GUARDIANSHIP AND ADMINISTRATION AMENDMENT (MEDICAL RESEARCH) BILL 2023

Second Reading

Resumed from 16 March.

HON STEPHEN PRATT (South Metropolitan) [2.09 pm]: I rise to make a contribution to this piece of legislation following some of the discussion in this chamber late last week and also given my keen interest in the medical research space and anything to do with health. If members will indulge me, initially I would like to go through what the bill before us aims to do. It is twofold. The first recommendation in the Department of Justice's *Review of the Guardianship and Administration Amendment (Medical Research) Act 2020 (WA): Final report* was to amend the definition of "lead researcher" in section 110ZO of the Guardianship and Administration Act 1990 by changing "medical practitioner" to "health practitioner". That might not sound that exciting, but it will broaden the definition and open the door for a wider range of people to benefit from this legislation. I hope that this will in turn lead to more medical research taking place in Western Australia.

The fourth recommendation is to delete sections 2(b), 13 and 15 of the act, which together make up the sunset clause. Last week, Hon Tjorn Sibma and Hon Nick Goiran took us back to the timing and context around why this clause was introduced by Hon Michael Mischin and accepted by the government of the day. We found ourselves in a unique situation with the pandemic in its early development stages. Governments across the globe were acting swiftly to introduce different pieces of legislation so that leaders in the community could act quickly, respond to changes in an agile manner and pivot, if necessary, to respond to the circumstances that we were confronted with.

The review found that, in essence, the bill will provide authorisation and safeguards for represented persons to participate in medical research through their nominated research decision-maker, either with consent or in urgent circumstances when consent is not obtained prior to participation. The bill is in line with similar recommendations made in the forty-eighth report of the Standing Committee on Legislation titled *Guardianship and Administration Amendment (Medical Research) Bill 2000 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*.

I wanted to touch on some of the comments made by Hon Tjorn Sibma in his contribution, referencing both the sunset clause and the perceived impact that the amendments have had on medical research. I feel like there were some negative connotations when he spoke about how medical research has benefited from these amendments. I would like to respond by sharing my personal view on that. As I said, I think everyone can understand the reasoning and thinking behind introducing the sunset clause. I will try to be as accurate as I can, but I think Hon Nick Goiran used the terminology of the legislation being "rammed through". The timing was accepted by both sides of Parliament, given the context and nature of the situation that we were confronted with.

Hon Nick Goiran: I think it's an interesting use of the word "accepted", but I understand the point.

Hon STEPHEN PRATT: Perhaps I should use the term "agreed to". Hon Michael Mischin decided to introduce a sunset clause, which was perceived to potentially provide some sort of safeguard or guardrail that Hon Tjorn Sibma referred to. With the passage of time, we have discovered that although the intent behind that was sound, the bill will be able to provide those requirements without the sunset clause being necessary. Today we are attempting to remove that sunset clause and allow the legislation to continue, as hoped.

Taking members back to the COVID-19 pandemic, I think Hon Tjorn Sibma said that we were in the early days of the pandemic. We were certainly getting towards the middle stages when there was a lot of uncertainty and fear in the community and a requirement for governments to act fast. What happened at the time? I have gone through the context. We have seen some reference to the report and the consultation phase. I note the reference made to the submission of the Mental Health Commission that the sunset clause should remain. However, the following events, such as the referral to the legislation committee and the Department of Justice's *Review of the Guardianship and Administration Amendment (Medical Research) Act 2020 (WA): Final report* resulted in a unanimous view from the key stakeholders that the existence of the sunset clause provided no benefit to incapacitated research candidates. Although I can understand the thinking at the time, we are gathered here today to consider amendments to the act to remove the sunset clause from the legislation.

This debate also gives me the opportunity to talk about medical research in Western Australia. Hon Tjorn Sibma made some observations about the inability to quantify what levels of funding WA has potentially missed out on from the National Health and Medical Research Council or similar or the financial impact to medical research. I can understand why this is difficult, or near impossible, to quantify. This pool of funding is hotly contested. To be honest, WA does not get its fair share. We do not know whether any amount of funding received here may have resulted in a breakthrough. It could have led to some sort of commercialised product, which could bring endless benefit to Western Australia. I guess we do not know what we do not know. I can understand completely that, if

requested, an agency would potentially struggle to provide a finite definition or clear information on quantification of the benefits that have been brought.

Reference was also made to a fantastic event that will take place in the WA Parliament this evening—the launch of the Parliamentary Friends of Medical Research, which the member for Nedlands, Katrina Stratton, MLA, Hon Wilson Tucker and I are hosting this evening. I am sure all members who are able to get there will have a great experience. I am excited to take any opportunity I can to promote the amazing work being carried out by the medical research community in Western Australia, as is the Deputy Leader of the Government in the Legislative Council, who is enthusiastically promoting the work and achievements in his portfolio of medical research. My hope is that this amendment legislation and the broadening of the definition to allow more health practitioners to take the role of lead researcher could open the door to funding opportunities, more health breakthroughs and more people employed in medical research positions here in Western Australia. I thank members for the opportunity to say my bit on medical research, and I would now like to come back to the purpose of the bill. The parliamentary secretary referred in his second reading speech to the report of the Department of Justice about the sunset clause in stating —

> 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.

That is a pretty clear indication of the thinking that came out of the well-planned consultation process that resulted in the final report. The parliamentary secretary's second reading speech went on to provide the following example —

> 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 …

That paints a picture about the context at that time—namely, the need for urgency and to ensure that people who were working in health could act quickly and were given access to what they required as things changed and developed. It went on to say —

> 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.

That is a clear and concise explanation of the situation that we were confronted with and how we should respond.

In closing, I again want to touch on the content of the bill. I hope I have covered off on most of it. The 2023 bill proposes to broaden the category of researchers by amending the definition of "lead researcher" to replace "medical practitioner" with "registered health practitioner". That might sound like a small change, but it will broaden the range of people able to access the benefits of this legislation. The amendment differs slightly from the recommendation that was suggested in the final report, but it is necessary to ensure that health practitioners who fall within the definition of "lead researcher" in the Guardianship and Administration Act will also be registered under the Australian Health Practitioner Regulation Authority. The 2023 bill specifically refers to the definition of "registered health practitioner. It will also remove the sunset clause.

I am very pleased that there has been an indication of support from the opposition on this bill. I think I have said my bit. I trust that this amending legislation will pass through this chamber quickly to enable people working in the medical research field to continue to carry out their work, and hopefully the sky will be the limit in what they will do. Thank you very much.

HON DR BRIAN WALKER (East Metropolitan) [2.24 pm]: I listened to the debate last week on the Guardianship and Administration Amendment (Medical Research) Bill 2023 with some degree of concern. That may be because since 1971, I have been the only practising medical practitioner in this house. I note in a number of areas that things have been put into law that as a doctor I think are detrimental for patient wellbeing. The overwhelming moral law under which all doctors must operate is the ancient principle of primum non nocere—first, do no harm. It is a paramount law. Members should notice that is an active verb. As a doctor, I shall not do anything that will cause harm to my patient. We can compare that with the statistics that suggest that the number three or number four cause of death in the American population, which is likely mirrored by the population in

Australia, is properly prescribed medication that has been properly administered. That accounts for 120 000 deaths annually due to what doctors do. I do not know about other members, but when I discovered that statistic, it caused me to have a sharp intake of breath. We know from statistics in Italy that when doctors go on strike, apparently the death rate falls. Here we are as doctors trying our best to do no harm, and we end up being the number three or number four cause of death in the population.

Hon Nick Goiran: Honourable member, is that because of complications from the medication or because of overdose?

Hon Dr BRIAN WALKER: I am glad the member asked that question. It is not due to intentional misadventure or attempts to cause damage; it is due to the medication itself—or a combination of effects that are not predictable. It is said that if a person takes any three medications, it is not possible to predict what the adverse reactions will be. A good example is cancer drugs. One of the well-known causes of death is taking a drug against cancer. This applies also to other drugs. There are plenty of examples of how giving a beta-blocker to an asthmatic may cause sudden death.

Another area that causes me real concern is references to the terrible times in Nazi Germany when doctors did horrendous things in the concentration camps. How could that possibly be? The outcomes of those human vivisections and other abominable experiments brought benefits to the population because they resulted in information that was used after the war to enhance medical knowledge. It gives me a dirty feeling to think about how lives have been saved at the expense of those who suffered and died under those horrendous conditions, yet we are still making use of that information. That is a stain on the doctors who performed that procedure. It gives me pause for thought about what we do with the information that we collect. Should we then ignore it? No, because that would mean that people would die unnecessarily. We know what will happen when these horrible things happen to us. Will immersing people in freezing water to see for how long they can survive help airmen whose planes are downed in war and give them a chance of life? That is a very thorny ethical problem.

