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SENATE

FINANCE AND PUBLIC ADMINISTRATION REFERENCES COMMITTEE

Administration of the Pharmaceutical Benefits Scheme

THURSDAY, 21 JULY 2011

MELBOURNE

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SENATE

FINANCE AND PUBLIC ADMINISTRATION REFERENCES COMMITTEE

Thursday, 21 July 2011

Senators in attendance: Senators Di Natale, Fierravanti-Wells, Polley and Ryan

Terms of reference for the inquiry:

To inquire into and report on:

The Government's administration of the Pharmaceutical Benefits Scheme (PBS), with particular reference to:

(a) the deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee;

(b) any consequences for patients of such deferrals;

(c) any consequences for the pharmaceutical sector of such deferrals;

(d) any impacts on the future availability of medicines in the Australian market due to such deferrals;

(e) the criteria and advice used to determine medicines to be deferred;

(f) the financial impact on the Commonwealth Budget of deferring the listing of medicines;

(g) the consultation process prior to a deferral;

(h) compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010; and

(i) any other related matter.

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BULFONE, Ms Liliana, Senior Research Fellow, Deakin University

YOUNIE, Ms Sandra, Senior Research Fellow, Deakin University

Committee met at 9:29

CHAIR (Senator Ryan): Welcome. I declare open this meeting of the Senate Finance and Public Administration References Committee. The committee will now commence its inquiry into the government's administration of the Pharmaceutical Benefits Scheme.

Information on parliamentary privilege and on the protection of witnesses and evidence has been provided to you. The committee has your submission. I now invite you to make a short opening statement and, at the conclusion of your remarks, I will invite members of the committee to put questions to you.

Ms Bulfone: On behalf of Professor Rob Carter, Patti Whyte, Sandra Younie, I would like to thank the Senate committee for the opportunity to appear before you today. Patti Whyte and Rob Carter have asked me to convey their apologies. They are not able to come today. They both had prior commitments that they could not change at relatively short notice. All four of us at Deakin Health Economics have extensive experience with the PBS process. Patti, Sandra and I were senior evaluators that evaluated submissions going to the PBAC. Rob is a former member of the PBAC.

To let you know our potential conflicts of interest, we currently undertake assessments of medical technologies that have been proposed for listing on the Medicare Benefits Schedule. We are contracted to do that by the Department of Health and Ageing. We also either work or have worked as consultants to the pharmaceutical industry. But the views that we are expressing today are our own independent views.

As detailed in our submission, we have got a few concerns around the process concerning the deferral of medications that have been recommended for listing on the PBS by the PBAC. We are mostly concerned about the extra hurdle of a set of potentially arbitrary criteria, those criteria being non-transparently applied and those criteria dividing PBAC recommendations into two groups—those that should be listed without delay and those that can be deferred. So the introduction of some criterion is of concern to us. We are concerned that that extra hurdle is going to lead to further delays for patients with respect to accessing medications that are effective, safe and also cost effective, as considered by the PBAC.

Also, these reforms will introduce some uncertainties for manufacturers. In some circumstances, manufacturers may consider that the extra risks and costs that are involved in trying to have a drug listed on the PBAC, beyond just having it recommended by the PBS, outweigh the potential benefits of having the drug available on the PBS, particularly where the drug will be high cost and used for a small number of patients. That may mean that some manufacturers—I do not imagine there will be a massive number of drugs that fall into that category, but it may be bigger than we think—may choose not to bother to engage with the process of trying to get a PBS listing at all.

We are also concerned that the department of health's rationale or their defence for doing this is that they are not going to disadvantage patients because alternatives are available. We are not sure that that claim holds any weight or is valid for a few reasons. First of all, if you think about the drugs that have been listed on the basis of cost effectiveness, for a drug to be considered cost effective it has to have been accepted to be superior to what is already available. So, by definition, there is no equivalent drug for people to use.

Two examples of that are Targin, for severe pain. That is a measure that prevents constipation in patient's who have these very strong painkillers. The alternative is to wait until they have the consequences and then treat the consequences. I do not think they are the same; they are quite different. The other drug is Botox for severe sweating. I think that the whole concept of severe sweating has not been appreciated by cabinet. This is not about someone like me who sweats a bit more, especially when they are in front of a Senate committee; these are people who often do not leave their homes. It is a very severe condition. That is the cost effectiveness group.

Then there is the group of drugs that have been recommended for listing on the basis of the fact that they are no worse than what is already there. They are essentially cost minimised, which means their cost is limited by the cost of the currently available therapies. I think it needs to be appreciated that when a drug is equivalent at a population level it does not mean the drug is interchangeable patient by patient. If you have got 50 per cent responders and 10 per cent having adverse events with one drug and you also have 50 per cent responders and 10 per cent having side effects with another drug, it does not mean that they are the same patients that are going to respond and have adverse events. Invega Sustenna, which is used for patients with schizophrenia, is an example of a drug where we thought the deferral was inappropriate. We also think that this policy actually introduces

inequities because, if you are a patient who responds to Consta, which is the drug that was the comparator in this particular case, you have access to a subsidised drug, but if you are a patient who does not happen to respond to that drug or who has adverse events, you do not have the same equity of access to an equivalent drug, a drug that is as cost effective and as effective.

The other argument with the cost minimisation drugs is that, if a drug is listed on a cost minimisation basis such that the cost is no more than the comparator and, as the government is saying, one is a direct substitute for the other, it is a false economy to say you are going to get savings by not making the new drug available and having only the old drug available. If they use the new drug, they are not using the old drug. The cost of one is just transferred to the other, so that is a false saving. For that reason the government is trying to say that it is having it both ways and that is just not possible.

In a perfect world there would be no need for a cabinet review of PBAC decisions, but we do acknowledge that affordability of medications in the short term is definitely an issue that the government may need to consider, particularly in circumstances where the drug has an effect over a very long time horizon. For example, drugs like vaccines and smoking cessation aids, where the costs are borne upfront but the benefits accrue over a long period of time, may mean that the government is left out of pocket substantially in the short term. So we can understand that the government is going to want to be on the lookout for those sorts of instances.

However, we would argue that the threshold of $10 million used to trigger cabinet review, which was introduced by the Howard government in 2001, is too low a threshold. I believe that a previous Senate inquiry also found the same thing, not to mention that the current process where everything goes to cabinet review is probably not so good. We believe it should only be in exceptional circumstances that affordability in the short term should be a barrier to making drugs available on the PBS. From our experience and having watched the PBAC at work, we think the PBAC is qualified and experienced enough to be able to alert the government as to when those situations are coming up, as they did when they considered the listing of Viagra on the PBS. That is all I wanted to say. Thank you again for the opportunity.

CHAIR: Ms Younie, do you have a statement?

Ms Younie: No, thank you.

CHAIR: We will go to Senator Fierravanti-Wells.

Senator FIERRAVANTI-WELLS: Thank you. I have a couple of questions in relation to your submission. You say on page 3 of your submission, 'Our greatest concern is that a set of non-disclosed and potentially arbitrary criteria, if any exist, are being used.' This is taking the whole issue into a new realm, is it not? The government is effectively deciding who they want to help and who they do not want to help. Isn't that what it really comes down to—the government picking and choosing life and death?

Ms Younie: I would not necessarily go quite so far.

Senator FIERRAVANTI-WELLS: Well, it starts the debate, doesn't it, first thing in the morning.

Ms Younie: It certainly leaves the government open to being seen to be making decisions not on a transparent and open basis and that they may be subjected to pressure. It is sort of like management by squeaky wheel. Whoever yells the most, whoever has the most money to throw at a marketing campaign after a drug has been deferred—it leaves you open to that.

Senator POLLEY: That is an assertion. That does not mean that is the reality.

Ms Younie: No, I am not claiming it is the reality. It just leaves that sort of perception open, because you do not have clearly defined criteria on which the decisions are being made. Nobody quite knows what the bases are for the decisions. I do not think it is good governance.

Senator FIERRAVANTI-WELLS: You talk about 'lack of clarity over the process, if any!' in terms of competing priorities. Do I take from that comment that you are effectively saying that the government is substituting one rigorous assessment, which has been proven, with an assessment process now where we really do not know what it is because we do not know what the criteria are?

Ms Bulfone: I think the issue we are trying to highlight there is that, on the one hand, you have the expenditure of funds on drugs that goes through this very rigorous process, where the companies need to demonstrate the effectiveness and safety and cost-effectiveness of their drug. With a lot of other government expenditure programs there is not that level of rigour in determining whether they are cost effective, so you do not know how cost effective they are. I think the example we give in the submission is of the bowel cancer screening program. That program may or may not be a cost-effective use of funds. We do not know, because it has not been evaluated in the way that a drug has been evaluated. So to say, 'We are going to direct our funds from something

we know is cost effective to something we do not know is cost effective' is potentially putting money into an area that gives you less return, less bang for your buck, effectively.

Senator FIERRAVANTI-WELLS: It is the same whether it is the bowel cancer screening program or whether it is the grand hospital plan that is now falling apart or anything else. It is the government determining priority as opposed to a rigorous process.

Ms Bulfone: Exactly. So if there were a way that this was done in an open and transparent way, where people could understand what was going on, that would be fine. But currently you do not know the cost effectiveness of one and you know the cost effectiveness of the other and you are saying, 'We will direct our funds here instead of there'—and I am not sure that is what actually happened; that was just a statement made by the minister, but I thought it was a very poor example of weighing up different priorities and deciding where you are going to direct your funds.

Senator FIERRAVANTI-WELLS: It certainly was the clear inference of her comments.

Ms Bulfone: Exactly.

Senator FIERRAVANTI-WELLS: You say at the bottom of page 5, 'Really, how can industry or the public have any confidence whatsoever in the process?' That is quite a serious statement. I accept the strength of that. From your observations and the work that you do at the moment, how are you seeing that manifested—obviously, apart from the submissions we have seen?

Ms Bulfone: For us it is more about the way we would see it if we were sponsors wanting to put in an application. You have got a hurdle of getting a PBAC recommendation and you know that if you pass that hurdle you are likely to have access to the market. If another hurdle is introduced on top of that where you may end up getting deferred and you do not know the basis on which you may or may not be deferred then that uncertainty in itself creates uncertainty as to whether you should invest in bothering to go through the process of applying.

Senator FIERRAVANTI-WELLS: Why bother? Look for another.

Ms Bulfone: Why bother in the first place when you do not know, especially when it is so costly to put together a submission for a drug to be listed on the PBS? It is a very expensive process. It is not just the evaluation side of it; it is the assembly of all the information that has to be presented.

Senator FIERRAVANTI-WELLS: Are you aware of the potential patients who could be affected as a consequence of this measure? Is that this sort of work that you have done at the university?

Ms Bulfone: The work that we do for MSAC is looking at specific interventions, looking at the evidence, supporting whether they should be reimbursed or not and then conducting the economic evaluation or assessing an economic evaluation that may be submitted and determining if there are any issues with it. Every now and again, yes, we do see that. Sandra was formerly a nurse and I was a pharmacist, so we do know what a lot of these patients go through. Sometimes I wonder whether some of the people in cabinet actually understand. In fact I thought one of the submissions that you have before you, on hyperhidrosis, really explained very well what it is like for a patient.

Senator FIERRAVANTI-WELLS: But in the end, when all is said and done and you are looking at the savings in the long term, this is just penny pinching at its worst. If you are going to look for savings of money you are jeopardising people's wellbeing for the sake of what is really a very small amount of money.

Ms Younie: Trying to make the PBS affordable in the longer run is absolutely something you need to do, but it needs to be done in a systematic way, in a way that everybody knows and has agreed to the processes that they are going to go through to try and reduce ongoing costs if it is seen to be becoming too expensive. But we do not think that this is the process for doing that, because the basis on which these decisions are being made is not clear.

Ms Bulfone: The other thing is that it is not just about reducing costs of downstream health interventions over the long term that is important. When you add to a patient's quality of life or you extend their survival there are not going to be cost offsets, because they live longer. They are going to use other treatments down the track.

Senator FIERRAVANTI-WELLS: They are going to be productive. Take the young girl with the hyperhidrosis.

Ms Bulfone: Exactly.

Senator FIERRAVANTI-WELLS: That is a classic example of a person who is now going to be a lot more productive. She will enter the workforce and probably—

Ms Bulfone: You just engage with society. In itself it is a value to the community, and just to talk about other costs offset by savings down the track is not of value—and it is certainly not what the PBAC is about. Their

typical metric for whether something is cost effective is for them to look at what the incremental cost of a drug is relative to the incremental gain it gives us in quality of life and survival. PBAC does recognise the value of that. They do not just look for cost offsets down the track.

Ms Younie: They also take into account those other considerations—whether there are other drugs available or whether it is your will of rescue, end of life type issues. It is not just the incremental cost-effectiveness ratio they look at; they also look at other issues.

Senator FIERRAVANTI-WELLS: What is the long-term effect for patients who will not now be able to get access to these drugs?

Ms Bulfone: I do not think we know. But to say that they are not disadvantaged I think is wrong.

Senator POLLEY: Thank you for your submission. Can you name any of the drug companies that have withdrawn their pharmaceuticals here in Australia due to this deferral?

Ms Bulfone: I know of one drug that went through the PBS process, was recommended and went to cabinet. It is a very old drug; it has been around for many years. The manufacturer of the drug had discontinued the drug. Even though it was not going to make a large company much money, it was going to make a smaller company enough to survive. A very small company took this drug on and they got a positive PBAC recommendation. After it went to cabinet they referred it back to PBAC and they said that it needed to have cost effectiveness, but because the drug is so old—and this just happened in this last week—the evidence is not as strong as evidence that is generated in the current climate, where there is a much better process for clinical trials and everything. That company has decided not to make the drug available on the PBS or bothered to apply again because it is unlikely to get a positive PBAC recommendation, again because of the requirements—

Senator POLLEY: But the drug is still available in Australia?

Ms Bulfone: Only by patients paying for it at their own expense.

Senator POLLEY: But it is available?

Ms Bulfone: Yes, and that is true for every drug that goes through TGA. If the government is not about subsidising drugs that are cost effective that is fine, but let the public know that.

Senator POLLEY: As we all know, there is a requirement on all governments to consider budgetary requirements. When you are talking about health, I think if we spent every dollar of the Australian budget on health there still would not be enough money.

Ms Bulfone: We recognise that.

Senator POLLEY: So there are decisions. The process is one which has been extended from the one introduced by the former government—to take these sorts of issues to cabinet. Before that, I understand it was a $10 million threshold. So now every decision is taken to cabinet and the processes by which those decisions are made are confidential. I am not privy to them because I am not in cabinet. In so doing, there are decisions that have to be made on the health budget and there will always be some drugs that do not make it onto the PBS. It is not the first time it has happened, has it?

Ms Bulfone: There have been two prior occasions where the PBAC has recommended a drug, found it to be effective, safe and cost-effective, and has alerted the government that the expenditure in the short term is likely to be high, so there may be affordability issues in the short term. But that has been a very rare occurrence in the whole history of the PBAC, as compared to seven in one meeting.

Senator POLLEY: Can you just go through those drugs that have been deferred? I might have missed it, forgive me if you have given it in evidence before. Are there alternatives for those drugs?

Ms Bulfone: Yes, but what we would argue is that the alternatives are not equivalent on a patient by patient basis. For example, Invega Sustenna for schizophrenia is a really good example of where the drug on a population level results in the same average benefit to patients in a clinical trial, but for an individual patient, particularly as this drug has different pharmacological properties to its comparator, the profile of side-effects that goes with it is also different. A patient may not be able to tolerate Consta, which is currently available and was the comparator in that case, but they will be able to tolerate Invega Sustenna, or they may respond to one but not the other. Yes, there are alternatives, but they may not work.

Senator POLLEY: You said your organisation had some vested interests?

Ms Bulfone: Yes, we do work for the Medical Services Advisory Committee and we also take on work for pharmaceutical sponsors as individuals at times.

CHAIR: Just to clarify, it is not uncommon for people in the health economics space to do contract work for either the PBAC—because I know some work there is outsourced—or to help compile the health economics submissions for the PBAC on behalf of sponsor companies, is it?

Ms Bulfone: Yes, but what you cannot do is work for the PBAC and do evaluations of PBAC submissions and work for a sponsor. That is a conflict of interest and is not permitted. We do MSAC work and some of us work privately as consultants to industry at times.

Senator DI NATALE: Thank you very much for your detailed and thorough submission. Clearly we are having this discussion based on the decision of the current government, but earlier you touched on the long-term economic sustainability of the PBS. I am interested in your thoughts about a more open and transparent process, to use your words, for improving that long-term economic sustainability. Some proposals, which we have already heard, in other nations in how they look at reducing the cost of medications once they come off patent and other examples of tendering and so on. Have you any thoughts about how you would see the long-term economic sustainability of the PBS improved?

Ms Bulfone: I think it is the approach of having a cost-effectiveness ratio that somehow reflects the average productivity gain that is associated with a gain in a quality adjusted life here in a full year of health. If there is a link between the two then you are going to make sure that any investment is returned. In the short-term that is very difficult to manage because, say, for a vaccine you invest the money upfront and the benefits are accrued over a long time. That is a difficult thing because it takes time for the balance to occur. I think it is a really good question that would need a lot of thinking and certainly more than I can do off the top of my head to come up with a solution to how to bring things in slowly so that it does not leave the government in a difficult position. But we do appreciate that these short-term affordability issues are issues that have to be dealt with. We are not going to try and solve the world's problems off the top of our heads and it would not do justice to the enormity of the problem.

Ms Younie: I suppose one of the other issues would go back to the MOU. From the department's submission the MOU has been delivering some gains in the longer term. It has been reducing the growth in the PBS, as reported by the department, and that is on the basis of the MOU with the pharmaceutical industry. It has gone from a reported growth of 9.2 per cent down to 7.7 and then 6.5 per cent. They are the sorts of things that, if you can deliver, will be long-term reductions in the growth of the PBS. It is going to grow anyway. With population growth you will be getting an increase in the PBS.

Ms Bulfone: I do think there are other ways to generate savings in the generics' field. I have written a paper, which has been published, about introducing more competition into that market which would help. There are lots of little things that can be done.

CHAIR: I want to get to the idea where you talked earlier about population assessments of medicines' effectiveness versus interchangeability and try and use some common examples that people might understand. There are, for example, lots of different medicines in the SSRI class, or lots of different medicines in the ACE inhibitor or A2RA class. Is it fair to describe what you are saying as: there might be five different chemical additives in the SSRI class to treat antidepression. They are all considered equally effective when you consider large clinical trials of 10,000 people and they might be effective for 500 of them—and I am only guessing at the numbers—but with each of them it is not the same 500 people. Is that the easiest way to explain it?

Ms Bulfone: That is it exactly.

CHAIR: When the government is saying that there is a medicine out there, that is only the assessment taken upon the 10,000 people not on which 500 it might work for.

Ms Bulfone: Exactly.

CHAIR: Conscious that there has been a cabinet threshold in the decision-making process in place now for several years, would it also be fair to say that if we moved to a pharmaceutical subsidy system, which required the health department to make offsets for the listing of a new medicines, that that would be a fundamental and profound change in the nature of the one of the pins of the PBS which is the cost-effective listing of pharmaceutical products?

Ms Bulfone: Absolutely and I also believe it would be detrimental to require these cost offsets downstream because some of the benefits generated by a drug may not have a cost offset. If you cure cancer, there are no cost offsets because eventually people die, or they may get cancer again and eventually die or get a different disease and die. There are no true cost offsets in the long term. But there are massive gains in quality of life and survival, which led to productivity gains and engagement in society, that are of value to the community, and it is important to value health in itself.

CHAIR: Is it also fair to say that when we list a new medicine that might be cost effective—let us say a treatment for a chronic disease that might lead to fewer presentations in hospital, and asthma or diabetes being two common ones—we do not achieve cost savings to the health system in essence for the listing of this new medicine; we simply have fewer people potentially turning up at a hospital for emergency treatment for that, which effectively allows us to more efficiently use the hospital system and the next couple of hundred people get in the door more quickly? Would that be a fair way to characterise it?

Ms Bulfone: That is right.

CHAIR: As there are no further questions, I would like to thank you for your time.

ELLIS, Mr Robert, Board Member, Generic Medicines Industry Association

LYNCH, Ms Kate, Chief Executive Officer, Generic Medicines Industry Association

[10:02]

CHAIR: Welcome. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee has your submission. I invite you to make a short opening statement, and at the conclusion your remarks I will invite members of the committee to put questions to you.

Ms Lynch: Thank you. Firstly, I would like to table apologies for Dr Martin Cross, Chairman of the GMIA. He is overseas with his company business today and could not be here. The PBS has appropriately been described as a national icon. Its responsible administration by the government is paramount and highly complex. We thank the committee today for the opportunity to come and present on this important issue.

