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SENATE

SELECT COMMITTEE ON THE FREE TRADE AGREEMENT
BETWEEN AUSTRALIA AND THE UNITED STATES OF
AMERICA

Reference: Free Trade Agreement between Australia and the USA

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SENATE

**SELECT COMMITTEE ON THE FREE TRADE AGREEMENT BETWEEN AUSTRALIA AND
THE UNITED STATES OF AMERICA**

Monday, 21 June 2004

Members: Senator Cook (*Chair*); Senator Brandis (*Deputy Chair*); Senators Boswell, Conroy, Ferris, Harris, O'Brien and Ridgeway

Senators in attendance: Senators Boswell, Brandis, Conroy, Cook, Ferris and O'Brien

Terms of reference for the inquiry:

To inquire into and report on:

1. The Free Trade Agreement between Australia and the United States of America to ensure it is in Australia's national interest; and
2. The impacts of the agreement on Australia's economic, trade, investment and social and environment policies, including, but not limited to, agriculture, health, education and the media.

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Committee met at 3.44 p.m.

COBBOLD, Ms Christianna, Director, Trans Tasman Group, Therapeutic Goods Administration

DEADY, Mr Stephen, Special Negotiator, Office of Trade Negotiations, Department of Foreign Affairs and Trade

FAUNCE, Dr Thomas Alured, Senior Lecturer, Australian National University Medical School and Law Faculty, Australian National University

HAIKERWAL, Dr Mukesh, Vice President, Australian Medical Association

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LOPERT, Dr Ruth, Medical Adviser, Pharmaceutical Benefits Branch, Department of Health and Ageing

SHAW, Mr Bruce, Senior Policy Adviser, Aged Care and Therapeutics, Australian Medical Association

CHAIR—I thank all of those who have made themselves available for this roundtable this afternoon. This roundtable brings together people with considerable professional expertise in Australia's pharmaceutical policies. The committee hopes this afternoon's discussion will clarify a number of issues raised with it in evidence to date on the possible impacts of the free trade agreement with the US on the Pharmaceutical Benefits Scheme and on drug prices in Australia. My understanding is that the Department of Health and Ageing is represented this afternoon. We welcome your attendance, the attendance of Mr Deady—the chief negotiator—and the attendance of all of you. The purpose of this roundtable is for the committee to hear the discussion and probe that discussion with our questions in order to resolve in our minds how we evaluate and weigh the principal questions that are under consideration by us as a committee and to which we are required, by virtue of our terms of reference, to direct our attention in framing a view to put to the Senate.

The proceedings today are formal. There will be a *Hansard* transcript produced, and the normal rules of parliamentary privilege will apply. People are expected to answer honestly and directly. Not to do so could be construed in certain circumstances to be a breach or an offence against the Senate. If individuals are to be named in an adverse way, people speaking should give thought to whether they wish to do that, because if we regard that individuals have been named adversely we are obliged, quite appropriately, to extend to those individuals the opportunity to have a right of reply. If there is some compelling argument to name individuals, then you might wish to indicate to me that we should go into camera and do so in private so that

their names are not broadcast. I am not directing that to anyone here; that is a standard comment that we make.

We have had two roundtables during the course of the Senate select committee inquiry. The first was on the economics and trade impact of the free trade agreement, and the second was on intellectual property issues. This one on the Pharmaceutical Benefits Scheme has considerable importance to us as well. We would like to ask you all to begin by making a brief statement of what you see as the implications of the agreement, from the perspective that you bring to the table. People can put their views forward, and we can then hear from the negotiator and the department. There may then be some questions of clarification. I do not want those questions to delay us or to reopen issues in the debate, so we will deal with those quickly.

I will then ask the committee to put questions at large to all of you. We will then quickly run back across the panel so that you might respond to the questions the committee have put up. When we have completed that stage, the interactive discussion will commence. You will have an opportunity to put your views to us and clarify any quick matters. The committee will have a chance to canvass the more general elements of our concerns and you will have a chance to respond. We will then move to individual follow-ups and individual discussion between the committee and the panel.

