CHAIR: We will now move to outcome 5, Regulation, safety and protection, starting with program 5.1 'Protect the health and safety of the community through regulation'.

Senator SINGH: I wanted to ask some questions about the Special Access Scheme for medicinal cannabis.

Dr Skerritt: I should clarify that the Special Access Scheme covers all sorts of unapproved medicines, of which we get 20,000 requests a year for approval.

Senator SINGH: Yes, I understand. I just wanted to let you know so that you knew where I was coming from.

Dr Skerritt: Thank you.

Senator SINGH: Let us just start generally. Since the regulatory changes to the Special Access Scheme late last year, how many applications has the TGA received for access under category B? And how many have you approved?

Dr Skerritt: I have the figures from 1 January 2016 to the present. I do not have them from another point in time. We can take that on notice. I actually have seen an acceleration since the regulatory changes in the number of applications per month. To answer your question, since 1 January 2016 to 26 May 2017, last Friday, we have had 66 approvals. Of those, 34 are still pending, where we have asked for further information. So they are not sitting with us. We have gone back and said, 'You've written "medicinal cannabis" on this form. What form of medicinal cannabis?' That is an example where we have asked for further information. We have had 19 applications withdrawn — by the doctor, not by us. That brings it to a total of 119.

Senator SINGH: 119 received or —

Dr Skerritt: All together — applications received.

Senator SINGH: And 66 approved. Okay.

Dr Skerritt: And zero rejections, I should add. We have not rejected a completed application.

Senator SINGH: But you have 34 pending?

Dr Skerritt: We have 34 pending where we have gone back to the clinician and said, for example, 'You have written "medicinal cannabis"; what do you mean?'

Senator SINGH: I understand. What is the TGA's average processing time for medicinal cannabis applications under category B of the scheme?

Dr Skerritt: The average processing time during calendar 2017 for applications is 2.38—don't you love scientists; they always give you too many figures—per day. That is two days and a couple of hours.

Senator SINGH: Okay. But obviously some applications would take longer to process.

Dr Skerritt: That is the average with us. Of course they do take longer to process if we go back to a doctor and ask what type of medicinal cannabis and they take a week to come back to us.
Senator SINGH: So what is the average time for all applications?

Dr Skerritt: I do not have the figures with me. We would have to take on notice the time that it is with the actual doctors.

Senator SINGH: You can take that on notice. Thank you. That would be good. One of the issues here is that clinicians do not necessarily understand the current pathways for accessing medicinal cannabis. In February, the minister undertook that the TGA would rework information on its website to provide simple guidance on the application process. Firstly, has that happened?

Dr Skerritt: Yes, it has. We have reworked the information on our website and provided a simple flowchart. We have also had a number of clinicians' meetings around the country. Just a week and a half ago we had a meeting in Melbourne. Before that we had one in Sydney. We have some planned in South Australia and Queensland. We also have met with the individual state departments and asked them to simplify the information available on their websites. Some have, and some unfortunately are still a bit complex.

Senator SINGH: Could you table the old and new versions of website?

Dr Skerritt: I can certainly table our website. I think we will have captured the old version but I can certainly table what we have now. If we are able to give you what it looked like pre-February, we can table that.

Senator SINGH: I would like both of those. Thank you. The minister also undertook that the TGA would publicise the existing 1800 number for any clinicians who require personalised advice. How are you doing that? And do you have any examples of this kind of publicity?

Dr Skerritt: We have publicised a consumers' number and a clinicians' number as well as an email address. We have advised different clinical colleges of that number. We talk about that number when we have meetings of clinicians. But, most importantly, as you know, almost every day of the week there is something in the media on medicinal cannabis and the existence of a number — or numbers — and often the number itself has been described in the media. So the media has actually done a good job here in spreading the message. Is it on everyone's lips? No. But we have also spoken fairly regularly with the President of the College of General Practitioners and the president of the AMA about the importance of communicating the availability of these numbers if clinicians want to contact us for further information.

Senator SINGH: So do you have any examples — other than the free media you have received — of how you are doing this or how you plan to do this? The publicity, I mean, not the numbers.

Dr Skerritt: It is working with the doctors, so the publicity is first of all working with the clinicians' associations and colleges; having public meetings involving the clinicians; working with the state departments of health, because remember they have significant outreach into clinicians. And also it will be important to work with the pharmacists. For example, we have asked—and they have said yes — to have a major article in the next month or two, depending on when they go to publication, in the Journal of pharmacy that goes to every pharmacist in this country through the Pharmaceutical Society of Australia.

Senator SINGH: I understand that. I understand you work with clinicians and colleges and in the states and territories to provide more information on clinical evidence and so on, as minister's letter said, to assist them in prescribing medicinal cannabis. But how exactly how are you doing this? How are you working with these colleges?

Dr Skerritt: I think I have given a fairly specific description. We sit and meet with them, talk about

the aims of getting the information out there to doctors. They highlight opportunities where we could talk about it. So our principle medical adviser was invited to speak at the college of physician's congress in Melbourne recently at a special session they organised on medicinal cannabis. That gave him an opportunity to talk through the access pathways to Australia's main conference of specialist physicians. So part of it, frankly, is getting yourself invited to speak at places, and getting invited to put information into magazines, newsletters and so forth.

Senator SINGH: Another issue is this duplication between Commonwealth and state processes. In February, the minister undertook that the TGA is 'working with every jurisdiction to seek further harmonisation'. What are you doing about that?

Dr Skerritt: In March, we met with senior representatives of each jurisdiction here in Canberra — with the exception, I think, of the Northern Territory, who were on the phone; I think all the others came and met face to face—for a full day meeting. That was one of the key subjects of the meeting. I need to preface this by saying that, of course, there are specific issues in state law that are the responsibilities of the states; they regulate pharmacies. They also have better information than the Commonwealth will ever have on whether there are particular prescribers they want to watch because of questionable prescribing behaviours. So there is a valid and important role for states here. However, the meeting in March talked through the elements of the state systems and where there is, in our view, some duplication. The other thing that we covered at that meeting was the need to unpack the state processes. Many of the states have also followed our lead in putting simplified information up on their websites, explaining their processes to patients and doctors. After that, we have also done an analysis of the situation in every state and territory, and we provided the minister with advice on where, in our view, there is potential duplication. He has made a public commitment to contact, speak with and write to every minister about those issues. He has made that commitment publicly.