Administration of the PBS requires a comprehensive understanding of health technology assessment, as we heard from the previous witnesses. Decisions such as how you can list on the PBS one product that meets the needs of one patient group but deny the listing of another product that treats another patient group and how you can restrict the usage of a PBS product for one patient group but deny a different patient group who would benefit from that product access through the PBS, through the subsidised funding, are difficult questions for anyone, and the establishment of an expert committee to make these decisions is good management of the PBS. Not to listen to that committee is poor management.

Secondly, administration of the PBS requires responsible setting of prices for products listed on the PBS. Since the 2007 reforms the PBS has used two different pricing mechanisms. For the initial or first round of a product, price is established based on the health benefits delivered by that product in the nominated patient population. The other method is where the price is derived from constructed market competition upon the introduction of follow-on generic medicine. Both mechanisms require responsible administration by government. If prices are set too high the public is overcharged; if prices are set too low the product will not be launched in Australia or will be withdrawn, and the public will be denied subsidised access to these medicines.

Thirdly, administration of the PBS requires oversight of the total PBS budget in the context of the overall Commonwealth budget. It was the government's management of the overall Commonwealth budget that was the trigger for the government's announcement this year on 25 February. Firstly it announced the indefinite deferral of PBS listing of new medicines that have been found to be highly cost-effective. This is denying these patients access to beneficial medicines. Secondly it announced the indefinite deferral of the implementation of PBPA recommended price increases. That jeopardises the ongoing supply of these already-listed PBS medicines.

The GMiA submission points to areas where government can better leverage saving opportunities stemming from the recent reforms to the PBS. This will ensure that the PBS is sustainable and, significantly, it will eradicate the need for the government to defer PBS listing of new medicines and impose indefinite deferrals on PBPA recommended price increases. In most jurisdictions, the generic medicines sector is seen as part of the solution in the administration of medicines budgets. Australia should also be fully exploiting the important benefits delivered by the generic medicines sector.

This inquiry has come about because of a crisis. An unexpected and negative event occurred without warning. For the first time ever—and I say 'the first time ever' because I believe that the two prior precedents represent different cases; they did not represent indefinite deferrals awaiting a better budget climate but rather were predicated on the overall cost of those medicines to the government—the government has indefinitely deferred the PBS listing of some new medicines purely on the grounds of fiscal constraint.

The vast majority of the submissions to this inquiry are calling on government to PBS-list these products. This submission also comes with some solutions to better administer the PBS and free up the funds to pay for new and highly cost-effective medicines. Let me briefly run through the three solutions that were outlined in the GMiA submission. Firstly, the government must counter market practices that are being deployed increasingly by the holders of IP, or intellectual property, for PBS-listed medicines. These are the initial brands of the medicines that come on on the basis of the cost-effectiveness arguments. The sponsor for these medicines is increasingly inappropriately impeding the market entry of the following generic medicines after the market exclusivity period for those medicines has expired. This is happening in Australia but is also an international trend. These inappropriate practices are specifically designed to delay and/or block follow-on generic medicines entering the market, and this unnecessarily imposes additional costs on the government, the PBS and the public.

These tactics are being pursued due to a combination of factors including increasing downward pressure on prices paid by the Australian government for PBS-listed medicines. Reduced new product pipelines for the R&D companies are resulting in reduced overall profitability for these companies. And the 2007 PBS reforms introduced the two different mechanisms to set pricing: the health based F1 schedule, where we set prices on the basis of the health benefits delivered, and the F2 part of the schedule, which sets prices on the basis of constructed market competition. This reform has had the inadvertent consequence of adding a further additional commercial incentive for sponsors to maintain their F1 listing for as long as possible as it shields that product from price competition. The government must ensure that it is not possible for initial-brand sponsors to engage in practices that inappropriately render markets inaccessible or commercially unviable for the sponsors of follow-on generic medicines and impose a significant and unnecessary cost to the community.

There is good news. Recently the government has intervened in the market to address a loophole that was being exploited by a sponsor of an initial-brand medicine. The Therapeutic Goods Legislation Amendment (Copyright) Bill 2011, which was given royal assent on 27 May this year, ensures initial-brand sponsors can no longer use copyright on the product information to block and/or delay follow-on generic medicines from entering the market. However, there is still more work for the government to do in addressing these cases of inappropriate use of intellectual property rights.

The Australian legal infrastructure must stay in step with these current market practices by appropriately balancing protection of truly innovative medicines and simultaneously supporting challenges of potentially weak and invalid patents. GMIA commends the government on the introduction into the Senate on 22 June this year of the Intellectual Property Laws Amendment (Raising the Bar) Bill. We seek your support to ensure the speedy passage of this bill through parliament.

The Australian legal infrastructure must again stay in step with current market practices by providing protection against unjustified attempts by a patent holder to use court proceedings to delay the market entry of follow-on generic medicines. Poor quality patents may block market entry of follow-on generic medicines, unnecessarily delaying the introduction of competition and the associated benefits of more affordable medicines. Poor quality patents are highly expensive and very time consuming to revoke by litigation. GMIA can point to an opportunity currently available to the government which, if acted upon, would bolster consolidated revenue to the tune of $60 million. This opportunity is completely legitimate and the government should be taking this step. Apart from raising moneys that can be used to reduce the budget deficit, especially in regard to the cost of the PBS, if the Australian government were to take this action it would send an important message to the owners of patents over pharmaceuticals that the cost to the Australian government of any delay occasioned by inappropriate use of intellectual property rights will need to be met by the owner of that patent.

The Australian legal infrastructure must stay in step with current market practices by also ensuring that the application of the five-year patent term extension for pharmaceutical patents is appropriately applied to patents of pharmaceutical substances per se, as required under section 70 of the Patents Act. The five-year patent term extension was intended to provide a molecule a single extension—that is, where a molecule is protected by multiple patents, and the products listed on the PBS are typically protected by tens if not hundreds of patents, at most only one patent extension is applicable per molecule. There are cases where multiple patent extensions are being granted for the same molecule and this should cease.

Turning now to the second issue raised in—

CHAIR: Ms Lynch, we try to keep opening statements to no more than 10 minutes, which you have had. Please keep going for a couple more minutes, but then I will move to questions. You should feel free to make a supplementary written submission if you wish.

Ms Lynch: Just to run through the key points of the second issue raised in our submission, sponsors should be given the opportunity to successfully obtain price increases for specific medicines granted under the PBPA mechanism. I will table a case study we have prepared, which responds to a statement made in the department of health submission on page 14, where one sponsor has withdrawn a product from the PBS due to the government's decision to defer the PBPA recommended price increases.

The third issue raised in the GMIA submission is that the government should direct new policies at prescribers, pharmacists and patients to ensure that further savings accrue to the government from increased usage of follow-on generic medicines. In summary, the key to a sustainable PBS is keeping medicines affordable and accessible and delivering better health services for all Australians. Generic medicines have made a major contribution to affordable and accessible health care for over 20 years. The government has implemented reforms that are intended to ensure the sustainability of the PBS; however, it is as if the government at the same time has one foot on the accelerator and one foot on the brake. Every time a follow-on generic medicine is dispensed in Australia in

place of the initial brands savings are generated to the national economy, but the government is missing out on making these significant savings. These savings should and could be realised just by implementing some common, straightforward policies that are routinely in place in other jurisdictions.

Mr Ellis: Apologies for ducking in at the last minute.

CHAIR: We were early.

Mr Ellis: I think just broadly and from some of the comments in the earlier session we say and our colleagues in the other industry associations and the Australian industry globally say the PBS is sustainable. There is no argument by any measure. To have people keep saying there is an issue about sustainability we just cannot accept. I think that has to be put on the record. By any measure—by economic measures, by other comparators and by global reference—it is sustainable. That is the position that we come from and we will very much hold to.

I draw the committee's attention to the agenda, which is very focused on the PBAC. I think the last two items are perhaps more important. If the committee can broaden its focus to other issues around the PBS management, particularly the MOU, and the way that has been mishandled, I think it would be very valuable.

Senator FIERRAVANTI-WELLS: In terms of the terms of reference, I understand that most of your submission is actually related to 'other related matters'. I am looking specifically for where you address the terms of reference. We have been in committees where you have talked about the sorts of matters you have raised again today. I am looking specifically for where in your submission you actually address the terms of reference.

Mr Ellis: That goes to my point. The terms of reference cover other issues and cover the MOU. The heavy focus on what is popular today, the press around the deferrals, is important I agree, but the damage being done to the industry and to the PBS globally by the management of the PBS, which is the headline title of your inquiry, is fundamental.

Ms Lynch: The government made the decision on 25 February to defer those listings because of the cost of the PBS in the overall context of the Commonwealth budget. GMIA recognises that and is seeking to draw to the government's and the parliament's attention that there are solutions to this issue—that there is no need to make these deferrals; the PBS is sustainable with good administration.

Mr Ellis: We are dealing with the issue at the moment where $75 million is to be saved by the government over three years by a minor IP matter and yet there is no attention to it. We are deferring important medicines and yet were not working on the areas where it could be offset.

Senator FIERRAVANTI-WELLS: That is all very well. I appreciate your concerns, but we are here to inquire as to the specific terms of reference as defined by the Senate. I want to ask you, directly in terms of the terms of reference, how many patients you believe will be affected by the current deferrals. Is that something that you can assist us with?

Mr Ellis: We could take that on notice. I am not aware directly, no.

Senator FIERRAVANTI-WELLS: What do you say are going to be the consequences of these deferrals for the pharmaceutical sector?

Mr Ellis: Again, I think from the perspective of our sector, they are not dramatically significant. It is more the impact on the industry overall.

Senator FIERRAVANTI-WELLS: What about any impacts on the future availability of medicines in the Australian market as a consequence of these deferrals?

Mr Ellis: Our concern is the principle, the principle being that decisions are being made contrary to the expert advice given to government. You are talking about sustainability. I believe the whole premise of the model of the PBS was around having expert input and expert advice in making decisions about how that model works and how that model goes forward.

Senator FIERRAVANTI-WELLS: What about the criteria that the government appears to be using? Do you have any comments in relation to the criteria and advice that have been used to determine the medicines to be deferred? Mr Ellis, I am trying to bring you back to the terms of reference and ask you to comment specifically on those. Given that they have not been specifically picked up in your material, I just wanted to afford you the opportunity to make any comments directly relevant to the terms of reference.

Senator POLLEY: Could I seek some guidance from the chair. When we look at the terms of reference it actually says 'any other related matters', so surely if the witnesses have something that they believe is going to add weight to this inquiry we should have the scope to hear that evidence.

Senator FIERRAVANTI-WELLS: I am not saying that.

CHAIR: We traditionally take a very liberal approach. My view, being particularly familiar with these issues, is that it falls under a number of the terms of reference, financial impact being one, because of course the listing of medicines now has an impact on whether they are genericised later on, for lack of a better way of putting it. Also, I know that Ms Lynch has spoken to a number of us before about a memorandum of understanding. My view is that this falls within the ambit of the terms of reference. I know you made some comments about the potential flow-on impact. So please continue.

Mr Ellis: My comment would be broad. The level at which government was involved in decision making prior to this change was reasonable in the context of having a material impact on the budget. I think reducing that threshold to such a minor level, where really it is not material, is of significant concern.

Senator FIERRAVANTI-WELLS: Did you have any consultation with the government before this decision?

Mr Ellis: No.

Senator FIERRAVANTI-WELLS: Have you had any discussions with the government since this decision?

Ms Lynch: No, nothing of substance.

Senator POLLEY: I was interested in your views in relation to the PBAC, which is obviously a qualified body to make recommendations to government. Surely we should not be deferring this decision making to the PBAC. Ultimately, the government is responsible for the overall budget, which includes the health budget, so therefore the process now—although you may disagree with cabinet making that decision—is that it is still the prerogative of the government. Do you have any comments?

Mr Ellis: Yes, the government sets policy in a framework direction and the PBAC has been established deliberately with the expertise to evaluate and make recommendations about what molecules should or should not be put up for listing. So, as I said before, I think the government has a responsibility to manage the budget and manage the economy and should be dealing with things at a material level. My view is that the change that has been made brings the level of, if you like, interference—because it would appear that there has been a blanket decision made not to list any drug, rather to do it on a drug-by-drug basis, which is what happened in the past. I think that is our issue. If it continues to be on a drug-by-drug basis, whilst we would have issue with the threshold, that would have some rationality; but to have a blanket lock just seems that, again, health is being seen as a soft target.

Senator POLLEY: In your submission you referred to the US and said that their generic medicines are more widely accessed and available. Can you add anything further as to why there is a different uptake of generic medicines in the US as opposed to Australia?

Mr Ellis: It is a vastly different regulatory, legal and economic framework. First of all there is a very strong incentive for a generic manufacturer to get to market, to be first to market, to take a patent to task and to defeat that patent and then go to market with a very clear access, with freedom from competition for a fixed period. So there is a return on investment for tackling a patent that is inappropriate. There is no return on that investment in Australia. There is no volume incentive for the market to be taking generics. These are just two examples of the many differences between the two economies which could be considered as some measures to be brought in here.

Senator POLLEY: In relation to the decision to defer, is your concern that you do not believe that cabinet should reject any recommendation from the PBAC?

Mr Ellis: No, my concern is that I think cabinet should be dealing with things at a level material to the economy.

Ms Lynch: I would just add that I think at the heart of the GMiA submission is the fact that there is no need for cabinet to be doing this, because there are more measures that can be taken to make the PBS more sustainable.

Senator POLLEY: Can you outline those for the benefit of the committee and for the public record?

Ms Lynch: There were the three that we discussed: that the government should be better countering market practices employed by the holders of intellectual property, where there are inappropriate tactics used in this marketplace to block and/or delay the market entry of follow-on generic medicines.

Senator POLLEY: Can you outline those measures that you say are blocking them? Can you give us an example of what you are citing?

Ms Lynch: A very common way in which we are seeing this occur today—

Mr Ellis: We call it evergreening.

CHAIR: As I understand it, evergreening is a legal term referring to the extension of patent life through legal means, is it not?

Ms Lynch: No, evergreening is a colloquial term. We do not believe it has that meaning.

Mr Ellis: We use it generically.

CHAIR: Ironically.

Ms Lynch: Yes.

CHAIR: I think there is some contention about that term, because I know that it has been used in a legal sense as well. Sorry, Ms Lynch, please continue.

Ms Lynch: What we are seeing are new technologies coming onto the PBS through being able to obtain a listing on the F1 schedule to have market exclusivity, while not actually providing significant additional clinical benefits to what already exists. As a product nears the end of its patent life that product will be withdrawn and patients will be shifted from that product onto a new variation. It might be a switch of a salt or a switch from a capsule to a slow-release tablet. What we would consider fairly minor clinical improvements are nevertheless costing the PBS substantial sums of money. This is a government funded scheme that should target the truly new and innovative medicines. Medicines that do essentially the same job should, as they near patent expiry, be subject to market competition with the generic medicines sector. We want to bring new brands of those older medicines into the market to make them more affordable, not to allow the small, trivial changes to the structure of the molecule to preclude real competition in the market.

CHAIR: Can I ask a few technical questions here. Just to clarify: this can work because the actual patent on the chemical molecule, which forms the active ingredient of the medicine, is set unless there has been a patent extension process granted. This is not evergreening through the extension of that; this is through, for example, a different presentation or formulation of a tablet, a salt or something for which a separate patent exists. I want to get this on the record, because it is not an easy area to understand.

Ms Lynch: It is not easy. We could give some examples of where that particular pathway was followed. It can present itself in many different ways. Intellectual property is a commonly used tool to do that; there can be other ways. It does not have to be around use of additional patents.

CHAIR: I note you have used the term 'use of intellectual property', which obviously would be contested. None of what you are proposing or occurs is illegal, is it? It is actually all using entirely legal means?

Ms Lynch: That is right.

Mr Ellis: Yes.

CHAIR: So it is not that there is, for lack of a better way of putting it, dodgy behaviour here—it is all entirely within the rules of the pharmaceutical industry patent law in Australia?

Mr Ellis: Yes. To make it very clear, we support innovation and we support patents. We are very much of the view that the primary molecule patent and an extension attributable to that because of delays in getting to market are absolutely legitimate and should be protected. We are equally of the view that we should be able to get to market with a generic compound once that primary patent and any extension of that primary patent have expired.

CHAIR: To be fair, though, it is not quite as simple as that because no medicine has one patent. There might be a patent on the active ingredient, but then there are complex things like medicine delivery devices, for example, with patents that exist on a puffer or some sort of injectable mechanism, or even on the formulation of what might be a difficult compound to ingest. You are not asserting that the patterns that exist on those things should not be protected?

Mr Ellis: No.

CHAIR: Substantial R&D can go into those as well.

Mr Ellis: Where it is clear innovation and where it is providing a benefit, absolutely not. We are not saying that we are not supporting innovation where innovation is appropriate. That very clearly applies to devices, whether it be an inhaler or whether it be a subcutaneous administration device. They are all very important innovations.

Senator POLLEY: You said—I hope I have this correct—that the PBS is sustainable. From the evidence that has been given to us and on my information we are looking at somewhere between a nine and 13 per cent increase annually on the cost of the PBS. Surely like all decisions that are made by government, whether on health or infrastructure spending or age pensions or whatever, ultimately there is a limit to what a government can do with its budget. In terms of your criticism of the budget process, is it because those deferrals have been made or is the because you believe the judgment was made, which may or may not be correct, solely on a financial basis?

Mr Ellis: We certainly have disagreed with government, over this period since the first round of PBS reforms, about what the real savings are and what the actual growth is. We would probably beg to differ on the percentage growth going forward. But, using any measure of cost versus benefit and the relative cost of the PBS to the other elements of the budget, we say, and we will continue to say, that it is very sustainable. We are providing one of the lowest cost health systems of any OECD country. We are providing a brilliant quality of life here and a key part of that is the PBS, with the PBS being a very affordable instrument of government and an aspect of providing the healthcare system.

Senator POLLEY: Thank you for your submission. I do not have any further questions at this time.

CHAIR: Dr Di Natale?

Senator DI NATALE: Thank you very much for your detailed submission. I want to follow on from Senator Ryan's questions. I am interested in the discussion we are having around market strategies to delay entry of generics and the grey area that clearly exists between innovation and a strategy to delay competition. That clearly is a grey area because one person's innovation is another person's delaying tactic. You mention that government policy needs to change in response to that to ensure that we do not see delays as a result of strategies rather than genuine innovation. What, in your view, is the government policy that needs to change to allow that to happen? It is a very technical and difficult area to regulate. I am interested in what you see as appropriate regulation in this area to increase competition and drive down costs.

Mr Ellis: One of the clear opportunities to contrast the decision about the government making decisions on the listing of products of a certain value is to look at how the PBS is administering these issues around where there are, if you like, line extensions, which perhaps are not delivering any real incremental health outcome benefit.

Senator DI NATALE: Can you explain that?

Mr Ellis: For example, where a product has been in a capsule and the capsule is delisted and another product is brought to market in an extended-release product, one would have to question whether there is any significant benefit where it is shown clearly and the innovators claim that those two products are bioequivalent. Because to date we have had a very weak patent threshold in Australia compared to other jurisdictions, there are patents on particular formulations where there is very clear and known knowledge—for instance, how to make a simple tablet. There are some formulation patents in existence at the moment that will delay a product getting to market by three years going forward because it is a valid current patent in Australia yet the knowledge behind it has been known for 40 or 50 years. It covers all the basic excipients around how you make a tablet. Short of us going to spend however many million dollars are required to defeat that patent, we have to wait three years beyond the expiry of the basic molecule pattern.

Senator DI NATALE: Are you arguing for a change in patent law?

Mr Ellis: No. There is a change in patent law coming. I am just mentioning examples of what the industry has faced and is facing at the moment. Bear in mind that any changes that you guys ultimately pass through the upper house are prospective, not retrospective, so, in this case, we will be dealing with this issue in 2016 instead of coming to market in 2013.

Senator DI NATALE: I understand that and I certainly sympathise with the challenges that you are facing. I am just interested in what you see as an appropriate response from government.

Ms Lynch: The appropriate response, because this is such a technical and complex area, would need to be multipronged, and that is what our submission seeks to outline.

Senator DI NATALE: I will talk to you about some of the other prongs but I am looking specifically at this one at the moment. I want to tease out what you see as the role of government in ensuring that we perhaps shine a bit more of a spotlight on the area of deliberate marketing strategies versus genuine innovation. I want to pursue that if I can.

Ms Lynch: On the issue of a strategy versus a true innovation, I would still see that as multipronged. I think we need to look at the IP and what patents we are granting to make sure they are truly useful and innovative and that they are progress in science. But also, when it comes to the point where we make the reimbursement decision, we should be carefully considering that we only put into the F1 category of the PBS—that is, innovative medicines—innovative medicines that are an advance in science. There should be additional scrutiny coming to medicines that are slipping through the system under the rules as they currently exist. These are typically the cost-minimised medicines that come in. In some instances they are even shown to bioequivalent. They slip onto the PBS and then the medicine that has been in the market where the sponsors of the follower generic medicines have

been gearing up to get the substitutability of the first existing medicine is at the last minute taken off the market, and that creates significant impediments to the introduction of competition.

