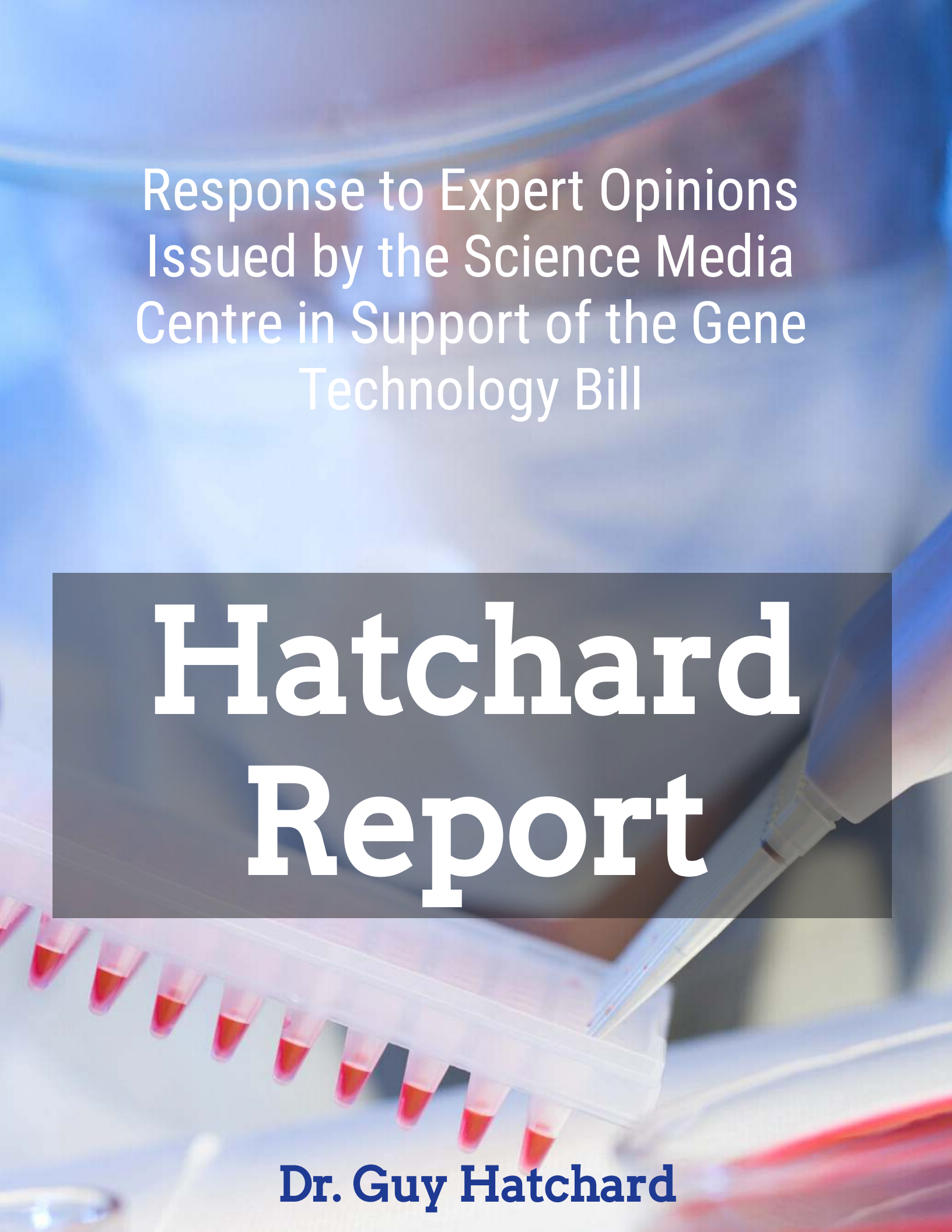

Response to Expert Opinions Issued by the Science Media Centre in Support of the Gene Technology Bill

Hatchard Report

Dr. Guy Hatchard

Response to Expert Opinions Issued by the Science Media Centre in Support of the Gene Technology Bill

Formal Response to the Expert Opinions Issued by the Science Media Centre in Support of the Gene Technology Bill introduced to Parliament.

For the Attention of: Media, Biotech Researchers, Members of Parliament and Cabinet.

A Public Resource

Author: Guy Hatchard PhD was formerly Director of Natural Products at Genetic ID (now FoodChain ID) a global food safety testing and certification company. He presented to the original Royal Commission on Genetic Modification in New Zealand during 2000 which helped to clarify the safety ground rules and labelling requirements for Genetically Modified Organisms (GMOs) which currently form a part of the New Zealand Hazardous Substances and New Organisms legislation. Dr. Hatchard is retired and has no financial interest in the outcomes of the current legislative initiative to deregulate biotechnology experimentation.

The Gene Technology Bill currently before Parliament introduces reforms to gene technology rules, reducing restrictions for scientists to work with biotechnology. It opens new avenues to commercialise the results of biotechnology research. It establishes a 'low-risk' classification for biotechnology research, applications and releases. Thereby it seeks to bypass the current requirement for labelling of GMOs. It devolves decisions about biotechnology safety to a government appointed regulator, rather than specific provisions of legislation.

