After thousands of years of evolution, the human genome is the "heritage of humanity".[1] However, with the development of emerging reproductive technologies, it has become possible to alter that heritage. Gene editing is a group of technologies that allows scientists and researchers to change an organisms DNA sequence, using techniques such as Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), which allows researchers to alter DNA sequences and as such modify gene function.[2] The application of this technology to the human genome has potentially life-changing consequences for many families, and society as a whole. However, despite the potential benefits that could result from the use of this technology, its use on human beings is an incredibly topical and controversial matter. Gene editing can be either on somatic cells, where only the individuals themselves and selected parts of the body will be effected by the treatment; or on germline cells, via embryonic application, whereby future generations may also be effected by the change. In regards to germline gene editing the potential permanent alternation to the heritage of the human race makes it particularly controversial and an area ripe with challenges for regulators. As Brownsword and Goodwin articulated in their work, there are four key challenges that must be considered when regulating an emerging technology such as gene editing: regulatory connection, regulatory effectiveness, regulatory legitimacy and regulatory prudence.[3] How regulators approach these challenges in the context of regulating germline gene editing has the potential to change the heritage of our species.

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[1] *Universal Declaration on the Human Genome and Human Rights*, XXVIII, (11 November 1997) at Art 1.
[2] Aparna Vidyasagar "What is CRISPR" (21 April 2018) LiveScience <https://www.livescience.com/58790-crispr-explained.html>.
[3] Roger Brownsword and Morag Goodwin *Law and the Technologies of the Twenty-First Century* (Cambridge University Press, Cambridge, 2012) at 5.

A large issue for all emerging technologies is the idea of regulatory connection, or, is the regulation an adequate description of the technology and will it regulate it as it develops. Gene editing on the human germline has been restricted from further advancements due to the prohibition under the Human Assisted Reproductive Technologies Act 2004 (HART Act).[4] As it stands and also moving forward should that prohibition be lifted, as with any emerging technology, regulators have a very challenging job. Science is always developing, the risk being that the regulation will misunderstand the technology, either initially when the regulations are drafted, or later on when the technology develops in a manner not expected by the regulators; we want regulation to "bind to the technology and evolve with it".[5] The tension here is between certainty and flexibility; certainty requires that the law is clear and applicable, while flexibility requires that the law is malleable enough to grow with the evolving world; the more you have of one, the less you have of the other. There are two potential strategies that regulators of gene editing may take to approach this issue; firstly, by taking the classic certainty approach and making a set definition, for example, defining gene editing in new regulations, or creating a definition for genetic modification in the current legislation, but perhaps incorporating flexibility by encouraging purposive interpretation.[6] The purposes in the HART Act include securing the benefits of reproductive procedures such as germline gene editing, while still protecting those affected, providing a good indication to courts or committees in charge of applying regulations, that any development that is more than the regulation describes must be beneficial and not harmful to those involved (as well abiding by the other

[4] Human Assisted Reproductive Technology Act 2004, s 8(1).
[5] Brownsword and Goodwin, above n 3, at 65.
[6] At 65.

purposes), thus allowing the regulations to stay relatively connected to the technology.[7] The second option is leaving it to self-regulation or a softer form of law. Due to the strongly controversial nature of gene editing, it is likely the strategy of using certain law would be preferable.

According to the literature, to be fully fit for purpose a regulatory intervention should be effective, economical and efficient.[8] As Lon Fuller stated in his famous work, for law to be effective everybody must know where they stand under it.[9] The current legislation on gene editing has a complete prohibition on germline editing, which prima facie seems clear. Under s 8(1) of the Human Assisted Reproductive Technologies Act 2004 (HART Act), all actions under Schedule 1 of the Act are prohibited, including 'implanting into a human being a genetically modified gamete'.[10] However, 'genetically modified' is not defined, though it is defined the Hazardous Substances and New Organisms Act 1996 (HSNO Act) the HART Act does not refer to the HSNO Act for the definition.[11] This results in confusion about what could constitute genetic modification in some cases; for example, does mitochondrial replacement therapy (MRT) constitute genetic modification? The definition of genetically modified organism in the HSNO Act is very broad in its application and cases such as *Sustainability Council of New Zealand Trust v The Environmental Protection Authority* demonstrate that the courts are taking a very cautious approach to the use of any form of genetic modification.[12] Thus it is likely that if