Senator DI NATALE: Assuming that we could strengthen that process a little, tighten it up, what sort of savings do you think we are talking about? I know that is a difficult question but do you have any idea of what the magnitude of the savings in that specific area might be?

Mr Ellis: As Kate has mentioned, typically we are talking about the examples that raise eyebrows. We have quite a number of products that the expenditure is in excess of $100 million. Delays of those per year—we are talking about $25 million; the example I cited before was $75 million over three years—and bring a few of those together and you are well past the threshold that the government had in terms of reviewing prospective PBS listings.

Senator DI NATALE: Thank you. I want to talk about the third part of your submission quickly if I can and that is the issue of policies directed at doctors, pharmacists and the general public—again, a little more detail around what you suggest for each of those areas.

Ms Lynch: The premise here is that when the generic medicine comes into the market, we have the statutory 16 per cent price reduction and that will generate savings—a very important saving. After that we have a subsequent policy, the price disclosure policy, where, after 18 months of market competition, the sponsors must supply the government with what their market price was—the actual price that the medicine is being sold at into the market. Then the PBS list price will be reduced to match the average of the actual market price. By definition, the sponsor of the initial medicine has 100 per cent of the market at patent expiry, so in order to get a foothold in the market, there is discounting on foot by the follow-on generic medicines. It is those discounts that go onto the pharmacists through the price disclosure mechanism and is recouped through government, and we are strongly supportive of the government and the public purse benefitting from the strong competition. Suppliers of generic medicines today are probably selling these medicines at world-competitive prices. We would like to see that mechanism where those savings are passed back to government.

In order to get the optimal savings from the price disclosure policy, the government should be putting in place policies that encourage the dispensing and the use by the patient of the follow-on generic medicine because they are the medicines that are generating the bigger discounts and will ultimately trigger the bigger savings to government on the PBS through price disclosure.

Senator DI NATALE: That is great, and I understand all of that but my question though is: what are those policies? You are saying the government should put in place policies that incentivise the prescribing of generic medicines; I am asking you what do you as an appropriate response in that area?

Ms Lynch: If we walk through the chain, we have got the prescriber. At the moment there is no market signal to the prescriber whatsoever. They purely look at the therapeutic impact on the patient. That is very unusual. In most markets there is some market signal to the prescriber. That would be the first price. At the pharmacy level—

Senator POLLEY: Before you go on, what do you think should be done to change that so that the prescriber has an incentive? What sort of incentive are you talking about?

Ms Lynch: There are many models internationally, and it is complicated to adopt. How do you pick up a model from another jurisdiction and place that into the Australian system? It has got to be thought through carefully.

Senator POLLEY: Can you take that on notice and give us some further evidence on that.

Ms Lynch: Sure.

Mr Ellis: What we are saying is that at the moment it is still balanced very much in favour of the originator compounds. The originator has a monopoly. When the patent expires, the originator product is usually—and now pretty well predominantly—benchmarked with the generic, so the brand goes into the market against the generic under exactly the same circumstances, including having the dispensing incentive at the pharmacy level for the pharmacist to dispense the originated brand alongside the generic. There is no differentiation at pharmacy level, which is the predominant channel between the originated brand who has had a market monopoly in the past—say, an average of 15 years effective market monopoly; maybe a bit longer if there is an extension—and has had great opportunity to get a reasonable return on their investment. Going forward, when that monopoly inferred by the IP rights has expired, there is no signal, there is no driver, to incentivise the channel to take the generic. The only mechanism that is in our market is discounting at the pharmacy level. That is where price disclosure is now addressing that, but it is addressing that by impacting on the manufacturers—and that is all manufacturers whether they be originators or generic manufacturers. It is not impacting on the channels, or the pharmacist or the patient.

Senator DI NATALE: I absolutely recognise the problem and I am very interesting in pursuing what some of the levers are that we can use.

Mr Ellis: We put one to government, for example, during the earlier round where we very strongly proposed that the pharmacy be responsible for price disclosure not the manufacturer. That is hard, and unfortunately people do not like tackling the hard bits; they tackle the easy or soft bits. We feel the government sees us as the soft bit.

Senator DI NATALE: I am happy to tackle the hard bits. You mentioned three levels: doctors, pharmacists and consumers.

Mr Ellis: We have been vocal in our criticism of government in this awareness campaign, and now in awareness campaign mark II, which is now going to consume some millions of dollars. There really is not, apparently, the energy to get the consumer thoroughly educated about generics. There are certainly negative campaigns run by sectors, but a positive campaign is proving very tough to get out there.

Senator DI NATALE: Do you see a role for a market signal for consumers as well as for prescribers?

Mr Ellis: Very much so.

Ms Lynch: It would like having two Gucci bags. Here is the original Gucci bag and here is the other Gucci bag. It is shown to be as good and is absolutely the same as the original Gucci bag. They are both the same price, so which one will the patient take. That is the predicament for the vast majority.

Senator DI NATALE: I am not sure that analogy is going to bring you a lot of support.

CHAIR: At the moment whether if I use off-patent medicine like simvastatin—I cannot remember what the brand name was, but it was something or other—and if I get prescribed simvastatin by my doctor and I go to the pharmacist, I might pay a brand premium for the old brand name product versus a product supplied by a generic medicine company. The truth is the government pays the same for both, doesn't it? Because it is so complex, at the point where the government hands over to the company supplying the medicine, the price is the same no matter who it is supplied by.

Mr Ellis: Yes, we understand that has been the government's argument many times.

Ms Lynch: That is where the price disclosure policy was put in place.

CHAIR: I appreciate that, because that tries to capture what was called rebating and discounting and other things.

Ms Lynch: The government has a mechanism in place.

CHAIR: That effectively averages out across all the players which then just leads to another single price. It does not matter which box, as a patient, I pick up as the government pays the same price.

Ms Lynch: Yes. The more of the follow-on generic medicines that are dispensed—

CHAIR: Let's call the generic 'off patents' for the sake of ease.

Ms Lynch: The more generic medicines that are dispensed during that price disclosure reporting period, the larger the reduction will be.

CHAIR: Doesn't that depend on who offers discounts or rebates?

Ms Lynch: If you have 100 per cent of patients on the initial brand, who is going to offer the bigger discount to get a share of the market?

CHAIR: If this is the market, then you might have other people trying to keep their share. They might say, 'Well, I'm going to lose 50 per cent; I might try and keep 45 and therefore go lower.' It is hard to say that just because one company or supplier starts with 100 per cent of the market due to a law we have around intellectual property that the only competitive pressure—because you do have multiple players, especially in the larger medicine markets—will come from the new entry. The old supplier will presumably then respond to try and keep market share.

Ms Lynch: When we are working in a constructed competition market.

CHAIR: I just think it is important for people to understand that, regardless of the campaigns for and against follow-on generic medicines, the government pays the same price in the end no matter what is supplied.

Senator POLLEY: Can I just come in there in relation to the government paying the same price. What is the benefit? My experience as a layperson of going to the chemist is that they ask you whether you want an alternative, and there is usually a price difference for the consumer. What is the average price difference?

Mr Ellis: There would not be a price difference for the consumer if it is above the co-pay. There may be if it is below the co-pay.

CHAIR: There can be a brand price premium, though.

Mr Ellis: Yes, there can be the brand premium. We are seeing some activity in discount pharmacies, and there has been a lot of disquiet about in various parts of the industry, including the government. That activity can happen below the co-pay.

Senator POLLEY: Can you take on notice to provide some more evidence in relation to what you see needs to be done to advise consumers of the alternatives that they have. The bottom line is that we are supposed to be looking after the consumers.

CHAIR: Can we put the issue of IP to one side. I realise that is difficult. There is a point here where it seems that you and the pharmaceutical industry—I do not know how you would like to describe the pharmaceutical industry; I would describe it as another part of the pharmaceutical industry—have reached a meeting of minds on one point, an approach that says there should not be a blanket 'we're not going to list new medicines until someone finds the money' and that is not the way to fund or manage the PBS.

Mr Ellis: Indeed.

Ms Lynch: Agreed.

CHAIR: It is fairly rare to have the two of you on the same page, isn't it?

Mr Ellis: No, you would be surprised at the number of times you would see us in the same room.

Senator FIERRAVANTI-WELLS: You might be in the same room but you are not always on the same page.

CHAIR: The other issue that has often come before these discussions is your concern about the viability of the generic medicines industry. Presumably you are dependent upon the expiration of patents and you bring competitive pressure into the market through producing medicines once the relevant patents have expired. Do you have a concern for your industry that if this approach is taken effectively it will be cutting off the channel of your future productivity?

Ms Lynch: Rob made comments earlier about that. I reiterate that GMiA supports appropriate intellectual property. We really think that it is great for the public and for the R&D companies to be bringing truly innovative and highly cost-effective medicines to the market. It is drawing a long bow to say that an indefinite deferral in 2011 is going to have a consequence for our industry.

CHAIR: There was a PBAC meeting last week or the week before. There is usually one in July, I understand. If the government kept on deferring indefinitely, the truth is that you need the flow of medicines onto the PBS because, whether it is five, 10, 15 or however many years later, that is what you produce and sell into the PBS, isn't it?

Mr Ellis: Yes, eventually it would have an impact.

CHAIR: Thank you, Ms Lynch and Mr Ellis.

Proceedings suspended from 10:53 to 11:09

FISHER, Dr Simon, Medical Director, AstraZeneca Australia Pty Ltd

GLOVER, Mr Mark Drayton, Vice President and Managing Director, Allergan Australia Pty Ltd

O'BRIEN, Mr Duncan Joseph, Market Access Director, Allergan Australia Pty Ltd

VIEIRA, Mr Jose, Managing Director, AstraZeneca Australia Pty Ltd

CHAIR: I will reconvene this meeting. As I mentioned earlier, we have changed some arrangements due to the confines of the room. From now until 11.50, we will hear from Allergan Australia and AstraZeneca Australia, and then we will switch and hear from the other three groups for slightly longer. I understand people have been consulted about that and they are happy. We have had some requests from the *Financial Review* to take photos. It is a courtesy that we ask witnesses whether they are happy with that, because it is up to the committee. If witnesses are happy with that, the only thing I would say is: please do not take photos of their notes and do not take photos of our notes. Thank you very much.

I welcome representatives of Allergan Australia and AstraZeneca Australia to this hearing. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee has your submissions. I invite each company to make a short opening statement, and at the conclusion of remarks I will invite committee members to put questions to you. I would ask, due to time constraints, that you not necessarily just restate what is in your submissions, but please feel free to emphasise the key points.

Mr Glover: Good morning. I would like to thank the committee for the invitation to address you today and the Senate for initiating this inquiry, which I believe is of vital importance to patients, doctors and the pharmaceutical industry and the supply of new medicines in Australia. Allergan is a specialty healthcare company focusing on discovery, development and commercialisation of innovative pharmaceuticals, biologics and medical devices. For more than 30 years, Allergan has been supplying Botox for clinical use for a range of neurological conditions. Botox was TGA registered for severe primary hyperhidrosis of the axillae—underarms—in 2001. This serious condition is manifested in severe, excessive sweating of the armpits. Left untreated, patients suffer constant wetness and staining of clothing, leading to dehydration and maceration of the skin, resulting in secondary skin infections. Chronic sweating can also cause difficulty in grasping objects and writing, making some occupations impossible. Sufferers may become withdrawn and depressed. Effective treatment has been shown to significantly improve social functioning and mental health. Botox is recognised in treatment guidelines as providing a unique second-line treatment for patients failing prescription topical aluminium chloride antiperspirants and before consideration of surgical procedures that are undertaken only in a minority of patients.

Hyperhidrosis sufferers petitioned the House of Representatives on 1 September 2008, requesting that Botox be listed on the PBS for severe primary hyperhidrosis of the axillae. Representatives of the Department of Health and Ageing testified before the House in response to this petition and verified the severity of the disease and its suitability for a PBAC application. The Minister for Health and Ageing, the Hon. Nicola Roxon, stated in her response to this matter, tabled before the committee on 24 November 2008, that she was 'sympathetic to the circumstances faced by people with hyperhidrosis', and she further advised signatories of the petition to contact Allergan to establish its intentions in respect of seeking an extension of the current PBS listings of Botox to include the treatment of individuals with severe primary hyperhidrosis of the armpits.

Allergan since provided two submissions to the PBAC for Botox for this indication and received a positive recommendation in March 2010. The PBAC had noted:

> … no other second line treatments for severe hyperhidrosis of the axillae were available on the PBS, and … that there was significant impact on the quality of life of the patients with hyperhidrosis and that there was a clinical need for botulinum toxin.

After a lengthy and rigorous process—I can attest to that—it was therefore extremely disappointing that there was no warning or consultation around the government's decision to defer the PBS listing of Botox in February 2011 due to fiscal considerations. The explanation provided by the government for the medicines chosen for deferral has centred around the availability of alternates on the PBS for a particular disease as well as the seriousness of the disease itself. What exactly constitutes the criteria for determining the seriousness of one disease versus another is not currently known.

In the case of Botox for severe hyperhidrosis, the minister has acknowledged that there is no alternate treatment available on the PBS. However the minister has publicly stated that this severe disease is actually, for many people, a mild condition. This contradicts both the TGA approved indication and the PBAC recommended listing for Botox which are for severe disease. Quite clearly, according to considerations around alternatives and severity of disease, the only know criteria we have for deferrals, Botox should not have been deferred from PBS listing.

The example of Botox for severe primary hyperhidrosis illustrates the dangers of ignoring an objective expert committee's recommendation on the basis of arbitrary criteria. The PBAC recommended Botox on the basis of acceptable cost effectiveness in the severe hyperhidrosis indication. This means that the expert committee found that the return to society in terms of superior health outcomes associated with providing access to Botox versus providing no treatment warranted the investment.

It is now one year and four months since Botox was recommended for listing on the PBS. Understandably the company is fielding inquiries from specialists and patients anxious to understand why this treatment has not been available and what we can do to address not only the delay but also the statements from government about why it has been deferred. This leaves patients and their doctors in great uncertainty as to what, until recently, has been a rigorous, transparent and independent process, which has been replaced by non-transparent criteria which, in the case of Botox, are not even applicable. I believe similar concerns have inspired the unprecedented response from patients and health consumers on the issue of deferrals in general.

Therefore the deferral of the PBS listing following recommendation by the PBS in March 2010 limits access for Australian patients to new medicines. It is inconsistent with the intent of the MOU between government and medicine and does not make for good health policy. I commend the committee for reviewing this very important issue.

CHAIR: Dr Fisher or Mr Vieira, do you have an opening statement?

Dr Fisher: Yes, we do. Thank you very much for the invitation and good morning. My name is Simon Fisher. I am the medical director at AstraZeneca in Australia and was previously a practising general practitioner. I am here today with my managing director sitting to my left, Mr Jose Vieira.

I would like to begin by acknowledging the large number of important stakeholders who have prepared submissions. To my knowledge there are 52 of them and 75 per cent of them are from patient groups, which is remarkable. Notably 100 per cent of the non-government submissions are in opposition to this policy. These submissions eloquently address any and all issues that are pivotal to this debate, for example, the inconsistency of the deferrals policy with the national medicines policy and the undermining of the PBAC. On behalf of AstraZeneca I am not going to reiterate the already well-described points. With regard to issues from the perspective of the broader pharmaceutical industry, AstraZeneca supports and agrees with the elements which have been presented in the submission by Medicines Australia. We are all very concerned with the government's deferral of PBAC recommended medicines and its impact on patients. This will be presented by Medicines Australia in Canberra next week.

My statement today relates specifically to AstraZeneca's experience with the deferrals policy and its direct impact on those patients and consumers in two areas: cost and treatment. Our experience and perspective is gained by virtue of the fact that our medicine, Symbicort, which is a treatment for respiratory disorders, has been recommended by the PBAC for the treatment of chronic obstructive pulmonary disease, a severe disease, but has subsequently, without consultation and on very short notice, been deferred. I am going to describe to you two risks that the deferrals policy represents to Australians and to patients. I will then make reference to our experience with Symbicort and illustrate to you what happens at the doctor-patient level at consultation. Risk No.1 is that the deferrals policy leads to decision that are detrimental to Australian patients. This is because this is a politicisation of a previously rigorous health related scientific issue which is being driven by cost and not patient outcome. Risk No.2 is that the deferrals policy being driven by a focus on cost without consultation or consideration of patient benefit will deny access to valuable medicines by Australians. It is often said by doctors that no two patients are alike. For chronic obstructive pulmonary disease this is very true. There is one alternative fixed dose combination of corticosteroid and long-acting beta agonists on the market already, but I want to take you through a bit of a journey which will explain that an alternative medicine on the PBS is an important step.

Before becoming a pharmaceutical physician—

CHAIR: Dr Fisher, because we are going to have lots of questions, can I ask you to truncate your statement to not too much more than about five minutes.

Dr Fisher: Absolutely. I understand. I was a general practitioner working in Windsor and I used to treat a wide range of patients, but a number of them were elderly. I wanted to talk to you about one elderly gentleman by the name of George who has chronic obstructive airways disease. I treated him with the currently listed PBS medicine. He unfortunately had an adverse experience on that medicine and he came back to see me because he had stopped taking the medicine and become much more short of breath to the point where his activities of daily living—washing, cleaning, walking down the street—were now impossible. So I looked for an alternative medicine, in a hypothetical today situation, on the PBS and I realised there is no alternative medicine for him, despite one medicine being TGA registered for the treatment of chronic obstructive pulmonary disease and in fact recommended by the PBAC. That is the medicine that AstraZeneca sponsors, Symbicort. I would be unable to use Symbicort for George because it is not listed on the PBS as a consequence of this policy. Therefore, I would have to put George in an ambulance to take him to hospital where he would be admitted, investigated, treated and stabilised for his chronic obstructive pulmonary disease. That is the doctor-patient interface consequence of the deferral policy. It is a direct negative effect on patients.

The cabinet deferral of medicines such as Symbicort prevents doctors from practising medicine as they should be able to in this country. Symbicort is just one example and other medicines are currently delayed but should be listed. The cabinet delay should not continue into the future. I am very concerned as a doctor and a previous treater of patients that if this deferral policy is continued into the future this will compound and numerous innovative medicines will not be able to be accessed by Australian patients.

So George is in hospital because of this policy and we sit here today discussing whether this policy is good or bad for Australian patients. There is really no question to be answered in my mind. This is an appalling policy and there are real risks to patients. AstraZeneca calls on the government to reverse it and terminate it as soon as possible. Thank you.

CHAIR: I will start off with a couple of questions. Dr Fisher, the example you mentioned of George in Windsor seems to be a good example of where someone who does not understand the way medicines work might say, 'There is a treatment out there and it gets a 50 per cent effectiveness ratio, so we do not need another one that is only 50 per cent as effective.' The problem you outlined is that we do not know before we use them which medicines are going to work in which individuals as opposed to a population-level assessment. That is why multiple treatments for the same condition are so very important.

Dr Fisher: You are absolutely right. I do not know if I could put it any better.

CHAIR: You probably could. I hope so; you are a doctor! This understanding has underpinned the assessments of the PBAC, whether on a cost minimisation basis or a cost effectiveness basis, and the listing of multiple chemical entities in the same class of entities for as long as we can remember this cost effectiveness process being used, which I think goes back to 1993.

Dr Fisher: You are right. Approximately 30 per cent of all admissions to hospital—and this is the best estimate of the rate of adverse events on any one medicine I could find—are due to an adverse event. An adverse event is an unwanted event on a particular medicine. So George is just a tiny drop in the ocean of patients who in the community experience an adverse event and therefore a change of medicine needs to be considered. In this case there is no option for change.

Senator POLLEY: I want to clarify that for the record. Are you saying that in relation to 30 per cent of all patients admitted to hospital their diagnosis will change depending on alternative medicine?

Dr Fisher: No, it is estimated—

Senator POLLEY: So you are saying that 30 per cent of all patients admitted to hospital are related to an alternative medicine being available to them?

Dr Fisher: No. It is related to an unwanted effect of a current treatment. Therefore, the patient needs to go to hospital and be remanaged.

CHAIR: Are there any comparative nations with what you might call national insurance models of health care with major public subsidy of medicines—and let us exclude the United States for a second because it is a unique market simple—so Canada or Europe, that say one medicine in any class is enough? Are you aware of any that we could compare ourselves to as a modern, industrialised economy with a good public health system?

Dr Fisher: The system in New Zealand is not dissimilar to what you are describing, but I would not call it necessarily a modern, progressive healthcare system.

CHAIR: It is not something to which Australians would aspire, is it?

Dr Fisher: Indeed not.

CHAIR: That is a place where they list only one cholesterol-lowering medicine, and medicines are not listed there on a cost-effectiveness basis; they are essentially tendered for, are they not?

Dr Fisher: That is true; there is a tender process.

CHAIR: So it is lowest price only?

Dr Fisher: Yes.

Mr Vieira: New Zealand is a one single molecule. Sometimes they bid for multiple molecules for the same disease.

CHAIR: So it is not an assessment based on the cost-effectiveness of the medicine, which Australia pioneered; it is an assessment based on how the government can get some medicines to some people at the cheapest cost.

