Senator DI NATALE: I have questions on medicinal cannabis. My first question is around applications for medicinal cannabis received by the TGS under the Special Access Scheme category A and B.
Dr Greenaway: I will be able to answer that, although as you probably realise I was expecting Professor Skerritt to answer the regulatory aspects of medicinal cannabis.
Senator DI NATALE: Is he not available?
Dr Greenaway: As of about an hour ago he was heading here.
Ms Beauchamp: I think that this session was scheduled for 3.30 pm. We are running a bit ahead of schedule.
Senator McKenzie: Which is rare.
Senator DI NATALE: I was going to say! I think he can be forgiven for not being here early.
Ms Beauchamp: He is on his way. He is in the building.
Dr Greenaway: Since 1 January 2016, there have been 513 approvals in SAS Cat B. I do know that of the authorised prescribers since 1 January 2016 and 33 authorisations to 31 December 2017, 193 patients have been involved in those. You would be aware that the Authorised Prescribers Scheme does by its very nature involve a notification rather than individual approval. So we would expect that to be updated next month.
Senator DI NATALE: Of the 33 authorised prescribers, do you have a breakdown of their specialties?
Dr Greenaway: The majority that I know are paediatric neurologists.
Senator DI NATALE: But are there other specialities?
Dr Greenaway: I would have to take that on notice to give you the exact number, but I believe that palliative physicians are also amongst the authorised prescribers.
Senator DI NATALE: Do you have the number of rejections for all categories?
Dr Greenaway: The category B approvals turnaround time for the TGA is very rapid. On average it is about 48 hours. So, again, I would need to take that on notice and get back to you because I didn't expect to be answering questions on notifications.
Senator DI NATALE: Yes. That's alright. What about the authorised prescribers? How many prescribers have been rejected under authorised prescriber status?
Dr Greenaway: Again, I am not aware. The Authorised Prescribers Scheme, as you know, requires approval by either the appropriate college or a NHMRC ethics committee. Once that approval if given, the authorised prescriber is a formality.
Senator DI NATALE: So you wouldn't have access to people who have been rejected by the college?
Dr Greenaway: Not off of the top of my head, but we can get it.
Senator DI NATALE: Welcome, Professor Skerritt.
Dr Skerritt: Good afternoon.
CHAIR: Never doubt the efficiency of this committee.
Dr Skerritt: I may need oxygen. Thanks to the committee for creating history and actually running ahead of schedule. I believe the question was about rejections. There have been no rejections in the last couple of years. The rejections in the system related to before about 2015-16 when there were applicants for very poorly defined products and, obviously, the evidence base was very poor at that time. So there haven't been any rejections. When a clinician comes to us and it is a most unusual indication and they haven't provided evidence in support of the indication or if they haven't defined the product and just written 'medicinal cannabis', we go back to them and ask them for more information.
Senator DI NATALE: What about in regards to authorised prescribers? I am not sure what the paperwork looks like, but the college needs to sign off on it?
Dr Skerritt: A college or a society. So there is a wider range—for example, the National Institute for Integrative Medicine, which operates out of Victoria. I was speaking for two days at a medicinal cannabis workshop there recently. It is an authorised provider.
Senator DI NATALE: Wonders will never cease. You will be a convert soon. Did you have a good