Senator SINGH: Okay. But at this point in time, there have not been any duplications removed?

Dr Skerritt: For example, the new South Australian scheme, which does not bring any additional requirements for a physician — unless someone has a history of drug abuse — for prescribing cannabis for up to two months. They had a range of options in front of them but South Australia had been at those meetings. I do not want to say it is our leaning on them but they reached a view that they did not need to put any additional framework in place. Similarly, other states, like Western Australia and Tasmania, have also brought in relatively streamlined systems. And, in states where on the surface of things the delays may have been considerable, it has been clarified that, even though there might be a legal maximum — for example, a 90-day approval period in Queensland — the real time is a matter of four or five days on average. So I think we have made progress but a key thing will be the minister communicating with each state and his equivalents, the state and territory health ministers.

Senator SINGH: Moving to the other scheme, cannabis is also available through the authorised prescribers scheme. As of February this year, I understand, there were only 23 authorised prescribers around Australia. How many are there now?

Dr Skerritt: We now have 25. It would have been good to have a greater increase but again we are responsive to what applications we receive from ethics committees. So we cannot write these things ourselves. What is quite exciting is that we now also have an authorised prescriber for chemotherapy induced nausea and vomiting in palliative care. That actually breaks new ground, because earlier—to date—the authorised prescriber approvals had been for paediatric epilepsy.

Senator SINGH: I did ask you last estimates for a breakdown by state and I remember it was very

New South Wales centric. Considering there are only two more from last time, I would imagine it is still very New South Wales centric.

Dr Skerritt: Yes, the New South Wales people have not withdrawn their authorisations.
Senator SINGH: But perhaps you could say what states those two extra authorised prescribers come from — the two new ones?

Dr Skerritt: I will just get that information.

Senator SINGH: Also, how many applications to become an authorised prescriber are outstanding at the moment?

Dr Skerritt: I do not believe there are any outstanding, but I will just double-check that.

Senator SINGH: I am a bit perplexed as to why you are not making more progress. You have not really moved very far since February, if you have only got two more.

Dr Skerritt: As far as authorised prescribers go, I go back to my comment that we are responsive to hospitals, state health systems, and individual doctors or groups of doctors in a practice putting up a submission through an ethics committee—because, for authorised prescribers, the application needs to go through an ethics committee - and then we receive the application and we review it. So we are fully responsive to what we get. It is the same as asking, 'Why haven't you received 50 applications for new medicines this year?' We review things as we receive them.

Senator SINGH: Yes, but how can you point to this as a viable pathway for accessing medicinal cannabis when it is not available in a number of states across the country?

Dr Skerritt: Well, there are both the Authorised Prescriber Scheme and the Special Access Scheme pathway, but, more importantly, there is a piece of work that we are working on together with clinical groups over the course of 2017, and this is the development of clinical guidance for the use of medicinal cannabis for a range of conditions. That will not only summarise the available evidence but also develop a fairly simple approach for where it fits in to therapy. That will extend the range of conditions into, as I have mentioned, palliative care, and epilepsy — both childhood and adult. It will look at areas such as nausea and vomiting, whether it is HIV treatment, although that is less these days, or chemotherapy induced. It will also look at a range of other forms of pain, which is an area of very significant interest. Working with clinical groups on this guidance will certainly increase the level of awareness, but, at the end of the day, it will be up to the clinicians to decide whether this particular form of therapy is appropriate for a particular patient. It is a clinical decision.

Senator SINGH: I understand that. Firstly, have you got that information on the breakdown by state; and, secondly, how many applications are outstanding?

Dr Skerritt: I will just check. I do have it somewhere. I have SAS approvals by state and territory. There have been approvals in every state, but none in the Northern Territory or ACT yet.

Senator SINGH: We are not talking about SAS; we are talking about the Authorised Prescriber Scheme.

Dr Skerritt: Okay — authorised prescribers. As we said, 23 are New South Wales. I suspect the other one is Queensland, but I need to check that in another part of my documents.
Senator SINGH: So there are still no authorised prescribers in Tasmania, South Australia, Western

Australia, Queensland, the Northern Territory, Victoria or the ACT?

Dr Skerritt: No. We would be very happy to consider submissions from those states, but, again, we have to react to what we receive rather than write the submissions ourselves. It is a reaction to the submission of a proposal.

Senator SINGH: Yes. That is why I was asking before about your publicity and your website and all of those other things.

Dr Skerritt: Again, it is a careful balance as a regulator. In the same way, we would not advocate for one particular cancer medicine over another. We have to provide information—and I agree with you wholeheartedly that there is a shortage of information among clinicians about these products. I have talked about the range of activities that we are doing, but it is also important that we are doing them jointly with clinicians. But, at the end of the day, it is not for us to advocate, the same way it would not be for us to advocate use of a particular unapproved cancer medicine. The clinical colleges and the groups of GPs or others have to come to us.

Senator SINGH: Okay. Obviously, the pathways that we have been talking about for medicinal cannabis products are yet to be approved by the TGA. Ultimately, approved products will be available under the national licensing scheme. What is your estimate of how long it will be before that scheme is operational?

Dr Skerritt: Again, we are reactive to receipt of a submission for an application.

Senator SINGH: How many licences have you?

Dr Skerritt: Are you talking about the licences for cultivation in Australia, or are you talking about approval of a medicine through TGA so, for example, it can be dispensed at every suburban pharmacy? Sorry, I am a bit unclear of your question.

Senator SINGH: Under the national licensing scheme, I presume.

Dr Skerritt: The national licensing scheme is registration of medicines—that is one thing. I think what you are talking about is approval of licences for the cultivation of medicinal cannabis in Australia. I am just trying to clarify the question.

Senator SINGH: I would like both figures, to be honest.