Senator BRANDIS—Mr Chairman, I was just wondering whether it might speed things up a bit if I could indicate to each of the members of the roundtable that there is one particular issue that I am interested in. For those of you who say that an effect of the FTA may be to expose Australian pharmaceuticals to higher prices, I would appreciate it if those of you who wish to make that case could indicate to the committee why it is you say that and, in particular, could identify those provisions of the agreement to which you point to support that proposition.

CHAIR—That is a reasonable request. Before we commence with opening statements, I should also say that we are sitting as a committee of inquiry concurrent with a normal sitting of the Senate. I am not sure if anyone can see this—nor is it necessary for them to do so—but we can see a screen monitoring the proceedings in the Senate chamber. If there is a vote—and there almost certainly will be a vote because there is a censure motion on at the moment—we will have to suspend the hearing briefly, vote and then come back. It may also be the case that, if there is a quorum, the same provision will have to apply. Mr Shaw, would you like to make an opening statement?

Mr Shaw—I will defer our opening comments to our Vice President, Dr Haikerwal.

Dr Haikerwal—Thank you for the opportunity to speak to the roundtable. The Pharmaceutical Benefits Scheme is a central part of Australia's health care delivery system and is a vital part of what we, as the AMA, feel needs to be maintained. The committee has had circulated a motion which was passed by our federal council in Brisbane in May. This motion talks about what we hold to be vital for the PBS and for the free trade agreement to ensure in order to make any particular scheme around the Pharmaceutical Benefits Scheme safe and effective—to maintain those properties—and also to allay our fears around the pricing that Senator Brandis has talked about.

I do not want to go through this motion point by point, because it is before you, but what is key to us is transparency. This word comes up again and again not only from our organisation but also from other people who are involved in the Pharmaceutical Benefits Advisory Committee and so on. The transparency is basically around when data is put to the PBAC for consideration. Obviously the PBAC considers that data and makes its decision about what the listing of a particular medication is going to be. When a finding comes out of that committee and it is listed on the PBS, if the listing is not a general restriction but one of restricted authority, there is often a lot of discussion as to why that is, but the PBAC is not at liberty to explain, show or reveal the data upon which it has based its decisions.

We feel that the transparency and clarity have to be that any clinical data that is presented to the PBAC for consideration for listing should be available to clinicians so that they can see and justify those decisions that are made by the PBAC on behalf of the government regarding listing decisions. That would remove the problems that we currently see of negativity around decisions made and a concern about the lack of clarity and transparency that people perceive of that PBAC listing process.

We also believe that, if there is to be a committee under the free trade agreement that will look at concerns around the PBAC listing, that committee has to consider the data as presented to the PBAC on that issue only, that the PBAC has to make the final decision and that it is the PBAC that needs to present back to the minister once that set of processes is accomplished. We certainly hear that that is the current consideration, and that is something that we are comfortable with should that be the case.

Senator BRANDIS—I do not want to delay things but I want you to clarify my understanding of your last point. You say that the mechanism set up by the FTA if it reviews a PBAC determination should only have before it the data on the basis of which the PBAC determination was initially made.

Dr Haikerwal—Correct.

Senator BRANDIS—Thank you.

Dr Haikerwal—The paper before you was endorsed on 28 May after consideration by our therapeutics committee and also by other committees that are involved in prescribing within the AMA. The federal council of the AMA's 33-member group of every single speciality came to this conclusion unanimously. We believe that the independent review process needs to be that. It should not be tilted in any particular direction, be it through bureaucratic processes or any particular member of a professional group. We believe that the reviews need to be appointed on a case by case basis to bring the best expertise to bear upon those decisions as they are reviewed. I think I might stop there. The rest is probably already on the record.

CHAIR—Thank you. And we do have a copy of your resolution.

Dr Lokuge—I thank the Senate committee for letting me speak here today. My submission is that particularly article 17.10 of the free trade agreement with the United States will lead to evergreening practices of patent and delays in the entry of generic competition. These delays are quantified in terms of—

Senator BRANDIS—17.10, you said.

Dr Lokuge—17.10, particularly 5(a) and (b).

Senator BRANDIS—Page 17-19. I am told that is renumbered 4.

Dr Lokuge—17.10.5.

CHAIR—The reference I think is 17.10. Perhaps we can let the doctor complete his presentation before we go into questioning.