Another area of intense interest for me is informed consent. A lot of this speaks to the heart of whether a person who is impaired can give consent. If they cannot give consent, do we withhold treatment from them that might enhance their chance of survival? Are we doing a good thing by not giving them the treatment in the first place? If we say that a doctor's first concern is to do no harm, are we then to say that we are not going to let doctors do potential good—rather, we will let them stay with what does not do good? Are we making doctors cause harm to people by inaction? That is a thought. We need to be concerned about that. Not another single member in this chamber who is debating this bill has any practical experience of what this means on the ground.

I recall very well when I was a cardiologist working on a patient who had flatlined. We tried everything. I was on the crash team, of course, at the head looking after the airway and controlling the people who were doing things—the lines that were open, giving medication here and giving shocks there. He had persistently flatlined. After trying good CPR for 40 minutes and good oxygen was coming through, he was not yet clinically dead. But if we stopped working, he would have died. I recalled reading that if I gave a patient an overdose of a certain drug, I might produce ventricular fibrillation, and if I got ventricular fibrillation, I could shock that and maybe he would come back into sinus rhythm. That had never been done before. Would it work? I did not know, but I got that medication, whacked it into his veins and there was ventricular fibrillation—holy moly! We got a shock to that and we managed to get sinus rhythm for a very short time, but then he died. Was it, I ask, ethical, to give someone a toxic dose of a drug to provoke ventricular fibrillation to try and put him back into sinus rhythm? We did not have permission from any ethical board, but had I not done that, he would have died anyway. We gave it a try so we could see what happened. Who here would criticise that? It was his last chance. He was not able to give consent. I could not say, "Excuse me, sir, this may not work, but we are going to try this." He was out. Gone. If I had been constrained to not do anything that had not been proven by medical research, he would not even have had a chance in the first place. The only sure way to ensure failure is to not try something. This is life and death. That is what we doctors deal with, while others may pontificate about the potential.

I recall, thinking back to the Nazi experience, working in Germany when it was brought home very forcefully to me by a lovely old lady who was beautifully presented in—I am trying to think of the English word—a farmhouse, if you like. I was doing a house call, and there was coffee and cake, as usual. When she showed me the door after I had checked her blood pressure and given her a script, she told me the story about a gypsy woman who came to her door with a baby in her arms during those horrible war years, and she peremptorily showed the gypsy woman the door: "Begone!" The words she said in German will haunt me to my dying day. I will translate them into English, for the benefit of *Hansard*. She said, "I let no blame be placed at my door." Off they went into an uncertain future, mother and child—possibly death. "But I did nothing wrong." This is what we are dealing with here as well. By not doing something, we are not giving people the chance to live. We are assuming that the doctors will behave according to primum non nocere—first, do no harm—and that they are honourable. We, as doctors, stand in front of patients and wonder how on earth these ethics committees can be so blind, dumb and slow, because we

want to do the work now—people's lives are at risk. We are going through stage after stage of getting permissions and lawyers are checking what we are doing. In the meantime, patients are suffering and dying.

Hon Kate Doust: Are you putting the argument that we do not need ethics committees or that they are too onerous?

Hon Dr BRIAN WALKER: That is an excellent question. The answer really is that what is happening takes so long that we are having delays. The ethics need to be there, but the understanding is that the doctors doing the study and the research are ethical, by definition.

Hon Kate Doust: That is questionable sometimes.

Hon Dr BRIAN WALKER: Because you question it, therefore these laws come in place and therefore people are suffering. This is the consequence of what you are doing. I understand why it is like that, but that has consequences. The actions have consequences.

I come back to informed consent. Very wisely, we are saying that we need informed consent. In this particular case, we are quite concerned that because the people are unable to give consent, we must have a special ethical approach to it. That is true. But let us get some congruence here. Informed consent at a governmental level does not really matter when we consider what just happened with the mandated vaccines. We can argue for or against it, but the fact is that by mandating anything, we do not, by definition, have informed consent. Here we are saying that informed consent is paramount and let us find ways of ensuring that those who cannot give consent have protections—informed consent.

Let me tell members about many patients who have been psychiatrically very unwell, threatening murder and mayhem, having been brought into a psychiatric ward where I was working, with murder in their eyes and then being subjected to chemical restraints—concoctions of stuff that I could inject by force because I was allowed to. I could write a section and they could be transported to a place of treatment and given treatment against their will because they were unable to know that they were not in control. They were not able to give informed consent because, by the nature of their illness, they could not, and therefore before either they or someone else suffered harm, for a while, we had to take away the right for them to give consent, and they were subject to being treated against their will for a period. Again, the legislation is such that we must observe that over two or three days and it has to be reviewed. Very properly, it is reviewed with a view to giving back the right to informed consent.

How is it then possible that we can say people have informed consent if we tell them that if they do not take an injection, they will lose their job and because they lose their job, they lose their home and because they lose their home, they cannot feed their family? Take the injection or not—you have been informed. Take the consequences or not. Therefore, they give consent. It is coerced consent. By no means is that informed consent. For a psychiatrically ill patient meaning harm, I can see why that is important and essential. But to say to someone who is completely compos mentis, "Take this injection or you will suffer quite a nasty consequence", is not informed consent. We do not have a congruence here in our legislation, do we? On the one hand, it is quite okay to coerce consent, while on the other hand we spend valuable time trying to find consent when someone is unable to give it. I do not say that to oppose the bill in any way. I am pointing out the ethical dilemma we find ourselves in. It needs to be brought to the attention of the chamber that these are the issues that we on the frontline are experiencing. I do not have an answer for members. I have questions, but I have no solutions.

Hon Stephen Dawson: Are you supporting the bill, honourable member?

Hon Dr BRIAN WALKER: I absolutely am supporting the bill, but I am bringing to attention that there are issues that we, as legislators, need to be aware of and that they need not be kept quiet. When I am at my practice, I am subject to what we are doing in this chamber, and I would like us to be aware of the ramifications of our actions and, indeed, our inaction.

HON SHELLEY PAYNE (Agricultural) [2.37 pm]: I stand to make a very brief contribution in support of the Guardianship and Administration Amendment (Medical Research) Bill 2023. We have not thanked the people and families of those who donate their bodies to medical research. This is really important. My stepdaughter recently finished her undergraduate medical degree at the University of Western Australia. I know they are very thankful for the ability to conduct this type of medical research. My stepdaughter has told me stories about her first experience with research on medical cadavers and how important it was for her and her learning. Interestingly, my great-aunt Muriel lived in the UK and wanted to donate her body to the University of Cambridge. She always used to talk about that. Later in life, she deteriorated and had dementia. She had to go through a process to donate her body, and she went on to donate her body to Cambridge university after she died. It is interesting that about a year after that, my aunt got a message from Cambridge university inviting her to go to an event for all the families of people who had donated their bodies to medical research. She and my dad went to Cambridge university and attended the memorial event and the afternoon tea provided for the families in recognition of those who had contributed towards medical research. This is very important.

I want to talk a bit about the history of the act that we are amending. The Guardianship and Administration Act recognises those occasions when people who are highly dependent on medical care or those with cognitive impairment may not be capable of making reasonable judgements for themselves and obviously may require someone else to make those decisions. The review of the act in 2013 and the ensuing report that was tabled in 2015 raised the issue of consent to medical research by people with decision-making difficulties. It emerged as a major issue during that review, particularly the practice of enrolling patients in medical research using the provisions of the Guardianship and Administration Act that relate to medical treatment.

Shortly after coming to office in 2018, our government sought legal advice on this from the State Solicitor's Office and, as a result, research activity involving patients who are unable to provide consent was suspended. Hon Stephen Pratt and Hon Dr Sally Talbot mentioned that we introduced the Guardianship and Administration Amendment (Medical Research) Bill in 2020, at the start of the COVID-19 pandemic. I commend the government for bringing this bill forward so promptly, as well as for putting the sunset clauses in the legislation so that we could come back and reflect on this issue, as we are doing now.

Hon Matthew Swinbourn tabled the report on the Department of Justice's review that was conducted in 2021 when he introduced the bill. I thank the Department of Justice for the review. It had a project reference group and consulted widely. As other members have talked about, the bill will implement the two recommendations contained in the final report. First, it will amend the definition of "lead researcher". Currently, only a medical practitioner is allowed to act as a lead researcher. The new term "registered health practitioner" will be inserted into the act to broaden the category of researchers who may lead research projects. That is really great. Also, as I talked about earlier, the sunset clauses in the act will be deleted. I commend the government for bringing this bill to the house.

HON KATE DOUST (South Metropolitan) [2.42 pm]: I rise to make a few comments on the Guardianship and Administration Amendment (Medical Research) Bill 2023. I note that there has been some very interesting discussion over the last couple of days about the content of this amending bill. Given that the legislation was addressed at the beginning of the COVID pandemic, we can appreciate that we were in an unusual set of circumstances—that frequently used and abused term "exceptional circumstances". The 2020 amending bill was obviously dealt with in an expeditious manner. The forty-eighth report of the Standing Committee on Legislation needs to be commended. We do good work in this chamber. We probably need to do more good work in our job of reviewing legislation, and I might talk about that in a bit more detail. Having been through the report and having listened to my colleague Hon Dr Sally Talbot, I appreciate that the level of detail that the committee engaged in and the nature of the contributions from people engaged in this space not only make it an interesting read, but also validate the work that was done in putting together the legislation in 2020 and certainly the bill before us today. I will probably go through some of that in detail.

