GUARDIANSHIP AND ADMINISTRATION AMENDMENT (MEDICAL RESEARCH) BILL 2023

Introduction and First Reading

Bill introduced, on motion by **Hon Matthew Swinbourn (Parliamentary Secretary)**, and read a first time.

Second Reading

HON MATTHEW SWINBOURN (East Metropolitan — Parliamentary Secretary) [4.08 pm]: I move —

That the bill be now read a second time.

The Guardianship and Administration Amendment (Medical Research) Bill 2023 implements two of the recommendations from the *Review of the Guardianship and Administration Amendment (Medical Research) Act 2020 (WA)*: *Final report*, which I now table.

[See paper 2040.]

Hon MATTHEW SWINBOURN: The bill proposes two significant amendments: to amend the definition of "lead researcher" so that a broader range of health practitioners may enrol represented persons in their medical research projects and it seeks to repeal the sunset clauses in the amendment act that will have the effect of deleting the urgent medical research provisions for represented persons in the Guardianship and Administration Act 1990 on 8 April 2024. The 2020 amendment act commenced on 7 April 2020 and has enabled urgent medical research to be carried out for persons who do not have the capacity to consent to it. The legislation contains various safeguards and a process of independent review by a third party medical practitioner to ensure the integrity of the represented person's enrolment in the research when their consent has not been obtained. There are many reasons that a person may be incapable of providing consent such as an ongoing disability, injury or acquired condition, or when they are temporarily incapacitated as a result of being unconscious or are receiving treatment owing to an emergency. The amendments to the GAA were an important reform during the early days of the coronavirus pandemic. This was due to the GAA not permitting represented persons to be enrolled in medical research at that time, either with the consent of their decision-maker or in urgent circumstances.

The effect of the 2020 amendment act was that it provided that authorisation and contained appropriate safeguards to enable a represented person, through their representative, to provide consent for their participation in medical research. There are two circumstances in the 2020 amendment act in which a represented person may be enrolled in medical research. The first is with the consent of their decision-maker and the second is in urgent situations in which that consent has not been obtained prior. In order to ensure the integrity of the process of enrolling a represented person in medical research, the 2020 amendment act also includes various safeguards. These safeguards are a requirement for an independent medical practitioner to provide a risk assessment that takes into account the conditions and symptoms particular to the patient that are prescribed in part 9E of the GAA and ministerial reporting requirements to Parliament. It is important to note that the medical research provisions that the amendment act inserted into the GAA are consistent with provisions that were already in the GAA for providing medical treatment to represented persons in Western Australia. When Parliament considered the 2020 amendment act, a review clause was included so that the operation and effectiveness of the new legislation could be assessed once 12 months had passed since the amendments commenced. In addition, as the house is aware, the 2020 amendment act was referred to the Standing Committee on Legislation on 2 April 2020. The committee made recommendations in the forty-eighth committee report directed towards particular aspects of the 2020 amendment act and the 2020 bill, and these issues are discussed in chapter 5 of the final report. Now that the Attorney General has completed the first review of the legislation, with the assistance of the Department of Justice, I am pleased to advise the house that the medical research amendments have, overall, been working well in practice. During the statutory review of the 2020 amendment act, the Department of Justice consulted widely with stakeholders including: the Department of Health; disability advocates; mental health advocates; First Nations health advocates; culturally and linguistically diverse communities' health advocates; medical researchers and practitioners, including emergency medicine in the public and private sectors; and other relevant agencies at the state and commonwealth government levels.

The final report noted that although the amendments to the GAA have been generally working effectively, there are areas of improvement for some definitions within the act. The definitions of "medical research" and "independent medical practitioner" have been operating effectively, overall, since the 2020 amendment act commenced. However, the definition of "lead researcher", as currently drafted, provides that only a person who is a "medical practitioner" may act as the lead researcher who has sole or joint overall responsibility for conducting a medical research project. The final report states that this limitation in the definition has had an adverse impact on medical research projects, which may be led by health practitioners other than those who are medically trained. This includes paramedics, nurses, physiotherapists, or any of the 13 other recognised health professions in the Health Practitioner Regulation National Law (WA) Act. It is important to remember that not all medical research occurs in a hospital or clinical setting. Many medical research projects are led by health practitioners who are based

in the community and conduct their research directly with candidates in various settings, such as home-based studies. The final report has therefore recommended that the definition of "lead researcher" be broadened to include other health practitioners, not just those who are medical practitioners. Broadening this definition will enable represented persons to have access to a wider range of new therapies.

Concerningly, during the review, the Department of Justice found that the impending sunset clause, which will remove the ability to enrol represented persons in urgent medical research in situations in which their consent cannot be first obtained, has caused a detrimental impact on medical research in Western Australia. The final report recommended that the sunset clause on urgent medical research be deleted. The sunset clause will take effect on 8 April 2024 so, from that date onwards, no new medical research projects can be commenced in which represented persons may be involved. It is important to consider what "urgent medical research" means in a practical context for the medical research community. As a result of the developing coronavirus emergency in 2020, the medical research community strongly advocated for the ability to provide urgent care to patients suffering from COVID-19 complications in the form of new and innovative procedures. For example, a medical researcher may investigate the effect of making minute variations in the standard dosage of a particular medication or may run an additional test or analysis during the routine collection of a patient's blood sample that is part of established treatment practices. The review of the 2020 amendment act heard from stakeholders that scenarios such as these, which are included as case studies in the final report, are examples of actual medical research trials that could not proceed because, prior to the 2020 amendment act, the GAA did not permit represented persons to be enrolled.

All medical research that involves humans must go through a rigorous approval process, as fostered by the National Health and Medical Research Council, and is regulated by the relevant human research ethics committees, funding bodies, research institutions and the Department of Health here in Western Australia. The *National statement on ethical conduct in human research* makes it clear there are two issues that must always be considered in medical research involving humans: the risks and benefits of the research, and the consent of participants. Research is ethically acceptable only when its potential benefits justify the risks involved. It is the role of a human research ethics committee to assess any proposed medical research project and determine whether it is satisfied that the benefits of the research justify any risks. Researchers must also be satisfied that the consent obtained from a research candidate is voluntary and sufficiently informed of the purpose, methods, demands, risks and potential benefits of the proposal.

I have spoken many times in this place of my own family's journey with my son Mitchell, and his life-limiting conditions. I have also spoken about the hope that advancements in medical research will provide him and others like him with opportunities for better treatments, cures and ultimately a longer and happier life. The possibility of such advancements should not be prevented by delaying or stopping medical researchers with unnecessary or overly burdensome hurdles. It is crucial to the advancement of our health system and the health of all Western Australians, including the most vulnerable members of our community, that medical researchers and health practitioners are at the cutting edge of technology and can access innovations in medical research.

Pursuant to standing order 126(1), I advise that this bill is not a uniform legislation bill. It does not ratify or give effect to an intergovernmental or multilateral agreement to which the government of the state is a party; nor does this bill, by reason of its subject matter, introduce a uniform scheme or uniform laws throughout the commonwealth.

I commend the bill to the house and I table the explanatory memorandum.

[See paper 2041.]

Debate adjourned, pursuant to standing orders.