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[7] Human Assisted Reproductive Technology Act 2004, s 3(a).
[8] Brownsword and Goodwin, above n 3, at 61.
[9] Lon Fuller *The Morality of Law* (revised ed, Yale University Press, New Haven, 1969).
[10] Section 8(1).
[11] Hazardous Substances and New Organisms Act 1996, s 2.
[12] *Sustainability Council of New Zealand Trust v The Environmental Protection Authority* [2014] NZHC 1067.

the current New Zealand legislation was used MRT would be 'genetic modification' and thus not permitted. However, the HART Act draws many parallels and similarities to the United Kingdom (UK) legislation on reproductive technologies, the Human Fertilisation and Embryology Act 2008 (HFEA). The UK government in an amendment in 2008 established that mitochondrial replacement therapy was not a prohibited form of modification and thus was able to be used.[13] These two different possible outcomes on a particular matter demonstrate the potential confusion that could arise without clarification. If one is to merely 'amplify' a particular code of DNA, or make a previously inactive stretch of DNA active, no physical change to the DNA is actually being made, would this still be genetic modification? These sorts of uncertainties can be a risk to the effectiveness of the system. It has been said that where regulation fails to be effective, it can often be put down to three factors, external issues, the regulators or the response of the regulatees.[14] Externalities are often unpredictable and difficult to address, however the other two are factors can be controlled. Importantly, when making regulations, regulators must be competent, knowledgeable in the area and have adequate resources.[15] New Zealand has addressed these needs with the formation of Advisory Committee on Assisted Reproductive Technology (ACART), which is an advisory committee on issues relating to reproductive technologies containing a wide variety of members from different disciplines and with different specialties.[16] However, with regards to germline gene editing, due to the prohibition, it will likely be a matter for parliament to resolve democratically with the advice of ACART and others such as the

[13] Human Fertilisation and Embryology Act 2008 (UK), s 3ZA(5).
[14] Brownword and Goodwin, above n 3, at 61.
[15] At 61.
[16] Human Assisted Reproductive Technology Act 2004, s 32.

Royal Society. It is also important that the public respond in the right way to the regulations for them to be effective. This requires on one hand that regulators account for and anticipate non-compliance with the regulations, and as such produce measures to account for that. Were the regulations to change to permit certain types of germline gene editing, the regulators would need to ensure that those who go outside of the boundaries of the regulations, or those in violent opposition, are all dealt with efficiently. In this regard it is also important that procedural legitimacy has been followed and the views of the public given appropriate consideration.

Ensuring that regulations are formed in a manner that includes the appropriate transparency and public participation as required for regulatory legitimacy, is an important aspect of our liberalist democracy; however in the context of reproductive technologies "this has proved an unusually demanding task".[17] Gene editing is by no means a fully developed technology, we are not even close to fully cracking the code of the human genome. The risks are not certain, nor are the benefits fully realized, yet it has been said that regulations on gene editing should be informed by the public interest identified through public participation.[18] In a technology such as this, public participation and debate is incredibly difficult as it is often based on theoretical arguments, and an individuals own ethical principles. Despite the potential benefits of the technology, people are often very reluctant to see it come into mainstream use, some without any

[17] Colin Gavaghan "Reproductive Technologies and the Search for Regulatory Legitamacy: Fuzzy Lines, Decaying Consensus and Intractable Normative Problems' in R Brownsword, E Scotford and K Yeung (eds) *The Oxford Handbook on the Law and Regulation of Technology* (Oxford University Press, 1st ed, 2017) at 992.
[18] Nuffield Council on Bioethics *Genome editing and human reproduction* (July 2018) at 100.

reasons they can articulate. In the words of Sandal "[w]hen science moves faster than moral understanding, as it does today, men and women struggle to articulate their unease."[19] However, a common argument with any reproductive technology is that human beings shouldn't play god.[20] For some, germline gene editing crosses an ethical line in that it demonstrates a lack of respect for the person to be born.[21] The issues promoted most often being that both that the person born from this technology is bearing all the risks while not being able to consent to such a thing.[22] The issue of consent is one of intense debate, many arguing that because this procedure would permanently change the genome of the child and thus have an undeniable influence on their future life, that this is not something the parent's can consent to on their behalf.[23] Others argue that parents are making decisions that have a permanent effect on their child's life everyday, for example, what school they attend, even decisions that seem to threaten the child's welfare such as taking their children on holiday to a remote and dangerous part of the globe, are seen as within the scope of parental authority.[24] Is this truly any different? A very precautionary approach has been taken to any use of gene editing in the human population, however the arguably "kneejerk precautionary response" can also be faulted in that it fails to take into account the potential benefits of the technology that will be impaired by the introduction