Dr Skerritt: Okay, we will give you both. I might call my colleague, Bill Turner, to the table. Senator SINGH: And a breakdown by category and state would be useful.

Mr Turner: There are three types of licences under the scheme. One is called the medicinal cannabis licence. That is for cultivation of cannabis for use in humans, through the Special Access Scheme, authorised prescribers or clinical trials. Seven of those licences have been issued. There is the cannabis research licence, which allows research into the plant and its medicinal properties. Three of those have been issued. And there is the manufacture licence, which allows the extraction of the cannabinoids. Two of those have been issued, at this time. With respect to state by state, can I take that on notice? I have the figures as a breakdown but we do not, generally, release those — because there are commercial sensitivities as well as security issues with location, so I would like to consider that before releasing those figures.

Senator SINGH: If I could ask for it to be taken on notice and then the committee can consider the

answer as far as our release of the information—is that something we could do, in relation to this?

Mr Turner: If I could, I can tell you where there have been announcements. The companies are allowed to publicly announce. We do not, but companies have. There have been announcements in Queensland, Victoria, Tasmania and Western Australia.

Senator SINGH: To do with one of those licences?

Mr Turner: Yes, with those types of licences.

Senator SINGH: I will finish on this because, obviously, the national scheme is redundant if state laws prohibit access. Labor has been calling on the government to work with the states to harmonise those laws. I understand harmonisation is not specifically in your portfolio, but are you aware of any progress on this front?

Dr Skerritt: To go back to my question, the minister made a public undertaking, earlier this month, that he would discuss the issue of removing any potential duplication between Commonwealth requirements and state requirements. He was going to speak with each state and territory health minister individually. I understand that those discussions will happen over the coming weeks. He has made a public undertaking.

Senator SINGH: But that is about duplication. I am asking about where access is prohibited to medicinal cannabis.

Dr Skerritt: Where is access prohibited? There is no state that prohibits access to medicinal cannabis.

Senator SINGH: Are you sure about that?

Dr Skerritt: There are states that have requirements for certain prescriber types and so forth, but there is no state in which it is prohibited to access medicinal cannabis.

Senator SINGH: But all the laws are different in each state, so what we have been calling on is for government to harmonise those laws so that we do not have these differences in each state to—
Dr Skerritt: If ever it be the case—of course, the Commonwealth can only go so far. Even poisons handling in pharmacies are regulated by state-by-state legislation. This is a power that sits under the states rather than under the Commonwealth. What the minister has made a public undertaking to do is to talk with his counterparts about removing any duplications and inconsistencies.

Senator SINGH: Yes, I know about the duplication. I was not asking about that.

Dr Skerritt: But there is no way for the Commonwealth to ride over the states.

Senator DI NATALE: How many people in Australia do you think - we have had this discussion before - would benefit from access to medicinal cannabis?

Dr Skerritt: I will not give a personal opinion. There have been various studies. I think one of the most comprehensive studies was done in partnership with the University of Sydney, and I think it gave a figure of about 30,000. A lot will depend on clinical evidence in pain conditions.

Senator DI NATALE: But we are talking about tens of thousands of people who, we have established, would benefit from medicinal cannabis.

Dr Skerritt: No. You have used the words, 'we have established'. I think that is a bit overstated.

Senator DI NATALE: The evidence indicates tha t—

Dr Skerritt: No, I disagree.

Senator DI NATALE: You have just quoted a study from the University of Sydney.

Dr Skerritt: I have quoted a study in which the University of Sydney estimated that they felt up to 30,000 may benefit from medicinal cannabis.

Senator DI NATALE: Quite, and your department has approved 66.

Dr Skerritt: We have not rejected a single licence.

Senator DI NATALE: Sixty-six?

Dr Skerritt: Correct.

Senator DI NATALE: You have rejected category A. We will get to that in a moment. This becomes very complicated and people do not get it. Authorised prescriber status has largely been given within the context of clinical trials, mainly based out of New South Wales.

Dr Skerritt: No, they are separate from clinical trials.

Senator DI NATALE: Explain to me who gets authorised prescriber status.

Dr Skerritt: A group of clinicians who may be specialists — for example, a group of neurologists —may initiate it themselves. It could be initiated by their regional health state service or even their state department of health, but they do not have to be civil servants. It can be a single clinician. It can be a single authorised prescriber. They identify that they have a significant and ongoing need to use an unapproved medicine. They then receive ethics committee approval for use of such a medicine and, subject to that ethics committee approval —

Senator DI NATALE: Why are they getting ethics approval?

Dr Skerritt: Because it is an unapproved medicine and to check that the requirement is ethically appropriate.

Senator DI NATALE: Who is the accrediting body?

Dr Skerritt: We provide the legal authorisation, but the requirement is that it goes through an ethics committee.

Senator DI NATALE: Are any of those 25 engaged in clinical trials?

Dr Skerritt: I believe that some of them are also doing clinical trials, but their access to the product for the purposes of clinical trials is quite separate.

Senator DI NATALE: You have 66 scripts being approved —

Dr Skerritt: No.

Senator DI NATALE: through Category B.

Dr Skerritt: Through Category B? Yes, so far.

Senator DI NATALE: Sixty-six?

Dr Skerritt: Yes.

Senator DI NATALE: The evidence points to the fact that there may be tens of thousands of people who would benefit.

Dr Skerritt: No. You keep on saying 'the evidence'. I quoted a study —

Senator DI NATALE: There is a published study from the University of Sydney we are both familiar with.

Dr Skerritt: Yes.

Senator DI NATALE: That is evidence.

Dr Skerritt: No.

Senator DI NATALE: It is not evidence?

Dr Skerritt: It is an opinion from that study —

Senator DI NATALE: It is not an opinion; it is a published piece of research.

Dr Skerritt: It is not in any refereed medical or scientific literature. It was a commercially sponsored study done by a group of business students and business lecturers published on the internet. You keep on saying 'the evidence', but —

Senator DI NATALE: In a briefing with me you have indicated you believe it is 20,000 people.

Dr Skerritt: You asked me for an estimate of the number of people, and I quoted this study.