Senator BRANDIS—I want to follow it, that is all. For the record, Dr Lukoge, in the ultimate edition that has been supplied to us there has been some renumbering and I am informally told by the secretariat that it is now in the final iteration 17.10.4. Would you be kind enough to check that that is the provision you are intending to refer to?

Dr Lokuge—Is this the final version?

CHAIR—What you have before you is, as I understand it, the version that has been signed by the trade minister and the USTR, which is the final legally approved text. What was in circulation before was the draft text.

Dr Lokuge—I appreciate that comment, Senator Brandis. My comments relate to 17.10 and subsections 4(a) and (b) related to that. That article will lead to the evergreening of patents, which Dr Faunce will explain in more detail. I have quantified the effects of this to the Australian pharmaceutical expenditures, particularly the PBS. I look at five drugs that are soon to come off patent and that account for 16 per cent of PBS expenditures. If the expected delays arise, the cost to Australia will be \$1.1 billion over four years, or an average of \$260 million a year.

These reforms to the intellectual property chapter and Australia's legislation will also impact on the price and the cost of non-PBS prescriptions, over-the-counter prescriptions, and the \$890 million expenditures in public hospitals. Additionally these effects will have an impact on the generic pharmaceutical industry in Australia, an integral part of the price competitiveness system of the PBS. The generic industry is expected to grow to \$2 billion due to patent expirations over the next four years, from \$800 million. My contention is that 17.10 will directly affect this industry and the ability to take advantage of patent expirations.

The industry currently employs 3,000 people and is expected to grow by 3,000 to 4,000. Therefore, if delays arise as a result of this article, that expansion will be affected. Additionally potential exports from this industry will be affected due to the provisions in that clause that lock in the current position of Australia's generic pharmaceutical exports. This is an important factor because Australia's patents usually expire after those of most countries. Additionally paragraph 6 of the Doha declaration on TRIPS and public health allows countries to export to nations where there are compulsory licences. This directly affects that ability to export.

Finally, I think it is important to outline that, if, as I am contending, generic competition is delayed as a result of these reforms, that will directly affect the PBS pricing system and will

weaken the effectiveness of the PBS. PBS reference pricing, PBS brand premium policy and the PBS therapeutic group premium policy all depend on the entry and the existence of cheap generic competitors in the Australian market. This will be directly affected. I am happy to explain in detail the calculations I have made and I believe there is a brief summary of my points which has been circulated to senators.

Dr Faunce—My submission in support of that of Dr Lokuge is that the combination of the intellectual property changes in this free trade agreement and various provisions of annex 2-C related to the Pharmaceutical Benefits Scheme will lead to a \$1.1 billion rise in the cost of the Pharmaceutical Benefits Scheme to Australia if there is a 24-month delay of generics. I believe that is a conservative estimate of the type of generic delay that we would expect if the evergreening provision in 17.10.4 were included in the Therapeutic Goods Act. It would be our submission overall that the Senate should fail to accede to the legislative amendments to the Therapeutic Goods Act which introduce these evergreening provisions.

I will direct the senators to a particular discussion of the evergreening provisions which are worse than the Hatch-Waxman provisions of 1984 in the United States. They are certainly also worse than the Canadian provisions set out in the Patented Medicines (Notice of Compliance) Regulations 1993. The reason why section 17.10.4 is so disadvantageous to the generic industry in Australia is that all that has to happen is that a patent is claimed, it does not say what type of patent. We are not talking about necessarily a compound patent, but if the senators would look at the High Court decision in the Alphapharm case they will see that one of the tactics of the original patent holders is to issue patents—

Senator BRANDIS—What was the name of that case?

Dr Faunce—It was the Alphapharm case—the High Court decision in *Aktiebolaget Hässle v. Alphapharm Pty Ltd* [2002] HCA 59, December 12, 2002. On page 4 of that judgment, the High Court noted that, although the original compound patent had expired, what had happened was the original drug manufacturer listed another patent with 17 claims. These involved various aspects of the delivery system of that pharmaceutical—its nature as a tablet, a gel and so forth. The tactic that pharmaceutical companies have been using in the United States on a provision such as 17.10.4 is to claim that they have a patent at the end of their initial compound patent. They claim that now they have another patent over the gel or over the capsule. As a result of that, they get an automatic injunction on marketing approval. In the United States, under the Hatch-Waxman provisions, it is 30 months, in Canada it is 24 months and there is no time limit under this agreement. So, in fact, we have an agreement that is worse than the United States and Canada.