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[19] Michael Sandel *The Case Against Perfection: Ethics in the Age of Genetic Engineering* (Belknap Press, Harvard, 2007) at 9.
[20] At 176.
[21] Heidi Howard and others "One small edit for humans, one giant edit for humankind? Points and questions to consider for a responsible way forward for gene editing in humans" (2017) 26 European Journal of Human Genetics 1 at 6.
[22] Ronald Green *Babies by Design: The Ethics of Genetic Choice* (Yale University Press, New Haven, 2007) at 92.
[23] Royal Society of New Zealand *Gene Editing Scenarios In Healthcare* (August 2019) at 7.
[24] Green, above n 22, at 92.

of prohibitions such as those we have in New Zealand.[25] Many reports on the topic of germline gene editing suggest the use of a harm-based approach: if the risks outweigh the detriment of living with whatever genetic condition is there, gene editing should not be performed; If it is an elective situation, there is a minimal requirement that the child not be worse off than they would have been without the intervention, a difficult test to establish currently when the true risks of gene editing are still unknown.[26] What "worse off" means is also a factor of intense public debate, conditions such as genetic deafness or downs syndrome, where the person often has a good quality of life, is it acceptable to say that their lives are "worse" than those without those conditions and alter embryonic genomes on that basis? On the flip side however, in situations where "worse off" is readily evident, such as Huntington's disease or Cystic Fibrosis, the potential benefits of gene editing for the future child cannot be overstated. Allowing carriers of these conditions to have their own genetic offspring that have no chance of suffering from or passing on these debilitating disorders, essentially removing them from the gene pool, seems to be a positive outcome. Some even go so far as to claim the principle of 'procreative beneficence', which suggests that we have a moral requirement to do these things that will improve our future children's wellbeing.[27] Clearly, there are opposing viewpoints on these topics, yet regulators must attempt to coordinate them to create regulation that the public will comply with. It has been said that for regulations to take legitimacy from the views of the public, those views have to be held strongly, widely and

[25] Brownsword and Goodwin, above n 3, at 47.
[26] Royal Society of New Zealand, above n 23, at 7.
[27] Julian Savulescu and Guy Kahane "The moral obligation to create children with the best chance of the best life" (2009) 23 Bioethics 274.

consistently.[28] Regulatory legitimacy will be achieved where the regulators consider all viewpoints when making their decisions, as we live in a democracy, particular importance should be put on the majority and those who would be directly impacted by the use of the technology in order to enable the regulators to get out of the bind that comes from equally passionate opposing views.

Gene editing is a new technology, mostly untested and not much is known about how it will work in practice, Munthe terms this the 'knowledge gap'.[29] He states that the knowledge gap really becomes a problem for regulators when there is the probability or vague likelihood of an 'extremely bad outcome'.[30] The short story "Sisters" by Greg Bear tells of a future where gene editing has gone mainstream and a possible 'extremely bad outcome'. 'Letita' a 'NG' or natural genome is a naturally conceived child in high school at an undisclosed time in the future. Pre-planned children or PPCs are born by gene editing techniques are now considered the norm. When the PPC children in her class start to 'blitz' and die, they find out that it is due to a defective chromosome sequence designed to be part of intelligence enhancement, many of her classmates have the enhancement and perish.[31] This provides an example of many people's fears in regards to gene editing, that by acting without knowing all of the potential risks and outcomes, we are putting future generations at great risk, raising questions of intergenerational justice.[32]

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[28] Gavaghan, above n 17, at 1008.
[29] Christian Munthe "The Black Hole Challenge: Precaution, Existential Risks and the Problem of Knowledge Gaps" (2019) 22 Ethics, Policy & Environment 49 at 49.
[30] At 50.
[31] Greg Bear "Sisters" in *Tangents* (Pulphouse Publishing, Oregon, 1992) at 199.
[32] Royal Society of New Zealand, above n 23, at 11.