two days?
Dr Skerritt: It was very integrative, Senator.
Senator DI NATALE: You have thrown me now.
Dr Skerritt: On a more serious note, that course was actually accredited by the Royal Australian College of General Practitioners for CPD points. It is the first time a medicinal cannabis conference —
Senator DI NATALE: Where was that?
Dr Skerritt: It was at the National Institute for Integrative Medicine, but it was attended largely by GPs and pharmacists.
Senator DI NATALE: I don't know anything about the college. Where is it based?
Dr Skerritt: This is a group that involves physicians looking at the whole care of the patient. They might, for example, use remedial massage or acupuncture together with pharmaceutical therapies with patients.
Senator DI NATALE: The college is based where?
Dr Skerritt: It is in Hawthorn in Melbourne.
Senator DI NATALE: So the education that was provided—
Dr Skerritt: We have been involved in a dozen or more—that is probably an underestimate—educational events over the last year or so.
Senator DI NATALE: Which attract CPD?
Dr Skerritt: No, this is the first one. Because the awarding of a CPD is not our decision. Obviously it is the RACP, the RACGP, et cetera.
Senator DI NATALE: The colleges, yes. So who accredited it?
Dr Skerritt: This one was accredited by the RACGP for the CPD.
Senator DI NATALE: What was the course that was run?
Dr Skerritt: It was a course about medicinal cannabis indications.
Senator DI NATALE: Run by who?
Dr Skerritt: It was obviously co-sponsored by the Royal Australian College of General Practitioners, but it was also run by the College of Integrative Medicine and the Institute Of Complementary Medicine at the University of Western Sydney, which is probably Australia's strongest complimentary medicine research centre.
Senator DI NATALE: So does that mean that this course is now accredited to be run around the country? I'm just thinking, as a GP—
Dr Skerritt: They are looking at running it again in Sydney because it was oversubscribed. In fact, they could have had another dozen or two general practitioners. Especially because a lot of these courses are on weekends, we all take the short straw and take turns giving up our weekends to present at them.
Senator DI NATALE: I don't know what that's like. The course is now, as you say, accredited for CPD. Are there other accredited courses for GPs?
Dr Skerritt: My understanding is that this is the only accredited course. There was a one day course run in the ACT this last weekend. That wasn't an accredited course, I understand.
Senator DI NATALE: I understand that there were some American speakers involved, facilitated by the ACT government. Is that right?
Dr Skerritt: The ACT government had an involvement. We have actually been talking with them because there was a bit of misinformation about the process to access medicinal cannabis. There was misinformation such as us having a list of preapproved indications and so forth. After discussions with ACT Health, they will circulate a few corrections to the people who attended the meeting.
Dr Greenaway: Can I just make the comment that Associate Professor David Caldicott was involved in organising it. So that wasn't directly something the TGA had an input into. But members of the TGA went in a personal capacity and there have been a couple of issues that, as Professor Skerritt said, were errors in fact. We are going to write to the organisers and to Professor Caldicott to correct it. Professor Caldicott works at Calvary Public Hospital, which is part of ACT Health. So,

