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Reference: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007

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SENATE STANDING COMMITTEE ON

COMMUNITY AFFAIRS

Friday, 15 June 2007

Members: Senator Humphries *(Chair)*, Senator Moore *(Deputy Chair)*, Senators Adams, Allison, Boyce, Carol Brown, Patterson and Polley

Participating members: Senators Barnett, Bartlett, Bernardi, Mark Bishop, Boswell, Bob Brown, George Campbell, Carr, Chapman, Crossin, Eggleston, Chris Evans, Faulkner, Ferguson, Fielding, Forshaw, Heffernan, Hogg, Hurley, Hutchins, Joyce, Kemp, Kirk, Lightfoot, Ludwig, Lundy, Marshall, McEwen, McGauran, McLucas, Milne, Nash, Nettle, O'Brien, Parry, Payne, Robert Ray, Siewert, Stephens, Stott Despoja, Watson, Webber, Wong and Wortley

Senators in attendance: Senators Adams, Allison, Carol Brown, Boyce, Humphries, Moore, Polley and Webber

Terms of reference for the inquiry:

To inquire into and report on: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007

WITNESSES

Committee met at 9.02 am

O'DEA, Mr John, Director, Medical Practice, Australian Medical Association

CHAIR (Senator Humphries)—I declare open this public hearing of the Senate Community Affairs Committee's inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007.

Welcome, Mr O'Dea. Information on parliamentary privilege and the protection of witnesses has been provided to you. In any case, you have been here a few times before and I am sure you know what to do. The committee has a submission from the AMA in front of it. Thank you for that. We will ask you questions about that but I invite you first to make an opening statement, if you wish, about this issue.

Mr O'Dea—Thank you. It would normally be our preference to send one of our elected representatives—it would normally be the president, or Dr Gullotta, the chair of our Therapeutics Committee, but at short notice he was simply unavailable and I apologise for that; you are stuck with me. I do not have detailed clinical expertise and if we delve into that too deeply I will be struggling. But I can certainly follow up any issues on that score that you want me to.

The AMA has made a brief submission. This bill is accompanied by a savings measure of close to $700 million over five years, which should allow further investment in the PBS. The PBS has been a stable scheme, delivering high-quality innovative medicines accessible by patients in an affordable manner. It is one where doctors trained in therapeutics can inform themselves regarding the prescribing options and prescribe without too many encumbrances, obstacles or hurdles. Doctors are not conflicted in this area, they do not benefit from prescribing decisions and they are basically without conflict in commenting on these issues.

We do support the bill. We think it strikes a reasonable balance between access, quality and affordability. We are particularly pleased about one aspect of the bill. Well, it hardly rates a mention in the bill, but the new streamlined authority arrangements are welcome news to us. Our friends at Access Economics calculated that the equivalent of 240 doctors spend their total time each year on the phone to Medicare Australia getting approval to prescribe authority drugs, and they pretty much always get a yes to their requests. So the new streamlined arrangements will enable a 30 per cent reduction in that, so we will only have about 180 doctors on the phone full-time all year, and we think that is a very good thing. The streamlined authority system is still an authority system. Some of the media and other commentators have referred to it as a removal of an authority system, but that is not the case. I am happy to answer questions, obviously.

CHAIR—Thank you very much for that. In fact you have raised the issue I was going to ask you about: the streamlined authorities. Obviously in removing that necessity to get authority from Medicare for the administering of a particular drug there is theoretically a greater danger that someone might be misprescribed some sort of medication. But I understand it has been replaced with the requirement to record in some way the medication that has been prescribed. Is there support that bodies like the AMA provide to their members to ensure that the integrity of that system is maintained, notwithstanding the removal of the need to refer the issue to Medicare Australia?

Mr O'Dea—Certainly the government has involved us in this all the way through and we are part of the monitoring arrangements to make sure when it is implemented from 1 July that it is implemented successfully. The last thing we want is for some big jump in utilisation or expenditure as a result of this measure. We want it to work. We welcome it. Get any group of GPs together in any meeting and this subject will come up: they hate having to phone over and over again asking the same question and getting the same answer. So we want to make it work, and we will work closely and are working closely with the government to make it work, but it is still an authority system. In many way it is a more auditable system. The phone call is not taped or recorded and there can be doubts about what was said between the parties, which cannot be really nailed for months later. But this will require the entering of a code on the PBS script and the code will relate to a reason for prescribing that particular drug, so it is there, it is written down and it is auditable.

CHAIR—Is the AMA satisfied that these changes won't compromise patient safety?

Mr O'Dea—Yes. The drugs that have been put onto the streamlined arrangements are the ones of the least danger, I suppose, or a lower safety threat. The dangerous drugs have been left to the telephone arrangements.

CHAIR—You make some comments about pricing arrangements. The submission says that you are:

... less comfortable with the decision to compensate retail pharmacy for the loss of profits as a result of the initiative.

You then say:

In our view, distribution costs of PBS medicines are already excessive and should be allowed to fall.

Can you give us an idea of how that might be allowed to occur?

Mr O'Dea—I think that comment is marginal to the bill today. It is something that has to be dealt with between the government and the guild in the context of the five-year pharmacy agreements. I do not think it can be dealt with in between. It is our view. Not everyone shares our view, but that is the case on a lot of things. I do not think there is an opportunity today or in this bill to do anything about that.

CHAIR—But you believe there is room for further savings if pressure is placed on that part of the distribution system?

Mr O'Dea—Yes, I think both. That is an area where we think the government should look.

CHAIR—I am sure they can comment later on whether they think are you price gouging as well. There will be a chance for payback there, no doubt.

Mr O'Dea—I am sure some of the people behind me might as well.

CHAIR—It might be the case.

Senator MOORE—Mr O'Dea, I want to give you the chance on record to restate point 3 that you put in your submission, because I know we have had this discussion before. So much of this legislation has been around use and effective use of generic drugs. We have had the discussion before about the role of the doctor working with patients, about making sure people have confidence and that there is that awareness of the whole element of what they are

taking into their body. I thought I would give you a chance at this stage to talk about the role of the doctor in that part of the transaction, which is at the end of the whole process and what you have pointed out to us again in terms of the myth, from your point of view and from the evidence you have given us, that doctors are not supporting generic medicines.

Mr O'Dea—We were all a bit surprised in the course of these discussions over the reforms. I think it was I who asked the question of how many times that 'not for substitution' box is ticked, and no-one knew the answer. So I think some people in the government were despatched to find a large sample of scripts in shoeboxes or wherever they are kept, and the count was about three per cent. That three per cent, I would think, is not always a patented brand that is being reserved in that case. It is often the fact that the box has been ticked in relation to a generic, because once you get on a particular medication, as you know, it is important to stay on that—for certain people—not only for clinical reasons but there are also issues around confusion and compliance. It is a small number of ticks and I think there was a general feeling that it was the doctors who were preventing a move to generics. That was useful information to point out that it was perhaps not the case.

Senator MOORE—When we have been getting briefings on this incredibly complex legislation—and it just is so complex, as you know—the department and the government's point of view is that the major thrust of this whole change is effective use of government dollar. In effect I suppose 'cost saving' is a little bit too simplistic but nonetheless it is 'best value' while maintaining safety. From the AMA's perspective, will there be any impact on consumers?

Mr O'Dea—There will be a $700 million saving, and some of those savings will be returned to consumers in less direct methods—in taxation and so on, in further investment in the PBS or in some cases by absolute reductions in the price that they pay for those drugs that, as a result of this, fall below the copayment level.

Senator MOORE—So you think the consumer will benefit. Rather than the wider aspect of going into government revenue generally, specifically for a consumer who is seeking to have a medication, from the AMA's perspective, do you think the consumer will benefit from this legislation?

Mr O'Dea—Yes, I do.

CHAIR—You make the point on the last page of the submission about the need to consider the safe use of generic medicines, given the potential for brand-switching and confusion, particularly with older people using multiple medications, unless a doctor indicates otherwise. You indicate that this is an area where further work needs to be done. Can you just elaborate a little bit on what sort of thing you think can be done or should be done in that area?

Mr O'Dea—We have representatives on this panel and a lot of the issues that they will consider are, no doubt, clinical issues that probably go beyond my reach. But it is important. We do have this view, as I said earlier, that once people are on a particular medication, even if it is not a patented medication or a generic medication, it is very important to keep them on it, and not to have that substituted, every time they go to the pharmacy or whatever, for something that might be cheaper. It is not always in their interest because it can create issues

around compliance and efficacy. I probably cannot give you any further detail about what will be considered in there, but we are represented on that group.

CHAIR—Are you suggesting that if a patient has been using an original brand for a period of time and then, in getting a re-issue of that script, they go for a substitute there might be some danger for that patient?

Mr O'Dea—I don't know whether I would say that. If it is a generic it is a bioequivalent. But there are differences in the compounds that are used to bind things and there are differences in colours and packaging and so on. For the elderly, all these things can be an issue. If there are not other great issues, around cost to government or whatever, then, prima facie, people should be staying on the same medication.

CHAIR—Okay. Mr O'Dea, thank you very much for your evidence today and thank you for the submission that the AMA has provided.

Mr O'Dea—Thank you.

[9.17 am]

FAUNCE, Dr Thomas, Senior Lecturer, College of Law and Medical School, Australian National University

HARVEY, Dr Kenneth John, Adjunct Senior Research Fellow, School of Public Health, La Trobe University

CHAIR—Welcome. Do you have any comments to make on the capacity in which you appear?

Dr Harvey—I am also on the research and development committee of the National Prescribing Service and also part of the policy advisory group of the Australian Consumers Association or Choice.

Dr Faunce—I am also the Director of the Globalisation and Health Project at the Australian National University. I have been the director of a three-year Australian Research Council grant into the impact of international trade agreements on Australian medicines' policy.

CHAIR—Thank you. Information on parliamentary privilege and protection of witnesses and evidence has been provided to you, I understand. The committee has your comprehensive submission in front of us, Dr Harvey. Thank you for that. I invite you to speak to that submission and then we will ask you some questions.

Dr Harvey—First of all, my submission is an editorial that was commissioned by the *Medical Journal of Australia* to overview two papers on the bill, one of which was written by Dr Faunce and the other by colleagues at the University of Newcastle. Also in the *Australian and New Zealand Journal of Public Health* there are another four articles on the bill. They are not, I think, part of the submission but they are referenced in Dr Searles' article, or at least one of those is. So clearly there has been quite a lot of academic interest in the bill. I think it is fair to say that the feeling is that, like the curate's egg, it is good in parts, but there are some concerns about other parts. I reiterate my approval, as has the AMA, of streamlining authorities. Certainly I think there is general approval of the move to try to get better prices to the government on generic medicines. And that, we hope, will also allow the introduction of more expensive, newer branded medicines, research based medicines, down the track.

I think the academic community is generally supportive of those principles, but there are a number of concerns. I think the key concern is that consumers will not particularly buy this bill. Yes, in theory, there will be some small cost savings for drugs that go beyond or below the copayment as a result of the generic price reductions, but in practice, regrettably, some of my pharmacy colleagues turn those scripts into private scripts and don't actually pass on the full value of those cost savings to consumers and I think it will be interesting to see just how much of those cost savings actually move on.

Most importantly though I think, the whole issue of copayments and safety net increases is of concern and this bill does nothing to remedy the steady increase in copayments in particular. I would just like to give you some figures. In 1997, the standard copayment was $20. The safety net threshold was $612 and for concessional patients the standard copayment

was $3.20 and the safety net was $166. This year, as you know, the copayment is $30.70 for a normal person. The safety net threshold is up to $1,059. The concessional copayment is up from $3.20 to $4.90 and the safety net from $166 to $274. Essentially, there has been a 50 per cent increase in copayments for both concessional and non-concessional patients over the last 10 years and a 70 per cent increase in safety net thresholds. Particularly in 2005 when the safety net was jacked up 30 per cent, we have seen a substantial decrease in scripts and we have seen I think evidence that poorer consumers are forgoing necessary medicines because the cost—especially for a person that is not on the concessional scripts and has a large family of chronic illness to reach a safety net threshold of over $1,000 and have $30 of script is a substantial problem. There are a number of surveys and they are referenced in the article by Dr Searle that suggest that consumers are forgoing scripts because of the cost. The concern of course of that is that if they forgo necessary medicines like antihypertensive medicines, they may well end up costing us more when they bounce back into the public hospital system with uncontrolled heart disease et cetera.

So there has been general concern, especially amongst the consumer organisations, about the increasing level of copayments. Originally they were just meant to be a price single, they were not meant to be a percentage reflection of the cost. The government was saying they were a price single to make consumers aware. As I say, our concern is that they are now at a level where poorer consumers are forgoing necessary medicines. We would have hoped that to improve the use of generic medicines that there would have a reduction in copayments for consumers that chose genuine generic medicines. We think that that would be a great incentive not just for consumers to choose generic medicines but it will also be an incentive to the generic industry. I was disappointed that rather than reducing the copayment for generic medicines, that the government is going to have yet another expensive advertising campaign.

I am not saying that there is not a need for more education about generics, but I would point out that I teach medical students. All our medical students know the generic names they prescribe generically in teaching hospitals. Give them five years out in general practice and they are writing brand names. That is of course the result of the promotional activities of the pharmaceutical industry. So I am concerned that simply an advertising campaign to consumers is not actually going to produce a great increase in generic drugs. It is the doctors that prescribe. It is the doctors that are being influenced particularly by Medicines Australia's companies to prescribe more expensive more expensive branded drugs.

As for our AMA representative who said that doctors are not ticking the 'do not substitute' box, or less than three per cent are—again, I have not seen those figures—but another set of facts which contradicts those is that the pharmaceutical benefits pricing authority figures last year show that 37 per cent of scripts are associated with a brand premium. So someone is writing an awful lot of scripts for branded drugs that are associated with a higher price, a brand premium that does not contribute to the PBS safety net. So my concern is that a research based innovative pharmaceutical industry—which I support, but, nevertheless, they spend twice as much money on promotion as they do on research and development—will actually continue to make sure that, unfortunately, doctors prescribe more expensive drugs.

My colleague Dr Faunce will say more about the F1 and F2 and our concerns about the increase in prices, but certainly I have some points that I would like to make. I would like you

to ask the department of health on my behalf and on consumers' behalf why the antidepressant escitalopram is put on F1 whereas a drug that is identical, according to the National Prescribing Service—an older drug—citalopram, is on F2. We are going to lose the actual price comparisons between these even though, as I said, the National Prescribing Service is convinced that they are identical. Perhaps we can come back to that after my colleague Dr Faunce has talked more about the F1 and F2.

CHAIR—Dr Faunce, you may wish to make a synopsis of your submission, then we will ask you both some questions.

Dr Faunce—Sure. The overall statement that I wish to make is that I think these are ill-considered and undigested amendments to perhaps the most central part of Australia's public health system. The PBS is the only component of our public health system that has been voted for by constitutional amendment. In 1946 the majority of people in the majority of states voted for the PBS, so this is an extremely important part of our public health system. We are now seeing legislation, which we saw for the first time four weeks ago, being rushed through parliament. We get one day for the Senate inquiry today. I do not think this is enough to fully digest the impact of the changes that are about to be made.

I have some specific recommendations about ways in which these changes could be ameliorated. Some of the adverse effects may have been unintentional through the desire to achieve lower generic prices. We may have thrown the baby out with the bathwater, with regard to fiscal controls over patented pharmaceutical prices. I will be making some specific suggestions for amendments about the way in which the system, as it is currently drafted, could be ameliorated.

Insofar as my researchers suggest that there is motivation for these changes running through the US-Australia Free Trade Agreement, I think that case is undeniable. Obviously there would be official reluctance to admit that, but there is no doubt. My article, that I think senators may have read recently in the *Medical Journal of Australia* makes the case quite strongly that there is no doubt the US wanted—in their words—the elimination of reference pricing under the PBS. I think this bill achieves that. As senators, you have to ask: was that necessary? My argument to you would be that, even looking at the terms of the free trade agreement with the United States on its face—and I am particularly referring to annex 2-C(1)—there was no obligation on Australia's part in that agreement to give away reference pricing. In fact, if you look at the definition of 'innovation' in annex 2-C(1), you will see there are two competing interpretations. These are the interpretations that underpin the F1 system and our regulatory response to it. You will see in annexe 2-C(1) that innovation is defined as being valued through the operation of what the US calls competitive markets, but, of course, most of us know are markets distorted substantially by collusion, advertising and the monopolistic practices—but they call them competitive markets. The Australian approach is to value innovation through objectively measured therapeutic significance. That is not my interpretation. Ruth Lopert, who was the senior health advisor to the free trade agreement on medicines, stated—in her submission to a similar Senate inquiry to this one, on 21 June 2004—that those were the two opposing points of view.

I do not think that the way we have approached the reference pricing parts of these new changes reflects the point of view that Australia has a differing approach to the US. We are

not alone in having a differing approach. The South Koreans have recently negotiated a free trade agreement with the United States. Their first request—in fact, the demand—in the medicines sector was to set up a similar cost-effectiveness and reference pricing system to the PBS. The draft text of that trade agreement has just been released and in it the South Koreans point out, as we did, that the US has a particular way of approaching medicines issues based on competitive markets and the South Koreans have a different approach, which is almost the same as the Australian approach, which is, we are going to do it scientifically and we are going to look at objective evidence. They are the two approaches.

Before I finish my introductory remarks, there are a few key recommendations that I urge the senators push for in terms of amendments. They will allow gains through lower generic prices but will ameliorate some of the long-term problems that these amendments may create. First, I think the definition of interchangeable on an individual patient basis in the new section 101(3BA) needs to be defined. I cannot believe that this new provision which we are now asking the experts on our PBAC to make part of every single recommendation they make to the minister is not defined in the legislation.

Leaving these words undefined simply opens the door to ongoing manipulation behind the scenes by our friends—and I use that word loosely—Medicines Australia. I am not a friend of Medicines Australia. As many people would know, I regard them as akin to the big tobacco industry. They are an extremely greedy and avaricious group of individuals who portray their concern about the Australian people quite openly but actually are just in the job to enhance their own profits. That is apparent when you look at their submission to this inquiry. You will notice that they state they are a supporter of the Australian medicines policy and then they misquote the medicines policy. On page 17 of Medicines Australia's submission in their support for the national medicines policy they have changed 'affordable' access to medicines, to 'timely' access to medicines. This is characteristic of the Medicines Australia position. The word 'affordable' is not part of their lexicon. They do not like their new products being referenced against scientific assessment of what we call, in the PBAC, their health innovation. Having a definition of those words would be important.

Following on from that, another core recommendation would be that we abolish this working group between Medicines Australia and the department of health which is to oversee policy development in the F1 category. Creating a working group between Medicines Australia and the department of health is like putting the fox in charge of the chickens. We are never going to be able to develop policies that effectively ensure that the Australian people do get affordable access to medicines if we have got Medicines Australia in charge of policy development.

The third major change I suggest the senators consider is an amendment which stops industry funding of the PBAC. This is a proposal that has come through the department of health recently and it is synergistic with these other proposals. It is again being driven by Medicines Australia. It is saving the Australian people a pittance, but what it is doing is creating a client relationship with our core cost-effectiveness regulator. There have been protracted calls in substantial US journals like the *New England Journal of Medicine* for this similar type of industry funding of their core drug regulator, the FDA, to be abolished. It has endangered public health. A lot of people suggest it is the major cause behind the Viox

scandal which led to thousands of deaths because the regulator was not at sufficient arms-length from the industry. That would be another amendment I strongly urge senators to adopt.

The fourth amendment I suggest is crucial. My understanding of these changes in relation to reference pricing—and this is something I have garnered from reading through the department of health's submission—is that they are designed to crack reference pricing over time, not at the point of initial listing. If a drug went into the therapeutic group premium policy and then if more competitors came in, that brought down the price of the whole group. I understand that. That is being altered.

What is crucial, though, if we are going see the continuance of scientific evidence based assessment of what we call health innovation of patented drugs, is that these changes do not affect the cost minimisation process on initial listing. I am not talking about listing over time, but when the PBAC does its first assessment of the health innovation of a new patented drug, it should be able to say at the end of that cost effectiveness rigorous process, 'Yes, we do not think this drug, despite its advertising, despite its molecular flamboyance, despite some tweaking and me-tooness, really offers any great advantage over existing cheap generic drugs. They should be able to cost-minimise that initial price of the drug down to those comparative F2 drugs.

That is not reference pricing over time, it is not affecting competition. All the reasons why you want to crack reference pricing to allow cheap generics do not apply to that situation. If we do not ensure that the cost minimisation process is allowed to continue, this is going to remove one of the few fiscal levers that the Australian government has over new patented drugs and it is going to expose us significantly when we are about to move into the new gene and nano-based revolution where almost every single drug, if you look at it in terms of its technological and technical development, will be presumptively innovative. And how do we know the prices of these drugs? For example, the Australia government just agreed to pay $60 thousand a year per patient for Herceptin.

We do not know how the pharmaceutical industry came up with that price—we have no way of digging behind the scenes and finding out what is the marginal cost of production. It will expose us to just having to create a subsidy system where we are creating an incentive for the patented pharmaceutical industry to jack up whatever price they feel like to the PBAC and we will have to pay it. We need to keep cost minimisation in place as an initial threshold that will not affect downstream reference pricing and the entrance of new competitors and all the arguments we have seen in the department of heath for altering reference pricing as far as it applied to therapeutic groups. We have to ensure that the cost minimisation process continues.