The work of the legislation committee has always been very important. As a participating member of the current committee, I say this to the minister in charge of the bill and I hope that he will take it back to his colleagues: I await with bated anticipation the opportunity to engage in deliberations on a piece of legislation with my colleagues on this committee. I think the work that comes out of committees better educates us as members and enables us to amend and improve legislation as we work our way through it. In my first term as a member of this place, I was a member of that committee and it was heavily engaged in the very serious bills that we had at that point, including bills to establish the State Administrative Tribunal and the Corruption and Crime Commission and a range of other pieces of legislation at the time. I know that the committee has always had a good track record of putting in substantial, educated, well-drafted reports with solid recommendations that governments have taken heed of. I note that that is the case with earlier versions of what we are dealing with today. I commend the work of all the members of that committee and I appreciate the work they have put into it.

I want to pick up on a contribution made by Hon Dr Brian Walker. I acknowledge his lifelong contribution to and ongoing engagement in his field of medicine, but in his commentary, he was basically implying that, aside from his good self, because we do not have that practical, lived experience of working in health or medicine, we should not pass judgement or make decisions in this area.

Hon Dr Brian Walker: It was simply to point out that there is a difference and to educate you on where we are standing.

Hon KATE DOUST: Thank you very much for that. What I was about to say is that when we come into this place, we come in with a variety of life and work experiences. None of us can be an expert on everything, but we seek to acquire knowledge and educate ourselves about how to act in the best interests of all. I see that that is reflected not just in this report, but certainly in the work and discussions that have been undertaken. I look forward to throwing back the same sort of argument when we deal with an industrial relations bill, a workers compensation bill, an equal opportunity bill or a bill related to veterinarians. I would hate to make comment on the valuable role that veterinarians play or the work that a lawyer or an educator does.

Hon Peter Collier: A teacher.

Hon KATE DOUST: Or a teacher, which is a highly valued job, absolutely.

Hon Nick Goiran interjected.

Hon KATE DOUST: I know; they always want the last word, do they not, honourable colleague!

It is interesting. It is the member's view; it is not my view. I think that we come into this place, we grow in our role, we educate ourselves and we do the utmost best we can with the tools we have at hand to make the best decisions for people. When we look at the guardianship and administration legislation that has been put in place to protect the most vulnerable people in our community at any point on the life spectrum, I think that we need to educate ourselves. The report that has been referenced is a good guide to assisting us with that. When we look at the issue of medical research, the issues around informed consent are essential. I was not sure whether I picked up the gist of what the member was saying. He seemed to imply that the arrangements currently in place are too onerous and that they impede medical practitioners from making decisions about research or engaging in research expeditiously or appropriately. I do not see that as being a barrier. I see that it is necessary that the structures are in place to ensure that consent is informed and appropriate. We would not want to go down the pathway as referred to last week by our good friend across the way Hon Nick Goiran when he referenced Mengele during the Second World War and some allegedly positive outcomes that arose from one of the most shocking betrayals of humanity. That was probably the worst example that could be provided, but it was perhaps done in the best context. However, what came out of that really shocking arrangement and appalling behaviour, as referenced in this report, is the Nuremberg trials and the systems that arose as a result. It is not possible that any of those individuals who were forced to participate in those shocking experiments ever gave any type of consent. In chapter 4, the committee outlined a whole range of situations, post that shocking example of betrayal of humanity, to try to ensure that those things do not happen again. I think that if it requires timeliness, filling out checklists and forms, making sure that the individual understands what they are going to participate in or their representative guardian understands exactly what is going on, so be it. People cannot, or should not, be able to conduct potentially invasive research upon an individual without them understanding the implications of that research. I do not think that if they proceeded that way, they would be providing validity and truth to that research at the end of the day.

I think in chapter 4, "Ethics of medical research", the committee has made a very good effort. It refers to the Nuremberg Code. Paragraph 4.7 outlines the 10 key principles underlying that code, which a lot of our ethics committees across all the systems look to as a baseline, if you like, before they proceed down a path of research. That is backed up in the report by the Declaration of Helsinki, which reinforces those core principles. I know that there are circumstances in which informed consent can be bypassed, such as in the case of an emergency or where it is non-invasive. Those circumstances exist and are referenced in another part of the report. However, at the end of the day, I think for both the patient and medical practitioner or researcher, it is a protective measure. It ensures that some diabolical invasive procedure is not practised on an individual in the name of science or medical research. Shonky research will not be published if it has not been permitted. I am thinking back to many years ago when I think we had a stem cell debate in this place and we were talking about the cloning of human stem cells or embryos. A particular Japanese researcher got worldwide acclaim in relation to cloning. It turns out that it was all shonky. We would question how that person performed that research in relation to the level or nature of consent.

I think that consent is absolutely essential for anyone participating in medical research, particularly if they are a vulnerable person. There are defined categories of vulnerable people, not just in law, but certainly also when we look at some of the research. I must admit, this is still a relatively new space that people are moving into in terms of medical research for vulnerable people, so there are not a lot of academic journal articles out there. I found one by Sara Manti and Amelia Licari headed "How to obtain informed consent for research". It specifically refers to vulnerable people and the nature of them, as well as the fact that informed consent means written, signed and dated informed consent. It goes through the types of people. It talks about why that consent is needed, whether it is dealing with human genetic material or personal data. It is necessary because a researcher does not know how that data or material will be used, or possibly exploited, at a later stage. I just thought that was a very useful article to go through. It particularly refers to vulnerable patients and the special needs of those patients.

When we think about somebody who is in a medical situation in which they might have dementia or another health issue that prevents them from articulating their concerns or needs, it becomes even more important to have somebody able to speak on their behalf who understands where they want to go and what they want to do. This article then goes on to talk about how to deal with the communications, privacy and treatment of those individuals. I note that in the committee's forty-eighth report, recommendation 7 refers to the problems that people in rural and regional areas have in relation to participating in this type of medical research if they are deemed to be a vulnerable person. There was some suggestion that telehealth might be incorporated to enable these processes to happen and provide assistance with linking in the appropriate medical staff for this research.

I suppose my question to the minister responsible is on recommendation 7. I cannot recall whether this was advanced last week. Has there been any progress made or discussion on whether or not telehealth would be incorporated as

a tool to facilitate this type of process in those in rural and regional settings? I appreciate that telehealth can be deemed controversial. I know the issue has been raised in other states in relation to how voluntarily assisted dying decisions are managed. It would be an interesting space to see how the government is progressing that in terms of this legislation.

I just want to again look at how we deal with this issue. Part of the second reading speech by Hon Matthew Swinbourn talked about the challenge of when a patient who is not in a position to provide consent presents to emergency and having someone else provide consent for them to enable the medical research element to happen. I listened to my colleague Hon Dr Sally Talbot last week. I think she might have referenced this as well. From the reading that I have done, both in the report and in a number of journal articles, it would seem to me—I am happy for the responsible minister to strike me down and tell me I am absolutely wrong here—that it is a really fine line. I would imagine that if somebody presented to emergency and was deemed to be a vulnerable person, any doctor would be doing whatever they could in that quick and highly volatile situation to provide the best medical care to sustain life. Sometimes they have to make decisions on things such as the level of medication, based on that individual's needs. I think my colleague referred to the level of oxygen flow in some cases. The doctor might ask themselves: is that treatment at that point or medical research? Is consent needed for the treatment to happen, or is consent needed for the medical research that might evolve as a result of the work that is done during the treatment? I asked this question of a friend of mine outside this place. The explanation I received was that there is a fine line when those sorts of situations happen and a lot of data can evolve from a different type of treatment happening in a circumstance.

Western Australia is at the forefront and has some exceptionally gifted medical practitioners and researchers. The idea of getting consent for medical research in this situation becomes more important to validate that work—to validate the nature of that experimental treatment in that circumstance if it produces a positive result. It might not have been something that was done before, but unless it can be validated and unless the results can be published as part of a piece of work, it may not be known how it would work in the future. My colleague Hon Stephen Pratt touched on that, in the context of where we can validate that research, we might come up with a new commercial product. It might also be that we come up with a better way of performing the task or procedure or the process in an emergency situation or in a non-emergency. There are lots of side benefits to doing that.

From what I have picked up, one of the key reasons we need to deal with this is to ensure that when there is a positive outcome—sometimes a negative outcome is needed to work out why things need to change—and if there is informed consent, that person's data, their detail, can then be used in a published format. That will improve the way we do business in the medical research space in Western Australia. I thought that was quite useful. The minister can tell me whether I am wrong on that. It is about enabling that to happen and removing the vagaries of what we currently have for that subset of people who are either being treated or could be part of a bigger cohort for research.