Dr Fisher: Absolutely. In fact, in the case of Symbicort, because of the nuances of the treatment of chronic obstructive pulmonary disease, the cost to patients of listing Symbicort will actually be lower than the current cost to patients by the current structure of the PBS.

Senator FIERRAVANTI-WELLS: They are the statistics that you outlined.

Dr Fisher: Absolutely.

Senator FIERRAVANTI-WELLS: So in the end so much for cost saving, because it is going to cost more in the end.

Dr Fisher: Absolutely.

Senator FIERRAVANTI-WELLS: Have you seen page 2 of the *Australian* today? I am sorry I do not have a copy of it to table, but I am sure that all present would have read page 2 of the *Australian* today. It states:

Acting Health Minister Mark Butler has rejected as a "rhetorical flourish" drug company threats to withhold new drugs and clinical trials from Australia now that cabinet will decide whether medicines get a subsidy.

Mr Butler said applications to be covered by the Pharmaceutical Benefits Scheme reached a near record high this month and there was "no evidence" the changes were causing a slowdown.

Is this another example of somebody who has not really worked at the coalface just basically shooting from the hip? I would have thought this was a serious issue. Would anyone like to respond to Minister Butler's assertions?

Mr Glover: Thank you for this opportunity. We need to go back to the purpose of the PBS process, which is to provide universal access to cost-effective medicines. It is a system that has been well entrenched in the psyche of Australians. I do not think anybody is saying from the industry point of view—and certainly I have not said it—that medicines are going to stop coming to Australia as a result of this deferral policy. Our concerns are really on behalf of the patients. What is happening—and has absolutely happened in the case of Botox for severe hyperhidrosis for the past 16 months—is that patients are being delayed cost-effective treatments. The great thing about the PBAC system is that we all know it is a very high and rigorous bar. The world knows that and our corporate offices know that but recognise that we need to supply quality data which is reviewed, to demonstrate clinical relevance and cost effectiveness for the healthcare system and for taxpayers in Australia, which all of us are. Therefore, our concern is that, due to this deferral policy at the moment, there will be—and there is—delay in patients accessing valuable medicines that have already been critiqued and which have had a positive recommendation.

Senator FIERRAVANTI-WELLS: Minister Butler has made this comment. What are your comments in relation to it? Is it just rhetorical flourish from him as well?

Dr Fisher: We are here today talking about access to medicines by patients. I hope you can hear in my voice the passion that we have for achieving patients' access to new medicines. We as an industry are dedicated to maintaining that access and in no shape or form would we or I ever wish to consider withholding that access or slowing it down. But that is what this policy does.

Senator FIERRAVANTI-WELLS: I know, but there will come a time when your company, and particularly your parent companies overseas, will have to make financial decisions. Clearly, this policy will not assist in terms of those financial decisions.

Mr Vieira: What will certainly happen is that we will postpone some important decisions in terms of investment and prepare our companies to launch new drugs once cabinet provides the final decision. There is no clear criteria now. We cannot anticipate anymore which products will or will not be approved. We need to put on hold some important decisions in terms of investment to prepare our companies and therefore delay in launching new drugs will come not only because of the deferral but because it is naturally delaying access. But also it will

take much longer for us as a company to prepare ourselves to launch new drugs. Sometimes we need to make some investment to expand production capacity and it takes time. The lead time to launch new drugs is long. An important business decision will be taken only after the final decision of cabinet.

Senator FIERRAVANTI-WELLS: Somebody asserted that it will cost $1.2 million to bring a drug to the particular point. If you are going to spend that sort of money—

Mr Vieira: That is billion.

Senator FIERRAVANTI-WELLS: sorry, and 12 years, you are going to have to think long and hard if you know that, rather than it being a world-renowned process, it is now at the whim of cabinet. Mr Glover, how many patients have been affected by the current deferrals in relation to your—

Mr Glover: It is very difficult for us to estimate that; there is no patient group for this patient population. They are a socially isolated group. They do not come out very easily because of the nature of their condition. There are no alternative treatments available and therefore understanding what that patient population looks like is very challenging, so it is difficult to give you a meaningful answer. What we can say is that, on a statistical population basis, as we work through our rigorous submission process we estimated about 40,000 patients—

Senator FIERRAVANTI-WELLS: 40,000?

Mr O'Brien: Around 40,000 would be eligible for treatment with Botox. Of that number, we would estimate a lower number actually get treatment. That is due to accessing specialist treatment and presenting for treatment. But around 40,000 would be eligible.

Senator FIERRAVANTI-WELLS: That is 40,000 lives that would be bettered as a consequence of a very small investment. Dr Fisher, in relation to your—

Dr Fisher: Thank you for the question. In relation to the incidence and epidemiology of chronic obstructive pulmonary disease, almost one in five Australians over 40 are affected by chronic obstructive pulmonary disease. That is a lot of patients.

Senator FIERRAVANTI-WELLS: And, ultimately, that is a lot of older Australians and the complications that come from the sort of George scenario, particularly if they are in aged-care facilities and, even more so, the hospitalisation and the costs that that already entails when there are 3,000 older Australians in hospitals every night who should perhaps be better cared for. That will add to that number.

Dr Fisher: Indeed, and their quality of life. I will not ask you to do it now but sometime, when you have a moment, take the biggest breath that you possibly can, breathe out a tiny little bit and then breathe in and out again. That is the sensation of chronic obstructive pulmonary disease.

Senator FIERRAVANTI-WELLS: Your respective companies would obviously have a financial impact from this. You have prepared stock. You have undertaken education campaigns. What happens to the stock on hand? Can you give me an idea of the financial impact of this deferral?

Mr Vieira: In the case of AstraZeneca I would say the stock on hand is not our major problem because that particular strength of Symbicort can be used in other indications such as asthma. It is just a matter of time. You have some capital waiting to be sold in the marketplace. Stock is not a major problem; it is just the preparation for launch. Our investment in people and training is not recoverable, but it is not necessarily the stock on hand for us at AstraZeneca. I can see in other companies where this is a single product for a single indication there is nothing to be done other than to write it off.

Mr Glover: In relation to us, Botox fortunately has PBS funding for eight different indications so far, ranging from kids with cerebral palsy to adult spasticity post-stroke to movement disorders. It has been around a long time and it is well funded. Our issue, which is on hold, is that with Botox treatment you need to teach people how to use it. It is an injectable and it is one of the few products that you really have to show because where you inject it makes a hell of a difference. Our education program has gone on hold for those specialists. The Botox access program is one of the most rigorous programs in the PBS to get access to. We are well aware of not making predictions until we have certainty around when we have approval. It is less of an issue for us because Botox is used for a lot of other very valuable medical indications.

Senator FIERRAVANTI-WELLS: I have one last question for you, Dr Fisher. On page 11 of your submission it refers to the preferential funding of life-saving medicines. Is that not really cabinet making a decision about what is and is not life-saving? As you said, it is a rather arbitrary assertion to make. A drug may not work for one person but the alternative may be life-saving for that person. So cabinet really will be making decisions about what lives to save and what not to save?

Dr Fisher: Absolutely. It is not just that cabinet will be making the decision, in fact, it is taking the decision away from the appointed independent panel of experts.

CHAIR: Are you opposing any cabinet threshold? There was previously a cabinet threshold in place, but are you saying that there should not be a cabinet decision process at all?

Dr Fisher: I think that is potentially a question to ask Medicines Australia, which is a group that represents the whole industry. They will be in next week. Personally, I believe that any decision in any area should be made by a group of experts and not by a less expert group.

Senator POLLEY: So what you are saying is that under the previous regime and the previous government, when the decisions went to cabinet for things over $10 million, it was okay for cabinet to make decisions then because there were not many deferrals; whereas now, because the decision is made more broadly because of the government's responsibility to manage the economy, you have an issue with it? So it was okay previously to have $10 million spent on behalf the Australian taxpayer, but not now because the whole gamut of medicines coming on the PBS goes to cabinet?

Mr Vieira: I think what they had in the past was a clearer rule about what would be approved or not. Historically, even though we had this rule about $10 million, really only a few products were rejected by cabinet and therefore the level of certainty was much higher. What is quite complicated right now with this new policy is that every single product will go—even products that may have zero impact or, as in our case, products that could potentially create savings for both government and patients. If we go to cabinet we cannot anticipate any kind of decision. These are products that we believe, based on our submission, would save money and co-payments for the patient, but they were rejected when they went to the cabinet. That is a major difference compared to the previous policy. The level of predictability was much higher under the previous policy and that is what we are criticising now.

Senator POLLEY: Dr Fisher, in relation to the comments about undermining the PBAC, that is in fact a body that makes the recommendations and the government has acknowledged their expertise. The usual process of cabinet is that recommendations are made and then the cabinet makes the decision. Why should issues relating to the PBS be treated differently to any other arm of government, other than because you did not get the decision you obviously wanted on this occasion?

Mr Vieira: Could I respond on this?

Senator POLLEY: I would like anyone to make a comment; that would be good.

Mr Vieira: I think medicines are slightly different from other sectors because an investment in patient health may save money and may save lives over a broader period, so budgetary time frames are not necessarily the best criteria to make judgments about healthcare products. That is what the PBAC does : it does not look at a simple budgetary, May-June, analysis, it looks at the broader picture and the impact on the full economy. We are delivering savings, but not into the budgetary period; in a longer period we are adding value. That is the reason why acceptance of that recommendation is a more valuable alternative, because if we move to the short-term budgetary view we may end up taking the wrong decisions in terms of the good of the patients.

Senator FIERRAVANTI-WELLS: The government cannot make any decisions on halls, let alone on complex matters like the PBS.

Senator POLLEY: We can debate the BER funding if you like, but I thought we were here to talk about the PBS.

CHAIR: We are pressed for time; we can address this latter on.

Senator POLLEY: I understand the process of the reference, but I thought we were here to get the best outcome not just for the pharmaceutical industry but, more importantly, for the consumers of the products. In the past the decision was made by cabinet when it involved more than $10 million. Every dollar we spend in health is of value, no question about that, but sometimes you have to make decisions on the broader issue of health. In relation to Botox and the one use that has been recommended for that, I am not a medical expert but there are alternatives. Apart from that exception, can you tell me how many people are not being treated because there are not alternative medicines? Can you give us an example of patients who are not going to be treated?

Dr Fisher: Patients will be treated, but a large number of patients—as I said, the best reference I could find is around 30 per cent—will have an adverse event. In the case of Symbicort for chronic obstructive pulmonary disease, there will be no alternative. That group of patients will be at risk of complications of their pulmonary disease due to this policy.

Mr Glover: If I can come back to your question about the $10 million level, the PBAC's role is to recommend to government to approve or decline. If we get through the hurdles, which takes us a number of submissions, these medicines have already been proven to be clinically relevant and of economic value. So with the process from the PBAC recommendation to when it becomes available to the general practitioner or the specialist to prescribe it, we are inevitably losing the clinical relevance, the patients will be losing out, and the economic value that we have had to demonstrate in order to get a positive recommendation is already being lost. So we are already losing economic value on this, if we are going to take this right down a dollar challenge—which is the government's challenge; I accept that.

On the $10 million bar, the industry for many years has been pushing: is that a relevant level in the whole scheme of health expenditure? We know that debate will continue. Our position is to ensure that, because we have gone through a rigorous process showing clinical relevance, showing patient benefits and showing economic value, those people you have appointed as experts make that review. When it comes to the cabinet decision, yes, you need to be aware of the financial impact, but where is the expertise in making those relevant decisions? Our proposition is that we accept the jury of the PBAC, and then it needs to flow through.

Senator POLLEY: Are you suggesting that if the PBAC make a recommendation it should automatically go on the PBS, irrespective of the financial impact or whether there are alternative medicines available?

Mr Glover: The drug review process is that you demonstrate clinical relevance, patient benefit and cost effectiveness. That is the rigour of the process. Recommendations that come through that process have gone through that rigour.

Senator POLLEY: You have not answered the question. Are you saying that, if you pass the rigour of the PBAC, any government of any persuasion should automatically make those drugs available on the PBS?

Mr Glover: There is always the prerogative of government to manage expenditure.

Senator POLLEY: Thank you.

CHAIR: And we wish they did.

Senator FIERRAVANTI-WELLS: We would not be here if you had managed better, Senator Polley. We would not be fiddling with small amounts of money.

Senator POLLEY: Mr O'Brien was about to make a comment.

Mr O'Brien: Just to add to what Mr Glover has said, when the PBAC makes these decisions it takes into account the issue of alternatives, clinical need—all those relevant factors. The question of alternatives has already been answered by the PBAC and it is embodied in this recommendation.

Mr Vieira: Would you allow me just one minute to add to your question, Senator Polley, on one impact of the decision for patients. On page 10 of our submission, when you compare two drugs—the alternative and the Symbicort—and you see the copayment and the impact for both the general and the concessional patients, because our drug is used for two months and the alternative is used for 30 days, one month, it means that for the general patient who has six prescriptions, six copayments per year rather than 12, the cost is double. Rather than having a copayment of $200, it goes to $400 a year. Clinically speaking, there are alternatives, but there are also some savings for patients, though that point has not been taken into consideration at all under other plans. That cabinet approval could lead to some decision that is not necessarily for the good of patients. I really wonder what criteria were used to defer this particular drug.

Senator DI NATALE: Thank you for your submissions. I certainly share some of your concerns about the impact of this decision on patients, but we all know that the heart of the problem is the question of economic sustainability around the future of the PBS. We know that costs are going up and they have been increasing over recent years. Governments are faced with the same dilemma that you, as managing directors of successful companies, regularly face about how to contain costs. My first question is whether you have any thoughts about how the PBS could be better managed to make medication affordable for patients and in providing access. Also, what are some of the possibilities for improving the efficiency and particularly the economic performance of the system? Perhaps I can ask Mr Glover and Mr Vieira whether they have any thoughts on that.

Mr Glover: Over the past decade the industry, together with the secretariat who runs the PBAC, has worked very hard to continually look for process improvements to make this very efficient. The discussions have not always been good, but they have been healthy and robust, and from the time the new rules were introduced in 1993 we have increasingly improved the understanding and the requirements, as a sponsor company, to the expectations of government and its appointed review committee to make sure that we provide clinical relevance, economic value and best patient outcomes through that process. That is an ongoing discussion that we have had as

an industry body, and I am sure that my Medicines Australia colleagues will pick up on this on Monday to support that it is a proper thing to do. The challenge that we have now been brought to—hence this inquiry—is the final stage of uncertainty that that has provided. We are really consumers who know that these drugs are coming through the healthcare review system, through a regulatory process through the TGA and then into a funding mechanism, so there are expectations coming through. The rigour that has been acknowledged and accepted by a very robust PBAC and PBS process as a world renowned review committee, to then throw in delays is really providing—so the improvement point is, in principle, the MOU that we signed not very long ago in parliament. It stated that the cabinet review process would happen within six months of us getting a positive recommendation at the PBAC. That was the spirit and the intent, and that has been woefully ignored in recent times.

We have worked hard. We have given up $1.9 billion worth of savings as part of that review process over forward estimate years. Those savings are starting to come through. We talked about price disclosure earlier—the GMA. Our report talked about that. Those are raw mechanisms to improve the efficiency and effectiveness of funding pharmaceuticals for consumers within the Australian market. As sponsor companies of R&D, that is what we bring. We bring new, innovative drugs to market.

Senator DI NATALE: But costs are increasing, and they have been increasing over recent years. If they continue to increase then clearly the scheme will face some further challenges. My question is: is there anything more we should be doing? It sounds like you think we are doing as much as we can.

Mr Glover: I think there will be constant tweaking of the system going forward. Increased productivity of the ageing population of Australians is going to be our biggest challenge collectively. Medicines are demonstrating and have demonstrated over many years that life expectancy and quality of life are significantly improved when you introduce medicines. The medicines in our healthcare system are the most rigorously reviewed part of the healthcare system. Of the $50 billion that is spent on health each year, $9 billion of it is drugs. We get thoroughly reviewed. We know that. For the other $41 billion I would suggest there is room for improvement.

Mr O'Brien: I would add to Mr Glover's comments. The industry has a very good track record of working with governments of various persuasions to deliver savings and reform to the PBS. The point is that those discussions take place in a broad policy context. They should not be related to individual medicines and their deferral.

Senator DI NATALE: Sure. I accept those comments. Did you have anything more to add on that?

Mr Vieira: I align to the same fights: Medicines Australia and the government work together in understanding the numbers and the factors to come. It happened with the memorandum of understanding, and I think it should happen more and more. That is the best way to sit together and to control the future of the PBS. We are part of the system, not part of the problem. I think the memorandum of understanding was a great demonstration of Medicines Australia and our companies sitting together, understanding the problem and offering solutions. I think that is the best way to do it, not making unilateral decisions in which we are all taken by surprise.

Senator DI NATALE: I take a point in your submission. The deferral happened on 25 February? The decision was made then? I think in point No. 4 of your submission you state that the deferral introduced a significant instability and commercial uncertainty and could result in delayed or diminished access to medicines. It has been five months, and I think you repeated that concern during your oral presentation. Can you point to one specific decision that has changed as a result of the deferral. You said that there were concerns about investment in future medicines. We have had five months for this decision to filter through. Give me an example of where that decision has impacted on your investment in a particular medication.

CHAIR: I ask you to be brief with this and potentially provide stuff on notice if it needs to be lengthy. We do need to move on to our other witnesses.

Mr Vieira: I can speak in general terms. All the launches that we are planning for new products in Australia—all the decisions to start the launch—will be postponed by the date in which the cabinet will take the final decision. We look at what happened in other countries, the probability of success, understanding their rules, the likelihood of approval. We need to hold back because we cannot allocate resources to prepare my company to launch new products if we can end up with decisions such as the one that I am describing. So it is happening.

Senator DI NATALE: I am asking for a specific example so that I can get a sense of where that has actually happened.

Mr Vieira: I can send you the list of products that we are going to launch. I can illustrate two or three. But we are just waiting. We need to wait until the cabinet provides a final decision.

CHAIR: It is also fair to say, is it not, that when it comes to the assignment of clinical trials, which is a particular area Australia has targeted, manufacturing and other what you might call less commercial based decisions, more on the R&D side, have a much longer time line than five months, don't they? They are made at the very least on an annual, if not longer, basis.

Senator DI NATALE: I am not talking about investment in research. What I am talking about is getting back to the claim made in the *Australian*. I think there is an opportunity to demonstrate whether in fact it is having a material impact on your decisions in Australia and it is an opportunity to demonstrate—

Mr Vieira: And it is clear: products that could have been launched a few months after the cabinet decision will take much longer because we will start to prepare our organisations just after that decision and not before that.

Senator FIERRAVANTI-WELLS: And following on from that, clearly any decision to undertake research or whatever must be considered in the same light, Senator. You cannot ignore potential research decisions just like that. It is part of the bigger package, is it not? Research and other issues like that would be part of that, wouldn't they?

Dr Fisher: Yes, and if I could address the R&D very briefly, in Australia we are in a global competition for research and development. Research and development can be placed in any country and it is up to us to demonstrate why research and development at clinical trials should come to Australia. With these types of deferral processes and ad hoc policies it becomes more and more difficult to justify the bringing of R&D into Australia.

Senator POLLEY: But you are not suggesting that any company is going to go broke over this decision, surely, or that they are going to withdraw all their research.

CHAIR: Senator Polley, I am going to ask a couple of questions. I have given quite a lot of latitude to other members. I just wanted clarification. There is always the constant concern about the increase in the cost to the PBS and the numbers are quite big; I do not think that is news to anyone. It a fair characterisation, is it not, that we are spending more on things because they did not exist 30 years ago? The best example I can come up with is probably HIV medicines. We spend quite a lot on them but I do not think most of those medicines existed 25 years ago. So aren't we just spending more because there is effectively more to spend it on and people are being treated where they otherwise would not have been?

Mr Glover: That is correct, Senator. That leads into the natural cycle. You heard from the GMIA earlier today. The process of patents is to protect R&D companies to bring new, innovative medicines for unmet medical needs. Certainly Alergan is very specialised in that area. Once the patent life expires, technically or not—you have had that debate—then that is where those medicines which have treated the diseases of the eighties and nineties certainly become very much more affordable and then we go up and—

CHAIR: I appreciate that. I just wanted to try to nail that point because I think it is something that occasionally gets forgotten. Thank you very much for your time and for your understanding about changing arrangements. I will now call the next group of witnesses.

BAVEYSTOCK, Mr Rob, Managing Director, Mundipharma Pty Ltd

GOODWIN, Mr Bruce, Managing Director, Janssen-Cilag Australia Pty Ltd

KETELBEY, Dr Bill, Country Medical Director, Pfizer Australia

KULKARNI, Professor Jayashri, Monash University, Faculty of Medicine

LATHAM, Mr John, Chairman and Managing Director, Pfizer Australia

WHITLAM, Dr John, Medical Affairs Director, Mundipharma Pty Ltd

[12:01]

CHAIR: The committee will now hear from our second panel of representatives from pharmaceutical companies Janssen-Cilag, Munipharma and Pfizer Australia. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee has your submissions. I invite each company to make a short opening statement. At the conclusion of your remarks I will invite members of the committee to put questions to you. As you know, with the last panel we did get a bit pushed for time, so I encourage you to make your statements as short as possible. Anything you can provide on notice later that would be easily be done, please feel free to offer up. I will try to move the questions along as quickly as possible. Janssen, would you like to start with your opening statement?