So in summary I have suggested there are four key amendments that need to be made to this legislation. I have indicated that none of these changes need to be driven through the free trade agreement, no matter how generously we regard our subservience to the US and our requirement to comply with their wishes. We did not agree to undermine reference pricing. We agreed in the actual text of the free trade agreement to preserve our evidence based system of assessing cost effectiveness and the health value of new pharmaceuticals. If we want to see the PBAC continue into the future and attract the best academics from around our universities, they are not going to stay with it if it is just a tokenistic system that nominally looks at cost effectiveness but actually cannot bargain down the initial listing price. I think the

senators need to think carefully about this rush to get these low cost generics. And, frankly, I do not buy that argument; I think we could have achieved low cost generics by keeping our unitary formulary in place.If this policy is revisited, as I hope it will be in the future, we will have to rethink this whole purpose of cracking this formulary into two. But if we are going down this path of cracking it into two, I think the changes that I have suggested need to be made to keep the Australian PBS going as it is, as a world class example of how to effectively value pharmaceuticals.

The last point I would make is that the rest of the world is looking to us as the champions and the people who created the PBS as a model of how to get out of the problems that they have in the US. At the moment there is a push in the US to create a PBS. I was over there three weeks ago talking to senior health policy analysts and they kept saying, 'It's only going to be a question of time until we have got your PBS here. We just cannot afford to sustain 18 per cent of GDP on health costs—most of that coming from patented medicines.' Now, do we really want to go from nine per cent GDP to 18 per cent GDP where we have created this PBS system that just subsidises whatever prices Medicines Australia want?

The last point I make is directed to the Medicines Australia submission. I guess if you are greedy you always want to be a bit more greedy—that is characteristic of greedy people. Medicines Australia have got more than what they want but now they want more. We have created this separate category for combination drugs and that was designed to stop them evergreening—when a job goes off patent they just stick it with an old drug and they create a new patent and they carry on. So now they want in their submission to get rid of even that.

The final point I would like senators to consider is that a lot of these changes about generics—and you read it in the Department of Health submission—are all predicated on the fact that we are going to have this glut of generics because patents are going off—there are so many patents going off and we will have all these generics. I think that is a very naive and simplistic understanding of the regulatory architecture that has happened since the trade agreement with the US.

We know that since the trade deal with the US we have now got changes to our therapeutic goods administration as a result of article 17.10.4 which promote evergreening and make it harder for generic manufacturers to enter the market. As a result of the changes to the Therapeutic Goods Act from the free trade deal, generic manufacturers now have to notify patented drug owners if they want to enter the market. This allows patented drug owners to then bring legal claims against them for infringing patents. There are usually about 50 or 60 patents around every one of these drugs. We have created that climate now where it is going to be very easy for these patented drug manufacturers to preserve their little territory in F1. This whole argument that we are going to receive a glut of generics as a result of these changes I think is incredibly flawed.

The other big conceptual flaw in this argument is that it is looking at European and US markets which are vast. Yes, you can run ground floor generic prices in these vast markets. You can make up for the smaller margins by the vast numbers. Here we have got a very small market. Do you really think this is going to encourage generic manufacturers over time to keep producing all these generic drugs? I do not think it will. I think we are being lured by the

Shangrila of generics—a bit like a cargo cult—and we are blinding ourselves to the big problem, which is the patented side of the question.

That is the whole problem with the government's policy on medicines at the moment: it is all focused on screwing the generics. Most of these were Australian companies. They have now all been taken over by foreign companies. Alphapharm, which was our biggest and perhaps strongest Australian company, has now been taken over by Mylan Laboratories by the US. You say, well, why is that a problem? Globalisation and just let foreign companies come in. It is a problem if we regard our generic sector as having the domestic manufacturing capacity which will allow us to get a compulsory licence if we have an avian flu epidemic, if we have a bioterrorist attack. One of the big flexibilities in the TRIPS agreement is to be able to say to our own domestic manufacturing industry, 'Pick up a compulsory licence to protect public health.' Can we really do that if the companies that are running these things are just foreign multinationals? It is going to be a lot harder for us if we don't have any domestic manufacturing capacity that is Australian at all. I do not think these changes are helping us at all. I hope those comments have been useful.

CHAIR—Thank you very much. Before I invite Senator Moore to ask you questions, can I just clarify one of the four key recommendations that you make. In your submission you have got recommendation 4 as the one dealing with interchangeability.

Dr Faunce—This is the submission to the inquiry.

CHAIR—Yes, the submission to the inquiry. That is the one dealing with interchangeability. Recommendation 5 was the one dealing with the composition of the Pharmaceutical Benefits Advisory Committee; is that right?

Dr Faunce—Yes, recommendation 5 is the one about the remuneration of the PBAC staying in public hands. I am obviously summarising the core ones.

CHAIR—You said you didn't want the pharmacy industry to be in that advisory role. That is the recommendation you are making there?

Dr Faunce—Five is about remuneration of the PBAC, that it should remain being done through public funds.

CHAIR—Which is the recommendation that deals with the role of the—

Dr Faunce—I guess you would say it is really an extension of 7, in which I state that the medicines working group established under the free trade agreement shall publish its minutes. I think that is crucial; we don't know what they are doing at the moment. It is really an extension of that. There is a separate working group apart from the free trade working group which is set up to develop policy in relation to the F1 category. At the moment there are only two stakeholders: the Department of Health and Medicines Australia. Is a bit like Heisenberg's uncertainty principle: if you stare at those two entities long enough you don't know which is which. For nominal purposes we will say it is the Department of Health and Medicines Australia on this, and no-one else. I do not think that is a sane way to develop health policy, especially as we have got affordable medicines which we have seen in their submission Medicines Australia don't want. I apologise, I haven't spelt that out expressly, but that is an extension of that recommendation.

CHAIR—What was the fourth essential recommendation?

Dr Faunce—The first is that we define—

CHAIR—Interchangeability.

Dr Faunce—Interchangeability, yes. That is recommendation 4. The second was that we don't allow private remuneration of the PBAC. The third I guess really is looking in relation to cost minimisation as a sort of summary of 1 and 2. I guess it is a clarification that I sort of developed to try and simplify exactly what was needed. So the third recommendation is that we make sure explicitly that these changes don't affect the process of cost minimisation on initial listing. That is not expressed here but I have sort of summarised it as a more particular recommendation.

I am trying to make it as simple as I can because, obviously, if you are bargaining in a situation like this, you do not want to throw too many suggestions out or you will not get anything. Firstly, we need a definition of 'interchangeable' on an individual patient basis. Secondly, we should ensure that there is no industry funding of the PBAC. Thirdly, we have to make sure that these reference pricing changes do not affect the initial process of cost minimisation on listing—not flow-on changes, the initial listing of a drug. Fourthly, we have the conjoint recommendation about the US-Australia Working Group on Medicines and the new F1 working group on medicines—the minutes of both those meetings need to be made public. They cannot be kept in secret. We cannot have Medicines Australia creating policy on F1 in secret and we cannot have them doing it either in a working group with the Department of Health and Ageing or under the free trade agreement working group. As the people, we have to know what they are saying. I think we should scrap the whole idea of Medicines Australia being in charge of policy development for F1—but in any event they should be able to publish the minutes.

CHAIR—Okay.

Dr Harvey—If we are looking at specific amendments, the end of my submission or the editorial could be transformed into an amendment to amend section 87(2) of the National Health Act to provide lower co-payments to consumers where doctors prescribe genuine generic drugs.

CHAIR—Lower co-payments?

Dr Harvey—Lower co-payments to consumers where doctors prescribe genuine generic drugs. That would need an amendment of section 87(2) of the National Health Act, which has been amended already to provide increased safety nets et cetera.

Senator MOORE—Dr Faunce, is there anything in the legislation that you like?

Dr Faunce—The name is good. I would have thought it could have been something like the PBS wonderful improvement, save, forever and a day, your children will be grateful act 2007.But it is actually just called the National Health (Pharmaceutical Benefits Scheme) Bill so that is good.

Senator MOORE—It is just that in most submissions, people find something that they support and I could not find anything in yours.

Dr Faunce—I know it is characteristic to do that and it shows that you have sort of got a balanced point of view and that you are more likely to accept what I say—I can understand that—and I am sure if I dig around—let me think.

Dr Harvey—Less authority—stream-lined authorities—you must agree with that one!

Dr Faunce—My colleagues like Ken and David Henry in their articles have pointed out that there are some good features like the low generics. I do not buy that. I think we were getting low generics anyway. I think this is a completely unnecessary piece of legislation. Why should I erode that argument by trying to pander with this? I think it is completely unnecessary.

Senator MOORE—In the background, you could have said, 'I reject this legislation.' That would have been fine.

Dr Faunce—But then that would have been spurious because it is not going to get rejected, so I would have just been wasting my breath.

Senator MOORE—That was actually my point. You have obviously been involved in this process a long time, you publish in the area and your public statements have been quite well known. You have come up with a number of recommendations which we have clarified. Have you raised these with the department directly or with the minister?

Dr Faunce—It is very hard. My research associate did approach the minister about six or eight months ago as we concluded our formal research and said, 'Would you like to hear what we have done?' He said, 'No, not particularly, put it in your report to the ARC'. So that door was closed. I have spoken to people in the department of health. I have spoken to Lloyd Sansom, the chair of the PBAC, and I should put on record that he has received a reassurance that the basic process of cost-effectiveness analysis and cost minimisation will be preserved. I do not know who from, but he has told me, 'I have had an assurance that the basic process of cost effectiveness and cost minimisation will be preserved.' I said, 'Who from and is an assurance better than having it in legislation?' Is this the type of regulatory climate that we have achieved today where we have to rely on assurances behind the scenes rather than actually seeing it in the legislation?

I have fought the US on this trade deal now since the whole thing started and we have had a continuous history of assurances—'No, the PBS won't be in the trade deal. Oh, it is in, but nothing major is in, just transparency things.' We have seen this gradual erosion. So that is why my feeling would be that it is time to put what we really want in the legislation. I think we have gone well past the point where we need to say, 'We need to protect our great strategic defence reliance with the United States and they saved us in the Second World War and we are all friends.' We realise it is just a commercial deal to them, we are just another country with opportunities for profit. We managed to negotiate a compromise and we are now at the point where we have to be strong enough as a nation to say 'Well, we have a different way of thinking about public health from the United States'. I hope we would take a much stronger approach in making these changes.

Senator MOORE—So the recommendations that you have given us in your submission and in the evidence so far have not been raised specifically with the department. So we do not know what their response is to the particular issues.

Dr Faunce—We do. For example, I think the issue of industry funding of the PBAC was raised by the most recent appointment to the PBAC with the minister and I think he is looking at that.

Senator MOORE—It is not in this legislation.

Dr Faunce—No.

Senator MOORE—No. So that is a general issue that you have been raising for a while, about industry funding and linking that.

Dr Faunce—Yes, I think this is the time to put it in the legislation. If it is not going in here, when is it going to go in?

Senator MOORE—Yes, but it is not in it, so—

Dr Faunce—We are not going to create a separate bill about it are we?

Senator MOORE—We will ask them.

Dr Faunce—I cannot imagine it. The whole thing is to set the context. It is not an insignificant thing to have industry funding of the PBAC, especially if we are going to have this F1 category.

Senator MOORE—It is a huge step and it is in not in the legislation.

Dr Faunce—No, and I am saying this is what happens—you get bits and pieces happening here. You get the evergreening changes, the industry funding of the PBAC, the new F1 category, all of these things taking place at once in different places. If you put them altogether, you change the architecture of the system.

Senator MOORE—Yes. From our point of view though the wider debate about the whole system is important. I am trying to clarify in my mind what is actually in front of us today that is going to be put to the parliament next week. I take your point, the speed with which this legislation has gone through the process is—

Dr Faunce—If you are asking me, you need a definition of 'interchangeable' and 'individual patient basis'.

Senator MOORE—Yes, and that is something that is definitely on the table now.

Dr Faunce—It is in there, but it is not defined. Why on earth is it not defined? Think hard about that and who wrote this policy. The second thing is that, even though the department of health makes numerous assertions throughout its submission that the basic process of cost-effectiveness has not changed, why do not we say in the legislation, 'The basic process of cost-effectiveness, including cost minimisation is not changed.' Why do not we say that in this legislation instead of sticking it in this policy where it can just be overturned behind the scenes by some bureaucrat putting a line through it or something. Why is it not in the legislation?

The medicines working group between Medicines Australia and the department of health is really important. Why isn't that debated? That is going to be the sort of unofficial policy development body about F1. There are so many unknown things about F1. How do you move from F1 to F2? What does interchangeable mean? If we are not careful, all of those decisions

are going to be made by that working group between Medicines Australia and the department of health and they will not be made by the Australian people. They will all be shunted off to that policy development body and we are not going to see what is happening until they suddenly produce some sort of photo session saying, 'We have developed some wonderful new policy.'

Senator MOORE—Have you raised that point directly with the department because that working group has been around for a while?

Dr Faunce—No, it has not been around for a while.

Senator MOORE—It has been talked about for a while.

Dr Faunce—Look, these suggestions have been floated for a while—

Dr Harvey—If I can just interject. Consumers and academics have been excluded. There has been no opportunity for—

Dr Faunce—How do we raise that with the department?

Senator MOORE—But that is my question and that is what I will be raising with the department. But specifically in terms of the role of this committee and what to get out—

Dr Faunce—The department is too close to industry. They have got this synergistic relationship—

Senator MOORE—I think we have picked up that that is your view, yes.

Dr Faunce—Yes, I can name names. I suppose I am under parliamentary privilege and I am tempted to, but I will not. I think it has been a disaster for public health policy. Medicines Australia and the department of health have had these cosy conferences on developing our future.

Senator MOORE—The particular point on this one that you want us to raise with the department and the government is that, in the process of developing these changes, you believe that consumers and academics have been excluded, is that it?

Dr Faunce—Absolutely. Looking at the so-called stakeholder meetings, they were always a tokenistic thing. We would come along with policies and things and try and make suggestions but we were always sidelined. There was always a feeling that they actually worked out what they wanted to do anyway. That is why there is this feeling that is being translated through this medicines working group. My paper shows you. Have you read the *Medical Journal of Australia* paper?

Senator MOORE—No, I have not.

Dr Faunce—There was op-ed piece discussed at that first medicines working group meeting on the trade deal which basically described the F1 category. That is all we have been able to find out about that medicines working group meeting. For the rest we did a freedom of information act application and just received pages of blacked-out text. That is not good enough in a democracy. We have these groups of people looking at op-eds, which end up being exactly the same as the F1 policy, we do not know what was discussed and then suddenly this thing appears in legislation. I think we are all entitled to be concerned about—

Senator MOORE—What was the date of that meeting?

Dr Faunce—The first medicines working group meeting was in January 2006 and the second one was on 30 April 2007. I know they discussed the F1 group because, under Chatham House rules, at an international trade meeting someone who was at the meeting said, 'Yes, we discussed the F1 category.' But that is not on the official web site.

CHAIR—Are you saying that the working group should continue but the membership should be widened to include other interested parties?

Dr Faunce—These would always be positive things. There is no doubt that if we actually had a wider membership of both the F1 working group which has been set up and the medicines working group under the free trade deal, and if it was more transparent, that would be positive. Under the free trade agreement there was a commitment to transparent and accountable procedures. I cannot see how that means having a faceless medicines working group—well, actually there was a picture of them at the first meeting; and you could see, if you looked really carefully, who they were. But we have no idea what they are saying. It is like being deaf—seeing these people and knowing that they are discussing something really important that you care about but not knowing what it is. And then suddenly we see these policies developed. We see little hints that they have been developed in this group but we are never able to trace it back.

CHAIR—Is the working group different to the Pharmaceutical Benefits Advisory Committee?

Dr Faunce—Yes, the PBAC is the group of pharmaceutic experts who do the final stages of assessing whether a drug is cost-effective and make the final recommendations to the pricing authority, which gets the minister involved in making the decision about listing. This working group is a new entity just set up to develop policy about the F1 category, and I think that is dangerous. It is a bit like having the fox in charge of the chickens.

Senator MOORE—What we will ask the department is: is there any common membership between those two groups?

Dr Faunce—And are they going to publish the minutes?

Dr Harvey—We have not really discussed the details of splitting the PBS into two formularies—F1 and F2—which is complex but important. I did allude to the antidepressant group. Would it be appropriate just to say a few words about some of our concerns in that area? At the moment with the unitary formulary—that is, one formulary on the PBS—it means that if an innovative company brings in a new patented drug then it will be looked at by the experts, by the Pharmaceutical Benefits Advisory Committee and its health benefits in terms of dollar cost will be assessed. If it is felt that this drug is cost-effective, it will get put onto the Pharmaceutical Benefits Scheme. That is right and proper. Indeed the evidence is that if a drug is particularly innovative in providing genuine health benefits, greater health outcomes and fewer side effects then Australian prices are quite similar to US prices.

Where we screw down the system is with so-called me-too drugs. A me-too drug is a drug which maybe in the same therapeutic class. Let us say it is an antidepressant. It might have a particular change to the molecule. The example that I alluded to was the antidepressants of the

selective serotonin retake uptake inhibitors, the SSRIs. There is a number of SSRIs on the PBS. By and large there is general agreement that they provide much the same benefits and have much the same side effects, and they are the reference price—so they have much the same reference pricing. When a drug goes off the patent list and competitors can come in then clearly they will have a lower price. The argument of course in Australia is that our prices for generics have not been so low, but we do reference price so the price of the originator nature will fall to the price of the generics.

Under the new arrangement, if we have, for example, an antidepressant—and citalopram is one such antidepressant, an SSRI—that is an innovator but goes off patent then its price will drop. Dr Faunce has talked about evergreening. One of the classic tricks of the innovative research industry is, when the patent is about to go off, to come up with a new variant of the original drug which they hope they can use to extend the patent and maintain a higher price. A classic example is what we call isomers of a drug where you have a right-hand molecule and a left-hand molecule. Indeed, citalopram and escitalopram are two examples of this. Citalopram is a left-hand glove and escitalopram is a right-hand glove. The last one is newer and therefore can be regarded as more innovative in the sense that it is a different molecule, but it does the same thing. It is actually a bit more active, but on a 10 milligram equals 20 milligram basis the National Prescribing Service has said—and I think the Pharmaceutical Benefits Advisory Committee has agreed—that these drugs are completely interchangeable.

What the department of health has done is put one of them, the right-hand glove, on F1 and the left-hand glove on F2—for reasons that appear to be completely obscure, to me at least and to other academic authors who have written about this. Putting the new one, escitalopram, on F1, means that that can continue at a higher price and will not be priced back and referenced to the generics. This is just one example of how this policy will maintain high prices for originator drugs by eliminating the reference pricing in competition when generics come in.

Of course the manufacturers will say that it is a different drug and that it is more innovative—it is a right-hand glove rather than a left-hand glove. But if it does exactly the same thing—if it produces the same health outcomes and if it has, as I say, exactly the same side effects—why should we continue to pay more? It is these concerns about dividing the formularies into two—that over time we are going to lose the price advantages of reference pricing—that concern us. The community and the department will end up paying more under this splitting of the formularies into two parts.

Of course Medicines Australia agreed. They are going to make more money and it is good for them. But, again, the principle is: should we pay for a molecular innovation that has got no health benefits? Should we pay for evergreening just to keep patents going? As you know, the whole purpose of the extensive marketing of new pharmaceuticals, which is twice the cost of research and development, is to produce patents in perpetuity—it is to get it into peoples' heads that 'pain equals Panadol' and not 'pain equals paracetamol.' I teach medical students: 'Your body does not recognise brand names. Prescribe generics.' But the whole purpose of pharmaceutical promotion is to produce brand names in perpetuity.

Senator MOORE—Dr Harvey, for us who work outside the system who are struggling to understand the system finding a concrete example is very useful. You identified the issue of

the antidepressants which you mentioned in your evidence. When you asked the department about this—because this is a particularly important element where they have created two new areas and they have given us briefings about what goes in either—what was their response? This is a specific example that you mentioned which I think we have to trace through the legislation.

Dr Harvey—I have had no opportunity to discuss this. This particular example was published in one of the papers in the *Medical Journal of Australia* rapid publication this week. This has been a concern we have had. There has been no opportunity to discuss these matters with the department of health.

Senator MOORE—I am just checking to see whether the department of health witnesses are in the room. They will be watching if they are not in the room.

Dr Harvey—This is a question which I would like you to ask them later.

Senator MOORE—If they are watching, could they actually take note of that question. Maybe they could give us some detail. We are struggling with the changes that have come through. They are described in detail in the submission, but to take us through an actual example of that kind would be very useful. If I screw up, it would be very useful if we had that—

Dr Harvey—The specific example is in a paper published in the *Medical Journal of Australia* this week, and I am happy to give it to you.

Senator MOORE—And we will give it to the department and get them to respond in detail to it.

Senator CAROL BROWN—I know my colleagues said that your recommendations have been explained but I just want to go to recommendation 5 where you say that the Pharmaceutical Benefits Advisory Committee shall only receive remuneration for their official duties. Are you saying—

Dr Faunce—From public funds.

Senator CAROL BROWN—Are you saying that members of the PBAC receive moneys from other sources?

Dr Faunce—This is a question you could ask them, but over the last six months the department has been developing a policy to get what they call 'cost recovery' from industry. In other words, they are going to fund the PBAC from industry submissions. This is a policy that works through the TGA at the moment.

Senator MOORE—I was going to say it is a TGA model.

Dr Faunce—It is also the FTA policy and it has got huge problems. Everybody wants to get rid of it from the FTA. I think it has made a client relationship with the regulator. They are not at arm's length; they cannot make the hard decisions. This is our world-class PBAC. I think we are only going to earn less than $10 million from it—a pittance really. For the damage it is going to cause I cannot see why this is in the public interest. It is only in the interests of Medicines Australia; it is not in the public interest.