In recent times, I have had to deal with both of my parents having significant health problems. I think back to last year when my mum had two strokes and spent two months in hospital. Her memory was impacted significantly, as was her balance and a range of other factors. She had some pretty nasty physical ailments and we had to deal with issues of consent for her. Trying to explain to her why certain things were happening was very complicated, to the point where I had to get the medical staff to write down everything. We also wrote down everything so there was a record and we would read it to her on each occasion so she understood what was going on at that point. I do not say this with any malice or negative feelings, but I must admit that sometimes it feels a bit like groundhog day. My mum is now retaining a little more and her brain muscles are regenerating a bit. She is in a much better space than she was last August–September, but it is still a challenge. I hope that out of her significant health issues, if some sort of research was being done about that element, having provided consent, that would be useful. Those are some of the challenges faced.

I will not talk about the sunset clause because I think that has been done to death—that is probably the wrong term to use! The sunset clause has been debated at length by a number of colleagues. This legislation is not what we would refer to as highly complicated; it will make some pretty straightforward changes. I think there will probably be a lot more to do in this space in the future. I note that in Victoria and New South Wales work has been done on changes to guardianship and administration of vulnerable people and medical research. I imagine that as that work evolves, more legislation in this area will come our way. I have thought about the difference between consent and assent in relation to how a person gives approval, if they are a vulnerable person who may have dementia, for example. I appreciate that assent is usually applied to children. I was not sure whether at some point it could also be applied to people in that circumstance. I understand that it is actually consent, not assent, that is being provided.

Hon Nick Goiran: It is why they talk now about supported decision-making as an alternative to substituted decision-making. That person can still participate in that process, even though there is still going to be somebody else there.

Hon KATE DOUST: It is an interesting area for people dealing with their own health if they do not have the capacity to make those decisions, and about the people who are making decisions on their behalf. The challenge for medical researchers is to ensure that the person making the decision on behalf of the vulnerable person understands what is happening and that they are able to make an educated decision that is in the best interests of the individual. I appreciate that all changes if the individual at the heart of it reverts to a position of being deemed to be capable and treatment either stops or the person decides that they will continue with it. The original legislation and the changes, certainly in 2020, have put significant safeguards in place to deal with that. It may be that over time that is tightened up—I do not know—but it provides that.

I think I raised this question when we had a briefing: is there a checklist that the participants—the medical researchers—engaged in this process have to sign off on to ensure that they have complied with all the requirements of the relevant ethics committees before they proceed with the nature of the research? I am sure the minister will be able to provide an answer.

Hon Stephen Dawson: Member, I am just making sure that there is an answer to provide for the last question. Can you repeat that?

Hon KATE DOUST: Yes; I raised this when I was in a briefing. I am curious whether there is a checklist, a structured format, that researchers have to work their way through to demonstrate that they have complied with all the requirements of their ethics committees in their place before they proceed with their research or the publication of the research. It is a relatively straightforward thing and I think the answer is probably, and hopefully, yes.

The other issue I picked up from the Standing Committee on Legislation's report, *Guardianship and Administration Amendment (Medical Research) Bill 2020 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*—I do not know whether it was referenced last week—is mentioned towards the back of the report. It deals with a couple of issues that were raised with the committee. Chapter 7 of the report deals, in part, with electroconvulsive therapy. This struck a chord with me because I have a young family member who has received this treatment. It is not something that people really talk about. I know that there was a lot of media about ECT in the 1970s and possibly the 1980s. Page 81 states that the committee asked the Department of Health whether electroconvulsive therapy had previously been used as medical research in Western Australia. The department provided the response that it had previously been the subject of medical research and talked about how certain stakeholders had reference the fact that ECT should not be excluded from medical research. There is actually a finding in the report. There was a suggestion that perhaps the prohibition on ECT should be removed, based on expert opinion. Recommendation 6 of the report also says —

> The prohibition on electroconvulsive therapy under s 110ZT of the Guardianship and Administration Act 1990 be considered in the statutory review required by s 110ZZE(1)(a) of the Act with a view to removing the prohibition.

I will ask the minister about where that is going, but I understand the committee canvassed this issue because there was some discussion by stakeholders about removing the stigma behind people having to seek this treatment. That is probably a positive thing. In fact, the report notes on page 81 that the Royal Australian and New Zealand College of Psychiatrists and the Australian Medical Association (WA) both made submissions about excluding ECT. They talked about how it perpetuates stigma around this proven treatment and how that is unhelpful. I encourage members to read the substantial quote on that page; I am not going to read it in. I just thought it was an interesting area—both that and the part around sterilisation, which I think is a whole other conversation to be had at another point.

The committee's 2020 report certainly canvassed a broad range of issues about not just the types of medical research that could be conducted, but also, and more significantly, the background and historical reasons for why structures had been put in place to protect all individuals, but particularly those in vulnerable situations. The report talks about why appropriately understood informed consent is essential. I mean, we all want to see positive change for our community from medical research. This is an area in which I have a keen interest. I was a very keen participant in the last term as chair of the ministerial council for precision health. I hope that we can have a discussion at some point about that very fascinating area of research and work on targeted health for individuals. Lots of very interesting pieces of research are happening now in that space and there is a lot of discussion around child health and rare diseases. I know that my colleague Hon Stephen Pratt is also heavily engaged in that parliamentary friendship group—I am just looking around the chamber to see who else is involved. There are many different elements happening currently in medical research in Western Australia. This type of bill will simply strengthen and tighten the responsibilities and requirements of the active players in that space.

I come back to the comments made earlier by Hon Dr Brian Walker. I have real concerns about some of the views he expressed about the requirements and rigour attached to having consent being a preventive measure. I do not think it is; I think it is about protection. I also reinforce the fact that although I may not be a medical doctor, that does not prevent me or any of my colleagues in this place, regardless of where they sit, from being informed, educating ourselves and trying to make the best decisions possible to protect those who do not necessarily have a voice for themselves. We need to ensure that if they are going to be participating in any of these types of processes, there are people who can speak up for them and make sure that all the appropriate requirements are adhered to.

I do not see how this type of debate can be connected to what happened during the COVID-19 pandemic with the mandating of vaccination. That is a very different type of issue. I am going to ramble on about this because I did not really have the opportunity to do so before; I was in another position that did not allow me to have that debate. When you are in the middle of a pandemic, sometimes the types of decisions have to change. What people sometimes call human rights might not necessarily be addressed in the way that people normally expect. In trying to make decisions for the greater good—I know that term is sometimes abused—and to afford greater protection to individuals, I think the government made the right decision in mandating vaccination to afford the greatest level of protection to everyone in our community. That is my personal view and I will not back down from that. I remember being abused in the car park by some of the anti-vaxxers. In fact, I think I got walked into Parliament by police on two occasions because I made the mistake of responding to their commentary.

This is a very interesting piece of legislation. I am just going to go back and again reference the report by the Standing Committee on Legislation, because what happened in 2020 was very unusual—the bill had already been passed when this matter went to the committee. I am trying to think of one other time that it might have happened, or when part of a bill was referred to a committee once it had been passed. The fact that the committee was able to look into all these matters once the bill had passed through the house is quite significant. Normally, this is done before a bill is debated during the second reading phase. I think it has some interesting connotations. The committee was able to do this level of research and provide such a good document for the house, albeit after that particular event. But I think the report has also provided us with useful information during this debate as we have been able to go back and look at the level of detail in that report, which is still relevant and still has currency for the bill that we are dealing with now. I assume this bill is going to pass, and when it does, I think it will not just provide clarity and certainty for those vulnerable people on whom it is focused by ensuring that their guardian or responsible person makes an appropriate informed decision about whether to consent to them participating in medical research, but also afford medical practitioners with the appropriate level of protection to enable them to make decisions and, importantly, use the detail and data obtained from those outcomes in written research that can be published and, hopefully, then used for other purposes to enhance and improve our medical research and our functions within our health department across the state.

I think this is a very useful piece of legislation; it is just adding value to work that has already been done. I thank the legislation committee and its members for the work they did. I note there were some differences of opinion, but I think it is healthy for that to occasionally occur in a committee; it adds to the debate, the colour and the movement. It also enables the parliamentary committee to broaden its outlook and better educate itself about the issues involved with or linked to the bill. Minister, I had only those couple of questions; they are relatively straightforward, I would have thought. With those few words, I look forward to the passage of this bill.

HON STEPHEN DAWSON (Mining and Pastoral — Minister for Emergency Services) [3.19 pm] — in reply: I thank all those who made contributions to the second reading debate on the Guardianship and Administration Amendment (Medical Research) Bill 2023: Hon Tjorn Sibma, Hon Nick Goiran, Hon Dr Sally Talbot, Hon Stephen Pratt, Hon Dr Brian Walker, Hon Shelley Payne and Hon Kate Doust. I should have said that I am responding today because the parliamentary secretary with responsibility for this legislation is away from the chamber on urgent business, so it is my pleasure to step into the breach.