Senator DI NATALE: In a separate briefing you indicated to me that you thought that 20,000 people would benefit from medicinal cannabis.

Dr Skerritt: I do not believe I have ever given you that figure.

Senator DI NATALE: We will disagree on that point. So far, through category B, we have 66 approvals.

Dr Skerritt: Yes.

Senator DI NATALE: Sixty-six?

Dr Skerritt: Sixty-six since 1 January 2016.

Senator DI NATALE: And in total?

Dr Skerritt: I will have to go to the numbers.

Mr Turner: It is 89 under SAS Category B since the first application in July 1992. We should also add into that 41 patients who have received it through authorised prescribers. There is always a lag with our figures on authorised prescribers because they only report six-monthly.

Senator DI NATALE: So far in Australia we have 89 people who have got it through category B. Is that right?

Mr Turner: Yes, 89.

Senator DI NATALE: Through authorised prescribers, of those 25, you said there were how many scripts?

Dr Skerritt: That is as of December last year.

Mr Turner: Forty-one were authorised prescribers. That is cumulative—it is the 89 plus the 41.
Senator DI NATALE: Yes, that is right. So we are effectively talking about 130 scripts in total.
Dr Skerritt: I expect that there are somewhat more because—

Senator DI NATALE: There might be some more because of the lag.

Dr Skerritt: Because that figure was as of December, yes.

Senator DI NATALE: It might be an extra dozen or so on top of that 130. The issue that I think Senator Singh was trying to get to is that this was established in an effort to try and ensure that people got access to medicinal cannabis, and so far, under what has been managed through the TGA, we have seen 130 scripts.

Dr Skerritt: The scheme was established to ensure that individuals who were assessed by their clinicians, with appropriate clinical oversight—and I talked about the ethics committee oversight for authorised prescribers, for example — were able to have access to this as a treatment option. But, of course, it is not a system for every individual who feels that they should benefit from the drug to get access to.

Senator DI NATALE: No-one is suggesting that. Regarding the authorised prescriber status, do they belong to one particular class of specialty?

Dr Skerritt: No, there are neurologists as well as people working in palliative care who have received authorised prescriber status.

Senator DI NATALE: The answer to a question on notice that I got from you was that all the authorised prescriber individuals were paediatric neurologists.

Dr Skerritt: That is because the question on notice was probably submitted in February or March, and today is 29 May.

Senator DI NATALE: How many of the 25 are paediatric neurologists?

Dr Skerritt: All but one are neurologists.

Senator DI NATALE: So there is one palliative care physician?

Dr Skerritt: At that stage. I do not know if you were listening earlier, but I mentioned the work we are doing with groups of clinicians on clinical guidances for ranges of different conditions, but, again, the clinicians will reach their own judgements having reviewed those guidelines.

Senator DI NATALE: You will forgive my cynicism here because earlier on you said that you believe that we should not be discriminating between classes of drugs. That was your proposition to Senator Singh.

Dr Skerritt: My proposition to Senator Singh is that we have a system for unapproved medicines, and the reason why these medicines require an approval is that they do not have clinical experience internationally as prescription medicines.

Senator DI NATALE: We have a system that exists for unapproved medicines, both through category B and through category A.

Dr Skerritt: Correct.

Senator DI NATALE: And it was the view of the department that we should not support access to medicinal cannabis through category A. Can you tell me what category A is, or would you like me to perhaps summarise?

Dr Skerritt: No, I think I know what category A is. The reason why —

Senator DI NATALE: Perhaps just explain, for people who might be listening, what category A is. Dr Skerritt: The reason why, in the department's view, it was not appropriate for medicinal cannabis products to be through category A—

Senator DI NATALE: Can we explain what category A is for people who might not be familiar with it?

Dr Skerritt: It is a system for access to medicines where people are at imminent risk of death.

Senator DI NATALE: They have a terminal illness—

Dr Skerritt: A terminal illness, yes.

Senator DI NATALE: And the patient might die without early treatment.

Dr Skerritt: Without early treatment, yes.

Senator DI NATALE: And people through that scheme can get access to unregistered medication.

Dr Skerritt: They can, but the medicines that they can get access to are those where there is a significant experience with those medicines being registered, for example in Europe for 20 or 30 years or by the FDA, or they could be recently approved cancer or other drugs that have been through the full FDA process.

Senator DI NATALE: With respect, this is a drug that has had a long track record in many other jurisdictions, and just because it is something that the TGA might not believe —

Dr Skerritt: I disagree with you. It is not approved as a registered or equivalent medicine in European countries or in the US or in Canada. So I do not know these equivalent jurisdictions are.

Senator DI NATALE: It needs a track record of clinical efficacy in those jurisdictions. Are you disputing that?

Dr Skerritt: I am disputing that. I am saying—

Senator DI NATALE: So you are disputing that medicinal cannabis has a track record of clinical efficacy for particular conditions?

Dr Skerritt: It does not have the same track record of clinical efficacy as medicines that have received registration, by and large. There was a very exciting trial on the use of cannabidiol in children with Dravet syndrome, co-authored by Australians, just last week—that was exciting. I was actually with one of the lead authors last week, just before it was published. But, in general, we do not include products that have not been approved as having had a track record of clinical evidence sufficient to get US FDA or European Medicines Agency or Health Canada or Japanese approval—the major global regulators.

Senator DI NATALE: Firstly, have any medicines that are used through the category A scheme—which is for terminally ill people who cannot get their medicine through a normal script through their doctor—not been approved by one of those regulators?

Dr Skerritt: We do not believe that that is the case, no—not that we know of.

Senator DI NATALE: You are not aware of any other —

Dr Skerritt: I am not aware of any others.

Senator DI NATALE: What you are saying then is that, despite the fact that we have gone through this process that says that we are going to start treating medicinal cannabis like we treat other medicines—which is that we are going to ensure that we have access available to people through a scheme like category A — we are going to treat medicinal cannabis differently?

Dr Skerritt: We are going to treat it differently until the time that there is the same sort of evidence for the other medicines that are under category A.