One particular person, whose comments deserve to be put on record, said this about what is happening in the United States:

When a drug patent is about to expire, one method some companies use is to file a brand new patent based on a minor feature, such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness. In this way, the brand name company buys time through repeated delays, called automatic stays, that freeze the status quo as the legal complexities are sorted out.

In the meantime, the lower-cost generic drug is shut out of the market.

Our submission is that as you shut out generics you shut out the major mechanism for lowering drug prices under the PBS. It is of interest to note that the person who said that is the President of the United States, George W. Bush. That was a quote from him on 21 October 2002 made in the context of trying to restrict a similar provision in the United States to simply one claim because of the result it is happening in the United States in terms of raising prices. Senator Brandis asked us to identify various other provisions of the trade agreement which we think will lead to price rises. I would specifically mention the following provisions: first of all, in addition to 17.10.4, there is 17.9.6. This will prevent the generic industry in Australia from earning profits by exporting generics to other countries. I will have to check whether or not that has changed as a result of the text change.

Senator BRANDIS—Can you have a look at your colleague's copy?

Dr Faunce—Yes, it is still 17.9.6.

Senator BRANDIS—What do you say that will do?

Dr Faunce—That will stop the generic industry in Australia from exporting medicines to other countries and earning profits through that mechanism. In a sense it will affect drug prices here because we do not have a generic industry in Australia and so we have no means of competing against the major pharmaceutical companies that drive prices up. Provision 17.9.4 also locks us in to an abolition of parallel importing. Parallel importing is not allowed here at the moment, but in a lot of other countries it is allowed. It is a major means of providing competition; and one of the only mechanisms—in fact, the only mechanism—by which drug prices are ever lowered is increased competition. So provision 17.9.4, by absolutely preventing us from ever having parallel importing, is another mechanism whereby drug prices will rise in Australia through lack of competition.

Senator BOSWELL—Could you explain parallel importing?

Dr Faunce—Parallel importing essentially means that you do not actually produce the drug here, but a manufacturer in another jurisdiction is able to bring it into this jurisdiction.

Senator BRANDIS—And you say that is prohibited at the moment?

Dr Faunce—It is not allowed at the moment, but what this agreement does is lock us into that position. So we can no longer say, down the track, for example, if we have a public health emergency—

Senator BRANDIS—I understand your point.

Senator O'BRIEN—What was your example, Dr Faunce?

Dr Faunce—For example, if we ever have a bio-terrorist crisis here or a public health emergency, such as HIV-AIDS is creating in South Africa, it may mean that our government—if we are actually going to treat the ills of our population without completely bankrupting it—will need to import cheap generic drugs from another country. Essentially what this provision does is lock us out from doing that. So we will have to keep charging huge prices. To conclude, there are

various provisions in this agreement that lock us into the additional patent terms for delayed marketing approval which we will not be able to go back on.

Senator BRANDIS—Sorry, you are going too fast for me, Dr Faunce. Can you slow down?

Dr Faunce—Yes, there is a provision in 17.10.4 which locks us into the increased patent terms where there has been prolonged marketing delays.

Senator BRANDIS—What do you mean by the expression ‘increased patent terms’?

Dr Faunce—Australia became TRIPS compliant in 1998. We have 20 years of pharmaceutical patent life. Thereafter there was an argument, and pressure applied under the special 301 provisions of the US trade act, to give an extra maximum of five years if a pharmaceutical company could establish that there had been delays in it obtaining approval. This agreement locks us into that so we can never walk away from that extension of patent life. That has been severely criticised as being preferential to pharmaceutical patents as opposed to other patents.

Another important provision is 17.9.14. This requires us to harmonise our intellectual property laws with those of the United States. In my previous submission to the Senate I mentioned the deleterious effects this might have if, for example, Australia decides to have a research or experimental use exemption in its Patents Act and allow its universities to experiment with, say, producing drugs for otherwise unprofitable diseases such as tuberculosis or malaria. At the moment in the United States medical schools are not allowed to do that type of research because universities are deemed to be profit making enterprises, so any such research is an exploitation of the patent. If this country decides as a social justice initiative that it does not want to tolerate that sort of position, this agreement will prevent us going down that path.