Mr Goodwin: Sure. Senators, thank you for the opportunity to appear before you today. I am the managing director of Janssen Australia. I have with me Professor Jayashri Kulkarni, who is a professor of psychiatry from the Faculty of Medicine at Monash University. Given that we have to talk about our product versus alternative medicines, it well be worth having the views of someone who has experience with our product that has been deferred.

Whilst Janssen's submission to the inquiry addressed the full inquiry's terms of reference, for the sake of brevity I am going to focus my remarks just on reference (b)—that is, any consequences for patients of the deferrals—by highlighting the impact of the deferral decisions on Australians who are living with schizophrenia. You may or may not be well conversant with schizophrenia. Let me just give you a few facts. There are around 100,000 Australians living with schizophrenia. People with schizophrenia have a life span of nine to 12 years shorter than the general population, are 12 times more likely to commit suicide and have workforce participation rates of less than half the general population. A high proportion of people with schizophrenia live in unstable housing conditions or indeed are homeless. I think it is fair to conclude at this point that patients generally cannot afford to pay for their medications if they are only available through the private market. The government deferred the PBS listing of Janssen's new treatment for schizophrenia, Invega Sustenna, which is paliperidone palmitate, which is a long acting injectable product. It is a product that works for four weeks. The principal argument for deferral appears to be that existing medicines are already available. The Department of Health, in its submission, listed two alternatives. The first is Risperdal Consta, which is actually a Janssen product, and the second is Olanzapine long-lasting injectable, a product that is available through Eli Lilly. It is important to realise that, for schizophrenia, no medicine is perfect and the aims of treatment are really about trying to reduce relapse leading to acute exacerbations of schizophrenia and hospitalisation. There is a well-established body of evidence supporting the use of antipsychotic medications to reduce relapse. In particular, long-lasting injectables are shown to improve adherence to medication. In fact, around 80 per cent of patients remain adherent on long-lasting injectables whereas only 50 per cent remain adherent on oral medications as an alternative. Of course, if you do not take your medication you are more likely to get sick again.

I want to specifically address the issue about alternatives available and the two that were listed. Firstly, I want to stay that Invega Sustenna has a TGA listing for both acute and maintenance in schizophrenia—that is, it has some significance because the two alternatives require stabilisation on oral medication before using the long-acting injectable. So the actual usage of the product is somewhat different in a hospital setting; you can use Invega Sustenna while the patient is in hospital, enabling the opportunity for a shorter hospital stay.

CHAIR: Mr Goodwin, can I ask you to wind up your statement.

Mr Goodwin: Yes. I am almost finished. I would like to mention a couple of facts around the two alternatives. The Olanzapine long-acting—

CHAIR: Is this material in your submission?

Mr Goodwin: I think it is.

CHAIR: With all due respect, we are pressed for time so I would ask you to wind up. The characteristics of the medicines involved have been made clear in the submission. I want to move to questions as quickly as I can because I know there are a lot of questions about the impacts of these medicines on patients.

Mr Goodwin: Okay. There is an argument about the frequency of injections. The preference for having only 13 injections a year rather than 26 injections is relevant to this patient population. A number of the patients that receive long-acting injections are on community treatment orders or involuntary treatment orders, so 13 injections rather than 26 injections is significant.

CHAIR: Thank you, Mr Goodwin. Mr Baveystock, would you like to make a statement on behalf of Mundipharma?

Mr Baveystock: Yes. I am the managing director of Mundipharma. Also appearing with me today and able to answer any questions is Dr John Whitlam, our medical affairs director. I thank the committee for the opportunity to appear before it today. The recent decision of the government to defer the PBS listing of several new medications recommended by the PBAC is unprecedented. The government's action, as we know, has triggered opposition from all stakeholders, including patient and consumer groups, peak medical bodies and the pharmaceutical industry. Indeed, some 52 written submissions have been made to this inquiry and all but one of them are strongly critical of the government's action.

The government has indicated that it has deferred the listing of some medications, including Targin, which is manufactured by Mundipharma, for essentially two reasons. The first reason is cost pressures in the budget, and the second reason is the availability of similar products or alternatives in the marketplace. The government appears to have attempted to justify its decision by listing in the submission by the Department of Health and Ageing what medicines it has actually listed. But how does a cabinet decision to list, for example, a new medicine for acne have any bearing on whether or not chronic-pain patients should be denied access to a new innovative pain treatment that would improve their quality of life immeasurably?

Chronic pain affects one in five of all Australians and up to 70 per cent of patients with advanced cancer. Approximately 15 per cent of those patients are treated with an opioid analgesic. Whilst these medicines are undoubtedly effective in relieving severe disabling pain, they are also potentially associated with serious side effects, including opioid-induced bowel dysfunction, often including severe opioid-induced constipation, and potential for addiction. What is apparently not understood by government is that this is not the type of constipation that otherwise healthy individuals might suffer from time to time. It is far worse; it is almost inevitable; it results in increased cost to the community and government; and, importantly, it cannot be treated with simple laxatives. Severe constipation can lead to impaction and hospitalisation and can aggravate cancer pain, resulting in a pattern of increasing opioid dosages in an attempt to relieve pain.

Disappointingly, whether through a lack of understanding or through poor advice, the government has deferred the listing of Targin for chronic severe disabling pain even though it will benefit between 50,000 and 100,000 Australian patients; the incremental cost to government is just $3.9 million in the first two years of listing, the critical period in which the government has committed to bring the budget back to surplus, and with the delay to the PBS listing already incurred this is now substantially less; and, finally, there is no strong opioid analgesic available in Australia which treats chronic disabling pain while simultaneously addressing the cause of opioid-induced constipation and helping to prevent it.

As Senator Di Natale would know as a drug and alcohol clinician, the issue of abuse and diversion of strong prescription opioids is a major concern for the community, the health profession, state and federal regulators, law enforcement agencies and, of course, Mundipharma. The potential abuse deterrence characteristics of Targin tablets were accepted by PBAC as an important consideration in the PBS listing recommendation. It is not clear to us why cabinet would delay the PBS listing of the first opioid analgesic that incorporates abuse deterrence technology to help address this major community issue.

In conclusion, it is our sincere hope that the submission and testimony the committee receives will persuade it to recommend that the government immediately reverse the deferral policy and list not only Mundipharma's Targin but all the deferred medicines for the benefit of Australian people. Thank you again for the opportunity to be here today.

CHAIR: Thank you, Mr Baveystock. Mr Latham, are you speaking on behalf of Pfizer?

Mr Latham: Yes, thank you. I guarantee our talk will be no longer than five minutes, because I really understand that the benefit comes from asking the questions and getting those responses. So I am going to briefly talk about some of the commercial things, probably for two or three minutes, and then throw briefly to Dr Ketelbey just to talk about those couple of products.

From the commercial side, the industry and the government signed a memorandum of understanding in September last year which demonstrated our joint commitment to sustainable health expenditure. The MOU was the result of the medicines industry and the government working hand in hand to solve PBS funding issues caused then by the GFC. By working collaboratively, we produced a sensible and well-thought-out agreement. Taxpayers maintained access to new medicines, the government banked nearly $2 billion in the forward estimates and the industry was assured that it would receive a predictable business environment in which it could make decisions about investment and employment.

A key commitment made by the government in the MOU for the guarantee of this $2 billion in savings was to place a time limit of six months for cabinet to approve or reject medicines which had received positive recommendations from the PBAC and which had risk-sharing agreements signed with the Commonwealth. The unilateral decision on 25 February to indefinitely defer listings of new medicines on the PBS is a clear breach of the MOU. Not only did the government renege on the cabinet listing time line commitment; it also appears that it has taken the $2 billion of price savings to general revenue rather than allocating that back to funding new medicines on the PBS. We believe it is an example of a short-term policy with significant unintended consequences to both patients and manufacturers. It provides very limited financial gain to the government but significant disadvantage for consumers, reflected in the number of submissions that have been received from consumer organisations. As I said, it does contravene the intent of the MOU itself. The unpredictable nature of listings will become a key consideration for Pfizer in making future investment decisions for the Australian market, particularly in view of the business changes we are facing.

My final statement is that the Pharmaceutical Benefits Scheme is envied around the world as the best system for providing medicines to citizens. This world-class status is not just based upon the fact that the system provides universal coverage to the newest medicines; it is more so because the decision making for which medicines are provided is based upon recommendations made by an independent group of clinicians and specialists, with cost-effectiveness as the key determinant for the selection criteria. The prices of new medicines in Australia are amongst the lowest in the OECD. Pfizer received no advance notice of these deferrals. We learned about it from the minister's release on the same day as everybody else, 25 February, and by that time we had already invested $1.3 million in the submission process for those drugs.

I will now throw it across to Dr Ketelbey to talk briefly on those two medicines.

Dr Ketelbey: I am going to make a few comments about the specific medicines impacted by Pfizer. The key issue with the delay in listing new medicines is that Australian patients are denied access to medicines that have already been shown through expert review by the TGA and PBAC to be safe, efficacious and cost effective. Importantly, as has already been mentioned in this hearing, interpatient variability in both response and the side effects to medicines is seen with all medicines, and therefore alternative treatment options are always required by doctors and patients. The therapies proposed in the department of health's submission as alternatives to Pfizer's deferred medicines are not appropriate for all patients.

I would like to make a few comments on the two products involved. The first one is Fragmin. It and the existing PBS medicine Clexane treat venous thromboembolism in cancer patients. You can look on that as DVTs, in more colloquial terms. However, the TGA approved product information specifically notes that these two medicines are not clinically interchangeable, which already contradicts the statement in the department of health's submission. The second product is Synarel. It is a hormone agonist used in the IVF/GIFT Program, and the proposed alternative, Ganirelix, is a hormone antagonist with a different mechanism of action. One is a nasal spray; the other one is an injectable product. They are clearly very different treatments and offer very different treatment options to patients and clinicians. In fact, the PBAC recognised the significance of Synarel by actively writing to Pfizer and inviting us to submit Synarel for the PPS.

As a final comment, the impact of these delays with Fragmin and Synarel, and with many other medications, is that some patients will not be able to access medicines they need.

Senator FIERRAVANTI-WELLS: Obviously I have read the quote from Minister Butler in the *Australian* today. Do any of you have anything further to add to comments that were made by your colleagues earlier in relation to Minister Butler's statements?

Mr Latham: The only thing is to reiterate what was said. The process for making submissions and listings, starting with the TGA and finishing with the PBAC, is an 18-month to two-year period. It is not as if I am going to bring in a product tomorrow and make a submission the next day. You cannot turn these things on and off. So the fact that he is saying that everything is going okay is fine. It is like the clinical trials. Clinical trials can stop. It takes time for clinical trials to turn around. The fact that we are here talking to you means, hopefully, we are not going to be pulling investments out of Australia or stopping clinical trials or research and development. We are here to work with you, to talk about more important things, like the sustainability of PBS.

Senator FIERRAVANTI-WELLS: There were many submissions to the last committee, and they were just things in the pipeline. So it is absolutely wrong of the minister to draw the conclusion that because of the numbers somehow it is business as usual. They were already in the pipeline and therefore it is a wrong assertion. Is that correct, Mr Latham?

Mr Latham: That is correct.

Senator FIERRAVANTI-WELLS: Mr Goodwin, in relation to Janssen's drug, on page 15 of your submission you talk about 100,000 people with schizophrenia. It is a drug that is going to cost less than $5 million over five years versus the potential cost of $52 million from admissions to hospitals. Is that the comparison?

Mr Goodwin: It is not $5 million over five years; it does not exceed $5 million in any of those five years. That is correct. If you look at the cost of a relapse it is around $28,000; whereas the cost of the medication is just over $4,000. So preventing one relapse saves a number of years worth of medication costs.

Senator FIERRAVANTI-WELLS: Absolutely, but it is certainly not cost-effective. The figure of $52 million is a hell of a lot more than this drug will cost the PBS. That is the bottom line.

Mr Goodwin: Correct.

Senator FIERRAVANTI-WELLS: Mr Baveystock, I understand that you are potentially talking about 675,000 to 825,000 people who could potentially be affected, just on the figures that are in your submission.

Mr Baveystock: The number of potential patients?

Senator FIERRAVANTI-WELLS: Yes, I am trying to get to the number of patients who will be affected, as far as you are concerned, by your product.

Mr Baveystock: In the first two years it is around 32,000 patients, but in year five it can be anywhere between 50,000 to 100,000 patients, based on the estimates that we were able to provide to the PBAC.

Senator FIERRAVANTI-WELLS: And you, Dr Ketelbey?

Dr Ketelbey: With the Pfizer products, in the case of Fragmin we are talking about 24,000 patients over five years. These are cancer patients with venous thromboembolism who we believe would be on treatment. For Synarel we are less sure of the numbers. We know that 50,000 IVF and GIFT interventions are done every year in Australia. Clearly not all of them are going to be on Synarel. We estimate around about 10,000 patients are potentially Synarel patients.

Senator FIERRAVANTI-WELLS: In decisions to bring products to market, bearing in mind the comments that were previously made by Mr Vieira, does the same apply to you? We are not just talking about what you currently have in the pipeline, but obviously what you might be thinking about in the future, such as research and development and those sorts of issues. Do any of you have a general comment in relation to that?

Mr Latham: When you look at the role of the pharmaceutical industry and what we do, our role is really to innovate and work in a system that discovers and brings new medicines to market. Those medicines are there to treat diseases. For critics to say that the industry are threatening to not bring new products to Australia because we do not like the system is rubbish. We are here and our job is to discover medicines and bring them to citizens around the world. The argument is really about the sustainability of the PBS and that is what we should really be talking about. How much should we be spending on the PBS? Senator Polley, your question earlier was: 'What should be the approval process? Should it just be the PBAC putting drugs on the PBS?' The answer to that is no; it should have a review. The process is in the act and it says that it has to be approved by the minister. The problem the industry have here is, 'What then should go to cabinet?' Should everything go to cabinet or should it just be those over a certain amount? Collins class submarines should go to cabinet and fighter planes should go to cabinet, but bullets and uniforms do not necessarily have to go to cabinet because there are mechanisms within those departments. In health is quite clear under the health act that all items have to be approved by the minister based on the PBAC. The history is that all but two submissions recommended by the PBAC were approved by the minister—that is how tight our system is.

Senator FIERRAVANTI-WELLS: Because you had been invited, if I can put it that way, in relation to your particular drug, have you taken legal advice or do you believe that there are legal consequences for your company in relation to that invitation by the government and its subsequent actions?

Mr Latham: No, we would not sue the government over this.

Senator FIERRAVANTI-WELLS: I am glad to hear that. But where would that put other companies which, may, like you, be once bitten twice shy, if, potentially, in relation to an invitation in the future, you or they were suddenly to find yourselves road-blocked by an arbitrary decision of government?

Mr Latham: You are absolutely correct. The reason we are here is to make sure that this policy is looked at and reversed so that you have a policy which provides certainty and predictability. That was what we had: it was certain, it was predictable, before. You had the PBAC. You had then a risk-sharing agreement. Once it gets through the PBAC with their approval, you have got to sit down with Treasury and Finance and actually nut out an agreement to make sure and to swear that you are not going to exceed the values that you put into your submission. So, by the time it gets to the minister and the cabinet, they know exactly how many dollars they are up for; if you go over those dollars then there is a risk associated with that for the company.

Senator FIERRAVANTI-WELLS: Mr Latham, you said that you are not going to sue the government, but have you taken legal advice in relation to that potential consequence?

Mr Latham: No. I have not gone to see my lawyers because I am not going to sue the government.

Dr Ketelbey: Ultimately, the disadvantaged parties in this whole process are the patients. They are waiting for the treatment and they cannot get access to the treatment. That is the end point.

Senator FIERRAVANTI-WELLS: My last question is: you mention, at page 4, the MOU. Do you see this, Mr Latham, as a breach of the MOU—or is that something I should be asking Medicines Australia?

Mr Latham: I personally believe it is a breach of the MOU but, then again, you are not going to sue the government for a breach of the MOU.

Senator POLLEY: Thank you for making yourselves available. My question is to Mr Goodwin. Could you go through with us and explain the findings of the PBAC in relation to your drug and its comparison to the alternative which is already on the PBS?

Mr Goodwin: Yes. Our clinical data was noninferiority versus Risperdal Consta, which is our own product. However, the PBAC recommended the product because it was felt to have a valuable place for people with schizophrenia in that it was to add value for people with schizophrenia. One of the issues here is that noninferiority does not mean that the whole patient population that benefits from one drug will necessarily benefit from the other one, and vice versa, and I think that is one of the reasons that the PBAC recommended it.

Senator POLLEY: To clarify: didn't the PBAC find that there was no evidence of clinical benefit from the new listing and, in fact, didn't they also say that any claim for clinical benefit was not justified? Was that not in the report?

Mr Goodwin: No, I do not think it is clinical benefit; I think it is around the clinical trials and how they are designed: are they non-inferiority trials or are they superiority trials? In this case we did not run superiority trials; that does not mean that there is no clinical benefit from the medication. So that interpretation is incorrect.

Prof. Kulkarni: Could I add: I am not related to Janssen or any other pharma industry; I am employed by the Alfred Hospital and Monash University. I run clinical trials. In fact, I have probably run clinical trials in schizophrenia with a number of different companies, but I have run a clinical trial in this. To put it shortly: if you have a patient who has severe schizophrenia—and that is the group that I work with—then to have something that is long-acting and effective is actually clinically superior to a two-week injection. It just makes a huge difference. It is not just about the cost of getting people back into clinics, which is a cost; it is also about the plateau, and reaching a level of medication impact in the brain that then has the capacity to give the patient the opportunity to have a sustained improvement. So to have a four-week drug that does not have the side-effects—I grew up in an era where we had two drugs in schizophrenia, and it was awful—means we have really come a long way. And we need to go further. These sorts of medications are really, really vital, and we were quite surprised that this medication, which has a lot of clinical superiority in using the drug, was not allowed in. So, as a clinician and as a clinical researcher, I would say there is huge benefit in having a four-weekly intramuscular injection as compared to a two-weekly one.

Mr Goodwin: Can I add one further thing to that? We should also be concerned about how these drugs get to people in rural and remote areas. It is just a fact that a two-week cycle, which is what our existing product is, is

not long enough to be able to treat these patients properly. What happens is they get put back onto older medications which have very debilitating side effects.

Prof. Kulkarni: There is another big factor here, which is the intramuscular delivery. In some of the other medications you have to give it in the buttock. For many of my female patients who have been traumatised, sexually abused and all the rest of it, that is very traumatic. This can be given in the arm, which is a much less privacy-interfering mode of delivery. Also, with regard to mixing this drug, we are in the era of community treatment. We manage most of our patients out of hospital, so you also have less capacity to monitor what is going on when people are not in hospital. This longer type of medication gives you a much better outcome in community based treatment, which is the preferred mode. We also have to mix drugs in the back of the hybrid Toyotas that we use in our community services. This is a convenient drug. We do not have the same problems that we have had with some of the other systems. Those are a few real-world examples of why we need a four-weekly injection.

CHAIR: And those benefits are not technically counted by the PBAC under cost-effectiveness analysis.

Mr Goodwin: No. There is a whole human aspect as well.

Senator POLLEY: Mr Goodman, could you run through with the methodology used by Deloitte's in their report, which I understand took into account direct and indirect cost to the community, not to hospitals and not to government? I do not think these have been very clearly explained. Can you run through the methodology used?

Mr Goodwin: I am not sure I am a full expert in how Deloitte went about it—

Senator POLLEY: If you would like to take it on notice, that would be good.

Mr Goodwin: We can certainly take it on notice.

Senator POLLEY: I then move on to Mr Latham. Can you point out which clause of the memorandum of understanding has been breached?

Mr Latham: Yes. It is the one where the government has committed to making clearer that they will not take more than six months to go through and make their decision.

CHAIR: The cabinet consideration stage can take no more than six months.

Mr Latham: That is right. That was one of the things that we had. We are giving up $2 billion in savings and bringing that forward. What we were trying to do was get the last flag to fall in the approval process. We had been working with the ministry of health on how long it takes the TGA to approve new drugs. That has gone from 500 days down to 300 days, and they have done a fantastic job doing that. We have been working with the PBAC approval process. They are now trialling ways of, rather than doing the PBAC process sequentially or after you get your TGA approval, doing that at the same time. All of these things speed up access to that Australians can get access to these new medications.