The New Zealand Science Media Centre (SMC) is funded by the Ministry of Business, Innovation and Employment, the same government department that is introducing the Gene Technology Bill. It has published two 'Expert Opinion' Media releases in support of the Bill see here (15 February 2024) and here (December 10 2024).

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Since 2000 the safety considerations pertinent to biotechnology research, applications and releases have changed considerably. There has been much new research published. There have been advances in our understanding of genetic structures and functions, both in the human body and nature at large. There has been a proliferation of biosynthetic compounds in the food chain and in medicine. The global commercial biotechnology sector has grown exponentially. It has been estimated to be valued at NZ$2 trillion in 2023 employing considerably more than 1 million people. For all these reasons it is certainly time for a review of the biotechnology safety legislation. Therefore this is one of the most important reports we are publishing in 2024. It is intended to inform and update public opinion on many of the key issues.

Containment

We have arrived at an extraordinary crossroads in the field of public health. For the last five years, the COVID-19 pandemic has dominated the sector. There is a growing consensus that the COVID-19 virus was generated by a biotechnology *'gain-of function'* research programme based in Wuhan China whose products subsequently escaped. The very obvious evidence of the pandemic has been that biotechnology cannot be 100% contained, inevitable mistakes can spread without limit and cannot be recalled. This is a very salutary lesson that must not be ignored. Biotechnology deregulation runs counter to the lessons of the pandemic.

Whether one supports the lab leak theory, as does the US government and a number of prominent biotechnologists, or whether one adheres to the idea of a zoonotic origin is largely irrelevant. The very fact that there is uncertainty and that no actual animal source has been discovered, reveals a great deal about the lack of certainty in our current understanding of the mobility and stability of novel genetic structures and pathogens.

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Public Health

The rapid spread of COVID-19 was followed by the global roll out of a number of experimental biotech vaccines after an emergency suspension of regulatory safeguards. These vaccines did not meet the promised standards of efficacy or safety. Their use and the circumstances under which they were mandated is currently the subject of intense global scientific debate and public interest. The true extent of their impact cannot be assessed without the release of key public health data including mortality and hospital admission statistics tabulated by disease category, vaccination status, date, timing and age. The fact that Health New Zealand has ceased publication of many key health statistics during the pandemic including cancer incidence is both concerning and damning.

Epigenetics

There is now a fuller understanding compared to 2000 of the functioning of genetic systems. DNA does not act alone. The cell forms a whole system—Nucleus (containing DNA), Cytoplasm (containing RNA) and Membrane (two-way gate and protective shield). DNA cannot function or even exist without RNA and RNA relies on DNA. Moreover the extracellular environment also has a mutual reciprocal symbiosis with the cell and its genetic functions. Introduced genetic structures even outside the cell can ultimately influence the internal structure and function of the cell and the pathways for genetic expression. Fragments of genetic information can under certain circumstances reverse transcribe into the nuclear DNA itself. The complexity is staggering and still only very partially understood. The potential for mistakes and accidents is huge.

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Precautionary Principle, Substantial Equivalence and Labelling

Many of the expert opinions published by the SMC suggest that the precautionary principle embodied in the current HSNO legislation is outdated and is in effect holding up research and scientific progress in New Zealand. The precautionary principle in essence states that new technology cannot be assumed to be safe before there is evidence of safety. In other words absence of evidence is not evidence of absence (or safety). The quoted experts argue that for many biotechnologies there has been sufficient use and improvements in method and precision to justify removal of regulation. In other words, some new applications and products can be presumed safe without testing or labelling to inform the public.

However, widespread use is not evidence of safety without testing and without traceability and labelling. Traceability is a foundational principle of the safety of foods and medicines. Any suggestion labelling can be removed without error is laughable and a regressive step.

The suggestion that some products of biotechnology are indistinguishable from their natural counterparts and hence *'substantially equivalent'* is not tenable. There are always detectable differences. The fact that these could be minor does not prove safety. Minor differences in atomic structures can cause differences in protein folding and receptor binding, both known to be disease vectors.

Manufacturing

The exact conditions of production of certain biotech products in a lab is not reproduced in upscaled commercial production processes. Commercial biotech processes entail higher levels of contamination and fewer safeguards. Product purities are variable. This was the case with mRNA vaccines which for example are now known to have high levels of SV-40 DNA plasmid contamination—a recognised carcinogen.

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Right of Choice

The existing regulatory structures have been inadequate, but not because the rules are too restrictive, rather too lax. During the last 25 years, there have been more than three thousand synthetic additives, flavours, colours, preservatives and processing aids approved by Medsafe for use in the food chain here in New Zealand. These include copies of natural foods produced via biotechnology such as rennets, yeasts, vanillas, etc. There is no requirement for labelling their origin. Many have been described as 'natural' on labels. Meanwhile there has been a rapid growth in the incidence of allergies, cancers, inflammatory conditions, etc. Without clear labelling, there is no way to trace the possible origins of such conditions in the food chain. Importantly, without labelling there is no way for consumers to reliably exercise their right of choice. They may be under the impression they are eating traditional foods, but may be consuming novel compounds. As a result some of our foods may now have a lower nutritional profile or hidden pathogenic potential. Without labelling, these effects will be untraceable.

