in the context of HGE, ‘safety’ cannot be guaranteed until the techniques are tried on human subjects who are created using the said techniques. In other words, ‘safety’ is a gamble with the future health of the resultant child. Scientists and clinicians might see such genetically edited babies as their first human trial and, arguably, some parents would be willing to take the risk as a part of exercising their reproductive autonomy with the hope of having a healthy child. But how do we protect the interests of the resultant children? Is their experimental procreation ‘fair’?

**Law’s relationship with science and technology**

So, what has law got to do with it? Good HGE – and, relatedly, good regulation of HGE – requires careful examination of different, potentially conflicting interests: scientists’ research agendas and ambitions, which cannot easily be separated from the current science culture and policy of different nations; would-be parents; the resulting children; and the next generations. But neither careful examination of such interests, nor good regulation, is within reach unless we take greater care in how we imagine law’s relationship to science and technology.

Today, the popular view holds that, when it comes to science and technology, law dawdles or it moves too soon. Law’s slowness is said to stifle innovation; meanwhile its counterpart, speediness, produces laws that target improbable, never-to-be technologies, such as the ban on human cloning. In essence, law is said to deter the wrong things, at the wrong times, in the wrong ways. There is also a sense that technology, once invented, has a life of its own – a sort of unstoppable momentum that law could never match.

The popular view leads to a stark conclusion: we can and should dismiss, or at least sideline, law. Law, in short, is hopeless. We believe it is time to challenge this conclusion; time for a different, more productive way of seeing law – a way of seeing that neither trumps nor trumpets law, but instead teases out its capacities and complexities. We call this ‘legal literacy’, and we believe that cultivating it will help us to answer the question, ‘What’s law got to do with good science?’

This blog follows the publication of I Turkmendag, M Fox, C Thompson and T Murphy, ‘What’s Law got to do with Good Science?’ (2019) 28(3) Social & Legal Studies 392–413. The paper is free-to-view for a limited time at the link below (correct as at [blog publication date])

[https://doi.org/10.1177%2F0964663919834173](https://doi.org/10.1177%2F0964663919834173)
Ilke Turkmendag is Senior Lecturer in Law, Innovation & Society in the Law School at Newcastle University. Ilke's publications include ‘It is just a “battery”: “Right” to know in mitochondrial replacement’ (2018) 43(1) Science, Technology and Human Values 56–85. Thérèse Murphy is Professor of Law at Queen's University Belfast. Thérèse’s publications include ‘Judging bioethics and human rights: Assisted reproductive technology at the European Court of Human Rights’ in Molly Land and Jay Aronson (eds), New Technologies for Human Rights Law and Practice (CUP 2018).

Acknowledgements: This piece benefited from discussions with Dr Michael Morrison during Ilke Turkmendag’s stay at the Centre for Health, Law and Emerging Technologies at Oxford University as a visiting scholar in June 2019. Special thanks to Professor Marie Fox, University of Liverpool, for her comments and suggestions.