We just don't know enough about our genetic makeup at this point in time to confidently say what is safe and what is not. Even in the most targeted of gene editing, for example with Mendelian conditions, there is still the potential for error; we may think by editing this piece of the gene we are removing the target condition, however that part of the gene could also code for other things, or have a relationship with other genes, causing unforeseen consequences.[33] Most conditions are polygenic, or caused by many separate genes working together, and risk is increased the more genes you begin to tamper with. This has been the main argument of opponents to germline gene editing: the unpredictability of the outcome. Another common argument is that it is a lot of risk to take when in many cases there are other options, for example the use of Preimplantation Genetic Diagnosis (PGD) to select an embryo that is not affected by the condition.[34] These concerns about risk were recognised by the recommendation of a moratorium on gene editing of the human germline by the International Bioethics Committee in 2015.[35] The potential benefits of gene editing on the human genome are significant, particularly in regards to crippling genetic conditions such as Huntington's and Haemophilia, which with these technologies we could remove from society. UNESCO's Universal declaration on the Human Genome and Human Rights recognises the importance of scientific advancement and the importance of people being able to access those advances.[36] The fears of potential harm caused to future generations has resulted in Australia, Canada and New Zealand among many others adopting a strict prohibition on all alterations to the

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[33] Green, above n 22, at 84.
[34] Nuffield Council on Bioethics, above n 18, at 21.
[35] International Bioethics Committee *Report of the International Bioethics Committee on Updating Its Reflection on the Human Genome and Human Rights* (2 October 2015) at [118].
[36] Article 12(a).

human germline.[37,38] Section 8(1) with reference to Schedule 1 provides a prohibition of implanting into a human being a genetically modified gamete.[39] Such a strict precautionary response could be said to stifle any further development in the area, effectively stalling development. It has been argued that this type of problem creates a 'black hole challenge' wherein the potential existence of an existential risk takes priority over everything else, and researchers continuously research the possibility. Munthe suggests that a way to approach this would be to set pre-set end and exit points, motivating a limit to the possibly endless risks present in these sorts of situations where the knowledge gap is so intense.[40] This suggests that if regulators feel that the knowledge gap is presently too much and the potential risks too severe without more research, then they will enable research and set a point where they will re-examine this research in the future to avoid falling into the continuous black hole of ever-emerging risks. In order to establish the safety of gene editing going forward for potential application in the general population for the correction of life altering genetic disorders, good research is necessary, including human trials. As it currently stands, complete prohibition on human research is stilting the development of gene editing technology. This is an important factor for regulators to take into account; the safety of the technology will struggle to reach the level required for the public to truly benefit from it without it being possible to research the technology.

In conclusion, regulators face many challenges in their task of regulating gene editing

[37] Prohibition of Human Cloning for Reproduction Act 2002 (AU), s 15(1).
[38] Assisted Human Reproduction Act of 2004 (CA), s 5(1)(f).
[39] Human Assisted Reproductive Technology Act 2004, s 8(1).
[40] Munthe, above n 29, at 57.

technologies, particularly in the context of germline gene editing. Regulatory connection is an important challenge they face, strategies include possibly providing hard definitions while promoting purposive interpretation of the regulations; as it presently stands, the ambiguous wording of the statute among other things means that the current legislation would likely be ineffective to regulate the rapidly developing techniques of germline gene editing should the prohibition be lifted, clarification is required. Regulatory legitimacy is potentially problematic with regard to the strong views people have on gene editing; it is important in a system such as our own that regulations reflect the public opinion, but perhaps full scale use of gene editing of the public should wait until there can be better answers given to the queries and concerns of the public. Finally, regulatory prudence is essential when regulating any new technology, the potential risks involved in any new technology need to be an important consideration in all regulatory assessments. The risks with gene editing are currently largely unknown, the knowledge gap we have can only be ameliorated by research, which is currently prohibited. Thus, regulators must strategise to solve these problems moving forward. A potential suggestion as the technology and society stands right now, would be to lift the prohibition on germline gene editing in cases where the harm of the genetic condition outweighs the potential risks of the technology, research is essential and limited research should be enabled to allow the technology to move forward and hopefully eventually relieve some concerns. Gene editing has incredible potential in this context to saves and provide individuals with better qualities of life, in the words of Bill Gates "it would be a tragedy to pass up the opportunity".[41] The heritage of humanity has in the past been refined by enabling only the

[41] Bill Gates *Gene Editing for Good: How CRISPR Could Transform Global Development* (online

healthy and strong to survive via natural selection; perhaps as science progresses in this area gene editing could be the next step in human evolution, a step that regulators would control: no pressure.

looseleaf ed, Foreign Affairs) at [19].