Effectiveness

From its inception the potential benefits of biotechnology have been exaggerated. They have been consistently subject to manipulation in the hands of PR writers who are working under commercial imperatives. The actual achievements of the sector to date have been much smaller than the hype suggests. Biotech publicity almost universally suggests cures for cancers, inherited diseases, and a wide range of illnesses are just around the corner—a fanciful gross exaggeration.

The idea has also been erroneously implanted in the public psyche that almost all illness is caused by genetic faults which can be quickly corrected with properly funded research and applications which edit genes. Moreover it is suggested that human traits like height, strength, beauty, longevity or intelligence will soon be improved through biotechnology. These ideas are so far from the reality of our current knowledge as to be misleading in the extreme. Apparently the aim of such misleading claims is to secure investment capital, government grants, freedom from regulation and public acceptance of risky experimentation.

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Economics

There have been unsubstantiated suggestions that our economy has suffered because our gene regulations are too restrictive. It is suggested that our successful and profitable participation in the global economy requires biotechnology deregulation. The experts cite the case of Lanza Tech, a New Zealand biotech company that relocated to the US to avoid the New Zealand regulations. However, during the last year, Lanza has not been a success story. Its share price has tanked. Moreover this is not an isolated example, many hopeful start ups have failed. Not the least because consumer acceptance of biotech foods and additives is not forthcoming. People like their traditional foods.

Nor have medical applications lived up to the hype. Insulin is an important part of the treatment of diabetes. Synthetic insulin, invented forty-five years ago, has been heralded as a biotechnology success story. It certainly made its inventors into billionaires, but during the ensuing 45 years the number of people with diabetes world wide has increased from 100 million to 600 million. Synthetic insulin is not curing diabetes. It is better prevented and actually treated by improvements in diet, exercise and lifestyle.

Another highly publicised success story—gene therapy treatment for inherited genetic illness sickle cell anaemia—has so far only been available to 100 people worldwide out of the 8 million suffering from the condition. The treatment is risky and doesn't always work. Its long term efficacy is unknown. It costs about NZ$6 million per person. Whilst potentially life altering for a very tiny number of individuals, this is hardly a prescription for a global health revolution.

In fact there are very few commercial biotech success stories, unless products are supported by government mandates as happened during the pandemic. Worryingly, mandated biotech interventions in animal diets such as Bovaer for ruminants are now proposed. Don't forget the disastrous run on effects of antibiotic feed additives which have helped to create untreatable infections from superbugs.

New Zealand's agricultural economy benefits from our clean green image. Biotechnology deregulation may ultimately tarnish this image and have a negative effect on agricultural exports.

Higher Functions

Perhaps the most concerning feature of biotechnology deregulation is our lack of knowledge about the relationship between genes and the mind. Human life begins with a single cell. The promise of all that we cherish in life, our emotions, our aspirations, our intelligence, our joy is somehow contained in that cell, but no one understands how exactly that unfolds. Genetic pathway interventions inside and outside the cell alter cellular functions and could affect our capacity for those higher abilities which characterise the greatest achievements of human life. Those involved in biotechnology research are operating on the belief that our abilities can ultimately be enhanced. Given the current state of our knowledge, that suggestion is infantile. There has been a general principle in gene therapy—there will be off target mutative effects. How much genetic experimentation will affect human consciousness and its self-reflective capacity for mental health, sound and fair judgement is a total unknown, but a very real risk that biotech regulatory measures have so far completely ignored.

Conclusion

Those offering expert comment to the SMC are biotech industry insiders with admitted conflicts of interests. During the last 25 years, the biotech research sector around the world has sought to fend off regulation. The current New Zealand proposal for biotechnology deregulation is another example of this. In fact, the level of deregulation proposed by our government in the Bill is extreme. In practice, regulatory personnel inevitably become facilitators.

The experience of the COVID-19 pandemic should be hitting home some hard truths about risk/benefit balance. The tabling of the Gene Technology Bill at this time speaks volumes about an industry determined to ignore risks and override precautionary voices. In 2000, many of the potentially serious risks of gene editing cited at the Royal Commission hearings were ignored in favour of a *'go ahead with caution'* recommendation. This approach is no longer tenable. Inevitable mistakes CAN spread without limit and CANNOT be recalled. The current Royal Commission Phase 2 will not report until 2026. Passing the Gene Technology Bill now jumps the gun and prejudges the issue. It imperils public health.

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For more than three years our websites HatchardReport.com and https://GLOBE.GLOBAL have been publishing scientifically referenced articles covering the above issues in depth. We encourage everyone to closely review these resources. In 2000 some of the risks of biotechnology were theoretical, we now know them to be inescapable and world shattering. This is not the time for biotechnology deregulation, it is a time to take stock and strengthen public health protection.

The following experts wrote for SMC in support of biotechnology deregulation. You can access their comments here and here. The Science Media Centre release is encouraging people to send them comments and questions:

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You may also like to write to your MP

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

Dr Guy Hatchard

12 December 2024