

s 9(2)(a) [redacted]  
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Dear s 9(2)(a) [redacted],

Thank you for your 6 June 2018 letter about the need for an urgent review of the Accident Compensation Act 2001 (the AC Act) cover exclusion of commercial clinical trial related injuries.

You suggest that removing the AC Act cover exclusion would provide commercial trial participants with more certain compensation arrangements than those currently provided by commercial trial sponsors. You also suggest that such reform could be funded by ACC levies.

We agree with you that it is important that participants in commercial clinical trials have appropriate protections, and where people are injured as a result of their participation that they receive appropriate compensation.

We do not consider, however, that there is a sufficient case at this time to shift the responsibility for compensating people injured in commercial trials from the commercial trials industry to ACC.

It is not clear, for instance, that shifting the compensation arrangements to ACC would necessarily offer additional certainty of compensation to trial participants. Injury claims not accepted by sponsors under current arrangements, may equally be declined by ACC. Like trial sponsors, ACC would have to determine the circumstances relating to the injury before providing any assistance. For example, ACC would need to determine whether an alleged injury was caused as a result of participation in a trial, or through underlying health factors before accepting a claim. It is difficult to therefore know whether the unresolved case that you note in your letter would have been covered by ACC in the absence of the exclusion provision.

It is also uncertain whether the determination of cover for treatment injury claims would be necessarily always faster if it was managed by ACC. Determining cover for treatment injury claims can be more complex than for other claims, and the AC Act accordingly gives ACC a

longer period (nine months as compared to four months) to decide whether to accept a claim of this nature (refer section 57).

Given the small number of known disputes in this area, it is not clear that commercial trial sponsors are not taking responsibility for injuries relating to their trials and that people who are injured are missing out on compensation.

If the accident compensation scheme was expanded to cover commercial clinical trials participants, and a levy was introduced to cover the costs of those injuries, it would be important but also challenging to establish levies that fairly reflect the differing risks of different types of clinical trials. Appropriately risk adjusted levies would be important, for instance, to avoid incentivising more risky as opposed to less risky trials seeking to be located in New Zealand, which would place greater pressure on the regulatory system governing trials. Setting such levies would be challenging, however, given the limited information on the numbers and severity of trial related injuries, and the small scale of the New Zealand trial industry.

More broadly, we are pleased to inform you that the Health and Disability Ethics Committees have updated the informed consent template wording for commercial trials. We trust that this will address the immediate issue of insufficient information on compensation arrangements being provided to participants in clinical trials.

You may also be interested in a forthcoming exposure draft for a Therapeutic Products Bill (the Bill) that the Ministry of Health is developing to update the regulatory scheme around medicines, medical devices and other therapeutic products in New Zealand. The Bill would, for example, strengthen the regulatory oversight of clinical trials and address a number of issues in the clinical trial regulatory system, including gaps in the ethics approval coverage of trials of therapeutic products other than medicines (e.g. devices). The consultation process on the exposure draft will provide an opportunity for further discussion and consideration of the issues.

We would like to assure you that the Government is committed to ensuring that health and scientific research in New Zealand is done in a safe and responsible way.

We appreciate your interest in this important area, and that you have taken the time to write to us.

Yours sincerely

Hon Iain Lees-Galloway  
**Minister for ACC**

Hon David Clark  
**Minister of Health**