Senator DI NATALE: Let me just talk through what some of the safeguards are against category A. If you have a terminal illness, you have to go and see a doctor first; is that correct?

Dr Skerritt: Yes.

Senator DI NATALE: The doctor then says: 'You have end stage cancer. You are having chemotherapy. Drugs that we have given you to try and treat your nausea are not working.' You cannot, under those circumstances, go to a doctor and say, 'I've got a terminal illness. I know this stuff works. I am getting it illicitly because at the moment it is the only thing that is preventing my nausea', and, through the category A scheme, get a doctor to prescribe that?

Dr Skerritt: Not through category A. But remember that we are taking, on average, two days to approve category B. And also that there are now three companies with significant stocks of material in this country—

Senator DI NATALE: But why would you deny access to somebody who can get it quickly through category A, given that we have seen only 66 approvals through the category B scheme?

Dr Skerritt: As I said, we take 48 hours to approve. In the last couple of months there are now stocks of these products available in Australia. So there is not a delay in accessing these products from overseas.

Senator DI NATALE: You have only issued 66 approvals?

Dr Skerritt: We have not rejected a single application.

Mr Cormack: Chair, I think this is going round and round in circles. I think Professor Skerritt has clearly outlined to the senator the tests that he applies as a regulator. He has applied them consistently. It appears to be the case that there is not sufficient demand from prescribing doctors to be able to access the scheme as structured —

Senator DI NATALE: I am not worried about the doctors; it is the patients I am concerned about.

Mr Cormack: In this country, as you would know, Senator—

Senator DI NATALE: It is the patients who cannot get access to it.

CHAIR: Senator Di Natale, are you going to move to other questions?

Senator DI NATALE: I am going to continue. I have some other questions on category A.

CHAIR: Other senators also have questions.

Senator DI NATALE: Just to confirm, through category A the doctor needs to make an application to the Office of Drug Control; is that correct?

Dr Skerritt: No.

Senator DI NATALE: What happens?

Dr Skerritt: In category B the application is to TGA —

Senator DI NATALE: Category A.

Dr Skerritt: Category A is not an application; it is a notification. We get told afterwards. When we get those notifications — because, of course, with a notification system you are never sure whether you actually get the notification.

Senator DI NATALE: What does that mean?

Dr Skerritt: When you are told that you have already done something, human nature is such that, well, we have no idea whether 90 per cent, 99 per cent or 100 per cent of people actually send in the forms. We have no way of knowing that.

Senator DI NATALE: You have said you have this wonderful safeguard through the category A scheme—

Dr Skerritt: No, category B —

Senator DI NATALE: Let me finish now. You indicated that there is a safeguard that these

medicines must be approved oversea by overseas jurisdictions, and now you are indicating that there is a flaw in the scheme, that you would not even know if somebody, through category A, got access to a drug that is unregistered here in Australia?

Dr Skerritt: They are committing an offence if they do not notify us within a certain period, and of course that would be viewed rather negatively, apart from the straight offence, by AHPRA and by their own professional bodies. We also can trace importations of medicines through companies that specialise in importing unapproved medicines. There are some audit trails available to us, and we are able to use those, but can I say that we get 100 per cent versus 99 per cent or whatever? I cannot.

Senator DI NATALE: Given all of the checks and balances; given that you have got to, ultimately, have a doctor see a patient and the patient then needs to send a notification to you to indicate that they have done that; and given that they also need to ensure that, in terms of getting the substance over here, there are a range of other safeguards — the rationale that was used against providing access through the category A scheme was that it would open up the floodgates.

Dr Skerritt: I think that you are confusing a couple of things. The recent disallowance motion had three parts to it. Where there was significant concern was around personal importation, which also would have been opened up had disallowance been successful. This is personal importation of cannabis-based products.

Senator DI NATALE: Medicinal cannabis, for use —

Dr Skerritt: Medicinal cannabis-based products. There was also concern given the challenges of working out what an appropriate quantity was and the practical challenges of customs and border service people working out whether it was appropriate personal use for a period of three months.

Senator DI NATALE: But we do that all the time.

Dr Skerritt: Yes, we do it all the time, because —

Senator DI NATALE: We do it all the time in medicine. We make those distinctions all the time.

Dr Skerritt: If I can answer—there is personal importation all the time. Someone may have a personal importation. They have a prescription and it says that they are personally importing some medicine that is not available here, or that they are travelling. Their script will say, 'Two tablets a day.' Now, you are allowed to bring up to three months in. Three months, ninety days, two tablets a day: 180 tablets. The challenge with medicinal cannabis products is, of course, that they vary hugely in the concentration of THC and cannabidiol and so forth in them. Whether you are a customs officer or a 10-year-old, you can count 180 tablets. Someone can count 180 tablets, but what you cannot do, if you have a kilogram, five kilograms or whatever of cannabis, in a practical sense — unless you sent it off to a lab to say, 'Yes, that is 22.4 per cent THC.'—is confirm whether or not it is a dose just for yourself or a much larger trafficable quantity. That is where it is not practical.

Senator DI NATALE: Well, with respect, you could draw the threshold at the higher limit if you were interested in getting this support through, couldn't you?

Dr Skerritt: The higher limit of what?

Senator DI NATALE: Well, you could choose the highest potential concentration of THC and say,

'We're going to base our three-month quantity on that.'

Dr Skerritt: I would suggest that that would open the prospect for very significant diversion.

Senator DI NATALE: Hang on. This is a whole other argument against it. Why isn't that an issue for people who get scripts in Australia?

Dr Skerritt: The people who get scripts in Australia are receiving material that is provided by an Australian pharmacist, dispensed by a pharmacist and provided —

Senator DI NATALE: It is still the same thing.

Dr Skerritt: It is very different turning up at an airport with a suitcase of cannabis and saying, 'Oh, look, this is only one per cent, so I need a whole suitcase.'

Senator DI NATALE: Please! That is disrespectful to those people who —a suitcase of cannabis? We are talking about a three-month supply. If you are talking about a high quantity of THC, it would be a very small amount. Many of these substances come in oils and other preparations.