Once we did that, did the risk-sharing agreements and signed off on the dollars and prices, it went into cabinet, and it was in a black hole. Our frustration was that it was taking six months, nine months, 12 months. We said we need predictability. If you can do it in six months, that is fantastic. For us, that was a major thing that we took out. We gave up $2 billion. There are other things in there as well, but that predictability was one of the main things that we asked for. And we were pretty comfortable. Ninety-nine per cent of the time it is yes, and that is because of the strict system that we have in doing that. So that was the final pin to fall before Australians could get access to those medicines. That was the clause.

Senator POLLEY: In the process of cabinet having considered these drugs within the six months, hasn't it been very clear that they have considered it within that time frame but there was never any guarantee of agreement?

Mr Latham: You are absolutely right. They did not say no. If they had said no, then fine, but they did not. They did not say yes and they did not say no. It is the decision that you have when you are not having a decision. If they had said no, that is fine, but they did not; they said it is deferred. That is the uncertainty that we are dealing with. Patient groups now know that these treatments are coming on for schizophrenia, sweating—all of those sorts of treatments. They know these medications are coming down. They have read the literature. These things take 10 years to come through and then all of a sudden you are that close and then it falls down at the end and we are told we cannot afford it. We should be talking about whether we can or cannot afford it rather than putting this thing into limbo for the next 18 months because we are told this decision is going to apply until we come back into surplus. That is where we have a problem as an industry and as Australians.

Dr Whitlam: I want to add one thing from Mundipharma. Senator, you asked the question about whether there was anything that was different in any of the cases from the previous witnesses. In fact I think two of the

previous companies made the observation that it did not really matter and that they had stock levels of their products because they had different indications. The situation is a little bit different in the case of Mundipharma because we do have stock. Quite reasonably, we imported that stock on the assumption that we were going to get PBS listed. In fact we cannot move that stock, because we do not have the product listed on the PBS for another indication whereby we can transfer that significant amount of stock.

Senator POLLEY: I want to go to you, Mr Baveystock, in relation to your assertion that your product is better than existing alternatives. Is there in fact potential for a private and hospital market for your product? Is it not correct that potential abuse still exists, even though it is taken orally, and that only a small proportion of abuse will be through injection or snorting?

Mr Baveystock: In answer to your first question, yes. There is undoubtedly a small private or hospital market. But chronic pain is essentially treated by general practitioners, who really need PBS listings to be able to make the product affordable for patients. So we would estimate only a very small proportion of the application of this product would be in the private or hospital market. In terms of the deterrent potential, yes, you are correct. The addition of Naloxone really comes into play when the product is crushed and then used intranasally or injected. Whether or not that is a small proportion of the total abuse is difficult to know. Certainly in our discussions with the department the PBAC took this strongly into consideration. They estimated that 3.8 per cent of patients are abusing strong opioids and so on. Whilst it may be small, it is certainly a positive step in the right direction to address this key community issue.

Senator DI NATALE: I am not going to ask any of you about your specific products, because you all went through the process. It has been a thorough and rigorous process, and each of your respective medications has been found to be effective and to provide a benefit to the community. So I think that is a given, from my point of view. As you say, I am somebody who has worked in this field. I think there is real potential for the reduction of opioid abuse, and it would be a significant advance. But you have been through the process.

I obviously have some very serious concerns about the decision that was made. It was made because the costs of the PBS are increasing. I am going to ask the same question to each of you. You do not have to answer. Obviously some of you will say that you have already done as much as you can. Can you see any obvious areas for savings? That is my first question to each of you in terms of decreasing costs associated with the PBS.

Mr Latham: It seems that the main one is the fact that over the next five years we have $2.4 billion worth of products currently on the PBS which are coming off patent. You heard the GMIA talking about that. That is going to be a major savings for the government. Once these drugs come off patent you have competition, you have prices coming down—you have a mechanism for that. Unfortunately, the government is not allowed to put into forward estimates the savings, unless they have a price agreement, which is the reason that they got a guarantee for us. When PBS reform came in originally, when we split generics away from these innovative new products, we thought there was going to be a $3 billion saving. The latest estimate is that there is going to be $6 to $8 billion worth of savings to the government. Those savings are coming through. The government is not allowed for accounting reasons to look at those, but they are there, they are tangible and they will start as early as 2012. We are already seeing now in price disclosure price reductions of 31 per cent and 71 per cent in some of the Pfizer drugs that we have in hospitals. So the system is in place and is working.

Senator DI NATALE: Good. Does anyone have anything to add?

Mr Baveystock: I think it has all been said by the other witnesses.

Senator DI NATALE: I would like to tease out the issue of what sort of impact this has had on some of your commercial decisions. As I said, we have known of the decision for five months, and obviously you plan ahead. Can you point to any specific examples where this has made a material difference to a commercial decision that you may have made here in Australia?

Mr Baveystock: We have certainly delayed the employment of a significant increase in our company size because of this. That has gone on hold. We were looking to make quite a significant increase in company personnel on the basis of the approval of the PBS listing of Targin.

Senator DI NATALE: Related specifically to this medication being listed?

Mr Baveystock: Correct.

Senator DI NATALE: Any others?

Mr Goodwin: Similarly to what some others have said, it is re-evaluating the timing of when we bring some of these new medicines through.

Senator DI NATALE: Have you re-evaluated the timing? Have you made decisions about that?

Mr Goodwin: Sure we have. There is a higher risk associated with some of our new products coming through that was not there before. If the delay occurs it significantly impacts on the commercial viability. We have at least one product in that situation.

CHAIR: Would you provide to the secretariat on notice what, if any, consultation you had with the government before the announcement was made and what you have had since so that we can get an idea when we look at how this was brought about and where it is heading.

Senator FIERRAVANTI-WELLS: Can that apply to the companies who gave evidence previously?

CHAIR: Sure. I have a question of Mr Baveystock. Some language that you used in your submission leapt out of me—and I was not at the estimates hearings. You say that the testimony of the department of health was misleading. If you would briefly expand upon that, we will give them a chance to respond when we hear from them on Monday morning.

Dr Whitlam: On 31 May, there was a Senate estimates hearing, as you are well aware. In response to one question, the deputy secretary of the department described Targin as containing oxycodone and another component, naloxone, which acts as a laxative. This product is clearly not a laxative; it is a product which is a new discovery in the way that it approaches opioid induced constipation. I think everybody around the table needs to understand that bowel dysfunction and constipation associated with—

CHAIR: We are very pressed for time. The misrepresentation was about the nature of the product and the components of it?

Dr Whitlam: Correct. There were three misrepresentations.

CHAIR: Please keep to those.

Dr Whitlam: The second one was that, in answer to a question, the deputy secretary said that there will be no savings from the reduction of opioid induced constipation. In fact, we agreed with the department itself that there will be a saving of $6.5 million over five years. The third misrepresentation, I believe, was that in answer to a question—would there be any cost savings to the government through the reduction in abuse and diversion of OxyContin—the deputy secretary responded that he was not aware that the government would have those figures. In fact, we agreed with his department that there would be a cost saving of $8.4 million over five years. Therefore, inherently, Targin is not just oxycodone containing a laxative if we are getting cost savings of that nature.

Mr Baveystock: There are cost savings. It is illogical to suggest that there is an alternative.

Senator FIERRAVANTI-WELLS: I have a question for all the companies to take on notice, please. In relation to costs associated with reconsideration, it has been deferred, we do not know till when. There obviously will be potential costs. Are there costs in relation to any reconsideration or will there be costs in relation to withdrawal of your product for consideration?

CHAIR: Is this question to be taken on notice?

Senator FIERRAVANTI-WELLS: This is only on notice.

CHAIR: Do you have a question to be taken on notice.

Senator POLLEY: Yes. Could you take on notice to give us the quantities of stock that will expire in December 2012 and 2013 and whether there is going to be a wholesale destruction of those medicines? If you could provide that to us on notice, that would be most useful.

Prof. Kulkarni: I would like to make a comment.

CHAIR: Is it something that you can provide on notice?

Prof. Kulkarni: It is in relation to Senator Di Natale's question about how you actually make cost savings. One of the things that strikes me is that we have such a fragmented system. We have a drug budget and then we have a mental health budget and another things. So I do not know how we do that.

CHAIR: That is an issue that regularly comes up in these hearings. We welcome any further commentary on that.

Proceedings suspended from 12:46 to 13:39

ELLSUM, Ms Chey-Anne, Private capacity

TRAPANI, Ms Elizabeth, Private capacity

CHAIR: I welcome Ms Chey-Anne Ellsum and Ms Elizabeth Trapani. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee has your submission, and I invite you to make a short opening statement, at the conclusion of which I will invite members to put questions to you. Do you have anything to say about the capacity in which you appear today?

Ms Trapani: I am here as a mother and for personal reasons.

Ms Ellsum: I am here for personal reasons.

CHAIR: Sure. Do you have an opening statement you would like to make.

Ms Trapani: Yes.

CHAIR: Please go ahead.

Ms Trapani: Thank you. We only found out about Botox a few short months ago, but that does not mean living with hyperhidrosis has not affected us since Chey-Anne, who is now 17, was three. She would have chronically sweaty hands and feet and would fall over on tiles. When puberty happened, the heat started, and she could shower three, four or five times a day and it did not matter; by the time she was towelling off, she smelt as if she had been training with the entire AFL footy team collective for about six hours. As you can imagine, heading into the puberty years the hyperhidrosis had a massive effect on her and her self-esteem, and it created depression problems. From an early age—three—she could not handle paper without making it soggy and she could not walk on high-gloss tiles because her feet would go out from under her.

Hyperhidrosis has no known cause or cure; it is a trigger in the brain that says you must sweat now. There are surgical options available, but surgery, as we have been informed by the Skin and Cancer Foundation and the professors there, is the absolute last resort for the worst of the worst. Side effects include a permanently collapsed lung and can include permanent palsy at the side of the face, increased sweating in the areas affected or worse sweating in other areas, in places like the groin, the face and the backs of the knees. An alternative surgery is to completely cut out the skin of the armpit and free-graft new skin on. As you can understand, there are complications with free grafts; they do not always take. When we found out the dangers of this surgery, it was not an option I wanted to pursue for my daughter.

Although I had never heard of Botox for medicinal purposes and I was quite floored—I thought it was for the rich and vain—when we found out that that was an option for her armpits only, we took it. The initial 30 millilitres per armpit—which comprised about 20 or 25 injections in each armpit, which she took with a big smile on her face because finally it was a solution—cost just under $1,900. When we went back four weeks later, she required a top-up of up to 50 millilitres in each armpit, which was about another 10 injections in each armpit. But we had a result. She still smells on occasion—we cannot get away from that—but on the whole she smells like a girl now, not a football team.

Now I am going to let the bravest young woman I have ever known talk to you a bit about it, because I cannot stress enough the guts it has taken for her to come forward and make this known. Two per cent of the Australian population have this condition that we know of, and the treatment just for the armpits is prohibitively expensive. Do you want to talk about what it has been like to live with it and how it is now?

Ms Ellsum: I guess, yes. I have had it since I was three, but it got really bad in puberty. That was when I was in high school, so I was like the magnet for bullying; everyone went at me, because they did not understand, and no-one understands. It caused my depression. There were days when I did not want to get out of bed because it is so controlling. I blamed myself lots of the times when I had it; I thought it was just me who had it. It draws people back; it stops people from doing things. It deprived me of most of my youth; I did not do the things I wanted to do because it was so controlling and conflicting with my life. I could not do my deb this year because I was afraid of what people would think, and that really made me sad.

With the Botox, it has been amazing. It is the biggest improvement that I have ever heard about, and it has worked. I am planning to do my deb next year, and now I am doing all the things that I have always wanted to do. I am here now. This is not something I would have done back then. I am here because there are people out there who cannot get this. I would be stuck if it were not for my grandparents, because they are the only people who are getting me through this. I would not have this if it were not for them.

Ms Trapani: The price of it is far and away outside my means to cope with. I have been a single parent now for nearly eight years. I have done the best I can by my kids but oftentimes that does not leave a lot left over. I must say that Chey-Anne would not touch people. We need physical touch. It speaks to something deep within our souls. We caress, we hold hands, we touch people's faces and we need hugs, but Chey-Anne would go out of her way to avoid that because people would smell her or feel her sweaty hands. She starved herself of physical touch. Now, I can't get the rotten kid off me! I am not complaining—really. She holds her boyfriend's hand now and she high-fives her friends, which made me nearly drop out of my tree! The other week, in a shopping centre, she actually took off her jacket to try on another top. I nearly fell on the floor, because before she would never stop layering. There are just simple things like that.

CHAIR: I think I can speak on behalf of the committee, Ms Ellsum, and commend you on your bravery, quite frankly, in speaking publicly. I know you have done so in the media before this committee. It is a particularly valuable insight. Too often inquiries done by Senate committees lack a personal touch. We talk about big numbers, big companies and enormous numbers of people, but it is good to have a very personal perspective. I have a couple of quick questions. How often do you expect to have to undergo the treatment and that expense, or is it unknown?

Ms Trapani: No, it is fairly clear-cut. Chey-Anne's hyperhydrosis is in the extreme area. The hyperhydrosis treatment is known to work for approximately 12 months. In extreme cases it is six. In lucky cases you get 18 months.

CHAIR: So you would expect a slightly more than annual treatment for Chey-Anne.

Ms Trapani: I believe, knowing Chey-Anne's condition and how much it has helped, that we can expect to be doing this more than once a year.

CHAIR: Have you had any contact with the minister's office about this issue? I understand you have written—

Ms Trapani: We have written to our local member, Darren Chester. We have gone through him.

CHAIR: And Darren did actually suggest to you that you appear here.

Ms Trapani: Absolutely.

CHAIR: I know Darren quite well. This would obviously mean that it would be essentially affordable for you, because you would be using a PBS amount of money.

Ms Ellsum: Not just us but everyone who suffers from it. This is such a big thing. It would be amazing if people could use this instead of going for the operation, because that has such a high risk rate.

CHAIR: It does not sound particularly pleasant—not that the injections do, to be honest, but the operation sounds a lot worse.

Ms Trapani: Believe me, we have been pursuing this since Chey-Anne was seven and we first saw hyperhydrosis on television with a child with dripping hands. We were told we could not do anything until she stopped growing, so we thought that was it and we just put it aside. As to treatment, as I said, the worst of the worst get surgery. We are hoping never to have to deal with that surgery. I do not want to see my child permanently scarred; she has already been scarred enough, and I do not want to add to that. We know that Nicola Roxon did say on Alan Jones's program that it is not life threatening, and that is very accurate. But it is life altering in the extreme and it is life damaging.

CHAIR: You mentioned earlier, Ms Ellsum, that you experienced depression which was linked to this. Do you think that statements like that misunderstand the link between suffering from this condition, particularly in the extreme, and what technical people might call co-morbidity, which in reality means that you end up suffering from other conditions which not only damage your life but, in an economic sense, actually cause other costs to the health system?

Ms Trapani: Absolutely.

Ms Ellsum: Definitely. There is so much money going towards depression and stuff. If someone like me went and got diagnosed with depression that would only be stopping one problem that is going to come back constantly throughout their life.

Ms Trapani: You are dealing with the root cause if you deal with the hyperhydrosis.

CHAIR: You are preventing the depression by treating this condition.

Ms Ellsum: Yes.

Ms Trapani: Yes. I remember being broken-hearted. You can see that Chey-Anne is a stunning kid. Never has she been conceited about that, thank goodness, but it was heartbreaking to not have a solution and to watch her view at 13 or 14, when she should have been going out to the movies with her friends, the world outside as the enemy, to pull back from hugs from family and friends and to avoid people because of the way she smelt. That is not a life, not for a child in their early teens.

Senator POLLEY: Thank you very much for your submission. I concur with the chair's comments about your coming forward and giving evidence. Is this a lifelong illness? Will the Botox gradually reduce the effects?

Ms Ellsum: If I stop using it, it will come back. It is not a cure.

Ms Trapani: It can peter out in some cases; in other cases it is there forever.

Senator POLLEY: I guess those who have it have to weigh up the option of an operation or being faced with having to have Botox injections for the next 60 years of their life. Is that what you are saying?

Ms Trapani: Absolutely. The reason we did not swing straight to the operation is that the chances of it not succeeding are equal to the chances of it succeeding. For me, that is—

CHAIR: The operation is a 50-50 proposition?

Ms Ellsum: About that, yes—close enough. That is not a risk that a lot of people are willing to take and I am really not prepared to go under the knife for that.

Senator POLLEY: Personally, with so many injections I would have to weigh it up very carefully.

Ms Ellsum: They are really not that bad. When I first had them, it scared me and it hurt, but I realised that this is what is going to save my life, and it has.

Senator POLLEY: You obviously do not have private medical cover.

Ms Trapani: I just recently got it.

Senator POLLEY: Is there any capacity under that to cover the cost?

Ms Trapani: No. At the moment we are working with lotions on her hands and feet, which is another aspect. Twenty mils of the first one was $70, and it gave her hives. We are on a second one which has to build up in the system, and that is 20 mils for $170. You have to apply that every day because there is just no alternative. I would not put my daughter in the situation of having an operation unless they could give me a better than 95 per cent guarantee that it would work. The operation involves snipping nerves, and that has to be repeated because the nerves do make their way back, so it is not just a one-off thing.

Senator POLLEY: Thank you.

Senator FIERRAVANTI-WELLS: I commend you on coming forward. I hope the minister is listening today. Is it detected at a very young age?

Ms Trapani: On the hands and feet, definitely.

Senator FIERRAVANTI-WELLS: So there are potentially thousands of children around Australia who have this condition and thousands of mothers who are in the same position as you.

Ms Trapani: If they are wondering why their child's socks not only walk to the laundry on their own but do five laps of the house on the way there, the child probably has hyperhidrosis of the feet.

Senator FIERRAVANTI-WELLS: As a consequence of you coming forward, have you had people approach you? Have other young people in similar circumstances approached you?

Ms Ellsum: It has actually been quite eye opening because I used to think I was the only one who had it. I used to go to school and no-one around me had it, so I was like, 'This is not normal.' Then we put the article in the newspaper and we got so many responses from people just saying, 'I think that I suffer from this,' or, 'My daughter suffers from this.' People have contacted me personally and just asked for support. That is basically what I want to do for people who do not understand it.

Ms Trapani: Fortunately, the Skin and Cancer Foundation have set up an email address, and we are getting that email address out there. Just through the article in the *Herald Sun*, I have been able to put a number of parents on to how to get treatment. It took us ages. Our GP did not know where to send us; they ended up sending her to the endocrinology clinic at Monash. It was just happenstance that we got a consultation with a dermatologist who knew about the tertiary care at the Skin and Cancer Foundation. They actually have a hyperhidrosis clinic and a website set up. Their statistical information shows that at least two per cent of the population have this condition, and a lot of people just do not get it seen to. Even just making people aware is hard. Chey-Anne was told she was dirty. People would not go near her because they thought she was filthy. This child would wash and scrub, and we

used every lotion, potion, spray and roll-on we could get our paws on. We had no luck. We tried natural remedies, all with great hope, but the greatest thing that happened was on the day we went to that consultation. We thought it was just an initial consultation and we would make another appointment for the treatment. When that gurney rolled in with the injections she just burst into tears, 'At last, a solution!' Then when she had the injection she was holding my hand until my fingers almost fell off saying, 'This is all exciting!' It has brought my daughter right out of her shell.

Senator FIERRAVANTI-WELLS: I can only imagine how difficult it would have been for a young person at school, but she is obviously a very strong character but not everybody is as strong as your daughter.

Ms Trapani: Chey-Anne has had to move schools as a result of this. We had to take her out of a private school and put her into a public school which had a lot more support available for her. The bullying there was quite extreme, and we even looked at homeschooling just to avoid it, but Chey-Anne quickly worked out that I was not a very good teacher. We decided to attempt another school. But for about eight weeks she was never going to mix with kids again.

It has been hard to watch it and have no idea what to do about it. You want to do the best by your child and I spent so much time and effort on both my girls because I intended to raise women with self respect and dignity. I think I have done a pretty good job. We have such good support with mum and dad—we have great family support—and it is the only thing that has pulled her through. I dread to think what would happen to a child who did not have that.

CHAIR: The point is that there are probably others, which was the point you made earlier, but we do not know about them. Is there anything else you would like to add?

Ms Trapani: I think we have covered it all.

CHAIR: Thank you again, particularly you, Ms Ellsum, for coming forward. I know you travelled to Melbourne today for this, so we appreciate that. I think we can all agree that it has added a particularly unique view to the issues we are considering. We will make sure that you get a copy of our report when it comes out.

Ms Trapani: We would appreciate it.

CHAIR: We cannot change the decision as the Senate; it is a ministerial/cabinet decision. We can only use a loudhailer.

Ms Trapani: Okay, if you want to borrow her any time—

Ms Ellsum: My school is totally supporting it.

CHAIR: Where are you from in Victoria?

Ms Ellsum: Bairnsdale.

Ms Trapani: We are lucky because she told her teacher that she was coming down to do this today and he said, 'Why didn't you tell me?' He wanted to put a busload together, so you would have been inundated.