Dr Harvey—To be fair, it is probably not even in the interests of Medicines Australia because they are going to have to fund the applications. But clearly they have got the opportunity of passing that extra cost on to the public through higher prices of medicines. I have been exceptionally concerned about how the Therapeutic Goods Administration, in a like manner, has gone about it. It used to be 100 per cent funded by the public purse and then it was fifty-fifty funding. My own view was that that is fair and reasonable because they have got two clients: they have got the industry as a client and they need to deal with drug submissions efficiently; but they also have the public as a client in terms of public safety, and fifty-fifty was okay. But then in this thrust for cost recovery the TGA has gone to 100 per cent cost recovery and there are numerous examples that I could cite—although this is not on our agenda—where, really, the TGA seems to be paying much more attention to industry concerns than they are to post-marketing surveillance and public safety concerns.

Dr Faunce—I also support Ken's call for a fifty-fifty split. If you are into full 100 per cent cost recovery then you are just another private enterprise organisation and the argument is sometimes raised—I have heard it at conferences—that if the TGA is just a money-making body, why just have one? Why not have two TGAs? Why not have three? Then you would have competition.

Senator MOORE—I was going to say 'competition'.

Dr Harvey—If we can go back to the function—

Dr Faunce——Why not have five PBACs?

Dr Harvey—Let us go back to the PBAC. I would accept, and I know the minister has said the same thing, that just because the PBAC is 100 per cent funded by industry submissions it is not going to change people like Professor Lloyd Sansom—and I am absolutely certain that it will not change Professor Lloyd Sansom or other independent members of the PBAC. But it will change the Department of Health and the bureaucrats and it will change their responsiveness to the industry compared to consumer groups, and that is, as Tom said, already very bad. Clearly, they talk much more to the industry than they do to consumer groups and other people and my concern is that, if the department is 100 per cent funded by the industry on a cost recovery basis, that will provide pressure on the bureaucracy to move in favour of industry.

Dr Faunce—Just to pick up on Ken there, I think it will affect the quality of the people who go on the PBAC. You have got to realise that at the moment experts do not go on the PBAC because they get a lot of money from it—they get a pittance. They get truckloads of documents they have to work through. I interviewed 80 per cent of them under our research grants so I know their motivations. Their motivations are that they are experts in public health who feel they want to add something back to the Australian community. If the PBAC becomes fully industry funded, if we erode reference pricing in the way that we are under this legislation, I think you are not going to get that sort of person on the PBAC.

It is like the battle we had over blood fractionation and the Red Cross. If you start eroding the community value part of the institution, you do not attract the sort of people who have that as their primary motivation. You attract people who are in it for the money, and the ethos of the organisation changes. That is an intangible in some ways but in other ways it is a crucial

part not just of our health infrastructure but also of our social infrastructure. If you start stripping out these community value elements of our key social institutions, you are not going to have an egalitarian society. You are not going to have a fair-go society. You are going to have a society of ruthless individuals competing with each other, like the US, and then the system is going to be so dysfunctional you are going to have to insert by force elements of social justice, which always look a bit tacked on and expensive, and this is the US system. I think it is insane that we are creating this type of system at a time when the US is trying to move away from it and become what we were. We are going to have this strange situation in 20 years time where the US is starting to move back to what we were and we are what the US was. This does not seem rational.

To summarise: I do want to clarify my suggestions to take to the department. Why is there no definition of interchangeable on an individual patient basis? This is now part of every PBAC recommendation and it has got to be defined. There needs to be a clarification that these new words, 'interchangeable on an individual patient basis' will not affect the initial process of cost effectiveness and cost minimisation on initial listing.

Senator MOORE—Yep.

Dr Faunce—Not down the track—I understand we are changing that—but on initial listing, with the capacity of Lloyd Sansom and his people to say, 'We are looking at your new patented drug and we are comparing it against what we think is the best comparator and, if at the end of the day you cannot prove to us your drug is any better than this old cheap generic drug, we are going to give you the same listing price as that old drug. If you can prove that you have got innovation we will give you a premium—we will give you extra—otherwise you have shelled out the entire system if you let these changes do that.

Then there are the problems that Ken has just raised with industry funding of the PBAC. I think fifty-fifty is a much better split than 100 per cent cost recovery—at least that would be something. And the third thing is these two working groups. The working group on medicines under the free trade agreement and the new F1 working group between Medicines Australia and the Department of Health both need to publish their minutes in full on the website so everybody can see what is going on, and they need a wider range of stakeholders involved.

Senator ADAMS—I am from a rural area and I am very worried about this matter. I have had quite a lot of lobbying from rural pharmacists about these reforms. Dr Harvey, you might be able to help me with the consumer side of it. For the rural pharmacists I gather there are going to be compensation packages paid. Have you looked into that area and the issue of consumers having to pay the extra because the pharmacists are trying to keep their end up? Then there is also the rural problem of trying to keep a GP and a pharmacist in the town. If the GP does not stay the pharmacist goes, so the prescriptions are just so important to that pharmacy.

Dr Harvey—Yes, and rural pharmacists are important and they do provide a very valuable service. By and large, although there has been criticism of the pharmacist compensation side of these reforms, clearly at the moment the generic manufacturers have been substantially discounting prices to pharmacists to try to get market loyalty. Pharmacists have been relying on that remuneration, and I am sure we are going to hear more about that from the guild. The

progressive price cuts and price disclosures, which are part of lowering the price of generic drugs to government and what the pharmacists are paying, are undoubtedly going to mean that pharmacists, if they were not compensated, would be losing some income. And for some pharmacies in isolated areas where perhaps their income and their viability are marginal, this could have caused them a problem.

But there are generous compensation packages. There are also extra benefits for the pharmacists—and I mentioned a problem of doctors prescribing drugs with a brand premium which is over and above the copayment, which does not add to the safety net. These new measures—and again I support this—are going to encourage the pharmacist to prescribe the lowest price, a non-brand premium drug, by actually giving them a bit extra money. I think it is $1.50 if they dispense a drug without a brand premium. Some of my colleagues would believe that the pharmacists have been overcompensated—and I think that is something that one could ask the Pharmacy Guild—but I think it would appear to be a generous compensation which should enable the viability of pharmacies in rural areas to be maintained. I do not believe there is a problem there, though some of my colleagues believe that they have been too generously compensated—such as my AMA colleagues thinking that 30 per cent of funds going to distribution is perhaps too high. But there are special cases.

Going back to poor consumers, I have again a real problem in that doctors regrettably are still prescribing a lot of drugs with brand premiums. As I said, something in the order of 37 per cent of scripts are associated with a brand premium. I cannot believe that that is an informed choice between a patient and a doctor in all those cases. In some cases, as the AMA says, I agree it is important for a little old lady to keep on the red pills she is used to and not to change the green pills which are different. But I cannot believe that 37 per cent of brand premiums is appropriate. I do think that is a reflection of the fact that, regrettably, doctors do see a lot of drug reps. They do get convinced that they should be prescribing innovative brand names rather cheaper generics. There is a lot of misunderstanding about patent life and about the need to have a competitive generic industry amongst my colleagues.

Again, I think consumers are being disadvantaged at the moment: firstly, because there are too many scripts of brand premiums and, secondly, because these particular reforms provide no relief for consumers in terms of if they choose a generic medication or if they ask for a generic medication. The government does well, the industry is doing well because there is more room for innovative drugs but consumers get nothing. They still pay co-payments that, as I say, have been jacked up 50 per cent over the last 10 years. I am worried that poorer consumers are forgoing necessary medicines and I do think the amendment I suggested—amending Section 87(2) of the National Health Act to provide lower co-payments for doctors who prescribe genuine generics—would provide real help to consumers.

CHAIR—Thank you, Dr Harvey. We are on a very tight timetable so we are going to have to leave it there. I thank you both for the evidence you have provided to the committee today.

Dr Faunce—I would like to thank the senators for their time this morning.

[10.18 am]

SCLAVOS, Mr Kosmas Stan, National President, Pharmacy Guild of Australia

TATCHELL, Dr Michael, Director, Health Economics, Pharmacy Guild of Australia

CHAIR—Good morning. I welcome the representatives of the Pharmacy Guild. Thank you both very much for your appearance. I understand that information on parliamentary privilege and the protection of witnesses has been offered to you. We have a submission from you. It came in late. It is submission No. 7. Would you like to make an opening statement about the submission before we ask you questions?

Mr Sclavos—Yes, thank you. The guild welcomes the opportunity to appear today and, having addressed some of the other submissions, would like to clarify some issues for you. The guild welcomes the bill. Like any arrangement with government, there were a series of negotiations. We are not happy with all the elements, but in the spirit of cooperation we have signed up to the reforms. As the custodians of the PBS, as we see it, it will be our role to sell these measures to the consumers when they in fact start in less than two months time.

In terms of the reforms and the price to consumers, which has come up a lot this morning already, I would like to clarify, first of all, the safety net items, which are a significant number of items. I will clarify this as there is a lot of definition confusion. There is over 100 molecules, and that leads to 400 brands and around 1,400 to 1,500—we still lose count because there are new drugs listed all the time—different variants of brands. So there is an enormous number of products that will drop in price. We are very confident that they will drop in price—somewhere between 20c if they are only marginally below the threshold right through to $4.65. We have already discussed the incentive paid to pharmacist of $1.50. The guild's position was that we did not want the $1.50 on safety net items. We wanted to make sure the prices were as low as possible from the price cuts. So the $1.50 incentive to pharmacists does not apply to the sub $30.70 items.

Just to clarify, in terms of medicines currently, the average cost of an item on the PBS is just over $39. For the copayment of a general patient at $30.70, or for pensioners at $4.90, there are a significant number of medications that fall below that level. So it is still very much a highly subsidised scheme and obviously there are benefits both to the taxpayer and directly to the consumers.

From a pharmacist's point of view, I want to stress what happens at the end of each month. We have 15 software vendors that support community pharmacy. There have been numerous price drops in the past. We have already discussed in detail the price-referencing system. I have never received a single complaint that price drops have never been passed on to consumers, so some notion that somehow, all of a sudden at the end of this month or when those price rises take place, I will be sitting at my computer overriding the prices on 1,400 items is ludicrous. The Pharmacy Guild is extremely confident of that, due to the fact that it is just an automated process. We get software updates from our vendors: they add new PBS items to our computerised records and the prices change. This is an automatic process.

Again, the other key issue is that, as a community pharmacist, and my role is at the interface dealing with consumers and patients every day, I know that most patients know the prices of their medicines. As a pharmacist, I can assure you: even if the surcharge changes from 20c to 25c, patients know these details. There is some perception that pharmacists will try and change prices, but that has certainly never happened in my experience. Often my patients know better than me what the prices of medicines are, including the additional charges.

The second point we want to stress is that, if the fundamental measure of these reforms is the affordability of the PBS long term, then the budget forward estimates themselves have shown how much costs have been reined in. In real terms the costs over the forward estimates have gone from having an increase of over five per cent each year to only 1.5 per cent, which is the lowest for a significant period of time.

The guild is acutely aware of the sensitivities of the rising costs of medicines. When we had our first guild-government agreement the average price of a PBS medicine was $12.50. So we are fully aware now that it is $39 and I do not need to explain to you that one phial of Herceptin costs over $1,000. To give you an example from a pharmacist remuneration point of view, our remuneration currently is a flat $40. Pharmacists lose on that because, as the women on the committee would be especially aware, there is a body surface area measurement and it is produced in a laminar flow unit. The Pharmacy Guild has lots of data to show. For example, dispensing that item is a net loss to pharmacists of about $200. So it is swings and roundabouts on our remuneration process, and overall we are comfortable. That is one of the reasons why we have a five-year agreement with the government.

Senator Adams was inquiring about the rural pharmacies. We have a five-year agreement from the government, and the government of the day is always fair in terms of remuneration to pharmacists. Our remuneration is very well known. Because it is the PBS and a large proportion of pharmacy income is on the PBS, pharmacy remuneration is something that the government knows about very well. So, if there were a huge impact on our colleagues, we would be putting a case for change in that remuneration base moving forward.

Thirdly, I have addressed the issue of savings, but we also want to stress that the molecules coming off patent are known. Like any organisation, the guild monitors that. We have a whole division. We have four health economists at the guild. We are very proud of the fact that we are not just on the sidelines. We are a signatory to the guild-government agreement, which is a $30 billion agreement—that responsibility is the sort of stuff that keeps me awake at night. We are very cognisant of that. My colleagues such as Michael do monitor when drugs are going to come off patent for our forward estimates and assist in scoping these measures. We are very confident moving forward right up to 2012 or 2013, when the No. 1 drug on the PBS, Lipitor, comes off patent, that these measures that we have put in place to ensure transparency of pharmacy remuneration will allow the government to get fairer prices on generic medicines.

We also want to stress and put on the record, though it has not come up today, that the guild was always opposed to tendering. At the patient interface in countries overseas that have tendering arrangements—and obviously the guild liaises with colleagues—all you find is that only one manufacturer is left making that drug. For example, yesterday afternoon I checked in

my own pharmacy and there were 23 items that were short. Some of those could be from a manufacturer's shortage, some could be a wholesaler nationwide and some could be the Brisbane based wholesaler that I deal with.

What happens when you have tendering is that you find that consumers are out of medicines for months on end because there is only one manufacturer. Whoever is the replacement needs to bring that in. We want to put on the record that tendering would have been extremely dangerous. That is why we support the fact that that has disappeared. Obviously, we have heard a lot of discussion today about the differences of opinion, as seen in the submissions, between Medicines Australia and the GMIA. But I think it is important to put on the record that tendering in itself would have just seen an enormous influx of drugs from countries such as India and China.

As a pharmacist, my number one issue is to give consumers confidence in what they are taking. As soon as they have confidence you at least have concordance, which means they keep taking their chronic medicines regularly. That is one of the key principles about quality use of medicines—making sure that consumers keep taking them. Affordability and other issues are important, but one of the major drivers is making sure that they are confident that what they are taking is not going to do them any harm.

I guess it is quite open now that pharmacists' remuneration is very transparent under these new arrangements. This is something that the guild fought very hard for. You would be aware now that it is well documented that generic uptake in Australia is extremely low. It is one of the lowest in the world. If there were some notion that pharmacists were making windfall gains from generics, one would question why generic substitution wasn't the highest in the world. So the guild is extremely angered over the enormous amount of press talk about notions such as secret discounts and so forth when, under normal trading terms, generic substitution in Australia is extremely low. Obviously, one of the things we need to address moving forward is how we get generic substitution higher because of the affordability of the PBS in that regard.

There are a number of key issues. Certainty is one issue that we want to stress—giving certainty to the industry. Over the last five years I could name numerous measures where there has been tinkering to the PBS. At the end of the day I have tried to convince my colleagues—although it is a difficult package and I am sure that you are hearing feedback from pharmacists that they are not happy—and the guild has signed up to these measures because they are fundamentally large savings to the government and we are hoping that will allow the industry to move on with confidence.

There are three additional items that are not in your papers. The first is the remuneration and the restructuring of the Pharmacy Guild. We fought very hard to use that as a way to innovate in the Pharmacy Guild. One of those was with reference to PBS online. This is an important measure because it monitors, for example, people's true entitlements to medication records. We are very proud of the fact that, fewer than six months ago, only 200 pharmacies were on it. As of yesterday, we now have 4,700 of the 4,950 pharmacies signed up or using PBS online. Over 3,750 pharmacies are using PBS online today. That delivers further savings, perhaps, from people who are either unaware that their entitlement is no longer active or are deliberately using an old entitlement to get PBS benefits. That has been one of the success

stories from us already. Theoretically, the legislation has not gone through yet. The Pharmacy Guild has delivered on a major reform measure that the government was after.

Secondly, we will be monitoring the impact on consumers. The guild does monitor prices. We take that role very seriously. One of the things that I can report to the committee in terms of affordability and the downturn—the downturn in the PBS has been mentioned previously—is that we monitor, for example, affluent areas versus lower socioeconomic areas to see whether the script volume has remained high in affluent areas or if there has been an across-the-board downturn in the PBS. We do not have any tangible evidence from a pharmacist point of view—and obviously we have the benefit of guild monitoring of particular pharmacies in particular suburbs and particular locations. There is no evidence at all that affordability is an issue. Otherwise, it is affordability across Australia—it is certainly not a geographic or socioeconomic issue currently.

Finally, there has been a lot of discussion about consumers. As a pharmacist in the field, I can tell you that there is still an enormous amount of confusion. The guild does support an advertising program. The difference is that we would like to see it focused on getting consumers to speak to their pharmacists. At the end of the day, the decision point where a consumer decides whether to take a generic medicine is when they go to the pharmacy. It is no good advising them about this process because, at the end of the day, it is the pharmacist—that trusted health professional—that they are going to ask, 'Is this the same medicine or should I be sticking to what I am currently on?' Out of the money that has been allocated—the $20 million; it should be a focused campaign—we would certainly be encouraging that we ask our patients and consumers to be demanding of their pharmacists information in this regard. Sometimes the pharmacist just takes as is what is on the prescription. We do understand that, in terms of health policy, that assists the government in their measures in terms of raising awareness about generic medicines. I have spoken extremely quickly to try and leave plenty of time for questions. I do not know if my colleague Michael has any questions. We would certainly be happy to answer any of your concerns.

CHAIR—Do you have anything to add, Dr Tatchell?

Dr Tatchell—I have nothing to add.

CHAIR—We are short of time so that is convenient, thank you. You say that you estimate there are more than 400 PBS listed medicines which are likely to drop in price in the hands of the consumers. These are mainly generic drugs, I assume?

Mr Sclavos—There are two lots of price drops. There is a shaving of two per cent over three years for two types of generic medicines. The largest savings will occur on 1 August 2008, when there is the 25 per cent drop. That is where I have detailed, for example, the $4.65 right through, but there are across-the-board savings, because obviously a 25 per cent drop is a significant drop in the cost of a medication.

CHAIR—I come back to that statement you made about how we have the lowest take-up of generics in the world. Presumably these price reductions are going to occur most often in the case of generic drugs. That being the case, presumably the take-up of generics in Australia will increase. Is that a fair assumption?

Mr Sclavos—I can clarify this. There is some confusion in that when the price is coming off by 25 per cent off it affects the original off-patent medicine. Amoxil is the easiest example. Amoxil is the originator company and that has got an additional charge of $1 on it. So that also gets a 25 per cent cut. So even though it has come off patent, we call that the originator. That comes down as well. In essence, even though there is benefit in people using generic medicines, it is across the board. If somebody is on that molecule or on an off-patent medicine, the whole—whether it is a generic or it is the original branded company—come down in price. That is something on which there is some confusion from the consumer lectures that I give.

CHAIR—Of the 400 or so drugs that you believe will fall in price, how many of those drugs fall within, say, the top 100 drugs prescribed to Australians?

Mr Sclavos—In the top 100 drugs you will hear names such as those of certain heart medications, of which some are in fact above the $30.70 so they are really still subsidised by the government or below the threshold. As we are approaching winter, and I know from reports from my pharmacy that winter has hit in Brisbane, at this time of year nearly every antibiotic is certainly under that threshold, so there is immediate benefit for families. We are talking a lot about affordability where one child is sick or two children are sick and perhaps one child is taking capsules or tablets or using chewable tablets and the other one is having the syrup. There are across-the-board savings on those medications. In everyday items under the chronic therapies, as with that $30.70, there is that marginal area where the low dose—the lower strengths—of medication certainly will drop significantly in price, so there is benefit right across the board.

CHAIR—So the average consumer will notice these changes?

Mr Sclavos—Absolutely. We would be extremely surprised if they did not notice. As pharmacists, probably more than any other health professionals, one thing we understand is that a dollar on a medication is something that impacts because if it is on two or three medicines and the person takes those monthly, that is 12 times three. All those things add up for a family budget. So pharmacists are extremely sensitive to the need to be informing patients, but obviously in the past there has been stigma. That is why we are saying any campaign certainly needs to address the interface which is the patient with the pharmacist.

CHAIR—One of the previous witnesses asked the question: can we be sure that the savings made by this system will be passed on? I think this is more a reference to the savings to government than the savings in the hands of the consumers. I assume that the Pharmacy Guild's position would be that the savings made in this system should be quarantined or hypothecated towards paying for the cost of new drugs that may be more expensive. This is in relation to the PBS.

Mr Sclavos—As our minister always reminds us, it is an open system, so there is no capping. If there is a new drug and the PBAC thinks an item should be listed, there is a recommendation made. It is very dangerous in talking about making sure that some money is quarantined to go then into newer, innovative drugs, because by default that means that we are going to cap the current system. That would be extremely dangerous, because we just do not know what innovation is around the corner.

I have lost a child to leukaemia. The last thing I am ever going to say to a consumer is: 'Your child's medicine'—or 'your medicine'—'shouldn't be on the PBS.' If there is a case from a cost-benefit point of view and it has passed the PBAC that a medicine should be listed, then the Pharmacy Guild's position is that we should make room for it. I guess the frustrating thing as a pharmacist and as a custodian of the PBS is that people don't see PBS as an investment. If we go back to the sixties, people with epilepsy, for example, not only were not contributing by working and then paying taxes; they were a burden because they had to be under care. Now one in 50 Australians—one person out of the people in this room—is an epileptic. They are contributing to society. It is PBS medicines that do that. So the case for medicines being seen as some burden on our society is extremely frustrating as a health professional, as a pharmacist.

CHAIR—In one of the earlier submissions, a background comment was, 'The Pharmacy Guild is actually very angry that it was not consulted in advance about these PBS changes before signing its new contract with the government.' Have you got a comment to make on that?

Mr Sclavos—There were earlier discussions. The previous speaker spoke about early working groups that were meeting. The guild was not in those working groups and I guess that is frustrating, because with anything to do with medication, we are the link to the patient. So, in the early days, we weren't involved—and still aren't involved—in any of those working groups. We are not happy with everything in this legislation, but the guild has a reputation for compromising and working through the issues and I guess we always have the comfort of knowing that the role of Pharmacy Guild is important. We spoke earlier about rural pharmacies and the impact. As president of the guild, my role is to make sure that the network of pharmacies remains. It is the only commodity—people forget. I will go back a step.