In particular, I thank the lead speaker for the opposition, Hon Tjorn Sibma, for expressing the opposition's clear support for the bill. The honourable member took the time to walk us through the extensive history of reviews and parliamentary inquiries and, indeed, the global COVID pandemic that led to the bill that is before us today. The honourable member raised a query about the timing of the tabling of the final report on the review of the 2020 amendments, as did Hon Nick Goiran in his comments. I can advise the house that the Department of Justice commenced the review in mid-2021, being as soon as was practicable after the April 2021 statutory commencement date, and consulted widely with stakeholders from across the community, including health and disability advocates, medical researchers and representatives from the aged-care sector. That public consultation occurred over an extended period of seven months and ended in February 2022. The final report was then tabled as soon as was practicable, in line with other legislative priorities and the significant work being conducted by the government as part of its law reform agenda. I can confirm that the final report on the review was tabled in both houses of Parliament on the same date: 22 February 2023.

The honourable member discussed the information provided to him with regard to funding for medical research in Western Australia, and the low numbers of candidates enrolled as a result of the provisions of part 9E. I make the point that the limited number of people who have participated in medical research under the medical research provisions of the Guardian and Administration Act 1990 is not indicative of the legislation having not achieved its objectives, or of the sunset clause having caused detriment. Every person should have the right to treatment that is in their best interest, and every health researcher has the potential to uncover a groundbreaking treatment for their patient. All people with disabilities have the right to access the same range, quality and standards of health care as other people. It is discriminatory to deny health care and health services on the basis of disability or capacity; this includes being able to participate in medical research. Focusing on the dollar amounts that WA has missed out on because of the sunset clause, without acknowledging the broader context of people's lives, is probably not that helpful and, in fact, potentially misses the point. We are always going to have small numbers participating in research. We have a small population in Western Australia, certainly in the context of the world's total population, but every person in this state matters.

I now turn to acknowledge some of the comments made by Hon Nick Goiran in his contribution. I thank him, too, for his support for the bill, subject to a few concerns with some of the broader policy considerations behind the bill that he expressed during his remarks. I want to briefly address what seems to be a fundamental misunderstanding of the purpose and background of this bill. We should remember that we are amending the Guardianship and Administration Act—an act that has, at its heart, the protection and best interests of vulnerable people, and that takes a cautious and conservative approach to expanding the kinds of decisions that may be made about a person without their express consent. The bill does not diminish any of the existing protections for vulnerable people under the Guardianship and Administration Act. It strikes a balance between protecting represented persons—its core purpose—while facilitating medical research and innovation by permitting people who may be incapacitated, for a variety of reasons, from participating in clinical trials. I am pleased that the honourable member indicated that, despite his comments, he supports the bill.

I also take this opportunity to address the honourable member's query about the progress of the remainder of the recommendations arising from the 2015 review of the Guardianship and Administration Act. The state government remains committed to implementing the recommendations of the 2015 review of the Guardianship and Administration Act. Given the fluid nature of the pandemic in 2020, when the amendments were passed, the recommendations from the 2015 review that addressed the issue of consent to medical research were considered crucial. The 2020 amendments ensured that all Western Australians were given the opportunity to participate in world-leading medical research specifically targeted at combating COVID-19. The government continues work to draft a broader bill to amend the GAA as part of the Attorney General's legislative agenda.

The review of the Guardianship and Administration Amendment (Medical Research) Act 2020 had specific and narrow terms of reference and has resulted in a bill that is targeted and addresses the results of the review to achieve a specific objective. With regard to the honourable member's comments about what should and should not be included in the definition of "medical research" in section 3AA, I have been advised that we would be better off thinking about a continuum between clinical care and medical research, and demanding a similar level of oversight for both. Researchers are obliged to follow the National Health and Medical Research Council's *National statement on the ethical conduct of human research*, which refers in chapter 4.4 to research on people highly dependent on medical care who may be unable to give consent.

Medical research and treatment often overlap. With comparative effectiveness studies of two or more proven interventions, it would be ethically wrong to deny a person the opportunity to receive the benefit of the treatment because the person was temporarily incapacitated. In any event, the GAA takes a cautious and conservative approach to what constitutes medical research and it applies the same rigorous requirements to non-invasive, observational studies as well as to invasive interventions, which the honourable member specifically referred to. I note that some stakeholders have suggested that non-invasive research should be treated differently, but the review found that it is important that the amendments support the core function of the bill. At its heart, it is about protecting represented persons, and this warrants a cautious approach.

Finally, in response to the honourable member's comments that the bill needs an overt oversight mechanism, I make the comment that it already contains several mechanisms to keep the 2020 amendments under regular review. I firstly note that, out of all the Australian states and territories that have legislation dealing with medical research involving represented persons, Western Australia is the only jurisdiction that requires regular review of its provisions. We are the only jurisdiction that has committed to regular oversight and continual improvement of our medical research provisions that may involve represented persons. Further, the next statutory review of the original 2020 amendments is due to commence soon. Under section 110ZZE, it must commence after 8 April 2024 and be tabled by 8 April 2025, so I hope that provides some comfort to the honourable member. Thirdly, section 110ZZD of the GAA requires the Minister for Health to table reports on the number of people enrolled according to the provisions

of part 9E of the GAA every year. I am advised that the figures for the next reporting period, which commenced on 6 April 2022, are currently being collated and analysed and will be tabled by the Minister for Health as soon as is practicable.

I propose to expand upon all of the safeguard or "guardrail" processes that exist in the GAA to protect incapacitated persons who may participate in medical research without consent when we move into the committee stage of this bill.

I thank Hon Dr Sally Talbot for her contribution and for her measured and, indeed, eloquent comments on the bill. The honourable member drew upon her considerable knowledge of ethical questions from her past life in academia, and also her previous experience as chair of the Standing Committee on Legislation—in particular, during the inquiry into the amendments in 2020. I thank her, too, for her support for the bill and for providing valuable context to the changes that this bill proposes to the previous amendments made.

I also acknowledge the contribution made by Hon Stephen Pratt, who is away from the chamber on urgent parliamentary business. He provided a summary of the bill's purpose and history. I acknowledge his passion and enthusiasm for medical research and innovation in this state, and his ongoing support for the medical research sector in this state.

I thank Hon Dr Brian Walker for his comments. He provided us with not only valuable, but also thought-provoking insight on the important ethical issues that can arise in medical research from the perspective of a practising medical doctor. The honourable member touched on the tension between ethics and safeguarding procedures and the often urgent nature of medical research. There is no easy answer to this issue. I certainly appreciate the honourable member's candour and honesty in raising this issue. I thank him, too, for his support of the bill.

As Hon Kate Doust pointed out, from time to time in this place many of us from different walks of life obviously have to make contributions on things that we have not lived through or, indeed, may not have studied, but it certainly brings diversity to legislation and makes for a well-rounded debate in this place.

I also thank Hon Shelley Payne for her contribution, particularly for sharing her personal experience with medical research. I thank her for her support.

Hon Kate Doust spoke about the great work of parliamentary committees, in particular the Standing Committee on Legislation's forty-eighth report in 2020 on the previous amendments made to the Guardianship and Administration Act relating to medical research. The honourable member reminded the house of the importance of having safeguards enshrined in legislation to provide the best protection for vulnerable people in the community. She touched on a range of other issues, including electroconvulsive therapy. For those who have been in this place for a period of time, we have debated ECT in relation to the Mental Health Act 2014 and other legislation. It has been controversial in the community. Electroconvulsive therapy is a treatment that can be carried out only with the approval of the Mental Health Tribunal, according to section 409 of the Mental Health Act. It is doubtful that the Mental Health Tribunal would ever approve ECT being approved for research purposes because very strict objects guide the MHA. However, it may be possible for a guardian of a patient or other family member to participate in a hearing of the Mental Health Tribunal and give their views about whether an involuntary patient should have ECT as treatment, but certainly not for research. Research about ECT is limited to those patients who can provide consent. ECT is also expressly banned as an emergency treatment, according to section 202(2) of the MHA. As set out in recommendation 5 and finding 11 of the final report, the Department of Justice found that the prohibition on ECT was appropriate and should not be removed from the Guardianship and Administration Act. Eighty-nine per cent of stakeholders consulted during the review did not express a view on the prohibition on ECT for medical research. In fact, only one stakeholder opposed it.

Hon Nick Goiran: Opposed the prohibition or opposed the removal of the prohibition?

Hon STEPHEN DAWSON: I would have to clarify that for the honourable member. My notes do not clarify that. The Mental Health Law Centre opposed it, but I will check which part it opposed.

I turn to what safeguards are in place for a person who lacks capacity to consent to urgent medical research. Urgent medical research without consent can only be carried out in limited circumstances provided that a number of safeguards are met at various stages of the medical research. Before the research proposal can commence, it must first go through a rigorous approval process by a human research ethics committee plus site-specific or institutional approvals, which may be repeated if the research is conducted at multiple sites, and then Department of Health approval from its research governance service. The HREC must have specifically approved the medical research to be conducted without the requirement for prior consent to participate. Additional safeguards exist during the medical research, including the circumstances of urgency that must exist and the requirement for independent medical practitioners' determinations in relation to the specific patient.