Similarly, 17.9.7, the provision on compulsory licences, will also have an effect on drug prices. The compulsory licensing mechanism was a major strategy whereby the generic industry was established in Canada. By effectively restricting the situations in which governments can issue compulsory licences to particular manufacturers to produce cheap drugs, we are really giving a hostage to fortune in terms of public health. In an era where we are at risk of bioterrorist attack and unusual viral diseases such as SARS, this agreement essentially locks us out of compulsory licences in all except very restricted circumstances. As I say in my submission, this restriction is a breach of United States law. I refer senators to the provisions in section 2102, subparagraph 4, of the 2002 trade act of the United States, which requires any bilateral treaties such as this to respect the capacity of countries to use the flexibility to the full to implement the public health exceptions in the TRIPS Doha declaration.

In conclusion, I also mention, as I have in my earlier submission, the provisions in annex 2-C. In particular I refer the senators to annex 2-C.2(f), the independent review mechanism. In my earlier submission I mentioned that the independent review mechanism is a constructive ambiguity, but I think ultimately this will have to be interpreted according to the language of the treaty. The language that we see here is of words such as ‘invoked’. Put in context and interpreted in good faith with the terms of the treaty in accordance with the Vienna convention on the Law of Treaties, it is very hard to see how an independent review process could lead to any other mechanism than one that at least has the capacity to overturn decisions of the PBAC. If that is the case then one of the major mechanisms of restraining drug prices, which is the

capacity of the Pharmaceutical Benefits Pricing Authority to negotiate lower prices, will be undermined.

Senator BRANDIS—Before you go off that point, weren't you in your earlier evidence also making a point about the operation of article 21.2?

Dr Faunce—I was, yes.

Senator BRANDIS—Is that a similar point to the point you make about 2(f) of annexure 2-C?

Dr Faunce—You are referring to 21.2(c).

Senator BRANDIS—I thought when you were last before us you made some observations on what you asserted to be the effect of article 21, in particular article 21.2, the general dispute resolution mechanism. I am now asking whether the point you have just made about the operation of the review mechanism under subclause 2(f) of annexure 2-C is the same or a related point.

Dr Faunce—It is related.

Senator BRANDIS—How?

Dr Faunce—The way it relates is that the independent review process is a constructive ambiguity. It is a negotiated phrase where both sides think they have what they want. Ultimately that phrase is going to have to be resolved. The resolution is going to occur in a dispute panel under the chapter that you referred to, chapter 21. In preparing for this I have looked at the types of panel decisions that take place and, for example, compared them with those under the World Trade Organisation. These panel decisions stick closely to the interpretive provisions of the text, and the dispute mechanism often only arises after the parties have threatened various dispute problems requiring consultation.

The senator is referring to the section that allows one party to initiate a dispute where only the spirit of the agreement has been broken rather than a particular term. The way article 21.2(c) would work in this context is that all one party has to allege is that they expected a review mechanism would operate in a particular way and in fact, by not conceding to that approach—by, for example, not allowing it to be overturned—we have broken the spirit of the agreement. That is enough to initiate a dispute resolution process and therefore to go through the process of resolving it. In conclusion, I would like to emphasise—

Senator BRANDIS—You responded to the question of how that point is related to the 2(f) point in annexure 2-C. It is not quite clear to me exactly how you get from that review mechanism to the 21.2(c) issue. Do you say that, if there is a determination adverse to the interests of a party under 2-C(2)(f), that alone would be sufficient to enable that party then to invoke the dispute settlement procedure under chapter 21? Is that your point?

Dr Faunce—What we are ultimately asking is: how do we get to a situation where the panel set up under section 21 starts to actually look at the words 'independent review process' and

decide what it means? There is a committee set up under section 21 to examine the process of this agreement. There are various provisions saying that we have to harmonise our intellectual property laws. There is cross-retaliation allowed. So if, say, five years down the track we have attempted to set up what we think is a satisfactory independent review process—we have had the negotiation with the medicines working group and we have set it up—but the Americans do not like it then they may say, ‘This isn’t really what we wanted; it doesn’t allow PBAC decisions to be overturned.’ We may say, ‘Well, it does to a certain extent.’ They might not be able to prove that we have actually breached a term of the agreement, but they will certainly be able to raise an argument under 21.2(c) that we have not complied with the spirit of the agreement and given them what they want. In that sense, through the consultation process they are able to set up a dispute resolution mechanism that allows the panel to make the definitive decision on what an independent review process is.