Ms Ellsum: My legal studies teacher wanted to bring my whole class. I told them yesterday and they all said, 'We want to come; we are all supporting you.' It has been amazing how many people want to help when they find out about it.

CHAIR: Sure. Thank you again.

PASK, Mr Robert George, National Advocates Program, Multiple Sclerosis Australia

WALKER, Dr Christine, Executive Officer, Chronic Illness Alliance

[13:59]

CHAIR: I welcome Mr Pask and Dr Walker from MS Australia and the Chronic Illness Alliance. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee has your submissions, and I invite you to make a short opening statement, at the conclusion of which I will invite members of the committee to put questions to you.

Mr Pask: Good afternoon. Thank you for the opportunity to present to you. I hope you do not mind if I read the statement I have prepared. MS Australia is a member of the Chronic Illness Alliance and the Consumers Health Forum. I will be co-presenting with Dr Walker today, and I will just summarise the points. MS Australia represents over 20,000 people living with multiple sclerosis, a progressive neurological condition with no known cause or cure. It is an unpredictable disease and strikes in early to mid adult life, compromising people's ability to remain in work and be productive in the community.

Much is being done in the areas of research, employment support and community care for people with MS. However, as a group we have a substantial reliance on pharmaceuticals for the ongoing management of the disease. Access Economics in 2005 estimated pharmaceuticals to be 62 per cent of all MS health costs and 15 per cent of the total costs of the disease. People with MS are fortunate to have six immunotherapy treatments now on the PBS, with the most recent, the first oral medication, being listed only a month ago. These medications have a strong evidence base showing cost-effectiveness in slowing progression and enhancing wellbeing and productivity for people with MS. However, they do not eliminate symptoms. Indeed, people with MS in Australia fare better than people in other countries precisely because we have the PBS. In addition to the main MS medications, people with MS use a wide range of medications to manage the wide range of symptoms. Our submission lists those that are most used, including a number that are not included for MS on the PBS.

Dr Walker will give evidence as to the cost of living with chronic illness, and MS is one of the most expensive conditions the Chronic Illness Alliance studied. One of the highest costs for many people is for medications. There are a significant number of people with MS who live with more than their main chronic illness, so for this group the problems of cost and reliance on the PBS are compounded. People with MS are used to living with chronic illness, are well aware of their reliance on the PBS and feel somewhat exposed when things change. As we said in our submission, people with chronic illness are more vulnerable than other Australians to shifts in public policy. While some decisions are good, such as the pension increase or early access to employment services, others are not good. This PBS deferral is one of the latter. It has made people worry about their future more than usual.

MS Australia supports the call from a number of bodies for a return to the pre-February 2011 policy of the Minister for Health and Ageing being able to approve the listings of PBAC recommended pharmaceuticals with a cost impact of less than $10 million. The system worked well, and we have seen this policy work well regardless of who is in government. We have never thought of the PBS being politicised and, in fact, have high regard for the PBAC and the general operation of the scheme.

In the case of numerous medications that were deferred as a result of the government's February decision, there seem to be compelling reasons from the PBAC for listing. While the oral MS medication I mentioned earlier was in the batch of PBAC recommendations that went to cabinet after February, it had a cost impact over $10 million, so it was always going to be referred to cabinet. MS Australia welcomed the announcement by the health minister in June that this medicine, Gilenya, was approved for listing, particularly given that it had been recommended after its first submission, meaning that the time between recommendation and listing was not too long. As this was not an injectable medication, there is a keen interest among neurologists in having it as an alternative option. Our objection to the change in policy was thus not related to our own medication being part of the group of recommendations that was not going to cabinet. Having high regard for the rigour of the PBAC, we cannot see what more evaluation cabinet could apply that would alter the PBAC's view about anything recommended. Having already been through the tight filter for costs and clinical effectiveness, it appears that budget implications are paramount. We do accept the government must take responsibility for all its decisions on expenditure, but in regard to the PBAC there is unlikely to be more stringent tests applied to any potential expenditure in all portfolios. We believe the old process was effective and was largely not open to the risks that have been identified

in the new cabinet process. These have been clearly spelt out by the Consumer Health Forum: delays due to the crowded cabinet agenda, some potential budget impacts, a lack of transparency, risks of promoting divisive lobbying around these cabinet decisions and unintended cost-shifting to other health programs due to alternatives to new drugs being inferior or unavailable.

We see the arguments against the new process fairly clear cut. The feedback we have from people with MS and their families is that they do not want unnecessary barriers put in the way of assessing new and improved treatments. It is primarily a policy related position we have with the deferral. The best position that we can see with the new approach is that cabinet would approve every recommendation. This will get us to the same point as the old system but would build in needless delays, angst and risk. Simply put: the old system is superior.

Dr Walker: I am the Executive Officer of the Chronic Illness Alliance and Robert is a member of the alliance's management committee. The way we work together with our members is to have this kind of information fed into the policies and research that we carry out. In our submission to the Senate committee we wanted to point out that our interest is largely to do with the principles of deferring the listing of medicines, the role of cabinet in this process and the consequences that such deferrals has for patients.

I will start with the consequences. We have always argued that medicines and medicines policies and consequently deferrals should be seen in the broader context of people's health and welfare. It is often missed because both health and social issues are completely siloed from one another in government policies and services at both the state and federal levels.

The Chronic Illness Alliance is aware that many people with chronic illnesses are actually poor. Our research, which we quoted in the written submission, showed that there are many families with chronic illness that are living below the poverty line. We found in our survey that 41 per cent of households had incomes of less than $21,000 a year after their health costs were extracted and that this was 3½ times that of Australians who are living in poverty based on the 2000 statistics. We also found that medicines were about 30 per cent of those total healthcare costs.

It should be looked at in the context that many of these medicines now assist people to have better quality of life. I think the people who presented before were probably a very good example of that. We know, for example, young people with cystic fibrosis, older people with arthritis and people with epilepsy that is controlled by medication are all able to work because medicines have actually produced better health outcomes. When a medicine that is likely to improve health outcomes is deferred that actually produces two possible outcomes for people: either people pay the full price and then end up becoming even poorer, or people go without and that affects their potential to be able to work or to work full time. So when only the costs to the health system itself are taken into account in deferring a drug, the costs to the consumer and to the overall Australian health economy, such as through contributing to the tax income, are ignored. We argue that where a medicine is beneficial it should be considered in terms of those greater benefits, instead of just in terms of the health budget itself.

Possibly the greatest problem that the alliance sees—and this is something that Robert has touched on—is that members of the cabinet would not actually have the time or the expertise to make the judgments beyond government budget line. As elected people, they would be subject to all the wiles of the pharmaceutical companies in their lobbying, as well as lobbying by consumer groups.

In our written submission we looked at seeding, which is a means to produce researched outcomes. There is a recent article on Neurontin, which is gabapentin used in epilepsy, and the way that this was marketed as a piece of research but in fact was a marketing exercise. We also believe that Vioxx was subject to a seeding trial in 1999 and that none of the health professionals who were actually involved in that trial knew that they were in fact involved in a marketing exercise. That is based on US data.

There is also data mining. There is nothing wrong with data mining in itself, but it can be done according to the goals that are set, so a pharmaceutical company can look for the advantages to get PBS listing rather than the value to consumers and health outcomes. I believe Avandia, a type 2 diabetes medicine, was subject to data mining in the US and it showed that its use was not more likely to lead to cardiovascular events. However, the editors of the *Lancet* advised the FDA in the US that the treatment should be effective rather than just innocuous and that regulatory agents needed to look at the full safety consequences, because data can also be interpreted differently.

We also have the phenomenon of health consumers lobbying to get medicines on the PBS. This is sometimes both created and manipulated by the industry itself, but it is also based on emotions of the consumers rather than on the evidence that they may not be able to understand fully. It would be much harder for elected officials to withstand that kind of emotiveness than for an independent body.

We would also argue that there is an issue of transparency. Cabinet is not transparent, and we probably would not want it to be. I am not sure about that. However, the PBAC needs greater transparency and should be acting on that. We note the very recent report on the TGA which is recommending greater transparency so that the Australian public can have confidence in its decisions. I would say that that probably applies to the PBAC as well. I will stop at that point, thank you.

CHAIR: Senator Polley has to leave soon so I will give her the courtesy of asking questions first.

Senator POLLEY: Thank you very much, Chair. On your last comments about the need for the PBAC to be more transparent, can you elaborate a bit more on that for the committee?

Dr Walker: I think that people need to know more about the decisions and what those decisions are based on. They need to be able to make submissions. I know a lot of stuff that goes in is called commercial-in-confidence, and this is a constant frustration for groups like the Consumer Health Forum of Australia. It would be useful to know how some of that commercial-in-confidence stuff is arrived at, whether it is through data mining or seeding or things like that. It would also be an educational process for consumers to be able to understand the evidence on which a drug could potentially be listed, why that drug is considered to be beneficial, so that they could make decisions on that kind of thing as well.

Senator POLLEY: I neglected to thank you for your submissions. For some time now, decisions have gone to cabinet if the value has been over $10 million. I was wondering if you could elaborate on why you think there is greater potential for lobbying for the introduction of a certain drug's inclusion on the PBS than what has been the case in the last decade or so. I am pretty much aware of other interest groups lobbying for things to be put on the PBS, but I was wondering if you could elaborate why you think, now cabinet makes that decision, it is going to be any different to how things have operated previously.

Dr Walker: I am suggesting that pharmaceutical companies are far more likely to try lobbying elected representatives, going straight to members of parliament, senators and so on, to try to influence them and those people who are at a party political level. This is not just cabinet; this could be a whole new approach.

Senator POLLEY: I think that would happen across the board now anyway, or it does in my experience as a senator. Whether it has any effect or not is another issue. I was also wondering if you could outline to me your membership.

Dr Walker: We are an organisation that is interested in improving the focus on people with chronic illnesses in health policy and health services. We have 55 member organisations, nearly the whole alphabet.

Senator DI NATALE: Thanks again for your very detailed submission. We all understand that the decision was made with an eye on the budget. We also understand that the PBS is an expensive system but a very important one, and I certainly share your concerns about some of the decisions that have been made. You mentioned specifically the issue of reducing the price that we pay for generics. At the moment the 16 per cent reduction is mandated and your suggestion is that we could be getting generics much more cheaply than that. There are a couple of countries you quote in your example. Could you just elaborate a little bit on that?

Dr Walker: Yes. I know that New Zealand does a tender system for generics. I do not know a lot about it but I believe that it means that generics end up being somewhat cheaper in New Zealand. There is an article from the *Australian Prescriber* on that issue.

Senator DI NATALE: You could perhaps leave that with our secretariat. That would be helpful.

Dr Walker: Yes, I can. It actually has a table, which shows the difference between spendings on medicines in Australia, New Zealand, Canada and the United States. It is quite an interesting little article.

Senator DI NATALE: Has the alliance identified any other areas that you can see that might be potential areas for making savings in terms of the way the PBS is managed?

Dr Walker: Rather than health economists actually concentrating on the costs of medicines I would like to see them concentrate on the health system and the value of medicines to the whole of the Australian economy. This article says that about 45 per cent of all Australians have a chronic illness. Medicines must be working because, if 45 per cent of all Australians were totally dependent on both the health system and the welfare system, there would not be many people working. Maybe a lot of people do have chronic illnesses, but they are also still working. I think that treatments in general are contributing to them being able to work. We have never really researched that.

Mr Pask: Can I comment on that?

Senator DI NATALE: Sure.

Mr Pask: I live with MS. Dr Walker brought up the issue of multiple conditions as well. I have multiple sclerosis and I have type 2 diabetes—even though I do not admit to it—arthritis and a few other things, so I am dependent on so many medications. In theory, I am able to work three days a week. But I do work a lot longer than that. I do a lot of wheeling around in Parliament House, annoying senators and members in the House of Reps, but they love me. But I am only able to do that because the medications are there.

As Christine said before, I do not believe we look enough at the value of medications, as far as keeping people in work and getting people back into work. Obviously, the cost benefit is what we get out of it. Because of my medications, I have been given an opportunity to keep going and keep working and doing stuff that I really love doing. But if I were not working I would not be able to afford a lot of that stuff, such as Gabapentin, which Christine mentioned before. It is on the PBS for epilepsy. As far as pain reduction is concerned, it is one of the best neurological medications for people with MS or late-term cancer. I buy it because I can still afford it. It is subsidised by our private health scheme. It is not much. But, all of a sudden, that has been cut, because Gabapentin is on the PBS. It is on the PBS for MS, epilepsy and cancer. As an outpatient, people can get it. But those things keep me going.

The lady who appeared before me had needles. I have had close to 5,000 injections. I have had daily injections to keep me going with MS. With respect to the oral medication, we agree with the process it has to go through. It has to happen. I would hate to see it just be 'okayed' to go through. That option is there for a young person with MS and it is sitting in a silo—I hate that term—and they cannot get it. They are scared of injections and I can understand that. It gives me the opportunity to keep living and have a productive life and hopefully it will stop the progression of the illness. It is not just for MS; it is for any chronic illness. It stops that progression.

CHAIR: Do you think much greater ease of compliance actually leads to a better health outcome because of the means of taking it?

Mr Pask: We have the utmost respect for the PBAC. We have been fortunate enough to meet with Professor Sansom and, from what we have seen of the process, we would like to see it stay.

Senator POLLEY: Nothing has changed. The recommendations have to be made to government.

CHAIR: In my view, there is some obfuscation around the difference between what previously existed, which was a threshold for $10 million over the forward estimates for cabinet consideration. Anything higher than that required cabinet consideration, and there was always toing and froing about delays, pricing negotiations and price value of agreements, risk management and the like. But there was a path there and you knew that it had to jump that final hurdle. It is fair to say, is it not, that what we are seeing now is a major and significant change, which is effectively a refusal to consider? So there is no monetary threshold; it is simply saying, 'We're not going to consider the listing of these new medicines until someone in the health department finds the money to pay for them', which is an even narrower silo approach than the one you are outlining, Mr Pask. It fails to take into account other savings in the health system, let alone the broader economy. Is that a fair characterisation? Do you see a profound difference between the threshold and the refusal to consider?

Mr Pask: I would rather not comment on it, because that is really putting us into a position of making comments that—

CHAIR: The point is that the government is saying that it is the same as before—that it had to go to cabinet anyway. It had to go to cabinet before or not be considered if it was over $10 million. But now when they go to cabinet they say, 'We're not going to consider it.' You do not think that is a big difference and will delay the operation of the PBS? We did not have these problems before. We did not have 30 patient groups making submissions to the Senate inquiry saying, 'We've got all these PBAC approved drugs and the cabinet will not even consider them'—let alone say it takes a little bit too long and all those problems. You do not think there is a big difference there?

Mr Pask: There is a difference but the cabinet did let those medications through. So it was not actually held up.

Dr Walker: My concern with all of that process, as it was reported in the newspapers—I only saw it through it through the media—is that it was subject to a level of populism, in that the cabinet stopped them and then they went through when there was a public outcry. I do not see that as being a very good way to do medicines policy.

CHAIR: That is a fair point.

Senator FIERRAVANTI-WELLS: I am sorry if this has been covered. In your submission at the bottom of page 5 and then going over to page 6 you say:

Where people with MS are concerned the most important aspect of this deferral relates to budgetary considerations seeming to outweigh the established operations of the PBS evaluation system. People with MS already have very high health costs in addition to the currently subsidised treatments, and are very sensitive to the issues of cost and access.

Noting the schedules and the two tables, could you tell me the average costs? I do not know if you covered that before. What would be the average cost, Mr Pask, for someone in your position?

Mr Pask: I was spending over $250 to $300 on medications. I have reached the safety gap, so I can only go by my pharmacy bill. If I had one of the medications that has been approved for narcolepsy it would be another $300 a month. That is an anti-fatigue medication. I am not in a position to afford it and I am lucky enough that I can get through most days without falling asleep. When you add that on you can be looking at $600 a month.

CHAIR: Unless you have anything to add, that is all the committee has for you. As always, if there is something that you feel you would like to add to the discussion, feel free to contact the secretariat and they will make sure we receive it. Thank you for your time.

Proceedings suspended from 14:30 to 14:46

COUSINS, Professor Michael John, Director, Painaustralia

MURDOCH, Mr Paul, Vice-President, Australian Pain Management Association

[14:46]

Evidence was taken via teleconference—

CHAIR: Welcome. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee has your submissions. I now invite you to make a short opening statement, at the conclusion of which I will invite members of the subcommittee to put questions to you.

Prof. Cousins: I represent a new organisation called Painaustralia—a community organisation comprising both healthcare professionals and a wide spectrum of community members. The first thing I would like to say is that I have been involved in the field of pain management for over 40 years. I think it should be made very clear that pain treatment has been a neglected area of medicine for far too long. In fact, it was only very recently, in 2005, that pain medicine became a specialty. So in that environment it is not too surprising that patients with severe pain have had rather limited options. This situation is the reason behind the development of the National Pain Summit, which, as you are aware, attracted a very large number of submissions and saw close to 150 healthcare and consumer organisations participate in a summit at Parliament House in Canberra. This resulted in the publication of the National Pain Strategy.

Interestingly, running almost in parallel with this, the very prestigious Institute of Medicine in the USA—which, as some of you would be aware, responds only to direct requests from congress— has just completed a report on the current state of pain management in the USA and has made very strong recommendations which are almost identical to those of the National Pain Strategy. In both of those documents it is stated quite clearly that patients with severe pain, particularly those with severe chronic pain—and that includes cancer survivors—are currently denied equity of access to treatment compared to other chronic diseases. I think there is a general misconception in the community that pain is a rather trivial issue and that pain never killed anyone. I will perhaps comment on that one straightaway and say that there are now studies from Canada and elsewhere which show that patients with chronic pain have twice the suicide rate of members of the general community. So pain does kill people. Before doing that, it certainly causes a tremendous erosion of quality of life. Pain medications are a key component, but they are by no means the only treatment option available now, which is quite broad. They are a very important component of the management of severe pain.

I would like to just refer to a couple of goals of the national pain strategy. The mission of the strategy is to improve the quality of life of people with pain and their families, and to minimise the burden of pain on individuals and the community. The very first goal is that people in pain are a national health priority. I would like to emphasise again that people in pain have not been a national health priority. This is an area of treatment that is well behind other conditions. I will refer to one other goal in the strategy, goal five, which partly says:

Facilitate equity of access to appropriate pain medicines and treatments by:

- improving access to pain medicines not currently listed on the PBS …

We have a very poor range of medications for the treatment of pain. As an aside, there is not a single medication approved for the treatment of nerve damage pain, which is one of the most horrible and neglected areas of pain treatment.

I have a brief comment on the oxycodone/naxolone combination. I am not going to repeat what is in the Pain Australia submission, except to say that this combination is based upon some very excellent science. There are two key advantages of this science. One is that it allows quite a large range of the population who have great trouble taking opioids to do so because this preparation blocks one of the most important side-effects of opioids—that is, to activate receptors in the gastrointestinal system and cause quite a range of unpleasant symptoms, which can get in the way of patients resuming normal life after surgery and living a normal life with chronic pain.

I would particularly like to highlight the older population. Many of them are completely unable to take opioids, despite their great need for them since they have a much higher incidence of pain associated with degenerative diseases. Pain is one of the main things that gets in the way of the older age population living independently, and this incurs substantial costs in the healthcare system. The same is true of patients with chronic cancer pain. The number of cancers survivors is now increasing each year and many of them have chronic pain. But even in acute pain after major surgery, there is a much more rapid rehabilitation if the patient is receiving pain relief with strong opioids and there is a lower prevalence of complications.

Finally, I would just like to refer to the Declaration of Montréal. There was an international pain summit held in Montréal, Canada, in association with the World Congress on Pain, in August last year. I had the privilege of chairing that. One of the major outcomes of that international conference, which had representatives from over 80 countries, was the Declaration of Montréal. It is a declaration that access to pain management is a fundamental human right. It goes on to say:

> And, recognizing the intrinsic dignity of all persons and that withholding of pain treatment is profoundly wrong, leading to unnecessary suffering which is harmful; we declare that the following human rights must be recognized throughout the world:
>
> Article 1. The right of all people to have access to pain management without discrimination.

The declaration goes on to refer to the obligation of governments to provide appropriate facilities and methods of relieving pain. I think one could well view a poor response to recognising the very small range of options currently available as being in some way a denial of the human rights of a large number of individuals who are still suffering from neglect in this area.

Finally, I would like to underline what we said right at the end of our submission about the problem of opioid diversion. Opioid diversion is something we cannot just push aside; it is becoming a much, much bigger problem throughout the world. This preparation would be extremely unattractive to opioid abusers because it is not designed for intravenous use. If it was injected intravenously, because of the blocking drug contained in the preparation it would cause an immediate and very severe withdrawal. It is the start of our abilities to provide pain management with a specifically designed preparation that will not have any appeal whatsoever to opioid abusers. Thank you very much.

Mr Murdoch: I will refer to our organisation as APMA during this session. I would like to begin by thanking the Senate for actually responding to the widespread concern and disquiet by establishing this inquiry. I also thank the committee for the opportunity to appear and supplement our written submission.

