

Compensation call for people injured during clinical trials

January 31 2017, by Miranda Playfair

A legal academic and health law expert is calling for a change in the law to protect all New Zealanders who are injured during clinical trials.

Professor Jo Manning from the University of Auckland Law School says our current laws are inequitable and discriminatory as they only provide compensation to people injured in publicly-sponsored drug trials, who are covered by our no-fault accident compensation (ACC) scheme.

But New Zealanders injured in commercially-sponsored drug trials are not covered by ACC legislation, leaving them financially exposed.

Commercially-sponsored drug trials are undertaken by the pharmaceutical industry. By agreeing to take part in a commercially-sponsored trial, participants surrender their rights to ACC cover if injured, and must look to the sponsor for compensation.

Participants sign consent forms that usually state that they are not eligible for ACC cover, but that compensation would instead be provided by the sponsor in accordance with industry guidelines. This refers to Compensation Guidelines drafted by the [pharmaceutical industry](#), which apply if the company sponsor agrees to abide by them in the specific trial. These provide that the sponsor "should pay compensation" to healthy patient-volunteers suffering bodily injury. But that obligation is clearly stated to be "without legal commitment" and hence is a moral obligation only.

Professor Manning says "patients need to be better protected. Clinical trials benefit society yet participants who are injured in commercially-sponsored [drug trials](#) lack a legal right to compensation without having to prove a sponsor's or researcher's negligence in a court action. The chances of that are very low and the process is expensive, gruelling and protracted."

Details of specific NZ cases of research-related injury are hard to obtain as any commercial settlement is usually confidential but information made public by the National Ethics Advisory Committee in 2015 includes the case of a man in a gout trial who suffered atrial fibrillation. It took him around three years to get compensation. In another case no settlement has been reached many years after the participant was injured.

"If you were injured and unable to work for an extended period of time you are unlikely to be able to advocate for yourself with a large company or their insurance company, especially knowing that you have no legal entitlement to compensation unless you can prove negligence in a court," says Professor Manning. "Yet that is what we are asking participants to do."

"People considering taking part in commercially-sponsored clinical trials need to know that if they are injured there is no legal entitlement to compensation from the company involved," she says. The information given to potential subjects before they agree to participate needs to be changed to make this crystal clear to them.

She recommends that ethics committees look hard at and consider declining ethical approval for commercial trials where the risk is more than minimal in the absence of a legally enforceable no fault [compensation](#) arrangement put in place by the company. But ultimately Government needs to intervene either to insist that the Compensation

Guidelines are made legally enforceable by subjects, or to change the ACC scheme so as to cover all participants injured in [clinical trials](#).

Provided by University of Auckland

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