Senator BRANDIS—This is a very important point, and I want you to clarify this.

CHAIR—Set out what you want and we will ask Dr Faunce to take it on notice. When we come to the end of the presentations, we can do the clarification.

Senator BRANDIS—I think it is a very important point. What I want to know is: are you saying that, as you read the agreement, the chapter 21 procedure could operate as, in effect, a court of appeal from a 2(f) determination under annexure 2-C or are you making a different point—that is, that if the Americans after a period of time were completely dissatisfied with the way the 2(f) determination procedure operated then they could throw the entire procedure into question by bringing an application under section 21?

Dr Faunce—My argument was the latter point.

Senator BRANDIS—Could it be both?

Dr Faunce—My primary intention was to argue the second interpretation, but I guess it is possible that it could do that as well. In conclusion, the interpretive provisions at the beginning of 2-C then become crucial, because if you look at the way trade agreements such as this are interpreted by these three-person panels you see that they look at the literal text; they are bound by it. For example, in the recent World Trade Organisation case that Canada raised about a stockpiling, it argued that there was a social justice agenda that had to be followed. The panel simply looked at the words and said—as this panel will when it looks at 2-C—‘All these principles say is innovation, innovation, innovation; there is no social justice principle there.’ We will be locked into a determination about the independent review process that says, ‘Well, you have to have an independent review process that rewards innovation, not an independent review process that rewards social justice and universal access to affordable medicines.’

Dr Harvey—I am from the School of Public Health at La Trobe University. I am also a counsellor to the Australian Consumers Association, a consultant on pharmaceuticals to the Australian Health Insurance Commission and a member of the Doctors Reform Society of Australia. I am speaking here as an individual. Senators, I have set out my detailed concerns about the impact of the FTA on the PBS in written and public submissions to the JSCOT and your inquiry. I have answered 20 questions on notice from Senator Ferris, which address many of Senator Brandis’s concerns about specific sections of the free trade agreement with which I

have concerns. I do not propose to repeat those in detail at this point in time; many of my colleagues have already done this.

Senator BRANDIS—Have you heard anything from the others with which you disagree?

Dr Harvey—No. Clearly the PBS was included in the free trade agreement at the request of US pharmaceutical manufacturers; clearly their strategy was to achieve a TRIPS-plus agreement in order to raise drug prices; and clearly Australian negotiators, under pressure to conclude the free trade agreement, made a number of concessions concerning the PBS. Many, including myself, believe that these concessions undermine the basic principles of a PBS, especially the public health principle of equity of access and affordable access to drugs. Ultimately these concessions are likely to increase PBS costs, as my colleagues have pointed out. In particular, this agreement undermines Australia's reputation as an exemplar of pharmaceutical policies internationally. Only the government and vested interests, such as Medicines Australia, attempt to argue that these changes are benign.

What I would like to know from this roundtable debate is how these concerns about the impact of the FTA on the PBS can be addressed. Should the enabling legislation necessary for the free trade agreement be blocked by the Senate in its entirety on the grounds that a social policy such as a PBS has no place in a free trade agreement, or is it possible through a further exchange of letters to clarify the issues raised by the AMA, my colleagues and me—outlined in questions on notice to Senator Ferris—and allow the free trade agreement to pass, given appropriate clarification? I look forward to debating these issues.

Mr Honnor—I am here representing the National Association of People Living with HIV-AIDS. NAPWA is the peak community based organisation advocating for and providing policy advice on behalf of the 14,000 Australians currently living with HIV. In partnership with the Australian Federation of AIDS Organisations we work to ensure a national continuum community based advocacy and service delivery from prevention to care and support. Our 20 years of engagement aligned with the singular challenge that HIV has offered has given us a significant depth of experience in and with health delivery in Australia and also with a full range of stakeholder interests engaged in its provision.