yes, ACT Health was involved in that course, to my understanding.
Senator DI NATALE: If you are a GP working in Sydney and you want to get accredited for having done some professional development in this area, what happens next? Just to give some context, there are a lot of GPs who want to learn more about this and want to ensure that they are doing something that is accredited by their college and is recognised. At the moment there is not much out there for them to do. So I am interested to know, what is the next step?
Dr Skerritt: They have had such interest in this that they are going to run it again in Sydney. I think it is the first weekend in September and Professor Greenaway and I will probably toss a coin on that one. They are talking about running it in each capital city, depending on demand. It is a fairly modest fee, but obviously it has to recover its costs. I don't even know what fee is charged.
Senator DI NATALE: When you have completed the course, what does that give you apart from, obviously, a little more knowledge and satisfying your CPD requirements? From within the department, for example, if someone has completed the course are they more likely to get an application through? Does it give you, as the body that approves applications, some comfort? I mean, what is the value of doing this?
Dr Skerritt: You would say they are more likely to get an application through because they have attended a course and understood that certain indications have a stronger and clearer evidence base. They also were advised about the group of clinical evidence studies that were commissioned by the department and published on our website, together with over 200 research papers and the medical literature on the efficacy of medicinal cannabis. They will know about the existence of that information, because, as you have often said, the knowledge base is very scatty. There will, therefore, I hope, be fewer people who have their applications sent back with, 'Tell us a bit more about the evidence base.' What we don't say is that just because you have done a course, tick. We do have a system, as you are aware, called the Authorised Prescriber Scheme where a prescriber, once they get an authorisation, can prescribe in that category to either one or 101 patients.
Senator DI NATALE: Will this increase the likelihood of them being approved as an authorised prescriber?
Dr Skerritt: I don't have a crystal ball. What I do know is that the organisation in Victoria has already—
Senator DI NATALE: Which organisation?
Dr Skerritt: The National Institute of Integrative Medicine. They have already acted as an ethics body for a well-known GP—and I won't name the GP; you can understand why—in Melbourne as an authorised prescriber for medicinal cannabis for certain conditions.
Senator DI NATALE: Is he or she the first GP to be approved as an authorised prescriber?
Dr Skerritt: I would have to take that question on notice. You are right in that most of the authorised prescribers are specialists—
Senator DI NATALE: Before you arrived we had that discussion. So it is mostly paediatric neurologists, some palliative care people—
Dr Skerritt: Paediatric neurologists and palliative care. Of course, palliative care is often the domain of GPs. Of course, GPs are specialists in life, according to the RACGP. But it is often GPs who are the ones who are seeing palliative care patients.
Senator DI NATALE: Just to be clear about this—and I know that it sounds very technical—but access is still a very big problem. Would you expect that if the National Institute of Integrative Medicine becomes a body that says, 'We are happy to certify you as an approved prescriber'—although obviously that is your decision, but if you get a recommendation from them, will they then be—
Dr Skerritt: The way it works now is that the appropriate college's—and this is a number of colleges and societies—ethics committee actually makes the decision. We check that the application is complete and in alliance with regulations, but we don't second guess. And authorised prescriber is actually—
Senator DI NATALE: So you are a rubber stamp, really?
Dr Skerritt: When it comes to authorised prescribers, we are a rubber stamp if it is complete.

Senator DI NATALE: So this college or institute could become the vehicle through which GPs become authorised prescribers?
Dr Skerritt: They could be one of a number of vehicles. I don't have a list of accredited organisations for authorised prescribers, remembering that this is a broader system used for hundreds of different medicines every year. There is nothing, for example, that would stop, say, a palliative care college or some discipline speciality also having that. I would imagine there would be a number of GP members of a palliative care association or society.
Senator DI NATALE: What does that National Institute of Integrative Medicine require of a GP to issue them with authorised prescriber status?
Dr Skerritt: The requirements for authorised prescribers are documented. They are both our requirements and the NHMRC's requirements. Effectively it is a duly constituted ethics committee. The NHMRC have fairly detailed guidelines on what is required in terms of the skills of the members of the ethics committee, what considerations they have to go through and what evidence they have to look at.
Senator DI NATALE: I want to be practical here. I'm a GP. I'm working in the community, this is an area of interest, I've done this accredited course and I say, 'Patients are contacting me regularly, and, rather than having to put an application in for each patient, I want to be an authorised prescriber so that I don't have to do that anymore; I can just prescribe.'
Dr Skerritt: You can put your submission in to the committee I just mentioned, as did a suburban Melbourne GP.
Senator DI NATALE: So it's a submission to an ethics committee?
Dr Skerritt: Correct. It's a reasonably detailed submission, but it's a one-off. The GP puts a submission in describing the patients, describing how they're followed, describing the product and describing the indications. That's then considered by a committee duly set up by the relevant college or society. There may be dialogue between the committee and us, especially if it's a committee that hasn't done many of these, but the actual decision is made by the committee. We rubber-stamp it, to use your words, to check that it conforms with all the legal requirements, but it's actually the committee standing in review—
Senator DI NATALE: This stuff often falls down on the detail. It sounds reasonably straightforward in practice, but the nature of the submission might be enough for GPs to say, 'I'm just not interested; it's too difficult.'
Dr Skerritt: The guidelines from this particular college are on the internet. They've written their own guidance material, and, again, I can take on notice the web link—
Senator DI NATALE: No, that's good. I'll jump online.
Dr Skerritt: I wouldn't be surprised if some of the other GPs who attended this course in Melbourne or who are attending the one in a couple of months time in Sydney also go through it. There was actually a training session at the workshop on 19 and 20 May on training GPs and others on how to apply—noting that you have to be a registered medical practitioner.
Senator DI NATALE: That's progress, albeit slow.
Senator LEYONHJELM: Isn't it effectively a trial?
Dr Skerritt: No, it's not a trial. It's an approval to use an unregistered medicine. It's an approval. You write a normal prescription in the usual way, except it's a prescription for an unauthorised medicine and it goes through the authorised prescriber pathway.
Senator LEYONHJELM: Which involves an ethics committee?
Dr Skerritt: It involves that. The reason an ethics committee is involved is the medicine hasn't been assessed for safety, quality and efficacy by the TGA, as opposed to medicines that are on our register and all the medicines on the Pharmaceutical Benefits Scheme list.
Senator DI NATALE: Do you know if any other colleges are looking at the same process?
Dr Skerritt: There are now 33 different physicians authorised for 39 different conditions. Someone may have an authorisation for pain and palliative care. I know a physician who does have two. Those physicians will have been through different committees. I'm not sure how many different committees that adds up to, but several committees have assessed medical cannabis proposals for a