There is the original price that a medicine goes on the PBS, and there is no indexation. It is not like your groceries that go up and up and up and that are certainly going higher, by the duopoly, than they should be based on the costs. So the original price is there. The price can actually go down under the referencing system. The community pharmacy is therefore impacted. One of the things that we are proud of is that, out of our remuneration, we make sure that rural pharmacies are looked after. It does not happen in other professions. My colleague from the AMA spoke earlier; but our pool of money is fixed. In essence, the government, to be honest, would probably say, 'We don't care how you use those funds. That's your pool of funds.' So we use those funds to make sure that the network of pharmacy remains viable and strong for rural and regional Australia.

We are the only health profession that has increased services in the bush in the last 10 years. We do not see ads about enticements of half a million dollars to get a pharmacist to a rural town like we saw this week about a GP. The Pharmacy Guild takes its role in terms of equity of access. Because those pharmacists are looked after in regional and rural Australia, the $4.90 to a pensioner in Broken Hill, Broome or Burnie is the same price across Australia. It does not happen in any other commodity. That is something that the Pharmacy Guild is proud that we have maintained in these reform measures.

CHAIR—Thank you. Questions, Senator Moore?

Senator MOORE—There are only a couple, because your submission and your evidence has touched on the threshold issues. Do the workload and work processes of a pharmacist change at all with this legislation?

Mr Sclavos—Every time there is a legislation change obviously the role of the pharmacist is to explain those measures. Again, because of the issue of confidence, we have already moved to inform our members. We have 70,000 pharmacists and pharmacy assistants in pharmacies. One of the reasons we are keen to get the legislation through is that we are ready to roll out information to our members. Theoretically, because it has not passed the Senate yet we don't know whether it is going to go through yet. From our own resources we have kits and we explain the measures to pharmacists. At the end of the day, it is the consumer who may hear something on the radio or see a price drop or see some impact and it is the pharmacist they go to for those questions.

Senator MOORE—You do trace that; there is that extra workload when there is a change?

Mr Sclavos—Certainly. Every time there is a legislation change, there is an enormous amount of work for a pharmacist to explain the new measures. Even on 1 January, every time there is indexation of the prices or the thresholds, there is an enormous amount of work for a pharmacist to explain that. But that is our role. We are not upset about that role. That is one of our key roles in the healthcare team.

Senator MOORE—I know that you have spoken about the role that the guild has put into the discussion with the government and the agreements and so on, but I would not mind having something on record, from your point of view, as to why there is bad press about pharmacists gaining. I refer to the comments that have been made that the winners out of this legislation are going to be pharmacists. You would have seen that, so I am interested, for the record, in your response to that.

Mr Sclavos—Obviously the person who takes the money off the patient in the end is the pharmacist, so there is a lot of misunderstanding. My brother is a doctor and he does not understand that, of those additional surcharges, charges or premiums that we are talking about—so in that Amoxil example, that extra dollar—not one cent of that goes to the pharmacist. We pay the extra dollar for the item. So there are no profits—there is no incentive for a pharmacist, for example, to give a patient a more expensive product if I could explain it that way. But it is something that we understand because pharmacists are the people who charge a consumer for medicines. In the same way, when there are price indexations or co-payment increases, it is the pharmacists who are blamed. At the end of the day, my colleagues hopefully explain those measures.

Senator MOORE—You may have heard me ask the AMA the question about the information that seemed to be around that the reluctance of consumers to access generic drugs was because the doctors were not ticking the box. We talked about that ages ago. In terms of the role of the pharmacist, with your membership is there any particular process in place to encourage generic usage? I know that under this legislation there is that offset of a payment per prescription to go to encourage the pharmacists. But generally is there any particular guideline or directive that goes out through your organisation about generics versus brands?

Mr Sclavos—The quality assurance program for pharmacy is called the Quality Care Pharmacy Guild Program. That has a specific standard on generic substitution which is about informing patients. The difficulty is that some patients say, 'I'll take whatever the doctor wrote.' For some other patients, there is a misunderstanding about the medication. Perhaps they have seen stories about underdosing in some of the Indian companies. There was a story on SBS, say four months ago, and in the following three days I received over 100 calls from consumers saying, 'I just want to check if this medicine is one of those ones from India.' It is an issue that that pharmacists face every day. It is that confidence issue that I was referring to earlier. That is why, again, we want to have a strong manufacturing base here in Australia. To be honest, the guild does not care whether it is GMIA members or Medicines Australia, but we think a strong manufacturing base is important. In Queensland where we were talking earlier about Alphapharm, it was always easier to say, 'Of these medicines, that is a generic, that is made down the road—

Senator MOORE—Made in Queensland.

Mr Sclavos—And as you would know from being in Queensland, that was an easy case. It is difficult because there are stigmas or perceptions about generics. There is confusion in that they think of generics as in the home brands. With more dramas about home brands now with tinned food, how Woolworths and Coles get those from overseas countries and so forth, it is only adding further confusion to generic medicines in my opinion.

Senator ALLISON—Are your members financially worse off as a result of this legislation?

Mr Sclavos—There is an impact. Obviously because it is an averaging remuneration, naturally then 50 per cent of pharmacists will be worse off. The whole idea of the compensation package is that we have taken a broad-brush approach and depending on where the pharmacist is, perhaps if they had higher generic substitution, they would be more disadvantaged. As I have alluded to earlier, we have a five-year agreement with the government. We will be putting a case to government if the remuneration puts at risk our network of pharmacies. But by default, because if you are compensating on an average, then 50 per cent of people are above the average and 50 per cent are below. There are going to be some pharmacists who are slightly disadvantaged.

Senator ALLISON—I apologise, I have not seen your submission, but does it outline that compensation package?

Mr Sclavos—No, that is in the legislation, but in essence the key—

Senator ALLISON—Sorry, what is in the legislation?

Mr Sclavos—The legislation details the new remuneration structure for pharmacy. We did not see a need to explain it further. In essence, the key issue is that there is a change in the dispensing fee. The big one is the $1.50 incentive which has come up. But the $1.50 incentive for substitution is not on safety net items, otherwise theoretically then the consumers would have been paying $1.50 more for each item.

Senator ALLISON—So it is just the $1.50, and there is nothing else that is part of a compensation package?

Mr Sclavos—There is a change in the dispensing fee, which was the balancing item, but there are slight changes in the mark-ups. For example, take these new items that I alluded to. For example, with herceptin it is $1,030.80 for the one-unit phial. Currently, the remuneration for that is $40. That will go to four per cent—actually, it will go to $70, I think. So there is a slight increase in some of the higher cost items just due to the cost as a lot of those are specialised medications.

Dr Tatchell—There is also an incentive for pharmacists to move to PBS online as well. That is included in the package.

Mr Sclavos—That is a 40c incentive for pharmacists. That is important because there are direct benefits immediately, from a government savings point of view, because people are presenting cards but perhaps they went back to work last week and they should not be entitled to the card.

Senator ALLISON—You are saying these measures—the $1.50 and the $1.70, I think you said—will replace the previous discounting arrangements that were common between pharmacies and suppliers, is that correct?

Mr Sclavos—Yes. Can I stress, however, that pharmacists did not have any role in the PBAC as to the setting of the prizes. In essence, we were the innocent parties in that, a generic firm, to gain market share over another firm, was giving trading terms to pharmacists. What we have put in place is not only this compensation package but a transparent arrangement where the manufacturers have to declare those trading terms to the government. So pharmacy remuneration will be an open book, and we thought it was very important for the good name of pharmacists that that occur. There are no sorts of secret trading terms or discounts that pharmacists will get. This is one of the reasons why we signed up to the reform measures.

Senator ADAMS—I have a practical question—and obviously you work in your pharmacy. When people come in with prescriptions that are not for generics, how do you actually work it as to giving them the option? Do you speak to the clients, or do your staff deal with them?

Mr Sclavos—Each pharmacy is different. Most pharmacies have a script-in form. That script-in form will record the Medicare number, for example. It will ask the patient if they want a generic medicine if it applies. Sometimes if it is an originated product and it is not off patent, then there is no generic that they can take. If it is for a child, we record the date of birth and the weight of the child et cetera. So there is a standard script-in process that records on every occasion whether someone wants a generic medicine.

Senator ADAMS—But what of the actual interface between? Say you have an elderly person coming in with a prescription. Who actually speaks to them and helps them, especially in a pharmacy when everybody is busy. How do you do it?

Mr Sclavos—Mine is a busy pharmacy, but we have three pharmacists so we always have a pharmacist at the script-in counter so the pharmacist takes that. But every pharmacy is different. In some pharmacies it may be the dispensary assistant, a trained pharmacy assistant who has done a number of years of training. They are trained individuals who ask these questions and accept the prescription from a consumer.

Senator ADAMS—I come from what is probably a one doctor and a one pharmacy town. I am trying to get down to the real basics of it, because they are so busy that I don't know that people are actually offered a generic. I think if they are really flat out it just does not happen.

Mr Sclavos—To give you an idea, in my pharmacy we have patients who demand whatever the doctor has written. That would be recorded then on a patient's profile. As for a lot of patients, especially in a one pharmacy town, the pharmacist would know that about someone, even though they may not be asked. There is the original time when somebody is recorded on the system as to whether the patient prefers a generic medicine or does not prefer a generic medicine. It is a very systemised process. It is normally asked. As I said, pensioners know that items are $4.90 now. If you go back to the counter and say, '$7.60,' people ask very quickly. That is the thing that I find strange. Every patient I deal with knows what medicines they are. Whether it is a young woman asking for the contraceptive pill or a senior citizen with four or five medicines, all of them know the price of their chronic medicines. It is something that is well-known.

Senator ADAMS—So do you speak to the GPs and suggest that rather than prescribing the higher cost drug that they actually go with the generic? Is there any interface like that?

Mr Sclavos—No. We just do whatever the doctors say. We should not underestimate that in local areas, the local pharmacist quickly finds out whether the doctor supports generics or not. That is why I do not need to worry about whether something is ticked or not. The patient will be saying, 'No, the doctor has told me to stick to this.' You do not have to worry about the tick. Notions of tracking how many things are ticked are silly. Every pharmacy I have worked at, you quickly know from the information the patients are conveying to you whether the doctor is supporting generics or not.

CHAIR—Thank you very much Mr Sclavos and Dr Tatchell for your evidence today. It has been very useful.

Proceedings suspended from 10.50 am to 11.02 am

Ford, Ms Di, Executive Director, Generic Medicines Industry Association

Kim, Ms Jo, Member, Generic Medicines Industry Association

Pearce, Dr Gregory Alan, Member, Generic Medicines Industry Association

Ronai, Ms Robyn Michele, Member, Generic Medicines Industry Association

Smith, Mr Patrick James Peter, Member, Generic Medicines Industry Association

CHAIR—I welcome members of the Generic Medicines Industry Association. Do you all work for different companies?

Ms Ford—I am the executive director of the GMiA. All of the other witnesses work for different companies that are members of the GMiA. They are all here today to represent the GMiA.

CHAIR—Would you each name the company you work for.

Ms Kim—I work for Alphapharm, which is a member of the GMiA.

Mr Smith—I work for Generex, which is a member of the GMiA.

Dr Pearce—I also work for Alphapharm.

Ms Ronai—I also work for Alphapharm.

CHAIR—I invite you to make an opening statement before we ask you questions.

Ms Ford—The GMiA thanks the Senate for the opportunity to outline our sector's concerns about this bill. GMiA represents the manufacturers of prescription generic medicines listed on the PBS. Generic medicines are alternative brands to the originators'. They trigger price reductions on the PBS. They are not originators' brands whose patents have expired. GMiA strongly supports the PBS, which delivers equitable access to affordable life saving medications at a cost that the community, the taxpayer and the individual can afford.

Since the commencement of the legislation allowing generic substitution at the pharmacy level in 1995, generic medicines have saved the PBS more than $2.8 billion by reducing the benchmark price of medicines. The government's stated purpose for this bill is to establish pricing structures that will enable the government to achieve greater savings in the price it pays for medicines into the future. GMiA supports this principle but is concerned that the proposed bill does not actually meet these objectives. It is contradictory and it undermines the fundamentals of the PBS and, therefore, it is flawed.

In the short time available today, my colleagues and I will highlight key points from our submission. With regard to the fundamental impact on the PBS, the basis of the PBS is to provide universal, subsidised access to medicines to the Australian community. Medicines are provided to consumers to improve their health and, therefore, the value of a medicine to our society is determined by the health benefit it provides to a person taking it. Reference pricing is a system for comparing measured health outcomes and it is a mechanism by which the government determines how much it pays for a medicine. Reference pricing ensures that the government never pays more than is warranted by the health outcome a medicine provides.

Apart from savings to the PBS to date from generic substitution and reference pricing, further savings in the order of $8 billion during the next four years would be possible under the existing reference pricing system—and we have provided to you data from the work Econtech did for us two years ago. However, this bill dismantles reference pricing as we know it and may deliver savings of only half a billion dollars over the same period. Sadly, by eliminating the ongoing price link between patented medicines and medicines that produce the health outcome but are no longer patent protected, Australian taxpayers will be paying higher prices for essentially the same health outcomes. I will ask Mr Pearce to fully explain the point on health outcomes.

Dr Pearce—For the past 14 years, since there was a change in the National Health Act to introduce consideration of cost and effectiveness, Australia has essentially had a reference price system. That means that, for a new drug, you have to compare the health benefits gained from that drug and the health benefits gained from an existing drug on the PBS. The system operates by rewarding improvements in health outcomes by price premiums above existing products. The alternative is that if you show that your health benefit is essentially similar to that of an existing product then you cannot justify a price premium. One of the concerns we have is that the development of the two formularies—formulary 1 and formulary 2—breaks the nexus we have at the moment, and that shifts the reward for innovation from improvements in health outcomes to enhancements in molecular structures or physical changes. Essentially, that is one of our concerns about the two formulary systems.

Ms Ford—The bill undermines reference pricing, yet it is inconsistent in the case of combination products. These are not included in the formularies, and reference pricing is appropriately preserved. In the combination products we still have reference pricing, and we think that is how it should be. This is an unequivocal inconsistency and we urge the committee to recommend the reinstatement of reference pricing across and between all formularies.

I will now move to evergreening. Evergreening is the practice of unfairly extending the patent life of medicines through process or formulation patents to insulate them from generic competition. This delays generic entry to the market. Generic entry to the market on patent expiry is the single most effective brake on PBS expenditure. The creation of the formularies and the delinking of pricing between the two formularies will encourage evergreening. This will, paradoxically, increase PBS costs and make a mockery of Australia's robust intellectual property regime. GMiA supports a strong intellectual property regime. However, we need to differentiate between patentable innovation and health outcomes because, to date, the PBS has purchased on the basis of health outcomes and this is now under threat. Do you have any more to add to that, Greg?

Dr Pearce—You can debate whether it is right or wrong, but for 14 years the PBS has valued health outcomes above all else. With this bill we are saying, 'Let's look at protecting molecules that have patents,' and rewarding that innovation rather than rewarding health outcomes innovation. That is the dichotomy we have at the moment with this bill. We are moving away from purely rewarding improvements in health outcomes, through price premiums, to rewarding the patentability of a molecule through higher prices. I am not debating whether that is right or wrong, but that is the way it is going to be. For 14 years we

have operated on a process that has rewarded improvements in health outcomes. We are now considering rewarding improvements in health outcomes and also the patentability of follow-on compounds. To me, that may erode the efficiency of the system as it stands at the moment.

Ms Ford—So to ensure that the PBS pays only for health outcomes and not for frivolous patent extensions, we again urge the committee to recommend the reinstatement of reference pricing across and between all formularies.

I will now move to the uncertainty for industry. This is an important point for a lot of us, not just the generics. In order to be able to plan ahead for the significant magnitude of the proposed mandatory reductions, the industry needs to have some certainty about the starting point for some of these changes. In projecting the savings forecasts for this program, the government used the schedule of pharmaceutical benefits current as at 1 December 2006. We urge the committee, to recommend that the same schedule be used as the starting price for statutory price reduction calculations. Also, this bill is silent on the details of how price disclosure will operate. The industry's concern about the procedural aspects of disclosure is driven by the lack of transparency in the methodology and processes being proposed. We have already outlined this to the Department of Health and Ageing in the consultations we have had with them. This uncertainty will be very damaging for the local generic medicines industry, which guarantees Australians a reliable local supply of affordable prescription generic pharmaceuticals and an ongoing source of PBS price containment. I repeat the word 'local' there because, as was raised earlier in comments by the Pharmacy Guild, 80 per cent of generics dispensed in Australia are manufactured in Australia. That is what will be put under threat.

While the details of how the disclosure policy will actually be implemented are not included in the bill and, therefore, are not strictly a matter for this inquiry, we nevertheless urge the committee to seek assurances from the Minister for Health and Ageing that industry's concerns are addressed properly prior to the commencement of the legislation.

On the question of appeals, GMiA has obtained legal advice, which it has made available to the committee, which raises concerns about the lack of an appeals process under the new arrangements. What will be different under this bill is that many of the major parameters of the PBS will be set by ministerial determination and, as such, will be a reviewable by the courts and tribunals. We would like the committee to recommend that an appeals process be included in the bill.

I will now move to the impact on consumers—and consumers, not our companies, are the reason why we have the PBS in the first place. True PBS savings, under the new legislation, will not flow in total onto consumers. The savings from this bill are unlikely to be lasting. Our calculations show that consumers may only benefit to the tune of between four and 17 per cent whereas the government will reap a minimum of 25 per cent. Whilst the bill requires that premiums be reduced at the same time and by the same percentage as a mandatory price reduction, an originator company is able to increase its premium by that same amount, or even more, four months after the event or even prior to the event.

The point to remember when we are talking about the impact on consumers is that 83 per cent of consumers will not see any change because they are concession card holders. It will

affect that 17 per cent of people on the general list who access the health system. As we know from other research, many of them are from lower socioeconomic backgrounds. So the people who are at risk are those low-income working families—and I am sure you all have plenty of those in your states and territories. To ensure that consumers are not disadvantaged by these changing prices, we urge the committee to recommend an incentive for consumers to choose generics—such as a discounted co-payment, which has been mentioned earlier today—and at the same time become active partners with government and industry in sustaining the PBS.

We also suggest that the $1.50 payment going to pharmacies is going to benchmark price products, which is generics. They can be off-patent originators who, as I said earlier, do not trigger price reductions on the PBS. So we think that that $1.50 actually should be paid when a pharmacist dispenses a true generic—or a genuine generic, as one of the earlier speakers said this morning.

We welcome the government's initiative to undertake a generic medicines awareness campaign as an important for step in informing consumers about the choices available to them. We strongly support the government's aims for that campaign.

In summary, GMIA's position is this: (1) sustainability of the PBS is paramount; (2) reference pricing should be retained in the current format; (3) evergreening should not be encouraged; (4) uncertainty for industry should be reduced; (5) concerns surrounding disclosure should be addressed prior to the bill's implementation; (6) an appeals process should be included in the bill; and (7) an incentive for consumers to choose generics should be included in the bill. Thank you. My colleagues and I are now happy to answer your questions.

CHAIR—Thank you very much for your opening statement.

Senator POLLEY—Thank you for your evidence and your submission. In your opening statement you touched on the effect that it is going to have on low-income families in our community. Could you elaborate on that a little further and explain to us how you perceive the impact will be on pensioners and whether there are other groups within our community that are going to be disadvantaged with this legislation?

Ms Ford—Pensioners should be okay, because they are concession card holders. I do not know of any products—there may be a couple—that do not ever drop below that pensioner copayment level. So, if the pharmacist dispenses a generic, they will see no change, as is the case now. Unfortunately, according to the numbers stated earlier by Ken Harvey, there are a large number of people out there who are unwittingly paying brand price premiums. If they get the generic, they will not be affected. It is those people using those products that fall below the general copayment level where the concern lies. Although it is expected that those prices will fall, there is no guarantee or no audit process from government to monitor that.

We know that pharmacy mark-ups are going up for most of those products—from 10 per cent to 15 per cent. So there is a built-in increase to start with. One would hope that the pharmacist would not load up the price, but there are plenty of examples they do. When we have gone into get our own scripts sometimes—it is amazing; it comes to something like $29.90. There are instances. There is no control over these prices. They are not supposed to go above the copayment level, but there is anecdotal evidence that they can do.

CHAIR—Can you explain how this legislation makes that more likely to happen?

Ms Ford—Because the mandatory price increases are going to put a lot more products down below the general copayment level. It has always been an issue, but there is going to be a hell of a lot more products that are falling below that general copayment level as result of these mandatory price reductions starting in August next year.

CHAIR—Thank you.

Senator CAROL BROWN—You touched on evergreening in your submission and also there is some evidence given earlier today. Can you elaborate on how you believe this legislation will encourage evergreening and also how, if there is a rise in evergreening patents, how they will affect PBS growth?

Dr Pearce—It is my understanding that the majority of medicine on F1 are medicines that have a current patent. Patentability has nothing to do with improved health outcomes. Dr Harvey gave a nice illustration with citalopram and escitalopram. Escitalopram has a patent, citalopram does not. Escitalopram and citalopram, under the government's own therapeutic relativity statement, are equivalent. Ten milligrams of escitalopram is equal to 20 milligrams of citalopram. There is no differentiation in the health outcomes that they deliver, therefore the price offered is the same. If you restrict one to F1 and the other to F2, the F1 product will not be exposed to any competition or price reduction on generic entry. Most companies have a series of compounds in similar therapeutic categories that have changes in their chemical characteristics, their physical characteristics, that allow them to patent those products. In some cases they provide an improved health outcome, in other cases they do not. So just because they are patented does not mean that they deliver innovation.