I endorse what Professor Cousins has said. APMA is a founding member of Painaustralia and is a very strong supporter of both it and the National Pain Strategy, which Professor Cousins played a critical role in developing and which he has seen through to its current situation as a guiding light for those trying to improve the situation of people living with pain in Australia and, in fact, around the world. As Professor Cousins made clear, a pharmaceutical option is but one of a range of options available for people living with pain, but a critical one and one that is often necessary in order for people to utilise other opportunities such as self-management, returning to work and things like that. It is a key option in the suite of treatment options available.

During this session I intend to talk about the new government policy to reject rather than defer pharmaceutical listing. I think that is a semantic means of downplaying the seriousness and implications of this new approach. In almost any other legal jurisdiction, a decision such as the one taken by cabinet to date would be deemed to be refusal; hence, my use of that term during this session.

One final thing I will say about pain before I move on to some of the consequences of this new policy is to make it clear that as a consumer organisation representing people living with pain we are a little unique in that pain is still ubiquitous within the health system. There is a range of different illnesses, diseases and conditions from which people suffer for which pain is an element. We are not restricted to talking about people suffering from pain itself or cancer or multiple sclerosis; we have interests that are right across the board, often in a range of different medications. Having said that, I would just like to talk a little about a number of the consequences of this new policy, were it to proceed for very long. I note that it is fairly recent in place since being announced by the Minister for Health and Ageing on 25 February this year. My comments will relate very briefly to the consequences for the system, for patients and for the processes of assessment, while noting that there are consequences for clinicians, for industry and the government itself. On these last three I will not be making any comments, but I am happy to provide any further information that any of the senators would like to explore with me.

In terms of the consequences for the system, the national medicines policy objectives are, to paraphrase them, basically to provide affordable, timely access to the quality use of the most appropriate medicines. The Pharmaceutical Benefits Scheme and the Pharmaceutical Benefits Advisory Committee are both extremely highly regarded and successful in our view in achieving those objectives. Given that, we would query this short-sighted, retrograde policy. Some of the characteristics that have been used to describe the PBS and the PBAC include such terms as effective, robust, rigorous, integrity and strongly supported. I think the submissions to this inquiry are testament to the almost universal high regard in which both the scheme and the committee are held.

The government, which has brought in this new policy, has claimed to be committed to evidence based decision making. It has also sought, quite rightly, to introduce a greater transparency to a range of health

technology assessment processes, including of course the listing of pharmaceuticals and covering a wide range of other areas. This new policy in our view is directly contrary to these principles, being neither evidence based nor transparent. It is important to note that integrity, particularly of a system, is hard to establish but very easy to lose.

CHAIR: Mr Murdoch, I am conscious of the time. Could you bring your opening statement to a conclusion please?

Mr Murdoch: I would just like to say that there are a number of consequences for patients that are potentially very severe. The proposition which seems to underpin the government's policy is that the availability of alternative treatments is a proper basis for rejecting the listing of a medication and, while there may be substitutions of treatments available on a system-wide basis, the reality is that at an individual patient level no two drugs are necessarily exactly the same. Restricting clinical options to prescribed medications means reducing health outcomes.

Professor Cousins has covered the increasingly recognised link between chronic pain and suicide, so again the idea that pain does not represent something that should be a basis for lifting medications is erroneous. We would also argue that the quality of life for patients is just as important as saving lives. With those final comments I thank you for the opportunity to make a submission.

Senator FIERRAVANTI-WELLS: Mr Murdoch, I will stay with you for the moment. In your submission you talk about 3.2 million Australians from all walks of life who suffer from persistent chronic pain. Are they basically the membership of your organisation, if I can put it that way?

Mr Murdoch: We would aspire to represent all those, but we have only a tiny proportion of people who are members. That is an estimate based on Access Economics' report in 2007.

Prof. Cousins: I will just comment there. The epidemiological studies that produced those data came from the Pain Management Research Institute, which I head. There have now been of the order of 10 publications of very high quality that have been published in the top scientific journals in this field. So we are very confident about that figure of one in five Australians suffering from a chronic pain problem. Quite recently I referred to the Institute of Medicine report. The data that are available from America are extremely similar in terms of the prevalence of one in five and the $1.85 billion per million population—almost identical to our studies.

Senator FIERRAVANTI-WELLS: Thank you. The reason I was asking is that that on page 3 of your submission, Mr Murdoch, you say:

… APMA emails its members advising them of each pain-related medication listed for discussion …

It asks them, obviously, to make submissions and it seeks advice from members about past or present use. So your membership is reflective, basically, of those 3.2 million people—is that the case?

Mr Murdoch: We are not completely reflective. We do not have any young people who are members, for example, yet pain is present in children and adolescents. Also, a smaller proportion of our membership suffers from cancer, which of course is a fairly common source of pain. But generally I think our membership would be representative of the population that suffers from persistent pain, yes.

Senator FIERRAVANTI-WELLS: What is your membership, Mr Murdoch?

Mr Murdoch: We have only a couple of hundred. We are a very young organisation, so we are currently building.

Senator FIERRAVANTI-WELLS: Yes, but, as I have said, it is reflective. You have made some qualifications on that, but what your members may tell you is typical of what you would find amongst the 3.2 million who do suffer chronic pain.

Mr Murdoch: Yes.

Senator FIERRAVANTI-WELLS: You say at page 5 of your submission that you have concerns that the change in policy:

… will … compromise the ability of the Government to attract and retain the services of the highly qualified and eminent experts who currently undertake the assessment and analysis, and must over time influence the considerations undertaken by this … body.

Are you saying there that you think that the professionalism of the PBAC may ultimately be eroded as a consequence of this decision?

Mr Murdoch: Yes.

Senator FIERRAVANTI-WELLS: That will be because in effect we are starting to see its pre-eminence in terms of its decision making being eroded and, as a consequence, people will not see it as prestigious to sit upon that committee? Is that the sort of thing you mean?

Mr Murdoch: The membership of the PBAC is of eminent people who are also very, very busy. I think that, from their integrity, they would be reluctant to continue to contribute their valuable time to a process that is not treated seriously by the government.

Senator FIERRAVANTI-WELLS: Yes. Then, of course, you go on to say that this:

… must inevitably lead consciously or unconsciously to changes in how the assessment is undertaken and their conclusions and recommendations are derived.

Mr Murdoch: Yes.

Prof. Cousins: I spent some time on the National Health and Medical Research Council and back in the 1990s I was commissioned to write a report on the management of acute pain. I put a lot of hours and time into that. I think it was a high-quality report, probably rather similar to the sort of work that the PBAC members do. If that report had been put on a shelf, I think that would have been the last thing of that type that I would ever have done. I would have retreated to other activities.

Senator FIERRAVANTI-WELLS: Mr Murdoch, you then go on to comment most unfavourably in relation to the second-guessing of cabinet and the unclear criteria. You state:

It could also tempt future Governments to appoint less independent experts to avoid having to regularly reject recommendations to list large numbers of medicines.

Could you elaborate on that. That is a very serious scenario. It flows then on from in effect watering down the body and then putting in effect a lesser class of expert on the body, which will become a bit more malleable. That is in effect what you are saying.

Mr Murdoch: Yes, the availability of sufficiently eminent people, as Professor Cousins has just confirmed, is likely to be threatened where the eminent experts are not able to do their job. Were it not or even if it is, each time a government overturns or refuses to agree with an expert recommendation, such as one from the PBAC, it will invariably lead to at least some controversy. It presents political difficulties for a government so the temptation will inevitably be, irrespective of the composition of the government, to avoid that by having PBAC members who are not likely to cause controversies.

Senator FIERRAVANTI-WELLS: On page 8 of your submission you refer to the politicisation of the process and the squeaky wheel and the most heart-wrenching patients who can attract the most public attention suddenly finding themselves getting the drugs and as a consequence their condition attended to. I think you referred to the lottery of a PBS listing. That is a fairly strong comment as well.

Mr Murdoch: The reason why you have an evidence based assessment process composed of experts with clear criteria is to keep it at arms-length from the political system. It is in the interests of governments and politicians to enable them to concentrate on what they know about and leave the expert assessments to the experts.

Senator FIERRAVANTI-WELLS: You discuss the financial impact on the Commonwealth budget and you paint quite a bleak picture there because you say that the financial savings from the budget are far outweighed by the detrimental and other consequences in the long term, such as hospitalisation, worsening of conditions, increasing expenditure in the health system and of course those in receipt of disability pensions being unable to return to paid work.

Mr Murdoch: Certainly the potential is there for that.

Senator FIERRAVANTI-WELLS: Have you been able to quantify that at all?

Mr Murdoch: No, it is well beyond our expertise, but there is a very informative submission from a number of health economists at Deakin University. They go into some detail about the cost-effectiveness assessment process undertaken by the PBAC. Either they or another submitter compare that to the very narrow costs and savings calculations done by the Department of Health and Ageing. It would appear that the PBAC makes a far wider and more rigorous calculation of health costs than does the department advising the government.

Prof. Cousins: I could perhaps help with a reference on that. It is one of the studies that our epidemiology group has carried out. We know that in association with chronic pain in this country each year there are 36 million lost work days.

Senator DI NATALE: Professor Cousins, I have a couple of points regarding your submission. You mention that there is one preparation available in the Australian market that affords the same benefit. To which product are you referring?

Prof. Cousins: No, the statement is that there is only one preparation that provides the action.

Senator DI NATALE: Are you referring to the compound that was deferred?

Prof. Cousins: A combination of oxycodone and naloxone is the only such preparation on the market.

Senator DI NATALE: Sorry, that statement was ambiguous. I take your point. My second question relates to the assessment process. Was the benefit of reduced potential for drug diversion and abuse quantified?

Prof. Cousins: No, it was not, and I think it would be difficult to quantify except to say that withdrawal responses are life threatening and extremely unpleasant, and I do not think it would take very long or take very many individuals to try to inject this preparation intravenously for the keenness to do that to disappear. Sadly, you can see that there are a very large number of individuals who are currently involved in diversion of drugs. I do not have a dollar figure but it would be quite substantial.

Senator DI NATALE: I have some experience in this area, so the question I would ask is, given that that is one of the significant benefits associated with this product, do you see it having a greater role than envisaged because it would result in this very serious problem of abuse?

Prof. Cousins: It would result in ameliorating this problem of opioid diversions. I am not sure that it is going to do much for abuse. I think that will continue. It is a much more complex and difficult problem. But at least it would overcome the problem, when we are prescribing the current range of opioid drugs for a patient with medical indications, of us having to be concerned that this drug might, by various means, be diverted to other users. I think that is a very sad situation which tends to place some kind of stigmatisation on people with chronic pain. There is an implication that if you are taking these medicines you might be halfway towards addiction and that that might lead you to engage in the behaviour of people with opioid dependence and in diversion. That is a very undesirable situation for people with chronic pain.

Senator DI NATALE: Sure. I suppose my question relates to the possibility that over the long term this product may in fact become the default option when prescribing oxycodone, as a result of its potential benefits relating to abuse. Do you see that as a possibility?

Prof. Cousins: It is a possibility. It is early days yet. We do not have a lot of information about that. But it is certainly possible.

Mr Murdoch: Could I supplement that by drawing to your attention page 8 of submission 38, where there is a claim that the manufacturer of that particular product and the Department of Health and Ageing had reached agreement that there would be a saving of $8.4 million over a five-year period from a reduction in abuse of OxyContin tablets. It would appear that, notwithstanding the claim by the Department of Health and Ageing that there was no evidence basis to it, there were at least some discussions about cost savings.

CHAIR: Thank you. Unless you have anything brief to add, I will release you now and suggest that you can also add things by contacting the committee secretariat over the next fortnight.

Prof. Cousins: Thank you.

Mr Murdoch: I have just a couple of very quick points. I appreciate your time. We are hoping that this inquiry will lead to recommendations to restore the integrity and transparency of the process. We are most definitely not looking for an outcome which may have been raised by one or two of the submitters, seeking for you to perhaps recommend particular listings. We think that would merely reinforce the problem that this new policy has: instead of second-guessing the PBAC, you would be third-guessing the PBAC and cabinet. We desperately want to see greater transparency and clear criteria reapplied across the board to a listing of medications. So we look forward to seeing your report.

CHAIR: You can rest assured that, as a graduate with an arts degree, I am unlikely to be recommending individual medicines! Thank you very much for your time and your submissions.

MENADUE, Mr David, Special Representative, National Association of People Living with HIV/AIDS

[15:21]

CHAIR: Welcome, Mr Menadue. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. We have your submission. I invite you to make a short opening statement, at the conclusion of which I will invite members of the committee to put questions to you.

Mr Menadue: The National Association of People Living with HIV/AIDS, or NAPWA, is the peak community based organisation in Australia representing the interests of people living with HIV/AIDS. We are grateful for this opportunity today to speak on a sustainable, fair and equitable PBS system—or that is what we are hoping for. It is vital to the health and wellbeing of our constituency, as well as the health and wellbeing of the general population.

People with HIV are highly dependent on HIV antiretrovirals for their continued health. For us, getting access to the latest treatments to fight the virus is literally a matter of life and death. HIV has proved to be a very complex virus to treat, as it mutates, making it very difficult to find a cure. Although current treatments are able to keep people relatively healthy, the virus continues to mutate and adapt to the environment in the body, and this causes drug resistance in some people. As a result, we require new drug developments to keep people from developing AIDS' defining illness.

NAPWA believes the deferral of the listing of drugs recommended for the PBS is short-sighted and disturbing as an ongoing precedent and interference in the regulatory approval arrangements. We are at a loss to understand the reason for the government decision on 25 February 2011 to defer the listing of a number of new medications and all new PBS listings with a net cost to government to cabinet for approval. Is this about a short-term goal of balancing the budget, limiting the growth of the PBS in the long term or a perception that too many drugs are getting approved in Australia so listing should be slowed down a bit? If it is for any of the above reasons, Australia is throwing out a robust, workable system of drug regulation that currently has the confidence of the community and industry stakeholders alike.

There has been an ongoing PBS reform process that has been implemented across many aspects of the regulatory process and which has been delivered with consultation and buy-in from industry and patients alike. This was also done in a spirit of collaboration and transparency. The PBS deferrals currently upon us are not part of this, and they are most unwelcome. NAPWA has great confidence in the workings of the expert panels and mechanisms currently in place to evaluate cost-effectiveness and clinical benefit of any drug submitted for PBS listing. It has been evidence based, has had bipartisan support and has the confidence of the Australian population.

Our major concerns with the deferral of PBS listings are, firstly, drugs can potentially be backlogged ad infinitem. We have no way of knowing, as a community group vitally concerned with the progress of the latest listings of drugs and where they are on in the drug approval process, whether they are being held up in cabinet or under what time frame they will be considered. Secondly, important drugs can be easily lost in the Australian setting under this protracted process. Thirdly, we worry greatly about a return to competitive health lobbying among specific groups, including patient groups, to try to get their drugs up before others. This can lead to lobbying of politicians by the media, radio journalists and the like and special treatment of certain groups at others' expense. It is not the way to run a fair and equitable drug approvals process. Fourthly, drug companies lose interest in pursuing drug listings in Australia, putting health outcomes at great risk. This is of particular concern to us because the latest developments overseas in treatment of HIV are rapidly evolving and we would hate to be put in jeopardy of not receiving those. Fifthly, special access schemes by which new drugs are provided to people with life-threatening illnesses while regulatory processes are finalised are made smaller or even curtailed by drug companies as the environment is no longer able to certainty of time points for PBS listing.

Community stakeholders want to work with government to help keep a sustainable PBS. If there are pressures for government about the current PBS approvals framework, they should be articulated and discussed. The Australian public deserves more than a doorstop interview or press release to hear about such a critical and drastic development. If there is a need to consider policy review or analysis, then Australian health consumers and especially PBS patient groups should be consulted. Maybe there are ways we can all help resolve such issues. But government should not put a workable and robust system of drug approvals at risk and lose the support of the community about such an essential and life-sustaining part of the Australian health system. If it ain't broke, do not fix it.

Senator FIERRAVANTI-WELLS: We've heard that one before.

Mr Menadue: I bet you have—sorry about that.

Senator FIERRAVANTI-WELLS: You said that you represent the peak body so you have a range of associations as part of your organisation. Roughly how many people are living with HIV in Australia?

Mr Menadue: About 21,000 and the projections are that by 2020 it will be about 28,000.

Senator FIERRAVANTI-WELLS: Your submission is in general terms. There is no particular drug at this point, is there Mr Menadue?

Mr Menadue: Not particularly an HIV drug. The factor which does concern us is that a lot of us are facing an earlier ageing process. We have discovered in recent times—the scientists have told us—that our bodies are experiencing an inflammatory process as our immune system tries to fight the virus and this is causing other comorbidities apart from HIV. Even though I do not think there is actually an HIV drug at the moment, it will happen in the future of course, probably over the next six months, but there are other treatments to do with those comorbidities which may be affected. I just heard about OxyContin. Some of our people have severe arthritis and are on OxyContin. I do not know what the discussions were about, but other drugs are also part of our picture.

Senator FIERRAVANTI-WELLS: You talked in your statement about treatments and, being the area it is, you obviously look at what is happening around the world. Do I gather from your evidence that the treatment to date and the way that drugs have been rolled out in Australia have been—

Mr Menadue: World standard.

Senator FIERRAVANTI-WELLS: world standard, particularly in this area, as far as HIV dependent people are concerned.

Mr Menadue: Absolutely.

Senator FIERRAVANTI-WELLS: You intimated the point about six months. You mentioned that you are aware that there are drugs that are coming on internationally in the next six months. Could you just elaborate on that.

Mr Menadue: I am not the treatments expert of the organisation, but I do know of a number of classes of drugs that are at a reasonable stage, and we would be asking for at least special access to some of these drugs. You are going to ask you the names; I cannot tell you the names.

Senator FIERRAVANTI-WELLS: No, I will not ask you the names. You are just aware of them.

Mr Menadue: What I am saying is that it is a rapidly evolving process. There is a conference being held in Rome at the moment where new therapies are being discussed, so I would imagine the pressure will be on drug companies in Australia—the Australian arms, anyway—to look to whether they should be, say, trialled in Australia. Australia has a very good record, and that is partly because of our stable regulatory processes. But also we have a Medicare system, so people are able to come to the table and it is an even playing field for people in the clinical trial area. It is regarded as a good place to do clinical trials, so we often get some of the world's first treatments at the moment, and that is partly to do with the fact that we have a good Medicare system that allows doctors to do these trials and to run them fairly well. But it is also a matter of the drug companies being able to see something for their investment in the long term, and of course we are concerned about that being put in jeopardy.

Senator FIERRAVANTI-WELLS: That was certainly the evidence that we heard from some of the drug companies earlier today. You outline on page 3 of your submission a series of concerns which have been echoed by other submissions and you say that it is unacceptable. We really will see the squeaky wheel and, as I think Mr Murdoch said earlier, the PBS lottery.

Mr Menadue: Yes. I do not know. The media may craft certain interest groups as being more deserving than others, maybe because they have more clout. I am not sure that HIV is popular in all areas of the community.

Senator FIERRAVANTI-WELLS: They might live in certain seats, Mr Menadue.

Mr Menadue: They might.

Senator FIERRAVANTI-WELLS: I am sorry to be so cynical about this.

Mr Menadue: That is a very good point, Senator. We do not want to be caught up in the bind of—

Senator FIERRAVANTI-WELLS: I did not mean just people with HIV. I meant people from these particular groups.

Mr Menadue: I know. I am with you. I do not think we want one group disadvantaged because another has the larger ear of politicians because they have a particularly vocal advocate. There has got to be a fair and transparent system that provides equity for all.

Senator DI NATALE: Thank you for your submission, Mr Menadue. I think all of the senators present share your concerns about some of the risks with this decision. You mention, though, that if there was to be a change to the PBS and the way it is run it should be an open and transparent process. Have you got any thoughts about what should change?

Mr Menadue: Community organisations such as ours are very concerned with wellness models and health promotion. I could see partnerships developing with our agencies to get people to adopt health promotion regimes that stop them going on the statins, for instance.

Quite a lot of our people have heart, hydrotriglyceride and cholesterol problems. A lot of that is probably down to education about healthy living and exercise and so forth, and a lot of agencies were involved with trying to get that wellness model out there and producing programs in that area. I am sure lots of community agencies could be more involved in that side of things as could the GPs and the primary care sector.

All I am suggesting is to the limit of our expertise but, when it comes to the drug regulatory processes, I think as long as community stakeholders understand—like ours; we have been very involved with PBAC and submissions there—the parameters we are working with, we can work to those and understand the objectives of government. I think this is our concern: we are bit unclear about what the objectives are.

Senator DI NATALE: I think the objectives are clear—that is, to make the books balance. The process is probably what you are referring to.

Mr Menadue: I see.

CHAIR: Thank you, Mr Menadue, for your submission and for attending here today. You are welcome to submit further information in the next couple of weeks to the secretariat. Thank you for your time.

Committee adjourned at 15:36