range of conditions. Yes, the largest number are for epilepsy, but there are some for neuropathic pain, palliative care, intractable pain and so on.
Senator DI NATALE: Obviously the other issue is the layer of state regulation. Coupled with the hoops that need to be jumped through at a federal level, there are a whole lot of state regulations. Do you know of many instances where you've approved—not through the authorised prescriber pathway but through the other pathways—a prescription for an individual patient that was then blocked at state government level?
Dr Skerritt: There have been a couple of cases that were well publicised in New South Wales and Tasmania. You may be aware that ministers, state and territory and Commonwealth, met at COAG Health Council in April. At their ministers-only meeting, they discussed this issue, and they also discussed the need to streamline and avoid duplication between states and territories. There was an announcement made by Minister Hunt—it's in the public domain—on 13 April. Since that time, we've been working together with the states and territories. On 2 March, Minister Hazzard and Minister Hunt, jointly announced—I know because I was there, together with the Chief Health Officer of New South Wales—that New South Wales wouldn't be second-guessing or assessing the clinical suitability of a cannabis product, except to the extent that states have to, by law, look at schedule 8 controlled drug issues. That's separate from the special assessment of cannabis. Since that time, we've done a very significant number—I think it's somewhere between 100 and 200—New South Wales applications, all within under 48 hours.
Senator DI NATALE: What was the basis of the rejection at the time?
Dr Skerritt: Mainly on indications in the states and territories. In New South Wales—this is, again, prior to 2 March; there haven't been any rejections since 2 March, and the system's been working beautifully. Tasmania is an interesting situation. I'm sure I'm not the first person to say that.
Senator SINGH: Interestingly disadvantaged.
Dr Skerritt: On one hand, they're interestingly advantaged, because in Tasmania the government has made a commitment to fund access, through compassionate schemes, for medicinal cannabis.
Senator SINGH: At snail pace.
Dr Skerritt: On the other hand, it's a very small number of patients. One of the discussions that is underway is about, if someone off their own bat wanted to access medicinal cannabis and realised they might not get funded by the government of Tasmania, whether the government of Tasmania would be willing to do that. Discussions are continuing at officials level, and I know that they're also continuing between the ministers' offices.
Senator DI NATALE: Average time—you say you've got a 48-hour turnaround.
Dr Skerritt: Less than.
Senator DI NATALE: But that's your end of it. Then there is state approval.
Dr Skerritt: What happens with the state approvals with New South Wales—I can talk about that one because it's been up and running now for almost three months, come mid-June—is that the New South Wales approvals are nested within ours. We'll get the application electronically from the doctor. If it's a schedule 8 product—and again this is all going to be automated through a portal, but at the moment it's manual, as far as email's concerned. We'll whiz an email off to New South Wales Health if it's a schedule 8 product, and consistently—as I said, 100 to 200 times, so they've kept their word—they'll do the relevant schedule 8 approvals. They're about whether the doctor has any funny history to do with questionable prescribing of drugs of addiction or whether the patient has a history of going from doctor to doctor, doctor shopping. Each of the 100 to 200 times in New South Wales, since 16 March, when the scheme started to roll out, have all been done within that 48 hours. It hasn't been additional—
Senator DI NATALE: So it's not additional. What about other states?
Dr Skerritt: Other states are a work in progress. There have been several meetings—
Senator DI NATALE: That's a euphemism for 'you're not getting anywhere'?
Dr Skerritt: No. Victoria and Queensland, of course, have the challenge that they have actually legislated medicinal cannabis schemes. Repealing legislation obviously requires a slot in their parliament, and Victoria, for example, only have about 20 sitting days till their election. But

