The Risks of Biotechnology Deregulation are Unquantifiable

Hatchard Report

Dr. Guy Hatchard

The Gene Technology Bill currently being introduced into the New Zealand parliament and fast tracked will allow for the appointment of a regulator to categorise gene edited products by risk.

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The bill has already deemed a wide range of gene editing techniques as 'low risk' which will be proceeded, released into the environment, put into food or used in medicine without labelling, warnings or safety monitoring. In effect this will turn New Zealand into a laboratory for largely unfettered gene experimentation leaving the public at the sharp end of risk. So what are the risks and how do you assess them when it comes to gene editing?

In practice there are no standards for safety in biotechnology that actually work. The lesson of the pandemic is clear. Highly pathogenic gene edited products can escape the laboratory, they can spread without limit and can't be recalled or mitigated. It is hard to escape the reality that no laboratories are completely secure. To err is human, mistakes are inevitable.

In contrast, the proposed New Zealand legislation reads like a gentleman's club agreement: – *We are all jolly fine knowledgeable fellows who have high aims and unimpeachable standing so we should be allowed to do whatever we want.* The recent history of biotechnology experimentation points to the growth of this 'anything goes' ethic, extending to exotic clandestine projects and in some cases military involvement. Our government is naive if it thinks it can control local projects and foreign exploitation with its 'regulation lite'. An article in the Guardian entitled 'It's game over for facts': how vibes came to rule everything from pop to politics puts the post pandemic mood into context. If I feel its OK it must be. The Gene Technology Bill fits this criteria exactly. At the moment, the global commercial gene editing industry is supposed to be self-policed by the researchers and corporates involved. The extent to which this doesn't work is illustrated by an article in the UK Guardian on 12 December entitled 'Unprecedented risk' to life on Earth: Scientists call for halt on 'mirror life' microbe research. A 38 strong international group of Nobel laureates and other distinguished bioscientists have warned that *"mirror bacteria, constructed from mirror images of molecules found in nature, could become established in the environment and slip past the immune defences of natural organisms, putting humans, animals and plants at risk of lethal infections that could spread without check"*.

The DNA of all living organisms is made from "right-handed" nucleotides, while proteins, the building blocks of cells, are made from "left-handed" amino acids. *Why nature works this way is unclear.* Yet without beginning to understand what might be at stake, bioscientists have started programmes to construct mirror microbes with left-handed nucleotides and right-handed proteins. The concerns over the technology are revealed in a 299-page report and a commentary in the journal Science.

The report concludes *"We therefore recommend that research with the goal of creating mirror bacteria not be permitted, and that funders make clear that they will not support such work."*

The most interesting feature of this concern is its origin. Dr Kate Adamala, a synthetic biologist at the University of Minnesota and co-author of the report, was working towards a mirror cell but changed tack last year only after studying the risks in detail out of curiosity. In other words, researchers have been busy starting projects without considering the risks. The scary side of this is the fact that tens of thousands of biotechnology projects are in progress around the world without any adequate assessment of risk.

The Gene Technology Bill calls for assessments of proportionate risk. I'm stumped, proportionate to what—the end of the world? Proportion is a mathematical concept, but even some of the world's most recognisable bioscientists have been caught out and are now trying to play catch-up following a huge mistake themselves. They've had to resort to public appeals after the fact in journals and newspapers calling for bans, calls that will no doubt be completely ignored in some quarters. If they can't get it right, what hope is there for our government appointed local regulator? A little person cast adrift in a wild sea. We need to go back to fundamentals and start to understand the risks in a broader context.

The biological sciences have misconstrued the nature of physical reality

The biotechnology paradigm has adopted a mechanical approach to understanding life. The model requires understanding life in terms of billiard ball chains of cause and effect—interaction and outcomes—by specific molecular structures. Ultimately the DNA is conceived as a blueprint, a repository of all that is needed to maintain the life of an organism. Simply put, DNA can receive requests and supply answers in the form of molecules which can be distributed through identifiable channels in the physiology.

An analogy will help make this clear. A vending machine contains a lot of different drinks. You can place money in the machine and identify the required drink by pushing a specific button. DNA in the cell nucleus is conceived as playing a similar role, it contains tens of thousands of genes which encode for thousands of protein types. DNA is interrogated by RNA in the cytoplasm (cell body) by a process known as transcription whereby the required protein is produced from specific genes, which then eventually fulfils a need in the wider physiology.

In practice, the processes involved are nowhere near that simple. There are forty million proteins in the cytoplasm. Information is transferred across and into and out of the cell not just by the chemical composition of protein molecules but by other processes including molecular shape resulting from types of protein folding, molecule vibrational modes, water soluble properties, energy levels, electromagnetic field properties, electrical conductivity, surface lock and key properties, etc. The total picture is not understood, far from it, This lack or imprecision of our knowledge about intra-cellular and intercellular processes is a great source of risk itself when it comes to gene editing.

Moreover a single gene does not encode for a single protein, Genes are multi-tasking. Multiple genes work together to form proteins in multiple different ways. In other words, editing one gene will have effects across multiple biological pathways. There are always off target and unintended effects of gene editing, no matter how precise the editing. The Gene Technology Bill completely ignores this by exempting some gene editing techniques from regulation.

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More importantly, the biological sciences paradigm suffers significantly from the compartmentalisation of science and knowledge in general. Although we humans view life and nature from the different perspectives of physics, chemistry, etc..., life is one continuous whole governed by laws of nature working at different time and distance scales. Biological laws cannot be separated from the findings of other disciplines.