At the moment we have this double system, where patentability is judged on innovation to a molecule structure and the PBS judges innovation by the delivery of improved health outcomes. So there is this dichotomy. It does not necessarily mean that they are interconnected. You can have a patented drug that delivers large improvements in health outcomes, and some of the newer medicines that have been approved recently demonstrate that. At other times you can have a third or fourth compound coming into a new class, like an ACE inhibitor, that delivers exactly the same health outcome and therefore should be priced exactly the same as the existing products. That is where you are losing a bit of traction and leverage within the current system to exert price changes and it allows the opportunity for companies to bring in compounds that are patented but not necessarily innovative in the sense of improving health outcomes.

Ms Ford—Because the F1s are not going to be subjected to mandatory price reductions, companies have been, and increasingly will be, bringing in other patents to cocoon that original molecule. They cocoon it by a series of other patents so that it is protected. They hope that will make it difficult for the generic to plot its way through those cocooning patents to get to the molecule patent and then bring out the bio-equivalent of that molecule. So there will be all these road blocks along the way, called patents, on processes or formulations or whatever it is to protect that molecule, because we can only do a bio-equivalent study against that molecule.

Senator MOORE—Which they are already doing.

Ms Ford—Its patent is expired but it is protected by all these others.

Ms Ronai—The establishment of the two formularies provides an incentive for companies to keep a drug for as long as possible in the F1 formulary. That is evergreening.

Senator CAROL BROWN—Has the association produced any work about what the effect on PBS growth may be?

Ms Kim—Yes, it is highlighted in our paper by Econtech. Looking at all the patent expiries until 2010, if you keep the current reference pricing system across and between F1 and F2 formularies you potentially have an $8 billion saving, and that is through other tools like WAMTC and the TGP. The proposed legislation breaks that link—there is no link going forward between F1 and F2. There is also talk of breaking links between patented products and unpatented products that are in a therapeutic group within F2T. If that were to happen you would get half a billion in savings in that same time period. So you are comparing $8 billion to half a billion on the same patent expiry. That is based on current sales and market dynamics. That paper has been provided for you.

Ms Ford—We have not done any calculations on what evergreening would do because my members spend their time trying to find a way through and a lot of them finish up in court, as we know. They hope that they will find their way through but it is becoming increasingly difficult. Australia is behind the rest of the world with this current avalanche of patent expiries because in 1998 the government allowed patents to be extended by up to five years. So there was a drought of patent expiries from 2000 to 2005 and we have only just started to see patent expiries come into play again now. There has not been a lot of evergreening apparent out there in the market because the patents have been protected by extended patent entitlements. That is starting to happen now and you will see it happening in the future, but there are some very good examples already out there of products—

Ms Kim—You have citalopram and escitalopram. You have emeprazole and Nexium, which is the isomer of that. You have perindopril—that was changed. So there are examples in the industry which you could pull out. We have not done that for today.

Ms Ford—The perindopril one did not work because that was managed by the TGA, but there was a direct attempt by the company involved, which had originally patented perindopril, to evergreen that product. I think aspects of that are still in court.

Senator BOYCE—You spoke about some of the difficulties of getting generics into the market, but we heard evidence earlier today that Australia has one of the lowest rates for the dispensing of generics. Would you care to talk about what you perceive to be the issues there?

Ms Ford—There is no price signal for generics for consumers in Australia as there is in other parts of the world. Doctors do leave scripts open—97 per cent of scripts are left open—but the same amount is not being dispensed as generics because there is no price signal to consumers. It is the biggest wrong.

Dr Pearce—At the moment the price signal and the price benefit go to the government and the pharmacists in general. You pay your copayment regardless of whether or not you get a generic.

CHAIR—Can't the industry send those price signals? You do not have to charge at that level; you could charge below.

Ms Ford—It has nothing to do with the consumer. Our relationship is with the government, not with the consumer.

Dr Pearce—The government is buying it?

Ms Kim—Yes, the price is set by the government.

Senator MOORE—You do not sell direct to people; you sell to the government?

Ms Ford—No-one sells direct to people; everyone sells to the government.

Senator MOORE—So you cannot control the cost?

Ms Kim—No, and you cannot advertise prices for pharmaceuticals to consumers in Australia.

Senator MOORE—Do you think the education campaign that you talked about would help—and I am sure Senator Boyce would be interested as it seems to follow?

Ms Kim—Yes, I think so.

Ms Ford—It certainly would help people have a better understanding of the bioequivalence issue.

Ms Ronai—The equivalence of generic medicines.

Senator BOYCE—Have you done any modelling on the anticipated effect of that advertising?

Ms Ford—No.

Ms Kim—It is too early at this stage. But there is a committee so all the stakeholders' views will be taken into consideration. A working group is looking into that campaign.

Ms Ford—It is a rather immature market here in Australia and patent extension has delayed those patents expiring. In other parts of the world that has been happening sooner. But other parts of the world have specific generic policies. In the States all the insurance companies say that if there is a generic available it must be dispensed over and above any other. That is what the insurance companies in the States will say. In the UK they have fund holding for doctors and they have generic prescribing. Consumers in the UK will go in and ask, 'Can I have my simvastatin?' Here they will go and say, 'Can I have Zocor or Zimstat?' They will not call it simvastatin, which is its name.

We have put forward, through TGA working groups, that one of the problems is the packaging requirements. We say that the guidelines are now there but, unfortunately, they are not being generated into legislation as far as the proposed changes that are coming in with the Australia New Zealand Therapeutic Products Authority. The TGA guidelines say that the active name should be as prominent as the brand name. People should know what medicine they are taking. Brand is not what they are taking, and Dr Harvey talked about that. Your body does not know what the brand is. That is a very good point. Consumers should know what medicine they take rather than what brand they take.

We think all those things would go towards the uptake of generics. Remember, the generics are the sustainers of the PBS. We are the ones who bring in price reductions; it is not the off-patent originators. If the generics do not come on board, the price stays where it is. Under these new arrangements the price will most likely stay where it was 15 years earlier when they first entered the market because there is no reference pricing for them.

Senator ALLISON—In putting forward this bill, the government argues that the reason for it is that generic medicines in Australia are a much higher cost to government than they are in other countries. They have provided us with some comparisons. What do you argue is the reason for the higher comparative cost in Australia?

Ms Ford—One of the reasons is a historical reason. There is no generic policy here in Australia. There is nothing to encourage competition between generic companies in Australia. There is nothing in there that creates that competitive edge that happens in other parts of the world. We have just done some work on this—we have yet to publish this; it is early work—and we have found that in some of the comparisons between the products in the UK and Australia the prices are 400 per cent higher in the UK than they are here. So you can pick and choose. You can cherry-pick your prices, and that is what happens. The prices that the department has obtained from websites around the world are the published prices; they are not the negotiated prices. That is an important point to make.

Senator ALLISON—Are you able to provide the committee with other comparisons? You say that the government has cherry-picked. Could you give us a full list of comparisons?

Ms Ford—We have done some initial work. We can see what we can come back to you with on that. A lot of these prices are commercial-in-confidence.

Ms Kim—Can I add one comment there. We are not aware of what data has been disclosed by the department.

Senator ALLISON—It is in their submission, so it is available.

Ms Kim—The price in Australia that is listed on the PBS is DPMQ. That includes the pharmacy mark-up and the dispensing fee et cetera. I think we will have to go back, compare those prices and come back to you with some examples.

Ms Ford—A very good example was when fluoxetine went off patent some years ago. That is Prozac. Its price fell very quickly, with generic competition, by about 30 per cent. Omeprazole was another one. The prices do come down when there is some competition. But, as I said, this patent extension has delayed a lot of the activity. The cost of doing business for a generic company in Australia is just the same as it is for an originator company. You have to pay the same wages. You have to pay the same price for your packaging, your printing and everything else. In actual fact, for a generic to get into the market is slightly dearer in Australia than it is for an originator because they have to challenge a patent in the courts to start with. An originator does not have to do that. Their initial cost up-front is their TGA registration fees.

Ms Kim—I think it is very dangerous to look at different countries in one segment of the PBS, because they have other drivers and other mechanisms which control their funding. In the UK you have doctors who are accountable to a budget. So there are certain different

drivers that play into the dynamics of the industry. In Australia you need to look at that the totality of what cost benefit it derives for the health outcomes rather than asking: 'Are we getting the right price?' How do we determine the price? That is set by PBAC. If they are saying that it is cost-effective then that is the benchmark for Australia, given due consideration to all of the other environments that are at play in our industry. There are some medicines where probably the cost of the drug that we would be charging would be a small fraction of the dispensing fee, the margins and all the other logistics costs that are added on to the market. So the final price is a mixed bag of different prices.

Senator ALLISON—I understand.

Dr Pearce—One of the things that has got lost a little bit for all the industry in Australia is the fact that we do have a National Medicines Policy. One of the arms of the National Medicines Policy is to encourage a responsible and viable industry—that is, industry in a broader sense, which includes innovative, generic and biotech. There used to be mechanisms whereby research, development and investment in Australia could be rewarded other than directly through the price determined by the cost-effectiveness consideration by the PBAC. That is something that is lost. It has always disturbed me that we have moved a little bit away from trying to encourage and foster a viable Australian industry—a broader industry than just big-farmer generics—as well as the burgeoning biotech industry in Australia. That is something that is not being incentivised at the moment through the PBS process. We are now having to rely much more on manipulation of the pricing arrangements, based purely on comparative cost-effectiveness and patentability, rather than on what level of investment the company has made in employing Australians, investing in Australia and conducting research in Australia. I would personally like to see some more of that factored into the way that we price all pharmaceuticals.

Senator ALLISON—I would like you to respond to another important point that the government has made in terms of justifying this legislation—that is, that higher prices for generic brands are caused by heavy discounting to pharmacies, that this whole process is less than transparent and that this bill would clean up that act, as it were. Could you respond to that?

Ms Ford—Our members give discounts because there is no generic policy in Australia. There was no policy once the government, back in 1995, made substitution allowable. That was really substitution on the government's side of it. It was to make it legal for the pharmacist to get money back from the government. The pharmacy boards in each state legalised the practice of it. It is not generic substitution as such; it is brand substitution. In those days the originating companies brought multiple brands of their own molecule onto the market to expand their market share, and generics came in on the back of that to Australia. Discounts were given after the 1995 change, when consumers were told that they then had a choice to ask their pharmacist whether they could have the less-expensive medicine, that they did not want to pay the brand price premium. They could ask, but there was nothing to compel the pharmacists to stock generics on their shelves. So generic companies incentivised their pharmacists to stock generics, so that they were there for consumers if they asked for them. Basically, that is how it happened. There was no policy. There was never a government requirement for a pharmacist to stock a generic.

Historically in Australia, doctors prescribe by brand. They write a brand on your script; they do not write the medicine name on your script. So the pharmacist stocks what his local doctor writes on the script, which historically was an originator product. So, if we were to make generics available for the consumer, something had to give. That is how generic companies came to these trading terms with pharmacists to stock generics: so that the consumer had access to less-expensive medicines. In the intervening 12 years, since the GMIA began—six years ago—we have lobbied hard for a specific generic policy. Unfortunately there is not one here yet.

Ms Kim—What we are presenting here today is the fact that the generics industry can save the PBS $8 million, but that is on the provision that the existing reference pricing, which is about health outcomes, remains. Senator, we noted your comment earlier to the Pharmacy Guild President that $1.50 is indeed designed to replace that discount. We agree with all of that part of the legislation. What we are seeking here is for the reference pricing system to remain in place, because the $2.8 billion in benefits that the generics industry has delivered over the last 10 years can actually be $8 million, not half a billion until 2010.

We are seeking clarity for consumers because there are no price signals for them. They need to embrace the PBS for themselves. They need some signals that make them active participants rather than being sideline observers. You have heard this morning from several speakers that none of the consumer groups or academics in the medicines access working group have been consulted. GMiA members have also been part of the PBS reform team, which has been meeting since January in year. On a number of occasions we have made requests to have access to information that has been discussed at this group, because obviously that impacts on some of our products as well. We have not even been given the chance to review the minutes. It is still being vetted by the department and the AMA.

Senator ALLISON—There is a new group to be set up, is there not, for consultation? You are presumably not on that either.

Ms Ford—That is what we are talking about.

Ms Kim—We are not aware of that.

CHAIR—Can I just ask you to clarify briefly: you say that instead of the half a billion dollars that this bill foreshadows saving—

Ms Kim—Up to 2010.

CHAIR—it is possible to save $8 billion.

Ms Kim—Yes.

CHAIR—And that is through retaining reference pricing?

Ms Kim—Yes, and all the tools that are currently in place now across and between the formularies.

Ms Ronai—The creation of the two formularies does not maximise the savings to government.

CHAIR—Can I just be clear about your position. Are you saying to the committee that you oppose the bill or that you support it only if it is amended as you suggest or that you support it whether it is amended or not?

Ms Ford—We do not support the bill in its current form.

CHAIR—So if it is not amended you would oppose the bill.

Ms Ford—We do not have a vote, so we cannot do much about that, unfortunately.

CHAIR—No, but your opinion is important.

Ms Ford—However, we do not support the bill in its current form. We believe it should be amended, along the lines we said, to retain reference pricing. If you fixed up some of those issues around the formularies, it would make it even less attractive to evergreen as well. We believe that consumers should be given the opportunity to buy into their own scheme, their PBS. It is not the guild's PBS; it is not the PBS of companies who are members of Medicines Australia. Nor is it my member companies' PBS. It is the consumers' PBS and they do not even get a tiddlywink in there. They are not there.

Senator ALLISON—Do you put a figure on the discount you are suggesting for generics in the co-payment? I just quickly looked through your submission and could not find it.

Ms Ford—No, we do not. I looked at it. If everyone switched in one fell swoop, it would probably be—based on PBPA figures—around $30 million a year. But of course that would not happen, because consumers—

Senator ALLISON—I am sorry; what would you reduce the co-payment by?

Ms Ford—I would reduce it by about 50c. It would be around the $30 million mark if everyone switched to a generic. That would not happen, because people still have the right to choose what they take.

CHAIR—We are going to have to leave it there. Thank you very much for the evidence you have provided today and for the submission that you have offered to the committee.

Ms Ford—Sorry, it is 50c we are suggesting.

[11.44 am]

HOPKINS, Ms Helen, Executive Director, Consumers Health Forum of Australia

CHAIR—Welcome. We have provided you with evidence on parliamentary privilege and the protection of witnesses and evidence. I think you have appeared in these settings before, so I am sure you know those rules. We have a submission from the Consumers Health Forum and we thank you for that. Would you like to make a short opening statement before we ask you some questions about that?

Ms Hopkins—The proposed PBS reforms currently being considered should help increase competition within the generic medicines market and lower the prices of these medicines. We are paying too much for generic medicines by international standards. There are moves to increase competition between generic medicine manufacturers, recognising that they may also be manufacturers of innovative medicines, and provide more choices and lower prices for consumers. This comes up time and again in our consultation with consumer networks—they want to ensure that the PBS can continue to provide access to affordable new medicines over the longer term, recognising that there needs to be that trade-off in price over time with older medicines. We believe that the proposed reforms can go some way towards helping to achieve this outcome. So, in principle, we support the splitting of the schedule of pharmaceutical benefits into two separate lists of formularies as a strategy to try to achieve that.

We will be measuring the success of the reforms by whether they achieve the price reductions for generic medicines that we are looking for and whether the savings achieved through these reductions are balanced by PBS investment in new medicines that have demonstrated their comparative safety and cost-effectiveness through the PBAC, which we see as relying on health outcomes. We are perhaps rather puzzled by some of the suggestions that this is being bypassed.

Also, there are price signals for consumers at present with generic medicines. We certainly know that people are aware of price premiums. In fact, some of the low-income families that have already been discussed and higher-income families in our networks where several members have a chronic condition and they are perhaps paying quite high costs already for health treatments and medicines more generally can really suffer if there are too many brand premiums in there that they view that they need to have to pay for one reason or another.

We acknowledge that there may be some unforeseen consequences of these changes. It is new ground for Australia. We therefore believe that it is vital that the impact is monitored to ensure that there is no adverse impact on affordability for consumers or for the quality use of medicines. This is why we have been so keen to see good communication about these changes to consumers. We do not see the generic information campaign as simply a promotion of generic medicines but of providing consumers with information to help them make choices, to understand that there will be at least one brand of medicine available at the base price and they can avoid paying brand premiums. It is particularly important to people who use a lot of medicines to understand that the premiums do not count towards the safety net and that they need to be asking their doctor about lower-cost alternatives.

I guess the other concern around that area, though, is that frequent brand switching can increase the risk of medication errors. It is important that people are able to stay on the same brand of medicine, whether or not it is the originator brand that came in first or the brand that they started on that perhaps might have been at the lowest level. So we want to see that there is scope where there is a clinical need for people to stay on that brand. We feel that that has been introduced into the bill, although the details of how that will work out are by ministerial determination.

We also support price disclosure to increase transparency of pricing arrangements and to make sure that consumers and government are actually getting the price savings available rather than them getting lost somewhere in the under-copayment pharmacy prices. We perhaps share one of the concerns raised by the generic medicines industry before us that as a lot of medicines do fall below the copayment for general patients, those families that make up our membership do struggle to keep their jobs if they have a chronic condition or are facing a lot of high health costs. We have less audit protection in our system for those under copayment products. Because there is not a reimbursement claimed from the Pharmaceutical Benefits Scheme, it may be quite hard to monitor the actual price that consumers are paying at the pharmacy. We want to see that fair prices are there to ensure the best possible health outcomes for consumers in the future. That is what it is all about: the health outcomes and affordability for consumers.

CHAIR—You support an awareness campaign around the use of generic medicines. What do you think are the main issues that need to be put in front of consumers as part of that campaign? I assume you are talking about a campaign directed at consumers as opposed to, say, pharmacists or whatever. What sorts of messages should be contained in that kind of campaign?

Ms Hopkins—Our work with consumers shows that there is a lot of confusion or lack of understanding around generic medicines. We think that it is important that people understand that they have been through the safety and quality checks we have in Australia, that they did not fall off the back of a boat somewhere between here and Asia and that they do measure up to the standards we expect. We do get a lot of concerns that they are a sort of 'cheap as chips' brand. So it is important that people understand what the generic medicines in Australia are.

We also think that an important part of the message is that there is choice: you do not have to pay a copayment. There is a need for consumers to understand that these price reductions occur after the innovator products have had quite a long while to recoup their investment in research. You can appreciate that a lot of chronic illness groups will be quite concerned that innovative research continues to occur and so they need to understand that these products are at that later stage once the patents have finished.

We also think that it is imperative for people to be reminded that they have the right to ask about choices around cost. They are often a bit reluctant to have those discussions with their doctors. They are more likely to have them at the pharmacy but they need to know that they can ask and that there might be one that does not have a premium associated with it. There is a lot of concern about switching but perhaps not so much of an understanding that you could start on the one at the base price and stay there. I think that the challenge for the campaign will be if we get too much fluctuation in the base price product. We really want to see some

stability there and will be calling on industries to do their bit, come in with the savings and hold a reasonable set of base price products for consumers without too much see-sawing around the base-price brand.

CHAIR—So you are quite comfortable with the idea of a campaign that actually promotes the use of generic medicine?

Ms Hopkins—Promotes the choice to use generic medicines. Consumers need to understand that that choice exists and that they can avoid paying premiums for PBS medicines.

Senator MOORE—We have heard evidence this morning that in the whole development of this package, from the time that the minister announced that they were going to make changes to the PBS—in 2006, I think—there was a straight statement that consumers and academics were left out of the loop. From your perspective from the consumers' group, which has a large interest in these areas, what involvement and information sharing with consumers has there been as these policies have been developed?

Ms Hopkins—It is true to say that we had little involvement before the announcement of the reforms, although we did actually attempt to do so, because we did not regard it as something that should just be worked out by industry, as it were. However we did lobby fairly strongly from before the announcement of the reforms and at the time that the stakeholder group was formed around this legislative process we lobbied for a place. I have in fact sat on that stakeholder reference group since January on behalf of consumers. So we have been trying to keep our members informed of the progress since that time and raising the sorts of issues that are coming up.

Senator MOORE—Has there been interest?

Ms Hopkins—Substantial interest—in fact, so much interest that we prevailed upon the department to give a sort of trial presentation about the reforms at a small workshop that we were holding around medicines issues. I think that the question has demonstrated the substantial interest amongst consumers. Senator, following your questions about the communications campaign, there has been so much concern about knowing what is really happening and what we need to think about in using medicines.

Senator MOORE—And specifically in the understanding that consumers have of the process from the time when they actually purchase whatever medication they will be having—the awareness they have in what goes before that, in terms of how the price has actually built up. From your understanding, do people understand that and have confidence to question it?

Ms Hopkins—I have touched on some of the areas where I think there is uncertainty. People have been confused. There was quite a strong campaign a year or more ago, before the 12.5 per cent price reductions, to say that this would be the end of clinical trials in Australia et cetera. We had quite a lot of discussion and did work with our members at that time to really reinforce that we were talking here about medicines that had expired patents. So at that level we have done a lot of work. I think that some of the issues that are being addressed by the reform—pricing issues—are actually raised by us through our consultations with members. For example, people have been frustrated that, when they start to hear that there are generic

medicines available, perhaps their pharmacist might not stock them and they do not actually have the choice. We have clarified the rules with the Pharmaceutical Society—that they actually have to be able to get those to the patients. I think that there have also been concerns around the wholesale practices. People were feeling that the pharmacists were getting deals and that the price reductions that they received were not being shared. We appreciate that the people in our networks that are most likely to raise those questions are the people who have had a lot of experience at trying to use medicines and shop around to actually get the most cost-effective set of treatments for their chronic conditions. When we go out to local community groups, the understanding is much less. There are so many things that they do not know. They do not know that they can get an authority from their doctor to take a month's worth of medicines home. They will go back three times in the month. There is a lot of lack of understanding about how well the PBS can support those people out there.