Dr Skerritt: I disagree. If it is raw cannabis and a standard strain — if it is fairly low in cannabidiol —

Senator DI NATALE: I just said that you could base it on the strand that has the highest concentration of THC.

Dr Skerritt: Senator, if you would let me finish. A three-month supply for a low-cannabidiol product could well be a suitcase.

Senator DI NATALE: We have just established that you could draw that threshold at a very high level.

Dr Skerritt: If you drew the threshold at a very high level and said, 'Well, okay, we're going to assume that it is very high.' It may be that the person is only bringing in enough for one or two weeks. What would happen then, if they are thinking that they have got three-months worth of medicine?

Senator DI NATALE: It is better than not bringing it in at all.

Dr Skerritt: Why would you go through that pathway when there are already stocks of this material available, sitting under pharmaceutical companies in secure pharmaceutical storage, for schedule 8 and schedule 4 drugs?

Senator DI NATALE: Where people cannot get access to it. Did you actually remove from category A the drugs nabiximols and nabilone?

Dr Skerritt: They were available under category A prior to the regulatory change. However, let us go to nabiximols. It is primarily prescribed for multiple sclerosis — a chronic condition, not a palliative care condition. There are two drugs that were there. There is a third one: dronabinol. Between the two of them, there has only ever been one request under SAS B for that drug. These were not exactly high-demand drugs, especially in a palliative care situation.

Senator DI NATALE: Is it fair to say that it is now harder to access medicinal cannabis or related products

than it was prior to this legislation through category A?

Dr Skerritt: I think that there is a clear pathway for patients to be able to access the product. There is product sitting —

Senator DI NATALE: For 66 people.

Dr Skerritt: - in warehouses in major capital cities of Australia. The Commonwealth is taking two days in its approvals.

CHAIR: The committee will suspend for dinner and resume at 7.30, examining the same program.
Proceedings suspended from 18:30 to 19:33

xxxxxx Sen Watt: Regs

Senator WATT: Dr Skerritt, my other questions concern medicinal cannabis. We have gone over that in some detail. I just want to check a couple of details about the activity of the TGA in relation to the recent vote on the disallowance motion on medicinal cannabis regulations. Dr Skerritt, I understand you were here Parliament House on the day of the vote. Is that correct?

Dr Skerritt: I was requested to be here to accompany members of the minister's office in briefings that were agreed to by crossbenchers.

Senator WATT: So the minister's office requested that you attend those briefings?
Dr Skerritt: Yes. It is quite normal for senior officials to attend briefings of opposition backbenchers, crossbenchers and so forth.

Senator WATT: You were asked to attend to assist and brief crossbenchers on the disallowance motion and the regulations?

Dr Skerritt: Correct.

Senator WATT: Was anyone else from the TGA here to assist in that regard?

Dr Skerritt: I was the one who was invited. I should explain. The implications fit across both TGA and the Office of Drug Control, both of which fall under my purview. Other members were busy preparing written briefing material, so the office requested that only I come up. There were some other pieces of written briefing. Again, crossbenchers requested. But the minister's office requested that they stay back on their computers and prepare for review by the minister.

Senator WATT: So you were here in person?

Dr Skerritt: I was here in person, as I have often been for briefing senators and members.

Senator WATT: Which senators or parties did you brief in relation to the regulations on the day of the vote?

Dr Skerritt: Again, we briefed at the request of those senators. We basically briefed Senator Xenophon and his team and Senator Hanson and her team.

Senator WATT: Not any of the Independent senators?

Dr Skerritt: Again, it was on request and so forth. We did not knock on people's doors hoping they were in their offices.

Senator WATT: You briefed Senator Hanson herself?

Dr Skerritt: Yes.

Senator WATT: And Senators Roberts and Burston?

Dr Skerritt: I will have to check my notes as to who was at both meetings. I will take that on notice. I know that it is possible that not all members of all teams, of NXT or One Nation, were present at all those briefings. Together with advisers, they made for reasonably full offices.

Senator WATT: Mr Ashby was there, no doubt?

Dr Skerritt: Yes, he was.

Senator WATT: Did you brief anyone on the day of the vote other than political parties or senators — anyone external to government?

Dr Skerritt: No, it was pretty busy. I came straight out of a meeting and the request for briefing came in, so there was not much time to work the phones or anything like that. It was really for us to brief senators on the request from them and the minister's office.

Senator WATT: Did you or anyone else from the TGA brief any journalists on the day of the vote?
Dr Skerritt: I was interviewed by a journalist from The Courier Mail at their request and the interview was essentially: 'Can you explain what the changes to the regulations are and what the disallowance is?'

Senator WATT: Which journalist was that?

Dr Skerritt: I talk to a lot of journalists. I would have to take the name on notice.

Senator WATT: If you could, that would be great. Did you say that the interview was conducted at the request of the journalist?

Dr Skerritt: Yes, the interview was requested. Again, it was requested through the minister's office, as is quite normal. Many of our requests from the media come from a minister's office; some come directly to the department; some come to both at the same time.

Senator WATT: Was it the minister's office who requested that you conduct an interview with the journalist?

Dr Skerritt: The journalist had asked the minister's office that I speak with them. I accepted that request. It was a fairly factual interview which, I think, was reported in print in the Courier Mail.

Senator WATT: Is it usual for you to brief journalists directly?

Dr Skerritt: Yes. For example, in the last few months I have spoken on 60 Minutes and on Four Corners. We do a certain amount of media. I think it is important for there to be greater awareness of the regulatory framework and reasons for regulators' decisions.

Senator WATT: Is that the only interview you did on the day of the vote?

Dr Skerritt: That was the only interview I did on the day of the vote.

Senator WATT: Did you provide any written comment to journalists?

Dr Skerritt: No.

Senator WATT: So it was the only verbal or written one.

Dr Skerritt: I just provided verbal. Obviously, I have no knowledge of what anyone else may have provided,either from a department or from a Minister's office.

Senator WATT: Did you brief the Courier Mail before or after the vote had taken place?