Victoria, we believe, will be on board very soon, and we are slowly—as quickly as we can; maybe the slowness is on their side—working with other states to catch up. As always, the devil is in the fine detail. Some states have particular rules about not being able to disclose patient information outside their state, and so they've got to go to their Attorney-General's or their justice department and get advice on the legality of giving us that information. We're working there. Minister Hunt has a very strong interest in this. In fact, I understand that the letters are up with his office to send to ministers, encouraging them to continue with this commitment.

Senator DI NATALE: So at this stage, if you're in New South Wales, there's not a parallel process—or there is, but it's nested—

Dr Skerritt: It's invisible.

Senator DI NATALE: It's invisible because it happens within the same time frame—

Dr Skerritt: Within the 48 hours.

Senator DI NATALE: But in other states that doesn't happen, and so it can take weeks. I know you keep saying within 48 hours, but from the time a doctor writes a script to when the very few number of patients who are able to access it access it it can be weeks—yes?

Dr Skerritt: It depends what they're after. Despite the rest of civilisation walking away from fax machines, we know that doctors still use fax machines a lot. Even so, if a doctor faxes it to us, and we can receive faxes—I had to explain what one was to my 20-something-year-old daughter! But we can receive faxes. That fax goes into the electronic system, and the 48-hour clock starts then. If they're requesting one of the products that's available ex-stock—and as I've said in this place before, there are a number of products where stocks of them are in capital cities and secure pharmaceutical warehouses—they're generally dispatched within 48 hours. It need not be a matter of weeks.

Senator DI NATALE: It can be, but it often isn't.

Dr Skerritt: That's a commercial matter, from when a company gets an order to when they dispatch it, but most companies want to see cash flows, so they do dispatch product.

Senator DI NATALE: Cost is the other issue. We hear in reports that it's prohibitive for a number of patients. Is anything being done to try and bring down the cost for patients?

Dr Skerritt: The approach is, of course, that for registered medicines, they can apply through the Pharmaceutical Benefits Advisory Committee for reimbursement.

Senator DI NATALE: Yes, but this isn't registered.

Dr Skerritt: There's no government scheme at the Commonwealth level for funding or reimbursement of medicinal cannabis products.

Senator DI NATALE: Is there any work being done in this area to bring the cost down?

Dr Skerritt: Not that I'm aware of.

Senator DI NATALE: You're not doing anything in this space?

Dr Skerritt: No, it's beyond the role of the regulator. We'd also add that the first three commercial crops have been harvested from Australian-grown cannabis. I can't disclose their locations, as you'd understand. We would hope that in the coming months there would be Australian-manufactured product. And, with the announcement that those companies can also export, providing they service all Australian patient requirements, we'd hope that the size of that market and the local manufacture would bring prices down. In fact, just yesterday, we met with a particular company that currently isn't providing product in Australia but was of a view that they could provide product at about a quarter of the price of their competitors. And we said: 'Please submit import permit applications. Pricing is up to you, but you'd certainly get a fair bit of market share if you can do that.'

Senator DI NATALE: It's still true that in some states GPs can't prescribe medicinal cannabis, is that correct?

Dr Skerritt: There are some states that have an absolute—it varies almost day to day, state to state.