Mr ADAMS—Nice to see you. Regarding guidelines coming from your organisation, have you got any draft guidelines for consumers? When you have an inquiry, especially from consumers—coming back to my rural areas—people coming to you with questions needs answers. Do you have any published guidelines that we could have?

Ms Hopkins—We do. For a long while we have had 'Questions to ask your doctor' and 'Questions to ask your pharmacist' when you are getting a new medicine. We are also working with the National Prescribing Service, through the community Quality Use of Medicines program, at the moment to develop some more fact sheets to help people ask those questions. That has really been in response to the community sessions that we have been running over the last couple of years in rural and regional Australia, where there are so few simple fact sheets for people. So we are certainly trying to have that sort of information in place. It is mostly in the form of questions to ask your health professionals, because people generally want to be confident that the medicine that they are taking is the right one for them. There could be differences that we do not know about of why it is important for them, clinically, to follow a particular path.

Senator ADAMS—Would we be able to have a copy of those sent to us?

Ms Hopkins—The new fact sheets are not quite ready yet, but we can certainly provide some examples of the sort of information that we have been putting out there.

CHAIR—I think that has done us. Thank you very much indeed for that evidence and for the submission that Consumers Health Forum has provided to us today.

[12.00 pm]

CHALMERS, Mr Ian, Chief Executive, Medicines Australia

DAVIES, Mr Richard, Board Member, Medicines Australia

LILLEY, Mr Jeays, Chairman, Medicines Australia

CHAIR—I welcome representatives of Medicines Australia to the hearing today. Thank you very much for your submission and for appearing today. You have had evidence I think provided to you on parliamentary privilege and the protection of witnesses. We have questions to ask you about your submission, but would you like to begin with an opening statement before we move to that?

Mr Lilley—Yes, we would. You would have already gleaned from today's sessions that this is a very complex issue and so our opening statement is fulsome. But we beg your indulgence on that. I have four objectives to achieve in my opening statement. The first is to outline our interest in this bill and why on balance we support it. Secondly, we will contend that the legislation can yet be improved on at least two fronts to give full effect to policy intent. Thirdly, I will make some remarks in relation to improving regulations pertaining to biosimilars. Fourthly, I will draw your attention to recommendations which we emphatically ask the committee to adopt, supported by the evidence in our submission.

Why on balance do we support this bill? Medicines Australia represents the interests of 46 local and international research based pharmaceutical companies that discover and develop, and many of which manufacture, in Australia. We collectively provide 90 per cent of the prescription medicines and about two-thirds of the off-patent medicines for the PBS. Our member companies are key contributors to Australia's manufacturing export performance. Therefore, policy settings which either hinder or indeed foster the growth of our industry could affect not just future health outcomes for Australians but the futures of many of the 15,000 people whom we employ. Thus, we have a vital interest in the sustainability of the PBS itself, which we have contended for many years.

Turning now more directly to the reforms, under the proposed PBS reforms, mandatory price reductions will be applied to medicines that our industry delivers to the market. The reforms are also intended to provide a more competitive generics market in Australia. These changes follow many other reforms over the past three years in particular in our sector and they not only provide some opportunities but also present some difficulties for Australia's pharmaceutical industry going forward. There is no doubt that some of Medicine Australia's member companies will face significant and in some cases severe detrimental impacts from the proposed reform policy. Through the mandatory price reductions which are proposed, our industry and our member companies will contribute around $390 million per annum or two-thirds of the anticipated $570 million average savings to the government over the next four years. Nevertheless, on balance we do support the intent of the proposed reforms. The three major reasons for this are that sustaining the PBS will provide patient access to cost-effective new medicines into the future; it will provide certainty for pharmaceutical and biotechnology industry companies for future investment; and it will create savings or headroom for the

government to reinvest in new medicines which will come in the future as a result of development.

Whilst Medicines Australia support the broader content of the current bill, we contend that the bill should be further improved on at least two fronts. The two principal areas relate to the treatment of single-brand fixed-dose combination products and the management of patient premiums. I turn firstly to combination products. A combination product is one which is made up of more than one pharmaceutical entity. Single-brand combination products—that is, without competing forms—represent in the main patented innovations which have been developed by the pharmaceutical industry to improve patient outcomes. For example, combination products have relieved the requirement for patients to take multiple medicines for conditions such as asthma and HIV. These products do more than the sum of their component parts in many cases because they help to reduce the pill burden—shall I call it that—particularly for older and very ill patients and improve patient compliance with recommended treatment. Many have clinical outcomes which are superior to the individual components. Also patients pay less overall because they pay one co-payment for a combination product instead of two or three co-payments to fill prescriptions for the individual components if they took those separately.

The current bill treats combination products differently to single-molecule medicines. As a result, the bill will flow on statutory price reductions to the components of combination medicines and this is problematic for a number of reasons. Statutory price reductions, such as the now in vogue 12.5 per cent reductions or future two per cent price reductions which are embodied in the bill, are intended to claw back savings to the PBS from market competition between multiple brands. But to flow on these substantial price reductions to single-brand combinations could render some of them commercially unviable. The change will also reduce the incentive for companies to bring forward new combination products. I would like to briefly allude to some very famous science behind the development of some combination products. As a result of the combined use of medicines for the treatment of duodenal ulcer together with antibiotic and antimycotic therapy resulted in Professor Barry Marshall from Western Australia winning the Nobel Prize for Medicine two or three years ago. So I do not know that we can dismiss these combination products as simple attempts at evergreening. Many of these combination products have clinical outcomes which are superior to the individual components. Patients pay less overall because they pay one co-payment when they fill these prescriptions.

The risks are real and, as an industry, are something we wish to avoid as this will impact on patients. These patients would need to pay multiple co-payments for treatment if combination products were not available. We argue that devaluing innovation in this way is bad for industry, it is bad for science, it is bad for patients and it does not reflect sound public policy. The treatment of combination products in the legislation is inconsistent with the concept of interchangeability at the patient level which underpins the new formularies. Patients cannot in all cases simply switch from a combination product to its individual components without consequences, and many of those have been alluded to earlier by other speakers. To assume that single-brand combination products are equivalent to the collective of their individual components is also inconsistent with the current PBAC guidelines for the listing of these

products. These guidelines recognise that there may be clinical rationale for the use of combination products.

The bill's provisions for combination products will also have a detrimental financial impact on a number of our local member companies. A simple and logical remedy for this would be to amend the bill and classify the single brand combination products, which are presently under consideration in the F1 formulary, as they were originally when the draft formularies were first provided to Medicines Australia. The current placement of combination products into an undefined formulary was a late change introduced long after the original formularies were announced.

Secondly, let me talk about premiums. The management of patient premiums is the second major area in which the current legislation does not deliver on policy intent. The proposed legislation makes substantial changes to a government policy which has prevailed for a decade, but there has been no consumer-driven motivation for change. There has been recent public debate.

The existing brand price premium or therapeutic group premium policies have been effective in managing brand premiums. They have allowed pharmaceutical innovators to charge an additional patient premium when a substitutable generic brand is listed on the PBS. Those premiums are not a cost to government. But within the current PBS scheme a brand premium is the only price signal to consumers to drive usage of premium-free generics. Since 2000, the proportion of prescriptions dispensed at the benchmark price—and therefore without a premium—has steadily increased from 44 per cent to 63 per cent. That 63 per cent is the converse of the 37 per cent that we heard about before. But 63 per cent of prescriptions are indeed now being dispensed without a premium. Under the current arrangements, patients have freedom to decide for themselves whether they pay a premium for a particular brand or whether they take a substitutable brand dispensed with no premium. The freedom exists. Trends suggest that, increasingly, patients prefer to choose premium-free medicines. This trend will be accelerated by the government's proposed sponsorship—a $20 million program—for community education to incentivise the selection of generic products.

The contention that patients will be worse off from the proposed changes to the management of patient premiums is ill-conceived and factually incorrect. In fact, the changes proposed in the bill take away from the sponsor of a listed medicine the option to recover some of the damage to pricing which is occasioned by price reduction. That method has been acceptable to the government and has prevailed for a decade.

Price premium policies demand that there always be one brand available at the benchmark price. So patients would always have at least one option to purchase at the benchmark. Therefore, a question on which we ask the committee to reflect is this: how can patients be worse off, especially as the basis of this change implies a reduction in the benchmark of up to 25 per cent from 1 August next year for many medicines?

The bill, as it stands, places unnecessary controls on patient-paid premiums. This will result in reduced price signals at the patient level which, in turn, will reduce competition in the off-patent market—the very thing the bill is trying to stimulate. The bill is at odds with current

policy and contradicts the other reform measures which have been put in place to drive generic volume and stimulate price competition.

Importantly, this aspect of the bill will pose legal questions as to the government's power to move beyond controlling reimbursement prices to controlling market based pricing. More importantly, I would like to emphasise that no patient will need to pay more for their medicines than the standard copayment under the current premium policy or under the new policy proposed by this legislation. Doctors will also retain the ability to seek a premium waiver from Medicare Australia.

The approach to premiums in this bill delivers no additional benefits to patients, however it creates complexity and imposes extra burden on our industry. This legislative imposition can be avoided and it should be avoided. The remedy would be to restore the existing policy for management of premiums.

I want to make a short comment on biosimilars. The government has made some sensible amendments already to the PBS reform bill with respect to biosimilars and bioequivalents, which Medicines Australia supports. The Therapeutic Goods Administration has regulatory processes to determine whether a second biological product is a biosimilar; in other words, similar to an original biological product. Medicines Australia believes it is important to have further dialogue with government on the legislative treatment of biosimilars to ensure that the implementation of the legislation is consistent with these regulatory processes that are used by the TGA.

With respect to the consideration of this bill therefore, we have some clear recommendations to the committee for amendment to the legislation that we ask you to adopt. They are as follows. Firstly, that the Senate supports the bill with the amendments as described. Secondly, that the committee seek to amend the bill for single brand combination products to be classified into F1 formulary as was the original proposal. Thirdly, that the committee seek to amend the bill so that the existing policy for managing premiums be maintained. These recommendations will not reduce the overall policy intent of the reform.

In conclusion, Medicines Australia will closely monitor the impact of PBS reform implementation over the next one or two years. We will review and suggest further improvements to the legislation should other issues come to light. My colleagues Mr Chalmers, Mr Davies and I would be very pleased to take your questions.

Mr Chalmers—With your indulgence, may I offer some additional remarks?

CHAIR—If you can do that briefly Mr Chalmers, we have got a pretty tight time frame.

Mr Chalmers—I understand and I thank you for your indulgence. Medicines Australia particularly wishes to reference some thoughtful and considered observations made by two previous presenters this morning. In particular, we note the recommendations that were made to you very clearly and explicitly by Dr Faunce. To refresh your memory, those four recommendations were: that there is a clear requirement for a definition of 'interchangeability'; that the government's proposal to secure cost recovery of the PBAC process should not proceed; that the mechanism of cost minimisation for listing new medicines on the PBS should be retained; and that there should be increased transparency around the activities of the medicines working group and the access to medicines working

group. You may be surprised but I am pleased to say that Dr Faunce and Medicines Australia are not far apart on these issues.

Senator MOORE—Does Dr Faunce realise that?

Mr Chalmers—He is about to discover this, I suspect. As to the issue around interchangeability, the determination of interchangeability of pharmaceuticals is the responsibility of the Pharmaceutical Benefits Advisory Committee. It is that eminent body that does determine interchangeability and we are bound by their decisions. As to the process of structured definition of the way in which they determine that level of interchangeability, that is a matter for the PBAC and we are already in receipt of their decisions.

The second matter was the government's current proposal to recover the costs of the listing of new medicines process. That involves the deliberations of the PBAC and subsequently the Pharmaceutical Benefits Pricing Authority. This is by no means welcomed by Medicines Australia. This was a budget decision in the 2005-06 federal budget and it is being imposed upon us now. The government seeks to raise, in the next financial year, something in the order of $11.2 million from industry in this process. What that means for a company seeking to list a new medicine on the PBS is a fee of approximately $200,000.

That is, $100,000 is paid on the submission of an application and a further $100,000 is paid on the receipt of a favourable recommendation that the medicine be listed. If the result of the PBAC's deliberation is not favourable, then the original $100,000 application fee is lost to the company. When the company returns with a second application, another $100,000 application fee is payable, and that continues until such time as a favourable determination is made.

Cost minimisation will continue, as I understand it, to be a core element of PBAC's deliberation. We accept that.

Finally, in relation to increased transparency of medicines working group and the Access to Medicines Working Group, the medicines working group is a collaboration between the Australian government and the United States government. Industry has no part in those meetings; they are government-to-government meetings. The Access to Medicines Working Group has met once, on 24 April this year. The purpose of that meeting was to determine terms of reference for the committee's further consideration. My understanding is that the government is intending to release a communique and to publish the terms of reference. The purpose of that committee is not to investigate policy around the F1 formulary but it is to discuss mechanisms by which the cost effectiveness of new medicines may be evaluated in the future.

Let me now turn briefly to the issue of evergreening. Dr Harvey cited two medicines which he asserts are an example of evergreening. The basis for that assertion is that he believes one of the medicines is allocated to F1 and the other medicine is allocated to F2.

Senator MOORE—Which are these?

Mr Chalmers—The medicines are citalopram and escitalopram, which are antidepressants. Our information is that the appearance of one of those medicines in an early draft of the F1 formulary was a transcription error and I am advised that both medicines are currently listed in the F2 formulary. We often hear claims of evergreening. We are yet to see

any example of an evergreened medicine. Our assertion is that it does not happen. It is a great story, but let us see the evidence.

I have a final point to make—my chairman has asked me to be brief, so I will be very quick on this. Dr Harvey made an observation that too many doctors prescribe medicines with a brand premium. It is important for you to know that innovative patented medicines, and those are single brand medicines typically found on F1, do not have a premium. It is not permissible to apply a premium to an F1 medicine. Off-patent medicines, typically found in F2, may have a premium but there is always a premium-free alternative medicine available. There was an observation about pharmaceutical companies actively promoting medicines that carry brand premiums. In fact, that is not the case. The companies are focused on actively promoting innovative new products, and none of those carry brand premiums. Thank you.

CHAIR—Thank you very much, Mr Chalmers. Questions—Senator Moore?

Senator MOORE—Mr Chalmers, you took up the questions that I was going to ask. In relation to the working groups—and I was going to ask the department this too—the one between government to government on the free trade agreement is, I totally accept, a free trade thing that has limited relevance to this particular discussion. But with the other one which has been developed particularly around the PBS—I will ask the department this too—is there any reason that it is just Medicines Australia and the department on that one? Is it in fact just Medicines Australia and the department on that group? I know you have only had one meeting and you are still forming the terms of reference, but why not—and I should have asked this question before but this particular inquiry gives me a headache generally and I go round and round and round—

Mr Chalmers—There are pills for that!

Senator MOORE—GMiA? Is there any reason why GMiA would not be on that group?

Mr Chalmers—The reason that the working group is only representatives of innovative companies and government is that the purpose of the committee is to investigate the method by which the cost-effectiveness of innovative new medicines can be assessed for the first time—that is, the first time these medicines are brought onto the PBS. This reflects the research and development that is conducted in the development of a medicine and the way in which that medicine can be assessed—because, of course, no medicine is listed on the PBS unless it is deemed to be cost effective. The generic companies copy medicines that have previously already been listed and, years down the track, are no longer protect by patent. Indeed, going back to the cost recovery comment that I was referring to before, that was $100,000 to seek an application and then another $100,000 if you get listed. The generic companies, by contrast, pay $400. We pay $100,000 for our application and they pay $400 for their application. We are talking about a completely different issue. This is about highly complex, innovative new medicines and how we measure in a meaningful and transparent way the cost-effectiveness of these new medicines. That process is wholly irrelevant to the process of bringing a generic medicine onto the PBS.

Senator MOORE—You heard the discussion earlier; you have made a response. Is there, from your perspective as one of the partners in that group, a problem with minutes being available.

Mr Chalmers—No, I do no think that should be a difficulty.

Senator MOORE—So in terms of a future one, that is something you may be prepared to—

Mr Chalmers—Yes, and that was one of Dr Faunce's requests. I do not think we would have any great difficulty with that at all.

Senator MOORE—You have raised two quite specific issues with this legislation. My understanding is that you have regular dynamic relationship with the department in terms of the work you do. When you have raised these two particular issues with the department, what have the responses been?

Mr Chalmers—We have had an appropriately engaged relationship with the department and we acknowledge the effort that the department has taken to consult with stakeholders—and other presenters here today have equally participated in this process. I am conscious that the department is seeking to find an outcome with which all legitimate stakeholders can live. We have differed on many issues and these are issues on which we differ. We think the department's view is wrong. We feel that we have made a strong case in the submission we have put before you.

Senator MOORE—The two outstanding issues that you feel were serious enough to bring to this committee are the premium brand issue and when that process drops off—

Mr Chalmers—And the treatment of single brand fixed dose combinations.

Senator MOORE—Mr Lilley spelt out the position on both of those issues. For the sake of this part of the process, can you tell us the department's response on both of those issues?

Mr Chalmers—I think the department's response is embodied in the legislation, and that is that the department considers that fixed dose combination medicines—in particular, single brand fixed dose combination medicines—are of no intrinsic value greater than the combination of their parts. We think that is fundamentally wrong.

Senator MOORE—That is the core issue—the case that Mr Lilley spelt out for particular treatments and why a combination medicine is in fact a different entity than A plus B plus C?

Mr Chalmers—Correct.

Senator MOORE—The department's response has been that, from their perspective, each particular component still needs to be assessed individually for the process of the PBS?

Mr Chalmers—The department is suggesting that the combination has no greater efficacy than the component parts.

Senator MOORE—That it has no greater efficacy than if you took two tablets separately or whatever?

Mr Chalmers—Yes.

Senator MOORE—I know it is simple, but I cannot get across the complexity of this without reducing it to something quite simple. The second issue is the idea of the premium brand and when it drops off. What was the reaction from the department to the argument as put to us by Mr Lilley?

Mr Chalmers—We are mystified by the provisions that have appeared relatively recently in the PBS reform proposal—and I am talking only weeks ago—that relate to premiums. There has certainly not been a response to active consumer dissent. The status quo has been in place, as Mr Lilley said, for many years. We are particularly concerned to ensure consumer/patient certainty. This is particularly the case for elderly patients. Under the new premium regime proposed in this legislation, in the known event of statutory price reductions—that is, the mandatory reductions that medicines will experience over the next couple of years—the new arrangements will mean that both the underlying price of the medicine and the price paid by consumers will change. This is complex, and I do not want to draw it out too far, but the effect for many patients will be that the price of medicines they know well will change two or three times within a period of a couple of months. That is illogical. It is unhelpful for consumers and, in our view, it is of doubtful constitutional validity.

Mr Lilley—We can only speculate that this has been a rather oversimplistic view that if a base price reduces by 25 per cent then you should reduce the premium by a similar number, which overlooks the purpose of having a premium. We think its not a healthy general economic issue for the country when you move from legislating the reimbursement price through the PBS to legislating a free 'value recovery system'.

CHAIR—Can I clarify something about constitutional validity. I presume you are saying that the requirement to sell at a certain price means effectively that your property is being acquired and you are being made to sell it at a price when the Commonwealth does not have the power to regulate the price of something.

Mr Lilley—That is not exactly what we are saying. We are not arguing that, under the PBS, the Commonwealth has the right to set the price, because that happens through the appropriate authority. It is a reference to preventing a free movement or a free application for a premium.

Mr Chalmers—That is in reference to the commercial cost, not the reimbursed price that reflects the price paid by the Commonwealth to purchase the medicine and bring it onto the PBS.

Mr Lilley—If the application of a premium is a means by which one could compare a premium carrying medicine with a premium-free medicine, simple economics would suggest that, if you push the premium down by some mechanism as proposed in the bill, you are reducing the competitive price signal.

CHAIR—How is that unconstitutional?

Mr Lilley—We are taking some advice on whether it is permissible under the Constitution to impact on recovery premiums.

Senator BOYCE—I have just noticed that in the appendix to your submission you talk about the latest independent research showing that it now costs more than $1.2 billion to bring a new medicine to market. You do not give a reference for that. Is this Australian research; is that the Australian cost?

Mr Chalmers—That reflects global costs, because, given the nature of the enormous investment that is required to research and discover and bring to market a new medicine, most of this activity happens on a transnational basis. But a useful indicator would be Gardasil, the cervical cancer vaccine, which was listed on the PBS earlier this year. The potential for a vaccine was first identified by Professor Ian Frazer in 1991. It took 16 years of clinical trials and very extensive research and development, and massive investment by the companies that had to bring their resources behind Professor Frazer—that is, GlaxoSmithKline, Merck Sharp and Dohme and, principally in Australia, the CSL group—to make that medicine possible. It is important to know that, for every one opportunity similar to that which was recognised by Professor Frazer in 1991, there are thousands of others that our scientists identify and pursue and then it becomes clear that they will not work.

Senator BOYCE—For some reason or another, they do not quite make it to market. So when you mention the latest independent research, are you talking about a specific piece of research or is this just a—

Mr Chalmers—If I turn around I may be able to get the answer to that. We can provide it to you.

Senator BOYCE—Thank you. In the appendix, you speak about the pharmaceutical industry in Australia investing $457 million in R&D. I am assuming that was last financial year. Is that inclusive of government R&D grants and tax concessions et cetera?

Mr Chalmers—No, that is our actual spend. We particularly welcome recent announcements, in the industry statement announced a short while ago, of an increase in the tax deductibility of incremental expenditure. We note that the opposition, in its industry policy, has a similar proposal.

Senator ALLISON—I would like to test some further recommendations with you. The generics manufacturers suggested that there be a differential or at least a discount on the co-payment of 50c per script. Do you have a view about that proposal?

Mr Chalmers—We do.

Senator MOORE—You people should talk more together.