Dr Skerritt: Before. The request was, 'Can you explain what the regulation change was, and can you explain the implications depending on which way the vote went?' It was a statement of facts.

Senator WATT: It was a statement of facts; it was an on-the-record interview.

Dr Skerritt: I do not do off-the-record interviews; they do not exist.

Senator WATT: You should tell a few other people around here that! I am not a backgrounder; you see me coming. So there was just the one interview you did with —

Dr Skerritt: Just the one.

Senator WATT: Sorry, was it before the vote or after?

Dr Skerritt: Before, as I said.

Senator WATT: And you did not take any media requests after the vote?

Dr Skerritt: No, I did not. The department and minister's office may have, but I did not do any media relating to the subject. A vote had been made and we are moving on. It is not for me to run a commentary on the political process.

CHAIR: Before I move to Senator Leyonhjelm, Senator Rhiannon wanted some clarification around exactly where some questions related to —

Senator RHIANNON: Yes, to do with the testing of cosmetics on animals

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Senator LEYONHJELM: I am going to return to the same subject that Senator Watts and Senator Di Natale were talking about before we broke for the dinner break. I listened carefully to what you said in response to Senator Di Natale's questions. I am hearing from people who have sick family members—in many cases children, or youngsters anyway—with severe epilepsy, and I cannot remember what else. They are using cannabis or cannabis extract to deal with those symptoms. They are telling me that they cannot get it by prescription and that their only option is to buy it illicitly and that their suppliers are being raided by the police. I acknowledge that is a state issue. The New South Wales police are doing that, and it is not a federal matter. Why would that situation

be arising?

Dr Skerritt: It is hard to see, and it depends where you are. But as we discussed earlier, there are something like 23 or 24 authorised prescribers, who —

Senator LEYONHJELM: For the entire country, though?

Dr Skerritt: There are that many for the entire country. We would love there to be more, but as we mentioned before the dinner break, it is dependent on receipt of applications.

Senator LEYONHJELM: Perhaps that explains their difficulty.

Dr Skerritt: Their doctor can seek supply for that individual patient under the Special Access Scheme B. There are suppliers of the cannabidiol-rich medicines sitting in Australia sufficient to treat many hundreds if not thousands of children. So they basically have to go through the process, and I often muse on the time spent complaining about the process of a one-page form with some attachments when applying for access. You would get the access much faster that way.

Senator LEYONHJELM: Who has to apply, the patient or the doctor?

Dr Skerritt: The doctor, the same way with any other medicine. But prescription of a medicine is obviously based on medical opinion. The doctor has to submit the Special Access Scheme B form to us, which, as I said, is a one-page form that may require some attachments. Sometimes those attachments are only one page as well. So it is not a weighty a lot of paperwork.

Senator LEYONHJELM: Would most GPs be familiar with this process?

Dr Skerritt: We believe they would, because in last year, across all types of unapproved medicines, there were near to 20,000. I can give the exact figure for the last six months. I think I have it on me, and it was about 10,500. There were 20,000 applications made in the last financial year or in the last calendar year. It is running at about 20,000 per year, no matter how you measure it. If 20,000 applications are made, I would venture that this is not some obscure scheme.

Senator LEYONHJELM: You mentioned a relatively small number of people who are licensed to prescribe it, so if it —

Dr Skerritt: No, I should clarify: there are authorised prescribers who can provide for a hundred children, if they so wish. We do not require information on the individual children once they are an authorised prescriber. The terminology is sometimes a little bit confusing. They are people who are largely paediatric epilepsy specialists. They, or their employer if they are employed through a government health service, have gone to the trouble of filling out the forms, getting ethics committee approval and applying to us. But on top of that, any—let's use the example of neurologists—paediatric neurologist who see these kids could apply for access for any or all of their patients to prescribe these medicines. But, again, it comes down to their clinical judgement as to whether they believe that it is the most appropriate treatment.

Senator LEYONHJELM: Could a GP who is not a specialist prescribe it?

Dr Skerritt: It depends on the state, and this is one of the issues where our minister made a commitment to talk with his counterparts to streamline the system. In some states GPs can, and in other states GPs with advice from a specialist can. That does not mean a consultation, but just advice. In other states it is only specialist physicians.

Senator LEYONHJELM: If a patient had been using cannabis extract from an illicit source and wanted to obtain it from a legal source, would they require their GP to prescribe it, or would they have to be referred to a specialist, depending on what state they were in?

Dr Skerritt: Again, it depends on the state, but —

Senator SINGH: But it is only in New South Wales that you are authorised to prescribe it anyway.

Dr Skerritt: That is because it is only where they have come to us. But, remember, in the other states, a GP or a specialist, depending on the conditions, can go to us. We have doctors in every state. We have not had any in any of the territories yet, but we have had doctors in every state of Australia prescribe medicinal cannabis to patients legally.

Senator LEYONHJELM: If a patient was located in regional Queensland, outside Brisbane, and went to their GP, are you saying that they could legally access cannabidiol to treat childhood epilepsy?

Dr Skerritt: The answer is yes. If a patient has been going in occasionally to Brisbane under the care of a specialist, they might have to have a phone call to the specialist, as is quite common in complex and difficult medical conditions. These serious paediatric epilepsies are serious conditions. Queensland Health would also have to sign off. That is a thing that is unique to Queensland and Victoria for cannabidiol.

Senator LEYONHJELM: And if they were in New South Wales?

Dr Skerritt: I am just checking. I believe New South Wales does not require any specific New South Wales approval for cannabidiol to be prescribed. Again, they can go—let us say they are rural in New South Wales. If it was a kiddie with serious epilepsy, they would be seeing a neurologist at their local centre — like Dubbo if the kid was at Broken Hill or Nyngan or somewhere—and so the doctor would consult with them and then an application would be filled out. These are quite common processes for when medication changes are done anyway. If you are a GP seeing a kid, or even an adult, with epilepsy, you do not generally change their medication without at least a telephone call that person's neurologist because of a risk of seizures, and for adults of course that means you cannot drive.