Laws of nature are hierarchical. At smaller time and distance scales there is more organising power and more connection over greater distances—in a sense space shrinks. Fundamental physical laws such as gravity apply equally at every point in creation. Curiously, at smaller time and distance scales there is also more uncertainty. Things that we tend to take for granted such as specific positions in space and moments in time, velocities and energies become subject to uncertainties. Moreover their behaviour is linked to the presence of an observer.

Biological systems are continuously tied into fundamental physical laws and in a very real sense emerge from them. Their properties manifest in biological systems. The 37 trillion cells in the average human being are not standalone, they are interconnected. Together they support a single observer. How this is achieved is not understood or even consistently investigated by the biological sciences. This implies that any risk to human life as a whole including our sentient and self-reflective characteristics cannot even begin to be assessed, as the warning reported by the Guardian article begins to hint.

We can push our analogy a little further if we like, imagine trillions of vending machines each offering millions of drinks all linked and networked together without the help of any drinks re-supplier, that are capable of acting in a way that supports and protects the network in every location simultaneously. You can see we are no longer describing a mechanical system, but an intelligent self-referral system–life.

Will our immune responses protect us?

Proponents of 'low-risk' categories of biotechnology experimentation support their arguments with reference to Darwinian notions of evolution. They say that life evolves through accidental or random gene mutations which turn out to be advantageous for an organism. It is true that damage to genes occurs readily. Studies showgenetic information is constantly being attacked by intrinsic and extrinsic damaging agents, such as reactive oxygen species, atmospheric radiation, environmental chemicals, and chemotherapeutics. This can cause cancer, neurological disease and premature aging. In fact every cell repairs DNA tens of thousands of times every day. The implication is obvious: gene editing is not inherently evolutionary, it is inherently destructive.

So can we rely on our natural gene repair and immune response mechanisms to protect us and clean up genetic damage or mistakes as proponents of low-risk biotechnology classifications suggest? The answer is no for very good reasons. An analogy will make this clear. Many countries have air defence systems to protect them from missile attack. These function tolerably well in the event of small scale attacks, but they break down if hundreds of missiles arrive simultaneously. A highly pathogenic viral organism can multiply without limit once it has escaped as happened during the pandemic. Injections of gene therapy components can affect billions of cells simultaneously. Mass substitution of feed or food ingredients can lead to illness as happened in the case of mad cow disease. To be commercially viable, biotech product research specifically aims for mass release and as quickly and universally as possible. This inevitably raises the risk profile. Life is naturally reproductive and biotechnology is aiming to alter what is reproduced. Remember cancer starts with a single-cell genetic mutation which then reproduces and grows.

All this means there should be no go areas for biotechnology research. Genetic interventions that cross the cell membrane have the potential to disrupt the whole organism in unpredictable ways. At risk is our fundamental connection with the underlying laws of nature, the underlying intelligence of nature. We are not independent agents, we are part of a whole system. As John Donne wrote in 1624 and which today rings just as true

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No man is an island,

Entire of itself;

Every man is a piece of the continent,

A part of the main.

If a clod be washed away by the sea,

Europe is the less,

As well as if a promontory were:

As well as if a manor of thy friend's

Or of thine own were.

Any man's death diminishes me,

Because I am involved in mankind.

And therefore never send to know for whom the bell tolls;

It tolls for thee.

Biotechnology deregulation legislation coming to New Zealand is indeed world leading. As its government proponents including Prime Minister Chris Luxon, Minister of Business Innovation and Employment Judith Collins, Leader of the ACT Party David Seymour, and Deputy Prime Minister Winston Peters envision, but it is leading in entirely the wrong direction towards greater risk not away from it.

The fact that risky biotechnology experimentation is growing around the world is not something to encourage or normalise. Independently written recent articles in both the UK Telegraph and US Washington Post have reported scientists describing the risks of biotechnology experimentation as greater than the risks of nuclear war. Yet you can order deadly pathogens by mail in the US. Do we want or need that here?;

New Zealand has had a world leading precautionary legislative HSNO framework which has had some protective effects. In the light of recent developments in gene technology this legislation needs to be strengthened not abandoned. New Zealand has the advantage of geographic isolation and an efficient farming system that is the envy of the world. This is not something to be casually placed in the hands of a naive government appointed regulator by legislation that doesn't understand, discuss or specify the risks, merely promising everything will all be OK if it is left to chance. What sort of encouragement of negligence is that?

The 2001 Royal Commission on Genetic Modification published a 450 page report on the complex issues involved. The submissions are still relevant today. It endorsed the precautionary principle—the requirement for proof of safety before use or release which is now being abandoned by the Gene Technology Bill. In the meantime, the known risks of genetic modification of organisms have clearly increased in dimension severity and scope, not decreased.

No one needs to have a naive approach to these risks, farmers being sold on opportunities for enhanced productivity and profit should think again. They are the victim of public relations hype, the real aim is commercial exploitation controlled via plant and product patents and government mandated use, without consideration of risk or safeguards. Doctors and medical professionals need to learn the lessons of the pandemic. These lessons were bought with millions of human lives, they should not be ignored in the face of ministerial stupidity and cupidity.

Write to your MP and say no to the Gene Technology Bill. For more information see our report Response to Expert Opinions Issued by the Science Media Centre in Support of the Gene Technology Bill or go to the GE Free NZ website.

https://www.parliament.nz/en/mps-and-electorates/members-of-parliament

Dr. Guy Hatchard 16 December 2024