The provisions of part 9E of the Guardianship and Administration Act outline the specific circumstances that must occur for urgent medical research to be considered without consent so that the research candidate requires urgent care, as defined in the act, that the research candidate is unable to make reasonable judgements in respect of their participation in the medical research; that there is no research decision in relation to the candidate in respect of their participation in the research; that it is not practicable for the researcher who proposes to conduct the research to obtain a research decision in relation to the candidate from the research decision-maker for the candidate; and that it is unlikely that it will be practicable for the researcher to obtain such a decision within the time frame approved by the HREC.

The important role that the independent medical practitioner plays during medical research cannot be understated. The following steps apply to every instance when a person may be enrolled in urgent medical research and they have been unable to provide prior consent, so the medical researcher has received an IMP's determination that the candidate is not likely to be able to make reasonable judgements about their participation in the research within the time frame for the research as set out by the HREC; the researcher has received an IMP's determination that the candidate's participation is in their best interests or not adverse to their interests; the researcher has received an IMP's determination that the candidate's participation will only involve observing the candidate or will only involve carrying out non-invasive examination, treatment or procedure or will not involve any known substantial risks to the candidate; or where there is an existing treatment, the research will not involve any known substantial risks to the candidate greater than the risks associated with the treatment or will not involve substantial risks to the candidate greater than if they did not participate in the research.

Further to that, a researcher must not conduct medical research if they are aware or ought reasonably to be aware that the incapacitated person has an advance health directive in place and participating in that medical research would be inconsistent with that AHD. The researcher must also continue to take reasonable steps to obtain consent from the person's research decision-maker during the medical research. If at any point during the research, the research candidate regains the ability to consent or their decision-maker decides to refuse consent to the research, the research must be continued as soon as safely practicable and not recommence unless consent is obtained.

Finally, additional safeguards and additional independent oversight occur after the medical research has concluded, which further strengthens the protections of the GAA and provides for people who cannot provide consent. The Department of Health requires every medical researcher to complete a form when enrolling a person in medical research, either with consent or in urgent circumstances without prior consent. The forms extensively replicate the specific requirements set out in the relevant sections in the legislation and record details of the research and the candidate and provide a running sheet of the IMP determination in relation to the patient's best interests, the relevant time frame and the risks assessment undertaken for that particular patient. These forms become part of a person's medical record, which they can access to review the process that was followed in relation to their participation in the research.

Lastly, the State Administrative Tribunal can allow a person who, in the tribunal's opinion, is interested in the decision made under part 9E to apply for a review to the tribunal of that decision. It must also be remembered that the Guardianship and Administration Amendment (Medical Research) Act 2020 inserted two recurrent oversight mechanisms into the GAA in relation to medical research. The first, I touched on briefly earlier: section 10ZZE of the GAA requires the Attorney General to conduct recurring three-yearly statutory reviews of the provisions of part 9E to determine if they continue to operate effectively. These regular reviews will be an opportunity for stakeholders, including advocates, researchers and the research candidates themselves, to provide feedback on how the provisions have been operating in practice. The second, section 10ZZC of the GAA, requires all researchers to provide written notice to the Minister for Health of every instance in which a represented person has been enrolled in medical research under part 9E of the GAA as well as details of which specific provision was relied upon, the type of research, the purpose of the research and any other information that the minister includes on the relevant forms. The Minister for Health is then required under section 10ZZD of the Guardianship and Administration Act to de-identify the information, and to then collate the information in annual reports to Parliament. Two such ministerial reports have been tabled, and the next report is due in April. I hope that has answered all the questions that have been raised in the second reading debate. However, knowing that members have expressed a desire to go into Committee of the Whole, there will an opportunity to canvass those issues a bit further later on.

I also acknowledge that this week is National Advance Care Planning Week, which runs from 20 to 26 March. More than one in two of us will be unable to make our own medical decisions at the end of our lives, but only 15 per cent of Australians have an advance care directive. This debate and this week is an opportunity for us all to seek further information on that issue. People who are interested can go to www.acpweek.org.au.

I commend the bill to the house.

Question put and passed.

Bill read a second time.

Committee

The Deputy Chair of Committees (Hon Sandra Carr) in the chair; Hon Stephen Dawson (Minister for Emergency Services) on behalf of the Parliamentary Secretary to the Attorney General, in charge of the bill.

Clause 1: Short title —

Hon TJORN SIBMA: I scribbled down some notes while the minister was giving his second reading reply, but, unfortunately, I was not in a position to catch everything. I want to begin with the time line that the minister identified. In my contribution, I raised the timing of the tabling of the final report, *Review of the Guardianship and Administration Amendment (Medical Research) Act 2020 (WA)*. Can the minister go over that time line again? The minister mentioned something along the lines of the consultations effectively having been concluded by around February or March last year.

Hon STEPHEN DAWSON: I am happy to go over that again. As I indicated earlier, the review commenced in mid-2021, or basically as soon as practicable after the April 2021 statutory commencement date. The review panel consulted widely with stakeholders, including health and disability advocates, medical researchers and representatives from the aged-care sector. The public consultation occurred over an extended period of several months and ended in February 2022. The final report was then tabled as soon as was practicable. I am told that was in line with other legislative priorities and significant work being conducted by the government as part of its law reform agenda. I said also that the final review report was tabled in both houses of Parliament on 22 February 2023.

Hon TJORN SIBMA: I am at least relieved that that corresponds with the scribbled notes that I made at the time. I do not want to inject any speculation about the other priorities that might have occurred in the government's law reform agenda in the 12 months between when the report was substantially concluded and when it was tabled in this place, but would be minister be able to provide some insight into the timing around the drafting of this very simple bill?

Hon STEPHEN DAWSON: I think the member has been told previously that the draft bill was given to the Attorney General's office in October last year. That is certainly the information that I have been given. I normally do not represent the Attorney General in this place. However, it seems to me that Hon Nick Goiran has been constantly on his feet in this place dealing with Attorney General legislation. A lot of bills come into this place from that portfolio, and Hon Nick Goiran's good friend Hon Matthew Swinbourn, the parliamentary secretary, seems to be on his feet very often dealing with Attorney General legislation.

Hon Nick Goiran: The hardworking member.

Hon STEPHEN DAWSON: Yes—the hardworking member, as the member has said.

Hon TJORN SIBMA: I thank the minister and appreciate his endeavour to furnish me with a response. For the sake of accuracy, I think a report was provided to the Attorney General in late October last year. My interest in attempting to align or appreciate the sequence of activity between the undertaking of the review, which was an obligation under the act, and the tabling of the bill that we are considering is how the one task fed into the other. For example, was this bill that we are contemplating, which does not have many extensive clauses, drafted and printed this calendar year or was that task undertaken previously? The government has on occasion taken a constructive and helpful approach to satisfying my curiosity when I have asked questions such as that. I appreciate that there is partially a defence under cabinet-in-confidence to say that we are dealing just with what we are dealing with; however, that is only because the bill was read in at the same time as the report was tabled. I am curious to understand the degree to which the final report was reflected upon by the Attorney General before the bill entered this chamber in its current format. If the minister was able to provide any insight on that, I would gratefully receive that information.

Hon STEPHEN DAWSON: I cannot give the member any further information. That is all captured within the cabinet process, unfortunately.

Hon TJORN SIBMA: One of the substantial reasons for my curiosity is so that I will be able to understand not only the content of the bill and how it has materialised in the brief form in which it has, but also the argument that has been made about the need to deal with the sunset provisions. We have made the point that the opposition supports the bill, and that involves dealing with the sunset clauses. That was a recommendation in not only the forty-eighth report of the Standing Committee on Legislation of two and a half years ago, but also the final review report. One of the principal justifications, to verge on a polemic in which the government certainly engaged in the other chamber, was that the mere existence of these sunset clauses will have the effect of jeopardising future medical research in Western Australia in a not insignificant way. I think I made the point, and other speakers have made the observation, that, to a degree, that is a reasonable argument to make. However, can the government substantiate

that argument in any number of ways in terms of the funding pools lost and the research programs abandoned or not pursued with a review as to the benefit of the continuance of this on incapacitated people in an urgent setting? One of the basic questions I asked very early on of the exemplary staff who have fielded my inquiries thus far was to put a point estimate on the funding gap, or potentially the jeopardising of the funding, that the sunset clause represents. It is a long lead-in, I know. Again, when I was scribbling down my response, I think a claim was made that a fixation on the funding issue somewhat misses the point. I just want to understand that I actually heard that claim correctly.

Hon STEPHEN DAWSON: Yes, honourable member, words to that effect were said. It is certainly very difficult to quantify what the loss to research in Western Australia associated with the sunset clause may well be. I have to say, though, that early on in my role in taking on the portfolio as Minister for Medical Research, I had some senior clinicians from the WA health system talk to me about this piece of legislation. They spoke to me about the review and, from their perspective, the challenges they were facing with accessing funding. It is fair to say that Western Australia does not get its fair share of National Health and Medical Research Council funding anyway, but they clearly said to me that the sunset clause in the bill was an inhibitor. It stopped many from simply putting in applications in the first place. I am not casting aspersions or seeking to cast blame on anybody in relation to the sunset clause. The sunset clause was included in this bill by virtue of it being the will of the house at the time. The sunset clause is the sunset clause—it is in the legislation—so I am not going to reflect on a previous decision of the Council. But, clearly, it has been said to me as Minister for Medical Research, as it has been said to others, probably including in the review, that it was an inhibitor. But it is difficult to quantify exactly how much money we might have missed out on. I think our advisers may well have given a figure in one of the briefings, but it is an inexact science because, quite simply, many people did not apply for funding because they were unsure whether the sunset clause would be removed and whether they would be able to continue to do their research post that date in 2024.