Senator LEYONHJELM: Are you able to give us any information as to why suppliers who are endeavouring to provide these patients or the parents of these patients with cannabidiol are being raided by the police?

Dr Skerritt: I think the suppliers who are being raided by the police are actually those who are supplying the product illegally. Remember, cannabis is an illegal drug in all states and territories. The medicinal cannabis scheme carves its approval, as an unapproved medicine, when provided through medical prescription and pharmacist dispensed. It is not saying that anyone who has cannabis and says they are using it for medicinal purposes is somehow immune from the law.

Senator LEYONHJELM: Changing topic for a moment, when the disallowance motion of Senator Di Natale was considered by this Senate, it was relevant to category A approvals, which do not relate to epilepsy, as I understand it, but to cancer patients facing imminent death.

Dr Skerritt: A range of people utilise the category A pathway, and a range of physicians prescribe under it. Quite often it is more relevant to palliative care than, say, a longer term condition like seizures.

Senator LEYONHJELM: In answer to questions from Senator Watt, you indicated you had briefed Senator Hanson and Senator Xenophon, or some people from their parties. In the context of consideration of that bill, I was lobbied by a local producer, or an intending local producer, of cannabidiol. The gist of the lobbying or the gist of the message that was presented to me was they did not want the regulation to be disallowed because it would facilitate the entry of cannabidiol by import and that, as a consequence, they would be uncompetitive. Are you familiar with that argument?

Dr Skerritt: Yes, because there are different provisions that apply to the ability to prescribe imported medicinal cannabis products versus homegrown medicinal cannabis products. The Narcotic Drugs Act amendments that were passed in this place in February 2016 actually closed or did not make available the Category A route to homegrown products. So, had the disallowance been successful, you would have lost a level playing field. You would have had access to category A from imported product but not from Australian grown product. That would have been the lines along which I imagine your constituent was lobbying you.

Senator LEYONHJELM: The constituent was not actually very concerned about the patients. They were mainly concerned about their loss of business opportunity. Was that discussed in the context of your briefing with either Senator Hanson's group or Senator Xenophon's group?
Dr Skerritt: The differences between the frameworks are well-known. Again, we responded to questions that the senators asked us.

Senator LEYONHJELM: What do you think about the argument that the purpose of category A was to, as you put it, create a level playing field or, as others have put it, inhibit foreign competition?

Dr Skerritt: I do not think category A is set up to inhibit foreign competition. I guess I was reflecting on a provision in the Narcotic Drugs Act that was passed by this parliament.
Senator LEYONHJELM: I will leave it there.
Senator REYNOLDS: Good evening, Secretary, Minister and Professor

------ Discussion on AndroFeme

Senator REYNOLDS: Thank you. I think you could work for our security agencies, Professor; you are so oblique.....I have one final question. I would just like to come back to the issue of medicinal marijuana and some of the discussions you had with Senator Leyonhjelm and Senator Di Natale. I just want to ask you a bit further about the Greens disallowance motion and what you think—or maybe not, sorry.

Dr Skerritt: No, no.

Senator REYNOLDS: Of course, you are not asked for personal opinions, but what would the outcome of the recent Greens disallowance motion have been from a departmental perspective?
Dr Skerritt: Senior bureaucrats do not have opinions.

Senator REYNOLDS: No.

Dr Skerritt: I can only comment on what the practical outcomes in law would have been, and that was precisely the sort of thing we were asked to brief on. There would have been three outcomes. First, imported products would have been available through the Special Access Scheme A system. Second, there would not have been any Commonwealth controls on extemporaneous compounding of medicinal cannabis products. That sounds a bit obscure. That is where pharmacists compound

products. While most pharmacists are honourable people, there have been significant problems with the compounding of certain substances, be they hormones, peptides and so forth. The third implication which I talked about before the recess relates to the fact that it would have opened medicinal cannabis products up for personal importation, and the challenges it has—
Senator Reynolds: Yes. How does that —

Dr Skerritt: It is because many of the dose forms are not defined tablets or capsules. It could have been raw leaf coming in, and it is very hard to know whether a kilogram or 20 kilograms is the right amount for three months supply.

Senator REYNOLDS: Between those three potential consequences, are there law enforcement or border control implications for that?

Dr Skerritt: There would have been border control implications for all three, but particularly the personal importation. The potential disallowance was well known. As you know, it was out there for longer than the normal period of time. We had meetings with the states and territories, and they were essentially unanimous in saying: 'We don't want this. It will just create a nightmare at Brisbane airport, Darwin airport or wherever.'

Senator REYNOLDS: So the state and territory governments were supportive of this position?

Dr Skerritt: They were supportive of the position that ended up prevailing. I should say that that was at officials level. We have to be careful when defining governments.

Senator REYNOLDS: But at the officials level they were supportive —

Dr Skerritt: At the senior officials level they were supportive of the changes. They were consulted before the changes to the regulations were made, and they were supportive of the regulations staying as they were following the change.

Senator REYNOLDS: I want to make sure I have got it right. One of the implications of those three issues that you have been talking about this evening is that it would have actually made it harder to control the cannabis being provided in terms of quantity and quality?

Dr Skerritt: Very much so. It was particularly timely because there had been one and possibly a second death in California because of fungally contaminated medicinal cannabis. Also, very recently in Canada, some bright spark decided to use a fungicide that is used for lettuce on medicinal cannabis. You might say, 'So what?' People do not smoke lettuce — well, most people don't. When the fungicide on the cannabis is heated, smoked or vaporised, it breaks down and turns into cyanide. Some millions of dollars of medicinal cannabis had to be recalled and destroyed in Canada when this was discovered.

Senator REYNOLDS: Like any other medication that you get, you need to be able to control the dosage so you know exactly how much and what you are getting.

Dr Skerritt: And the quality. The view of the government, and I think it was echoed across people who spoke to the bill in February 2016, was firstly that this would be a medicine prescribed by doctors and dispensed by pharmacists and would be produced to certain quality standards. That was the whole advantage of a medicinal cannabis pathway versus a grow-your-own or get-it-through-the-black-market pathway.

Senator REYNOLDS: Thank you.