Mr Chalmers—They are good friends of ours. While we are active competitors, there is a high degree of collaboration. We of course oppose a differential generic co-payment—firstly, because this is potentially anticompetitive and may indeed be unlawful. It discriminates in favour of one group of multinational manufacturers of off-patent medicines versus another group of multinational manufacturers off-patent medicines. Let us be clear about this. There was a reference to the ownership of Alphapharm made by previous speakers today. Alphapharm, as was correctly noted, was recently purchased by an American group called Mylan. But what was incorrectly put to you was that this was an Australian company purchased by Mylan. In fact, Alphapharm has not been an Australian company for many years. Alphapharm was formerly German, owned by Merck KgaA, and was sold by Merck as part of a global disposal of its generic medicine assets. Mylan purchased Alphapharm as part of that process.

Senator ALLISON—What does that have to do with the discount?

Mr Chalmers—What I am saying is that this particular issue discriminates between one group of multinational pharmaceutical manufacturers and another group of multinational pharmaceutical manufacturers. At the consumer end, which is most important in terms of our deliberations today, if you provide an incentive for pharmacists to dispense or an incentive to consumers to purchase medicines from one group of manufacturers versus equivalent medicines from another group of manufacturers then you take the actual price out of the equation. Perversely, the government may well find itself encouraging consumers to buy more expensive versions of equivalent medicines. The most important issue is that consumers receive an incentive to purchase a premium-free medicine. It does not matter whether the premium-free medicine is a generic or an off-patent brand-name medicine. The important issue is that there is an opportunity for consumers to buy a medicine at the benchmark price. To artificially create an incentive for the purchase from one group of manufacturers versus another group of manufacturers, irrespective of whether those products represent best value, is a ludicrous proposition.

Senator ALLISON—What if they do represent best value?

Mr Chalmers—Then that would be right, but how can you guarantee that that would be the case in every case, in every circumstance? Indeed, if one group of manufacturers knew that they did not have to compete in order to attract business because government was providing an incentive then why would they be concerned to provide best value?

Senator ADAMS—Mr Lilley, you made a comment very early in your introductory remarks that there was no consumer-driven debate. My question is: why?

Mr Chalmers—Indeed.

Mr Lilley—I suppose that, in the main, consumers have understood that they have access to premium-free medicines under the current situation and there has been no clamour for a change of that situation.

Senator ADAMS—Do Medicines Australia have any guidelines that you hand out to consumers on any queries to do with their medicines and what is accessible and what is not? Is there anything that you could table for us?

Mr Lilley—Not in terms of pricing. We do not deal with matters of the detailed cost across the counter of the pharmacy between the patient and pharmacist, but there is a lot of information on the medicines themselves in the consumer medicine information insert that goes with every package of product.

Mr Chalmers—We also have a very close relationship with the Consumers Health Forum and other consumer organisations. From that engagement and liaison we gain an appreciation of issues that are important. It gives us an opportunity to develop strategies to appropriately respond.

CHAIR—You mentioned that two-thirds or so of the savings that will come from this scheme over the next five years will come from drugs represented by the organisations within Medicines Australia. I assume you have got a fairly strong representation from manufacturers of generic drugs. Is that the case?

Mr Chalmers—Within our membership?

CHAIR—Yes.

Mr Chalmers—No, not at all. Some of our member companies own generic businesses. Those subordinate companies tend to report not through Australian head offices but directly to global head offices. But it is correct that Medicines Australia member-owned generic companies generate more than half of the generics business in this country.

CHAIR—It is in those areas that these savings are principally to be found. Is that correct?

Mr Chalmers—No. The figure of two-thirds reflects the proportion of brand-name but off-patent medicines in the F2 formulary. So there are a very significant number of medicines produced by Medicines Australia companies which are now no longer single brand medicines and subject to competition but they are in F2.

CHAIR—That transcription error you referred to before—whose error was that?

Mr Chalmers—That is a question you might wish to direct to the Department of Health and Ageing.

CHAIR—It was on their website?

Mr Chalmers—Yes. That is our understanding. There may be another reason for the misallocation of that medicine, but we are advised that both those medicines are now on F2.

Senator MOORE—I may have this wrong, and it is one of the difficulties of getting evidence and not being able to see the transcript until later, but one of the comments that the professor made earlier was that he felt that the savings were probably not going to be as great as the department and other people thought they might be. He felt that the numbers coming off patent in the future may not be as great as predicted. There was a comment that a lot of the savings were based on the expectation of a large number of patents coming off into the future. Have you got a comment on that? I would imagine your industry would look very closely at that.

Mr Lilley—We do, our generic competitors do and I think that the department of health does as well, as do the central agencies. If I may say so, I think this is a very well-thought through construction, even though we disagree with parts of it. I am not too sure that the same person who has trouble distinguishing between Medicines Australia and the department of health has actually got his facts right on that issue.

Senator MOORE—You might want to have a look at the evidence when it comes out. It was towards the end. We asked about the amount of money that was there and that was one of the things that was said.

Mr Lilley—History shows that even in the past three years from the 12.5 per cent price reduction so-called policy that the estimates that were originally put and the savings that were originally sought were in fact exceeded. In the following budget the Treasurer announced that instead of the sum of $740 million that I think the government was looking for from that policy it was in fact just over $1 billion. So sometimes perhaps the estimates are conservative. It has not been our experience that promised price reductions have not been delivered upon.

Senator MOORE—Thank you.

CHAIR—Thank you gentleman for your appearance here today. I am sure we would like to spend longer exploring these issues, but we are very heavily constrained by our time frame. Thank you very much indeed.

[12.46 pm]

CAMPION, Ms Sue, Assistant Secretary, Policy and Analysis Branch, Pharmaceutical Benefits Division, Department of Health and Ageing

HANNON, Ms Wynne, General Counsel, Department of Health and Ageing

HUXTABLE, Ms Rosemary, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing

CHAIR—I welcome offices of the department. Information on parliamentary privilege and the protection of witnesses is available to you. I think you are all old hands at this, anyway. You will not be asked as departmental officers to give opinions on matters of policy, although this does not preclude questions asking for explanations of policy or factual questions about when and how policies were adopted. We have a submission before us, which is quite a comprehensive one. We thank you for that. There are a whole series of issues which have arisen during the hearing this morning. I assume that you have been listening to these issues so that we do not have to traverse again what the substance of them is?

Ms Huxtable—We were monitoring to a degree, but we have reviewed the submissions.

CHAIR—Do you want to make an opening statement about those issues.

Ms Huxtable—I would like to, if I may.

CHAIR—Certainly. Please proceed.

Ms Huxtable—Thank you for the opportunity to make a statement to the committee. You have the department's submission, which outlines the reforms in detail. I do not propose to repeat information from the submission. What I do want to do, however, is reiterate the intention of the measures of which this legislation is an important component.

The design of the PBS has served the Australian community well for many years. It ensures that patients get access to necessary and effective medicines in a way that is fair and equitable. Standard copayments apply and safety nets protect high users of medicines. It is underpinned by a process of cost-effectiveness assessment that allows governments to ensure that they are investing in medicines that work and are good value for money. This provides assurance also to the users of those medicines.

The purpose of these reforms is to make sure that the way that PBS medicines are priced into the future adapts to changes in the pharmaceutical industry and enables good value from listed medicines. By separating the PBS into single and multiple brand formularies and requiring price reductions for medicines that are operating in a commodity market, the aims of retaining necessary medicines on the PBS while paying competitive prices are met. Before responding to your questions, I would like to clear up a few issues that have been raised in submissions to the committee and so may have been discussed with you this morning.

Firstly, I want to clear up the role of the PBAC. The role and responsibilities of the PBAC are already in the act at sections l01 (3A) and (3B). In summary, a medicine cannot be listed on the PBS without a recommendation from the PBAC that it is effective and cost-effective compared to alternative therapies. This bill does not change these parts of the act. In fact it

expands the role of the PBAC to provide advice to the minister on whether drugs are interchangeable at the patient level and whether a formulation of a medicine is unique and therefore should be treated differently for pricing purposes. These are appropriate areas for the expert input of the PBAC and in reality put into legislation a function they already fulfil.

Secondly, there seems to be misunderstanding about reference pricing and therapeutic groups. There are six therapeutic groups on the PBS which group medicines that the PBAC has determined as interchangeable. Interchangeability means that these drugs are pharmaceutically related, have the same mechanism of action and provide similar therapeutic outcomes at equivalent doses at the individual patient level. These therapeutic groups continue to exist on the new formularies. Five of the six TGPs are on the F2T formulary.

There are another 106 reference pricing groups, which link medicines that are similar but not the same, that have been listed on a cost minimised basis. For example, the oncology reference pricing group comprises seven different molecules that treat three different types of cancer—lung, breast and ovarian. Some are only PBS listed for treating advanced stages of a cancer and some can only be used in combination with other drugs.

Under the proposed new formularies, single brand medicines in reference pricing groups will remain price linked. Eighty reference pricing groups will continue to link the price of 140 single brand drugs. Medicines across F1 and F2 will no longer be price linked. These are not the same molecules. This allows commodity prices to be paid for F2 medicines. It is important to stress that the price at which a medicine is initially listed will continue to comply with current cost-effectiveness assessment processes of the PBAC.

Finally, there are claims that these reforms will provide incentives for suppliers to resist generic competition by trying to extend patent life. It is important to reiterate that the trigger for a medicine to move from F1 to F2 is the entry of a bioequivalent brand, or, in the case of biologics, a biosimilar brand. This is a technical assessment made by the TGA based around the active pharmaceutical ingredient. Once bioequivalence has been determined the legislation will trigger the movement of the whole molecule and price reductions will occur.

In conclusion, these changes are intended to provide a foundation for the PBS to be sustainable into the future to take advantage of the many medicines that will come off patent in the next 10 years and for which much lower prices will become available, without affecting patient access to the medicines they need nor impacting on the fundamental cost-effectiveness requirements of the PBS. Thank you.

CHAIR—Thank you very much for that. There are a whole series of issues which have come up. I might just rattle some of those off. If senators want to raise an issue in connection with that, they can do that the same time that I am raising it. Can I raise the issue that has just been raised by Medicines Australia: the suggestion that a single brand combination product should in fact be listed in the F1 formulary. What is your response to that suggestion?

Ms Huxtable—The treatment of single brand combination products under these proposed reforms is highly consistent with the way in which combination products are currently priced—so the way which the PBAC has come to a view about the pricing of these products. There are around 50 of these that have been identified to be put on a separate list. In these cases the intention is that a reduction in the price of one element will flow on to the

combination, keeping the same relativity. So you will not have the combination products basically becoming priced in a different way to the component parts. That is simply reflective of what happens now.

CHAIR—Will that lead to those products being less expensive as a result or will it mean they are priced more consistently?

Ms Huxtable—That will depend on what happens to their parts. If both parts of the product, for example, are on the F1 formulary, then until there is competition within an element and it moves to the other formulary then triggering price reductions, it will remain at the price it is now. So the prices will reduce as price competition is occurring within the elements and that will flow through, whether it be through the mandatory price reductions in legislation or over time through price disclosure.

CHAIR—Okay. Can I move to another issue raised by Medicines Australia about premiums. It was in their submission. It was the argument that the existing practice of matching patient premiums be maintained. Why should that not be the case? Why shouldn't we retain the provisions as they currently stand with respect to those premiums?

Ms Huxtable—Largely, the existing arrangements are maintained. We have previously been through the circumstances in which a premium can apply to a medicine. That does not change under this legislation. So where there is an alternate at the benchmark price then there is a capacity for the supplier to make a decision about whether or not they wish to have a brand premium on the medicine. If there is no alternative at the benchmark price, they cannot have a premium. The only change here is that at the point in time when we are deeming price reductions—so these are mandatory price reductions which are being deemed under the legislation—there is not a negotiation occurring with suppliers about the price of the medicine. It is basically a mandatory or deemed outcome. It is a different way of pricing to the way we have priced in the past. I think our submission refers to that. Where in the past there has been a negotiation, underpinned by some consideration about a cost-effective price at listing—that may have been many years before, but then there is a negotiation over time around price—the difference here is, because we are dealing with mandatory price reductions applying across a very large range of medicines all on the same day, which will be 1 August 2008, it is pretty difficult to start negotiating in regard to individual brands and individual items at that time. So the way in which it has been drafted in the legislation is that it is a deemed price reduction and the price reduces from the claimed price.

Ms Hannon—It is from both the determined price and the claimed price.

Ms Huxtable—So where there is a premium, it will reduce by the same proportion, more or less, to the base price. Leading up to 1 August 2008 and after 1 August 2008 there is no reason why the premiums cannot be changed—they can be removed, they can be reduced, they can be increased. That is going to be a matter for the manufacturers to consider, taking account of their market plans.

CHAIR—But the onus of seeing those premiums lies more with the government than with the marketplace, doesn't it, under these arrangements? What Medicines Australia have argued is that allowing the existing arrangements to continue will complement the shift to a more

competitive generics market, preserve patient choice and avoid a more complex and burdensome regulatory environment.

Ms Huxtable—The point I am making is that the only time when anything changes is on one day when we are deeming a whole raft of mandatory price reductions. In the period before and in the period after, the current rules continue to apply. So we are not making some fundamental change to the premium policy, nor in the way in which premiums operate. The only time that something is changing is for that point in time when we reduce the price of a whole range of medicines. My recollection is that for medicines on the F2 formulary taking price reductions on 1 August 2008 we are talking about around 1,500 brands, so you can imagine the sort of administrative burden of trying to negotiate premium changes or potential premium changes at the same time. That is why it has been crafted like that, because it is a deemed price reduction, a mandatory price reduction.

CHAIR—Will this lead to some medicines dropping in price on that day to account for the premium and then bouncing up again, potentially, a few days or weeks afterwards as an adjustment?

Ms Huxtable—Again, the brand premium policy will apply, so there will always have to be an alternative at the benchmark price, but there is no reason why suppliers cannot choose to vary their brand premium after that point or before that point. Whether they take it off, reduce it or increase it, that will be a matter for them. There are price change points, so it is not going to happen every day or anything like that. It would be managed within the current arrangements that we have.

CHAIR—But it sounds to me as though there will still potentially be fluctuations in price as a result of this.

Ms Huxtable—To be honest, there is a fair bit of stability around this area of brand premiums generally. The average brand premium tends to be around the $2.50 or so mark, and the proportion of medicines that have brand premiums has been rather similar for a very long time. So I am not sure how much fluctuation there would be. I can only guess that suppliers take into account a whole range of factors when they are considering whether to have a brand premium and, if they have a brand premium, how to set that brand premium. That will be a market decision, in a sense, for them. But for the patient there is always an alternative at the benchmark price. One of the things—it is not in this legislation but it is part of the broader package—is that there is now a direct incentive for a pharmacy to dispense the premium-free brand. An incentive of $1.50 is a significant incentive to dispense a premium-free brand, which changes some of the market dynamics here as well.

CHAIR—Moving to another issue, Medicines Australia has also argued that there is confusion about the lack of a definition of biosimilar and that the TGA has a workable model there with respect to their processes for registering products that are biosimilar or bioequivalent. Why don't we adopt the approach that the TGA has used in this legislation?

Ms Huxtable—The TGA will actually be the authority as to whether or not a medicine is bioequivalent or biosimilar.

CHAIR—Yes, but I think they are talking from the point of view of whether bioequivalent or biosimilar products are treated as falling within, say, F1 or F2 when it comes to pricing.

Ms Huxtable—My understanding is that there is no dispute—or there is certainly a common view—that it is appropriate that bioequivalent medicine triggers a move from F1 to F2 and that the biological equivalent of bioequivalence is biosimilar. For reasons that are technical—I am trying to find my bit of paper—bioequivalence is proven by breaking down the chemicals and ensuring that it is the same thing, basically. With biosimilarity you cannot use that same sort of test, but there are international guidelines that the TGA follows to show that the medicine has the same sort of biological impact and so it has the same effect. I do not think that is so much in dispute as whether the test of biosimilarity will be appropriately applied. We have not gone into the detail of that in the legislation, because it is not possible or appropriate to do that. It is the TGA decision as to what is bioequivalent and what is biosimilar. In coming to that view they follow guidelines, undertake tests, review evidence. I cannot speak for them, but I think it is a complex process that they go through to determine bioequivalence and biosimilarity—biosimilarity being a fairly new concept and so probably still evolving somewhat.

CHAIR—Medicines Australia note that the TGA registers biosimilar products as being efficacious and safe and so on. It then says:

> Medicines Australia accepts that such registration may be used as a trigger for the cost savings identified in the PBS reform legislation. However, such cost savings must only be applied to the biosimilar and the reference innovator product. It is critical that the goals and outcomes of the PBS reform align with those of the TGA. This can be achieved, with subsequent cost savings, by ensuring that the appropriate regulatory body, the TGA, decides when sufficient evidence has been presented to achieve the above.

Ms Huxtable—That is what we are planning to do. the TGA will be the ones who decide whether something is bioequivalent or biosimilar. We will take their decision and we will translate that into a pricing environment.

Senator MOORE—There will only be one place of decision on that issue—the TGA?

Ms Huxtable—That is right, as happens now with bioequivalence. We take the decision of the TGA that something is bioequivalent and flag in the book that this is bioequivalent. We do not have a separate determination.

Senator BOYCE—There is another submission here from Amgem Australia Pty Ltd. We do not seem to have any further information about that. They appear to be concerned that you are not required to take the TGA's advice on this and suggest that there should be a regulatory process inserted in terms of assessing biosimilarity or equivalence.

Ms Huxtable—I am not aware of that particular submission. All I can say is that the 'biosimilar' issue was one that emerged quite late. We had drafted the legislation in a certain way, to capture that interpretation I have just discussed. There was an exposure draft. There was some concern from Medicines Australia at that time about how 'biosimilar' was in the legislation. We scurried somewhat, I would say, to introduce a government amendment consistent with what Medicines Australia and we had agreed at that time, and the amendment was passed in the House a few weeks ago. That makes explicit everywhere that 'bioequivalence' or 'biosimilar' has been inserted right through the legislation so it is clear that we acknowledge that biosimilarity and bioequivalence are two discrete things that need to

be tested. To be honest, this view that we need to do something more has not been put to us, so we obviously have not had a chance to assess it.

Senator BOYCE—Is there any regulatory requirement that the PBS use the TGA to assess biosimilarity?

Ms Huxtable—Well, it is what we do. And we cannot do it any other way. We have many pharmacists and they are very capable, but they do not have white coats and spend their time breaking down pills to work out what is in them. So the TGA is the body which does that and we do not err from their view on that.

CHAIR—Can I move to an issue raised by the Generic Medicines Industry Association. There is a process for the minister to make determinations in a number of areas but no capacity to appeal those determinations. I appreciate that you do not normally have, except for Administrative Decisions (Judicial Review) type processes, you do not generally have appeals processes for ministers. But is it appropriate for decisions of that importance to have an appeal mechanism, with perhaps someone else, such as the secretary of the department, making the decisions in those circumstances?

Ms Hannon—The GMiA submission actually says that the Administrative Decisions (Judicial Review) Act will not apply to those ministerial determinations because they are legislative instruments. We do not think that is correct and have sought advice from the Australian Government Solicitor who agrees that the fact that they are legislative instruments does not, of itself, mean that they are not subject to judicial review under the ADJR Act. It will depend on whether they are properly characterised as administrative decisions or not. So if they are of an administrative character they will still be able to be reviewed judicially under ADJR. Even if they were not of an administrative character, you would still have all the common law rights of review by the courts under the Judiciary Act. So there is still plenty of opportunity to challenge any of those ministerial determinations for error of law. So, if the minister was not properly applying the criteria in the legislation or was making an unreasonable decision at law, those decisions could be challenged through the courts.

CHAIR—Those are challenges based on error of fact, I assume—things like that. Should it be possible to challenge the decisions on their merit?

Ms Hannon—We did not take the view that it should be, and certainly the Attorney-General's Department was consulted during the drafting of the legislation and did not raise that as an issue themselves. To date, it has not been considered that the whole PBS process is one that is amenable to merits review and that, because there are independent committees and criteria set up in the way that they are, there were enough safeguards there without having a merits review process overlaid on it. Certainly there was nothing in terms of the ministerial determinations that we were setting up that caused us to suggest that that was appropriate. Most of the ministerial determinations do not involve a lot of discretion, quite frankly. They are pretty objective criteria.

CHAIR—Okay. I have a broader policy question. The GMiA argued that with a large number of medicines coming off patent in the next few years there is the potential for savings through the natural process of driving down costs in those circumstances to lead to a saving of $8 billion as opposed to the half a billion dollars which this amendment bill foreshadows will

be made. They say the continuation of reference pricing is one of the elements of that. What is your response to that?

Ms Huxtable—I think we have discussed before some of the reasons why it is very difficult to capture the market value of a medicine where the price of that medicine is linked back to a single brand medicine that may be similar but not the same. It is not the same molecule; it is a different molecule. It treats a similar condition; it may not treat the same condition. There may not be an alternative available for the patient. So in that environment it is very difficult to get the sort of price reductions that we know are available in the marketplace, and we know that by having some knowledge about the level of discounting to pharmacy that is occurring. It is very hard to capture those for taxpayers and for patients with respect to the under co-payment medicines when the current arrangement would drag down simultaneously the price of these single brand medicines. And then you basically get two outcomes: either these medicines are withdrawn from the PBS, and they will be necessary medicines and essential for patients, or there will probably be additional patient charges associated with those medicines. The fact that there is much better value to be had for medicines that are operating in a competitive market is driving these reforms. What they are trying to achieve is a structural change that enables those savings to be captured without affecting patients' access to other medicines.

In terms of the numbers, all I can say with regard to the package before you is that the costing for that package has been developed very carefully and under the close scrutiny of the department of finance. The net savings in the forward estimates period are about $580 million, though the gross savings are $1.7 billion in that period. But there are more savings down the track as more patents expire and as price disclosure delivers more the market price for medicines over time. Unusually, we have done a process with Finance that takes us over the next 10 years which suggests savings in the order of $3 billion from these measures.