Hon TJORN SIBMA: Thank you, minister. I appreciate that there are complexities and difficulties in getting point estimates of the values potentially jeopardised by the operation of the sunset clause or the disincentive that may have presented to people who were on the verge of participating in a particular research program or applying for like funding. However, without getting particularly overly sensitive about these issues, I do not think my fixation on funding is unreasonable, because it at least attempts to quantify a proposition. It is not the only measure. I absolutely acknowledge that. I thought there was a measure of sophistication in the tail end of the minister's response that actually put the emphasis on the need to present all people with equal access to—we will call it—"cutting-edge" or "world-leading medical treatment and medical research", which is a principal that I absolutely support. But I will reflect on two key reasons why I put the funding question in the way that I did. It was done to be helpful. That is because, at least insofar as the very good committee report that I referred to previously was concerned, on page 72 at chapter 7 of that report is the heading on the impact of dealing with the sunset clause matter titled "Impact on ability to obtain funding". I will quote two sources. At paragraph 7.28, it says in respect of the sunset clauses —

> Submissions from the Department of Health and Sir Charles Gairdner Osborne Park Health Care Group recommended the removal of the Sunset Clause on the basis that it might impact the ability to obtain funding for medical research projects with an expected timeline greater than four years.

I think that was a reasonable statement to make. It is very clear that the issue is about funding and our access to funding. That was, apparently, drawn from submission 25 of 9 June 2020 and submission 26 of 12 June 2022 to the Standing Committee on Legislation's review, which is another indication of why its reports are so valuable. There is also the final report, which I mentioned before, that goes into some detail identifying that one of the issues we are dealing with here and one of the more pernicious or confronting limiting aspects of the sunset clause is its effect on funding pools and funding pool access. I quote here from pages 42 and 43 of the final report. This deals with a submission to that review by the Australian Medical Association of WA —

> The department has heard from stakeholders that the sunset clause is causing disadvantage to medical researchers in terms of their ability to obtain funding for longer term projects, particularly from national funding bodies.

The AMA went on—I will not quote the whole contribution—to mention something that the minister has identified very recently, which is —

> *… WA routinely receives disproportionately less medical research funding than other states … Opportunities for research also help our health system to attract and retain the best doctors in their fields. If this clause remains, it will restrict the funding of vital research in our state and make WA a less attractive location for experienced clinical researchers.*

I was not asking questions about funding just because I thought I would throw it into the mix. I was asking questions about funding because this issue was identified in the standing committee's report and this final report. It seems to be the implied locus of angst in some of the verbatim reportage of the views of the medical research committee as they are distilled through government members as the conduit for the message. I appreciate that I might not get satisfaction about how much this is costing us. It is not a number that the government has. That is understandable. Perhaps a question I could pose to the minister in respect of this bill and also his portfolio responsibility is: to what degree does this sunset clause contribute even more in terms of the aggravation of Western Australia obtaining an appropriate share of national medical research funding? What is the proportionate impact of the offence created under the sunset clauses on our capacity to attract funding from national bodies?

Hon STEPHEN DAWSON: I am not sure that the honourable member will get any joy out of this answer either. We get about four per cent of the total national medical health research funding. Our population is about 10.4 per cent. In an ordinary world, we would expect to get about 10.4 per cent of the national to pool, but we get far less than that. It is very difficult to quantify how much the sunset clause has been a barrier to that. A substantial amount of time is required to conceive, fund, implement and complete a research project. The process involves the formulation of a research idea; planning the research proposal; forming the research team, often including external collaborators; obtaining a research grant after scientific peer review; seeking ethical and governance approvals; recruitment of participants; administering the research; analysis of results; reporting; and publication. It has been only three years since the introduction of the sunset clause. Given the length of time involved in setting up a research project, this period is probably insufficient to quantify how much research money has been lost as a result of the looming sunset clause in WA. WA Health has made an estimation of about $18.4 million over the next 10 years to show that the monetary impact is significant, even under a one per cent presumption, and that is conservative. We do not know. Certainly, all the submissions and stakeholders who were canvassed as part of the Department of Justice's final report, including the Harry Perkins Institute of Medical Research, the University of Western Australia school of medicine, Hon Eric Heenan, KC, the Australian and New Zealand Intensive Care Society, Dr Stephen Macdonald at the Australasian College for Emergency Medicine, the North Metropolitan Health Service, the East Metropolitan Health Service and the WA branch of the Australian Medical Association, said that this was an issue.

I am not sure where the member is trying to bring us with this. I cannot give him an exact amount, but it is not just the government saying that this an issue; the stakeholders who are affected by this are saying that it is an issue. It is very difficult to quantify what has been lost.

Hon TJORN SIBMA: I understand that, and by no means do I wish to reflect in any pejorative way on the esteemed individuals and organisations that the minister just mentioned. I do not necessarily disagree with the assertion; however, I want to reinforce the fact that it is a principal and meaningful focus of attention. My dealing with this is frustrating in that it would be assumed that some issues might be able to be substantiated to some degree. As we have discussed the relativities of research funding in Western Australia compared with those in other jurisdictions, can I get a sense of whether other Australian jurisdictions are presented with the same kinds of challenges in obtaining research funding or implementing programs as they relate to incapacitated people?

One way to ensure that Western Australia remains best in class is to have at least a sense of where the rest of the class is. It is an easier argument to make to say that Western Australia suffers in its attempt to obtain money from a limited pool of national funds because other Australian jurisdictions are not encumbered by concerns about the treatment or enrolment of incapacitated people who cannot provide consent to these forms of medical research and they do not have sunset clauses. I am attempting to understand how Western Australia features in the national map.

Hon STEPHEN DAWSON: I am not sure how much responsibility can be sheeted home to a sunset clause in legislation and then link it to how well or otherwise we do with National Health and Medical Research Council funding. Certainly, the stakeholders in this state have made it clear to me that this is an impediment. However, it is fair to say that there are probably other impediments or other things that we have not done as a state over 10 or 12 years that I am certainly trying to turn around at the moment as Minister for Medical Research. We have a great deal of tools available to us to help us on that journey. We have our $1.6 billion or $1.7 billion future health research and innovation fund in Western Australia, and we can spend the interest annually on medical research and innovation. We are using that more strategically than we have been in the last few years to help give the sector a leg up and help it be more competitive and help it access the NHMRC funding. It is fair to say that the vast majority of it goes to the golden triangle of Brisbane, Sydney and Melbourne. I think Melbourne is the place that is best represented in terms of the success of NHMRC funding. Whether it is funding from the NHMRC or the medical research future fund, we do not get our population share in Western Australia, and it is something that, as the minister, I am working on with stakeholders to see what more we can do. I cannot give the member a percentage or a dollar value for how much of an impediment a sunset clause has been, but I can reiterate that the stakeholders have said in their commentary to the Department of Justice, to me and to others that the sunset clause has been, and will continue to be, an impediment until legislation is passed.

Hon TJORN SIBMA: I think we can all support the state government's endeavour to raise this as an issue nationally. I genuinely think that the disproportionate funding—that is, the lack of per capita funding—is deeply problematic, and it is no surprise to some degree when there are population concentrations in centres in the eastern states. Certainly, the opposition is of the disposition that we should not, as a general principle, impose restrictions on ourselves that others do not seem to apply to themselves in the pursuit of that funding pool. Nevertheless, I want to understand where Western Australia presently sits with other state jurisdictions in the enrolment of incapacitated people in medical research programs. I want to ensure that my comprehension is correct. I think it is worth reading from appendix 5, "Medical research legislation in Australia", on pages 54 and 55 of the final report that was tabled on 22 February. This is part of the reason that I am slightly aggrieved that the bill was introduced at the same time as the report was tabled. I think it assists in the contemplation of these issues if they do not have to be raised in parallel to the degree that I am raising them now. There has been an intimation that a failure to remove the sunset clauses, which we all agree this bill will do, is principally founded on the fact that we face a funding challenge.

As I read it in appendix 5, "Medical research legislation in Australia", on pages 54 and 55, South Australia does not have specific legislation that permits an incapacitated person to be enrolled in medical research. I therefore assume that South Australia is not in a position to obtain research funding for that cohort of individuals. I think Hon Kate Doust made an intimation that there is a review in New South Wales of its guardianship-related legislation. Presently, under the New South Wales Guardianship Act 1987, there is no explicit provision that allows an incapacitated person to be enrolled in urgent medical research without consent being obtained from a decision-maker. I wonder to what degree its legislation presently acts as an inhibitor to or a constraint on researchers in New South Wales obtaining—I will say in a colloquial way—their fair share of medical research funding. The excellent people who put together this report advised that, in Queensland, the Guardianship and Administration Act 2000 is the relevant statute. There is no explicit provision in Queensland legislation that would allow an incapacitated person to be enrolled in urgent medical research without consent being obtained from a decision-maker. That is likewise in Tasmania, and I think also in the Australian Capital Territory.