Senator DI NATALE: Day to day?

Dr Skerritt: No. What I'm saying is that the requirements are being relaxed at the state level, and that is also—

Senator DI NATALE: But right now, if you're a GP in, I think, New South Wales and Queensland, you can't prescribe it.

Dr Skerritt: It varies. For some pathways, GPs can, in those states, and, as we go from day to day, that's being relaxed. It's a dynamic thing because, remember, what we're aiming for is a single process.
Senator DI NATALE: Yes. Dr Skerritt: And so it will be irrelevant whether in 2017 or 2016 a GP could or couldn't, or in early 2018.
Senator DI NATALE: But it's relevant right now.
Dr Skerritt: But we're hoping it won't be relevant much longer.
Senator DI NATALE: I know; we're all hoping. But right now, if you're in Queensland or New South Wales and you go and see a GP, you can't get it. You have to go and get it from a specialist. Is that correct?
Dr Skerritt: I believe that's the case as of today in Queensland. I know that there is some work being done— and again, this is still only work at officials level—on whether that system can be changed.
Senator DI NATALE: My final question is about the Medicinal Cannabis Legislation Amendment (Securing Patient Access) Bill, which was basically the change to Special Access Scheme Category A. That passed the Senate last year. This question may not be for you, Dr Skerrit, but does the government have any plan to remove the barrier through Special Access Scheme Category A?
Dr Skerritt: That bill is still before the parliament and, as an official, I don't comment on bills before parliament.
Senator DI NATALE: Senator McKenzie? Senator McKenzie: Sorry, Senator?
Senator DI NATALE: At the moment, you cannot access medicinal cannabis through the Special Access Scheme Category A. A bill passed the Senate. It hasn't been brought to the lower house yet. Does the government have any plans to make cannabis available through Special Access Scheme Category A?
Senator McKenzie: This is an area for Minister Hunt. I'll take that on notice.
Senator DI NATALE: Okay. Thank you.
Senator LEYONHJELM: Senator Di Natale went down a similar pathway to some of my questions, but there is still the issue of what quantities of medicinal cannabis can be imported—what will be allowed in—and what's here. Even assuming the successful navigation of the permit approval system—prescription and so forth, that you were discussing with Senator Di Natale—what's available in Australia?
Dr Skerritt: First of all, there's no limit on the quantity. That's written into regulation. It's considered on a case-by-case basis. Clearly, if someone wanted to theoretically import material for a million patients, you would start to raise concerns about diversion, in the same way if it were an amphetamine and those quantities were imported. I can tell you that the quantities that have been imported can do several hundreds of patients at a time. There are a couple of hundred companies that have applied for licences to import. There are at least a couple of dozen that have products in the country. Again, that list changes by the week, and it's published. Some companies say, 'We don't want to publish it,' but the companies that have consented to publish the information on what they have in the country is on the Office of Drug Control's website. A doctor can go to www.odc.gov.au and look down a list of products with various cannabidiol and THC concentrations and ratios and determine what they would like to prescribe for their patient.
Senator LEYONHJELM: The suppliers of these products can't make claims for them, because they're not registered. Are they bringing the differences to the attention of those who might prescribe them in some way? I understand there's quite a spectrum of applications.
Dr Skerritt: You're right in that an unapproved prescription medicine at this point in time cannot be advertised to physicians. However, we talked earlier with Senator Di Natale about the number of education programs. In these education programs, a strong emphasis is that with these high THC products there's more evidence for them in these conditions; ones that have both THC and cannabidiol are more suited for these conditions; and the ones that are high in cannabidiol might be more suited, for example, for paediatric epilepsy. So, it's not saying brand X or brand Y, but it's giving the prescribers information about what sorts of products to go for when they write a

prescription.
Senator LEYONHJELM: Are products in each of those categories, say, high THC, high cannabidiol or some sort of mixture being imported? Dr Skerritt: There's quite a range being imported. There's also quite a range of what we call 'dose forms'. There's everything from oils right through to certified raw product.