CHAIR—When you talk about the gross savings being wound back to a net saving of half one billion, are you taking into account new medicines that are funded by virtue of the savings? Is that what you mean?

Ms Huxtable—No. That is the difference between the gross savings and when you have netted off the pharmacy compensation arrangements, and then you get net savings coming out the end.

CHAIR—Okay. Can you tell me if the half a billion dollar saving is inclusive or on top of the savings which would be expected by virtue of all these medicines coming off patent in the next few years?

Ms Huxtable—To the degree that some of those expectations were in the forward estimates, it would be over and above that. It is a net outcome to the PBS forward estimates. We talked before about the 12½ per cent policy which had some assumptions in it about what would be happening over time, and they would already be in the forward estimates. So this is over and above that, basically.

There is also lots of underlying activity that will happen in the PBS. We may get ad hoc price reductions, for example, which will flow on to different medicines. That would still occur and go through our estimates process. We will be listing new medicines all the time

which will also have to be incorporated into the estimates. We do not tend to project forward and make assumptions about what might happen; we only factor in the things that we have some sort of control over.

Senator MOORE—The GMiA submission, which Senator Humphries was just alluding to, has given a detailed analysis of the importance of the current reference pricing system. It is a significant document and it was the basis of a component of the evidence by that group today on the issue of costs. I am sorry, there is a division being called in the Senate and I will have to go. Can I leave my question with you about all that information that came forward: how does that compare?

CHAIR—I actually have a pair, so I might keep asking questions, if that is all right.

Senator MOORE—Sure.

CHAIR—I always wanted to have a committee to myself, and now I've got one! We might leave that answer until Senator Moore gets back, since she has asked the question. I will ask a question about process. A drug comes off patent and it moves from formulary 1 to formulary 2. There is the requirement then for the 25 per cent reduction in price. If the manufacturer of that drug says, 'I am not prepared to accept a 25 per cent cut in the price of my drug and I will not be part of that process,' what happens then?

Ms Huxtable—Just to correct the story first, it is not the coming off patent that triggers a move; it is the entry of competition. So it is a multiple brand. The multiple brand entering moves the drug to F2A. The F2T formulary is a closed formulary. It has already been determined what is on the F2T formulary, so the move will only be to F2A. After the transition period, it moves to F2. For the next three years, it would take a two per cent price reduction, not a 25 per cent price reduction, and it would be subject to price disclosure. It is the new brand listing that triggers that move and it is the new brand listing that agrees to provide price disclosure information.

CHAIR—So it is moving to F2T that—

Ms Huxtable—It does not move to F2T. It moves to F2A.

CHAIR—Okay. So when a drug moves, can it move from F1 to F2T?

Ms Huxtable—No.

CHAIR—It has to go through F2A, does it?

Ms Huxtable—Yes. The only way that a drug can be added to F2T is if there is now a recommendation from the PBAC that there is a new drug that should be in a therapeutic group on F2T. You will have new brands of existing drugs that can be added to F2T, but you cannot get a new molecule added to F2T at this point. Sorry; I know it is a bit complicated and horrible.

CHAIR—So give me an example of a case where a drug would be subject to the 25 per cent reduction in price.

Ms Huxtable—The F2T formulary has already listed the drugs that will be subject to the 25 per cent price reduction.

CHAIR—Let's just take the example of one of those drugs then. What happens if the manufacturer of that drug says, 'I don't choose to accept a 25 per cent cut in the price of my product, and I will take it out of the system.'

Ms Huxtable—That would be a decision that they would make. In all these cases except for a small number of patented drugs which are being treated differently for pricing purposes, which I can explain, there are alternatives available, because we are talking here about multiple-brand medicines. For example, there are 15 brands of simvastatin.

CHAIR—So, by definition, this has to be a drug for which there are alternatives.

Ms Huxtable—There is competition. That is the point of these things: to actually take advantage of the competitive environment.

CHAIR—So, effectively, if a manufacturer did that, they would simply open the market up to their competitors to take that market share.

Ms Huxtable—That is right.

CHAIR—The suggestion has been made that one of the by-products of driving down price like that is that you will not see manufacturers take their products out but the profit margins will fall to the extent that there will be a concomitant fall in investment in pharmaceutical research in Australia. Do you have a comment on that view?

Ms Huxtable—One of the things we are talking about here, when we talk about capturing the benefits of competition in a multiple-brand market, this is about capturing the benefits of competition that already exists. These medicines are being provided at heavily discounted rates to pharmacy—some heavily and some not so heavily. The general characteristic of all these medicines that are on the F2 formulary is that there will be brands of those medicines that are being provided at a discount. The purpose of these is to actually have the government and the taxpayer getting better value from those medicines.

CHAIR—But there is a net saving, isn't there? So presumably we are shaving more off those prices to government than competition is actually achieving.

Ms Huxtable—No, I do not believe that is the case. I think that in the transition period there has been a relatively conservative approach to what is a reasonable percentage price reduction for these medicines. The 25 per cent and 2 per cent reductions are within the levels of discounts that are occurring for these medicines at the moment. We will move much closer to the market price when these medicines move into a price disclosure world. That happens over time. For those heavily discounted medicines that are on F2T it will be quite a long time. They will not be moving to price disclosure until 2011. The actual disclosed price will not start until 2012, so there is a really significant adjustment time before the government will actually pay the market a price that is more like the market price for these medicines.

One of the purposes of this package is to allow a reasonable period of transition and adjustment for industry. Therefore, for some of the premises that underpin your questions, I would argue that they are not a very accurate reflection of how the pharmaceutical supply chain works now, and what the likely impact will be. You know about the graph that I like; it is about capturing the shaded area where there are discounts already happening.

CHAIR—I asked the Pharmacy Guild of Australia before what kinds of savings might be expected to accrue into the hands of the customers of pharmacies from these changes. They talked about a significant number of drugs that will be cheaper at the pharmacy counter as a result. They could not be very specific about that. I think they said that around 400 items would now be cheaper. Have you got an estimate of how many of the, say, top 100 drugs prescribed in Australia might experience a price reduction as a result of these changes?

Ms Huxtable—We have not done that modelling independently. I am certainly aware of the guild's estimate that there are around 400 that they believe will drop beneath the general patient co-payment. The average saving is about $2.70, I think. But we have not done that independently. There is no doubt, logically, that there will be medicines—particularly those that take 25 per cent price reductions—where some forms or strengths of the medicines will be less than $30.70. Just remember that in terms of PBS scripts there are many more PBS-subsidised scripts—that we pick up in our data—dispensed to concessional patients than to general patients. There is no doubt that there will be a creep into that general co-payment area and then there will be direct benefits to patients in that environment.

CHAIR—Dr Harvey said to us that one way to reduce the low take up of generic drugs in Australia would be to provide a lower co-payment for consumers where doctors prescribe genuine generics. There is a $1.50 incentive payment already in the scheme as I understand it. Is that correct?

Ms Huxtable—Yes. That is for dispensing a premium-free brand, which may be the generic brand but is not required to be the generic brand. The requirement is that it is a premium-free substitutable brand.

CHAIR—Is there merit in targeting the genuine generics with a further incentive payment or a reduced co-payment.

Ms Huxtable—I think we are talking about two issues here. There is an issue around patient co-payments and whether there should be a different co-payment if you purchase a generic medicine. There is also a question about whether the $1.50 should be targeted at what is called 'true generics'—as opposed to innovator brand generics—or premium-free brands. In regard to the first of those differential co-payments—effectively—those options are not favoured by government. There are significant equity issues in patients being treated differently. So it is the patient who will pay a higher co-payment—say it is $30.70 now, which is the standard co-payment, and maybe it then would be $25.00. I do not know—some figure like that.

So for some patients there are not generic alternatives of medicines—the medicines that they take—so that would be having to pay a higher copayment. I think there are significant administrative issues about how a PBS safety net would operate in that environment and where you have got people who are paying different things. What does it mean when they get to the safety net—remembering that concessional patients, once they get to the safety net, pay nothing for their medicines. I think the fundamental point is that it is contrary to the idea of equitable access to the PBS, which includes standard copayment. That was on the first part. As to the second part, with regard to the $1.50, the focus is on the patient. It is about providing an incentive for the patient to receive a premium-free medicine. It is not about

providing a subsidy to a particular industry sector. I think there are also administrative issues about determining what a true generic is. It is pretty hard to work out what sits behind the manufacturing entities. Are they generic or are they not? That is hard to say. Again, I think my response to that is that the intent of the $1.50 is to benefit the patient, not to benefit an industry sector.

CHAIR—There was a suggestion from the Consumers Health Forum that there should be a public education campaign based around the lack of danger or the efficaciousness of generics. Is there any view in the department that there is merit in that?

Ms Huxtable—That was announced in the budget. There was a generic medicines awareness campaign announced as a budget and $20 million has been allocated to that. There is a stakeholder, an implementation working group, which is looking at that campaign, including the GMIA and consumers and some other stakeholders. That is an important part of this package to give people assurance that when they take a generic medicine they are taking a high-quality, safe, effective medicine.

CHAIR—You will forgive us for not being able to keep up with everything that was in the budget; there was so much there.

Ms Huxtable—When I was talking about the generics I forgot about it.

CHAIR—Fair enough. Senator Adams?

Senator ADAMS—On the stakeholder group for that particular issue, I did not hear what you said about who is on it. The Generics Medicines Industry Association, the Consumers Health Forum, the AMA, the Pharmacy Guild, the Pharmaceutical Society?

Ms Huxtable—And DBA.

CHAIR—I have just asked about the suggestion from Dr Harvey about lower copayments from consumers, where the doctors are prescribing genuine generic medicines. I want to put to you a couple of recommendations made by Dr Faunce. He suggested that there should be a definition of interchangeable on an individual patient basis. There was a problem in not having that defined in the new sections 101 and 84. Could you comment on that?

Ms Huxtable—I think there are some fundamental misunderstandings around some of these things, which is why, in my opening statement, I talked about the therapeutic premium groups and reference pricing groups. The TGP groups are part of the broader fabric of reference pricing groups. But they are unique in that the PBAC has come to a view that the medicines within those groups are interchangeable at the individual patient level. In terms of what interchangeability means, it means that the drugs are pharmaceutically related, have the same mechanism of action and provide similar therapeutic outcomes at equivalent doses at the individual patient level. That needs to be considered by an expert group and that is one of the things that the PBAC looks at. The only reason that it is in the legislation is that it is really formalising a role that the PBAC already has that has not really been mentioned. It does from time to time advise the minister that it believes that a group of drugs are interchangeable, applying these criteria. Here what we are doing is saying that the minister cannot form one of these groups unless the PBAC has looked at that and given a recommendation to him on that. It is trying to ensure that the experts are consulted in the formation of a new group or adding a

new drug to a group. It is something that would always happen now and does always happen, but it was not in the legislation. So it is one of the things where we have tidied up the legislation to reflect practice, and I think it is a sensible thing. There is no other intention of that.

Senator MOORE—Where is the definition that you read out, Ms Huxtable? It does seem to meet all those issues, but just in terms of referencing, where is it?

Ms Huxtable—I think you are asking not where it is in my opening statement but where it is in our compendia.

Senator MOORE—Yes, where is it? The question was that it needed definition, and that sounded defining to me.

CHAIR—It is not in the legislation, is it?

Ms Huxtable—No.

Senator MOORE—Is it in the guidelines of the PBAC?

Ms Huxtable—No, that is not in the legislation, but we have a compendium of guidelines around bringing things to the PBAC—

Senator MOORE—That is where I thought it might be.

Ms Huxtable—and the issue of interchangeability is addressed within that large compendium.

Senator MOORE—Can you have a look at that and just let us know. The issues that I am sure were the background to Dr Faunce's question were exactly what 'interchangeability' meant, and that sounded fine for the purpose, but it would be nice to know exactly where it was so that we can say.

Ms Huxtable—Sure.

CHAIR—Why shouldn't the criteria for new listings on the PBS of cost-effectiveness and cost minimisation be included in the legislation?

Ms Huxtable—I guess there is the short answer and the long answer. My view is that the roles and responsibility of the PBAC in regard to determining effectiveness and cost-effectiveness of medicines compared to alternate therapies is in the act, and we are not changing that legislation, so I am not sure what that means.

CHAIR—Does that apply to all medicines on the PBS?

Ms Huxtable—Yes. A medicine cannot be listed on the PBS without a positive recommendation from the PBAC, and in making that recommendation the PBAC is guided by—it is required to be; it has a statutory obligation—its roles and responsibilities around effectiveness and cost-effectiveness. In terms of how it does its work, there is a tome of guidelines which put into practice what it practically means to evaluate a medicine. These guidelines are available on our website. They have been recently revised in consultation with industry and continue to be reviewed, enhanced and improved. They are highly technical guidelines that underpin the highly technical evaluations that occur and that the PBAC considers.

There is nothing in this legislation which changes the role of the PBAC. All it does is provide some additional statutory responsibilities for the PBAC around therapeutic groups and also identifying unique formulations. These are functions it does now but they were not explicitly in the legislation.

CHAIR—Cost-effectiveness is in the legislation but cost minimisation is not. Should it be?

Ms Huxtable—I think we would argue that actually it is implicit in how the legislation is drafted.

Ms Hannon—Certainly I think the concept is covered by sections 101(3A) and 101(3B), because subsection (3A) requires the PBAC to have regard to the effectiveness and cost of a therapy including by comparing it with alternative therapies, and (3B) stops PBAC making a positive recommendation if it is going to be substantially more costly unless there is a significant improvement in efficacy or a reduction in toxicity. So that is where the cost minimisation comes in, both in the comparative analysis that PBAC does and in that it is prevented from making recommendations unless the alternative therapy costs do compare, unless there is some significant benefit in the drug. So I think that certainly encompasses cost minimisation as well as straight cost-effectiveness.

Ms Campion—The terminology has developed over time to help distinguish those where PBAC has recommended a higher price be paid because of the reduced toxicity or the greater efficacy, and those where it has not. So where it does not recommend a higher price, in a general term, we refer to that as being cost minimisation. Where it recommends a higher price we refer to that as being a cost effectiveness listing. It is a distinction that we use administratively to distinguish between the two types of recommendations made by the PBAC but to enshrine it in the legislation would not add any value or differentiate in any way.

Ms Huxtable—It is the operationalisation of what is in the legislation. I think that would be our view.

Senator BOYCE—We had a couple of witnesses this morning suggest that the Medicines Working Group membership needs to be expanded so that it includes more than Medicines Australia and the department, to aid accountability and transparency.

Ms Huxtable—That is the Access to Medicines Working Group. It is a bit confusing because there are two. The Medicines Working Group is part of the FTA. The Access to Medicines Working Group has been a little misunderstood. The reality is that over a long period of time there have been a variety of engagements that have occurred predominantly between the department, often the PBAC, and Medicines Australia, because the engagement has often been around the evidentiary requirements of brining new medicines and cost effective medicines to the PBS. There was a joint policy conference held in 2006. Coming out of that was an action plan. There was a working group set up for that. So there has been a variety of things that have occurred.

The Access to Medicines Working Group is really an opportunity to dovetail some of those things through a funnel. In my division there are quite a few people. Often I have different people doing this bit of work, that bit of work and something else, when often the people from Medicines Australia are working on the same thing. So I think it is quite sensible to try and bring this work together and make sure that it is consistent and being done efficiently et

cetera. It is our intention that where there is a very specific PBAC or TGA issue that we work with them.

Senator BOYCE—With whom?

Ms Huxtable—With PBAC or with TGA. I think there is a misunderstanding about what this group is. It is really working around some of the issues around listing new medicines on the PBS, so inevitably it is predominantly an engagement that we have with the industry organisation—and have had for a long period of time. It is just that now we are saying that it is good to have this ongoing dialogue. When we were developing some of the policy underpinning this—which occurred over a long period of time—we began to have a very constructive dialogue around what some of the issues had been. I think we realised that it was really useful to continue to have that dialogue so that we could work through issues, get rid of misunderstandings and work out the real facts. We might disagree but maybe we can at least agree on the facts. So there is nothing very different and exciting about this, we are just channelling the work that we already through a different avenue. The focus of it is on the process of listing medicines. For example, one of the things that will be discussed and has been of interest, is whether there are ways to streamline the TGA registration process and the PBAC consideration process more so that where there is a medicine that is first coming to market, we can find a way, without cutting any corners, to make sure that it goes through the process as expeditiously as possible. They are the sorts of issues. They are fairly administrative and process oriented.

Senator BOYCE—I think the concern of other organisations that are not in this group, when you describe the sorts of things that you are discussing, is that it is not a transparent process. You talked about getting this group together initially because of misunderstandings. I think some of the other groups who are not included in this certainly have misunderstandings on the basis that there is no transparency. I think academics and some of the industry organisations certainly have a sense that they are excluded. I think that has definitely led to some misunderstandings.

Ms Huxtable—This thing is very new.

Senator BOYCE—And the Working Group on Access to Essential Medicines?

Ms Huxtable—That is new.

Senator BOYCE—So that is new?

Ms Huxtable—That is the new focal point.

Senator BOYCE—So that has formalised something that you have been doing for years?

Ms Huxtable—Yes, a whole variety of things that we have been doing. What we are trying to do is to say this is a way to channel some of these other things through, plus have an engagement around some of these issues that are contentious and difficult for industry. We had a first meeting in April. There is certainly no intention to have a secret thing. There will be a communique.

Senator BOYCE—A communique about?

Ms Huxtable—There will be a statement about what the outcomes of the meeting are. There are terms of reference, but all this stuff is still being developed at this point. I do not think anyone intends to keep it secret; it is just that we have been somewhat caught up doing all this other stuff so we have not necessarily been doing the sort of administrative tidying up around that that one would normally do.

Senator BOYCE—Can you understand that there might be some concerns from people that it is intentional?

Ms Huxtable—I was not so aware of those until I read some of the submissions and then realised that there has been what I think is a little misunderstanding about what this is and what its role is. I would say its role is more about improving understanding and working collaboratively in areas where it may be possible to do so—for example, around the streamlining processes whereby it may be possible to come up with some mechanisms that might work better. But at the end of the day it is not a decision-making body; it will not make decisions. If there is anything significant that comes out of it, then the decision would be a minister's decision as it would have to have appropriate authority.

Senator BOYCE—I got the sense today that the concerns were that this group will inform decision-making and there will not be an opportunity for others to inform that decision-making.

Ms Huxtable—If it were the case that anything that was to come out of this group would affect others, then there would be a process of consulting and engaging with others as part of that. I think the minister would require that.

Senator ADAMS—I refer to criticism today that the regulator is not at arm's length from the government; that is the perception. Would you be able to comment on that?

Ms Huxtable—By 'the regulator' do you mean the TGA?

Senator ADAMS—I think they were referring to the PBAC.

Ms Huxtable—The PBAC's role is a recommending role. It is fiercely independent, I would say from my brief experience of it. It goes through very highly technical, comprehensive and sophisticated processes in considering what is before it and makes recommendations on that basis. I am not sure what that exactly would mean.

Senator ADAMS—I think it probably came from the need for a specific section preventing 100 per cent industry funding of the PBAC. It is possible that there have been two references.

Ms Huxtable—I think that is a criticism of a budget measure announced a while ago—I think it was in the 2005-06 budget—to move to a policy of cost recovery in respect of the costs of the PBS evaluation and listing process. The start date for that is 1 January 2008 and we have been going through a stakeholder consultation process according to the cost recovery guidelines of the Department of Finance and Administration. That will need to be put in legislation. So I think it is probably more a criticism of that policy per se, which was a pretty old budget decision. The rationale for that is that there is clearly commercial advantage to companies of being listed on the PBS. That is not its primary purpose; the primary purpose of the PBS is delivering necessary and effective medicines to patients. But there is no doubt that there is significant commercial advantage, and in that environment it was the government's

view that it was appropriate, as the TGA is fully cost recovered, that elements of the PBS listing process could also be cost recovered, and we are moving to implement that policy.

Senator ADAMS—I have another query on the remuneration of members of the PBAC. That was possibly another area—

Ms Huxtable—It is probably part of the same coin. The way cost recovery would work is that there would be a revenue stream where there was an application. The model that has been consulted on is one where there is an evaluation fee and a listing fee. That would be a revenue stream. But the day-to-day operations of the PBAC would not be different to how they are now. The PBAC members are provided sitting fees and the like under Remuneration Tribunal arrangements. I think now they are provided an annual payment. None of that would change. The only thing that would change is that there would now be a revenue stream that the PBAC would not see—it would not be transparent to them—which would come to the department and which would underpin some of the costs of running the PBS, which is a costly exercise.

Senator ADAMS—Thank you.

CHAIR—With that I think we will have to bring down the curtain on the evidence. Thank you very much to officers of the department and the other witnesses who have appeared today. The committee's report to the Senate on this bill has to be produced on Monday and therefore we have a very short turnaround in which to do it. I do not think any questions were taken on notice by the department or anybody else today.

Ms Huxtable—I think there was one. It was on the definition of interchangeability.

CHAIR—Yes. So lightning speed would be appreciated on that if possible.

Ms Huxtable—Yes.

CHAIR—This has been an exceptionally short inquiry in a very short time frame and the issues have been extremely complex. I therefore anticipate that it is quite likely that the report of the Senate committee will not adequately address a number of the issues which have been raised in the course of these hearings. I think it is important to put on the record that that is not a reflection on the quality of the presentations or the lucidity or power of the arguments but rather a reflection of the process that we are facing with this very short time frame. I thank those who have made submissions in a short period and who have prepared evidence for our hearing today. I also thank Hansard and I thank the committee secretariat who will be working over the weekend to make sure this report is available.

Committee adjourned at 1.47 pm