I am not regaling the minister with this snapshot of comparable jurisdictions in the treatment of these issues for my own entertainment—far from it. I think it is important to contextualise key claims. There was an implication that the sunset clauses, which will take effect in 12 months' time, have already served as an inhibitor for our own medical researchers to apply for funding, or that funding had been lost. This scenario largely appears to be the status quo Australia-wide.

I suppose an inverse question could be: what comparable advantage would the repeal of the sunset clauses through this bill give Western Australia as a destination for medical research funding over the other jurisdictions that I have just named?

Hon STEPHEN DAWSON: First of all, there are a couple of things to unpack there. We do poorly in terms of getting our fair share of medical research money from most federal bodies. I have written to the federal government on this matter. We also met with the CEO of the National Health and Medical Research Council last year, Anne Kelso, to express concerns and work out how we might better place ourselves to access some of the funding that comes from the commonwealth. That is in train.

In terms of those other jurisdictions, the honourable member quite rightly pointed out that they do not allow incapacitated people to participate in urgent medical research. I dare say that none of those jurisdictions is getting any funding to undertake research on people who are incapacitated. Victoria does allow it. I dare say that if funding is going to this area, Victoria is getting the lion's share of it at the moment.

In terms of the broader point, I am happy to say that we do not get our fair share of funding. How much of that has to do with the sunset clause? Who knows? We cannot quantify it. However, as I said, and I probably will not say it too many more times this evening, stakeholders have come to government with an issue—whether that is to me as minister or, indeed, to other members of Parliament. They have been consulted as part of reviews that say that the sunset clause is an inhibitor. I believe them. As to how much it inhibits us by? Who knows? It is difficult to quantify, but it is an inhibitor.

Hon TJORN SIBMA: Thank you, minister. I think it is unfortunate that that cannot be substantiated. However, I am not going to receive any further insight than I have received thus far.

One of the other matters that I raised toward the end of my second reading contribution, and forgive me if I did catch the response in passing, concerned the number of individuals who have been—I hate this phrase, but I will use it anyway—dealt with under part 9E of the act. I appreciate that the most recent population for the 2021–2022 financial year was 115 people, of whom 100 had decision-maker consent and 15 did not. Since the passage of the 2020 amendment act, there have been some 220 individuals who have been dealt with under part 9E of the Guardianship and Administration Amendment Act. I did want to get a sense of the population, if it is possible—it might be one of those unanswerable questions, though.

The reason for asking this is to attempt to understand—this is not an elegant phrase, I will not say "burden" of the population, because these people are also beneficiaries of medical research. What proportion of the overall population of Western Australia who have engaged as participants in medical research are represented by those 115 people? Is there any possible insight that can be thrown over the size, throughout any calendar year, of the number of Western Australians enrolled in medical research through, at least, nationally funded programs? There might be a range of other university-based or private institutions that the minister may not be able to speculate on. I just want to get a sense of what proportion those 115 dealt with under the GAA represent the entire cohort of Western Australians enrolled in some sort of medical research in any given year?

Hon STEPHEN DAWSON: I cannot answer that, honourable member.

Hon TJORN SIBMA: That is fine. The reason for asking it was, again, not to cast doubt on the advice that was provided to the minister by stakeholders on the funding issue, but looking as a layperson at the matter. If I take some of the arguments at face value, I am going to appreciate some of the implications there. Obviously, I am committed to the furtherance of medical research in this state, as just about everybody else in the chamber is, and I do not want to jeopardise it. I will put it this way: it would appear to me that the future of medical research in Western Australia seems to rely quite heavily on those kinds of people. I wanted to know whether or not that was a reasonable assumption for me to make in the context of all the other research that occurs in Western Australia.

Would there be a mechanism at some stage to determine a sense of the population size of Western Australians engaged in any form of medical research—at least the form of medical research that receives commonwealth government funding?

Hon STEPHEN DAWSON: The short answer is no. It is not just health service providers that might be involved in research in Western Australia; it is also the research institutes, the Telethon Kids Institutes of the world and organisations like Linear, which does stuff here in Western Australia for clients around the world. They do not necessarily need to get ethics approval from the WA health department. There are ways of getting ethics approvals from external organisations that provide approvals across the country. There is no central repository of how many people may well be involved in each of the trials. It is probably tens of thousands. It is difficult to quantify.

Hon TJORN SIBMA: I suppose in comparable terms, there was period between 2018 and 2020 that I will call the interregnum because of the number of individuals who were enrolled in medical research in this state due to an interpretation by the State Solicitor's Office and subsequent health department guidance. I would expect that during that period, there would have been effectively zero incapacitated individuals enrolled in medical research programs in Western Australia. Would that be a fair assumption to make?

Hon STEPHEN DAWSON: Sorry; could the honourable member ask that again?

Hon TJORN SIBMA: I assume that between 2018 and 2020, when we dealt with the legislation that we are amending today, zero incapacitated adults in Western Australia would have been enrolled in a medical research program. Is that a fair understanding to have?

Hon STEPHEN DAWSON: In 2018 everyone was told to stop, essentially.

Hon TJORN SIBMA: To make the obvious point, since the passage of the Guardianship and Administration Amendment (Medical Research) Act 2020, 220 incapacitated Western Australians have been enrolled in that study. Is it possible to forecast growth in the enrolled population to any degree, or is it just something that we discover, more or less, after the fact? I assume that is the case, but I would like to understand it.

Hon STEPHEN DAWSON: It is impossible to predict because we are talking about people having accidents, potentially. Some years might be bad years on the road and more people might die, but it is very difficult to quantify. So far, between 6 April 2022 and 24 February 2023, 96 candidates were enrolled under part 9E of the act, and that is what brings us to 220. There were nine, then 115 and now 96 between that April date and 24 February 2023.

Hon TJORN SIBMA: Of the 96 candidates, can the minister advise how many of that cohort did not have consent?

Hon STEPHEN DAWSON: I cannot advise. It is not published yet. My understanding is that it will be published in April. The advice will go to the minister, and the minister will furnish the tabling of the report.

Hon TJORN SIBMA: In reply to the second reading contributions, the minister dealt with safeguards to some degree. I would like to ascertain, for the chamber's curiosity, the degree of the safeguards. Safeguards is a relative term, but it is the language that generally the chamber has become comfortable with. I refer to chapter 13 of the report of the Standing Committee on Legislation, only to the degree that it is a useful list of the appropriate safeguards as they apply to the present act. I will forgo the opportunity to inquire into the lead researcher being a medical practitioner, which is dealt with under clause 4, and save my remarks for that time. I am not sure whether the drafters of this committee report put these points together in any order of priority, but the report states —

- medical research is to be conducted in accordance with a research candidate's advance health directive, if the candidate has one …

Can the minister elaborate on the practical process that is followed for this cohort to ensure that an incapacitated person is being treated in accordance with that advance health directive?

Hon STEPHEN DAWSON: The GAA guidance document from October 2020 provides a prompt for researchers to check whether the research is inconsistent with an advance health directive. In addition, across the WA health system, treating physicians must ensure that no AHD is in place as per their health service's policies and procedures. Further, under the *WA Clinical Alert (MedAlert) Policy*, MP0053/17, the existence of an AHD must be added to the Western Australian Department of Health patient administration system, WebPAS. Inclusion as an alert on WebPAS will ensure that the presence of an AHD is flagged to the treating team upon admission to any WA Health site. It should also be noted that patients with an AHD are advised to keep a copy on their person and ensure that a close relative has a copy and that they upload a copy to their My Health Record.

Hon TJORN SIBMA: It is always wise to advise people to have in close proximity to their person vital documents that concern them. Nevertheless, with the population that we are dealing with presently, if an individual was admitted and did not have with them a copy of their advance health directive in paper form or a trusted family member with them, the reliance would be on the WA health system having that information captured. Is my understanding correct?

Hon STEPHEN DAWSON: It is still up to them to lodge it with the health system, but if they have not done it and they have not got it with them and a trusted person does not have it, then it is a challenge.

Hon TJORN SIBMA: Do any of the internal reviews, perhaps in the form of advice going up to the minister, provide some guarantee or assurance that an individual who has been dealt with under part 9E of the present act has had their AHD complied with? Noting that there might be circumstances in which someone does not have something readily available—or, without being pejorative or stereotypical, perhaps more elderly people did not know or could not ensure that their advice, their wishes, were recognised and recorded appropriately by WA Health—how will the minister or the chief executive of the Department of Health satisfy themselves that in the case of all these enrolled people who have an advance health directive that, indeed, their AHD has been complied with at the point at which treatment was rendered and research consistent with that treatment, hopefully, was undertaken?

Committee interrupted, pursuant to standing orders.

[Continued on page 1157.]