We maintain a very specific interest in drug approval and listing processes, given our origins in the late 1980s epidemic experience. Effective HIV treatment did not emerge until the mid-1990s and the urgent need to supply new treatments to affected populations initiated overhauls of existing drug approval processes both in Australia and across the Western world. Our experience has given us a continuing appreciation not only of the importance of the PBS but also of the need to foster and maintain pragmatic, collaborative engagement with all those involved in the Australian response to HIV—government, industry, medicine and consumer health. NAPWA's own ongoing commitment to that philosophy is evidenced by the fact that NAPWA-sourced nominees have filled the consumer rep position on the Pharmaceutical Benefits Pricing Authority continuously since 1999. I in fact occupied that position too at one point a couple of years back.

We are not opposed in principle to an Australia-US free trade agreement, which we believe can be potentially beneficial, particularly to health and medical research, and need not be detrimental to Australian public health policy. However, we believe that the draft text currently

emphasises a commercial agenda and the needs of industry more than it does considerations of public health. The primacy of public health interests underpins the philosophy of both the Pharmaceutical Benefits Scheme and the Australian health care system more generally. We are concerned that the text does not unambiguously acknowledge the centrality of public health interests to the system; nor does it take sufficient account of the need to sustain this in the future.

In particular we believe that the draft text mystifies rather than clarifies key agreements relating to the Pharmaceutical Benefits Advisory Committee, the proposed medicines working group and intellectual property rights. We are also not convinced of the advantages of an independent peer review process attached to the Pharmaceutical Benefits Advisory Committee, given that there is already latitude for unsuccessful applicants to resubmit and to take advice from the PBAC on this—and indeed they do. Given that many of the points that I could make have already been covered and given that we are reaching the end of the statements, I propose to say no more at this point, but I am happy to join in the discussion. I look forward to having some of the questions I have got answered.

Senator BRANDIS—Chair, from at least some of the witnesses we have heard reference to particular provisions of the FTA, and it has been asserted that those provisions have a particular or likely consequence. I was just wondering whether in the interests of expedition it might not be an idea to stand the proceedings down for 10 or 15 minutes so that Mr Deady in particular and, if necessary, Dr Lopert as well can turn their minds carefully to those identified provisions, having heard what Dr Faunce and others have had to say about them, and come back with a considered response.

CHAIR—Mr Deady or Dr Lopert, would it aid your contribution to this committee if we did that, do you think?

Mr Deady—Yes, Senator, I think it probably would. There are a number of points there that have been raised, some of which might be useful for us to have a chat about.

CHAIR—All right. We will suspend proceedings until a quarter to five.

Dr Faunce—Chair, as a clarification of Senator Brandis's questioning on 21.2(c), I think I can see where he is going, in that that section specifically refers to intellectual property rights, so in that sense its effect on the PBS and the marketing would be an indirect one, through its effect on generics and so on.

Senator BRANDIS—I was not making a point, Dr Faunce. I just want to give you and the other witnesses every opportunity to explain the case you are making as clearly as possible so that it can be responded to and Mr Deady and Dr Lopert in particular know exactly what you are saying.

Dr Harvey—I had assumed that Dr Lopert and Mr Deady would have read our submissions and the various particulars that we have put and would be in a position to answer the questions without adjourning for 15 minutes.

Senator BRANDIS—They might want to consider what has been said.

CHAIR—That is a fair comment, but what this process this afternoon is about is for the committee to inquire of the experts, and both Mr Deady and Dr Lopert have said this would aid their reply—

Mr Deady—It would aid my consideration of the matter, Dr Harvey.

CHAIR—in which case it would—

Senator BRANDIS—Dr Harvey, I am not asking for a break just for them.

CHAIR—Excuse me, Senator, I am speaking.

Senator BRANDIS—There is a bit of an implication there.

CHAIR—Well, I am speaking. Do not interrupt me when I am speaking.

Senator BRANDIS—Sorry.

CHAIR—So, on that basis, I think it is a fair request and I will grant it. We will now suspend proceedings until a quarter to five.

Proceedings suspended from 4.28 p.m. to 4.48 p.m.

CHAIR—We will now resume the hearing.

Mr Deady—I want to make a couple of general points and then move on to some of the comments that have been raised this afternoon by others in the room. We very much appreciate and understand the level of concern about the PBS aspects of the free trade agreement. I must say my concern is that much of this public concern that is out there really demonstrates a misunderstanding of the commitments we have entered into under the agreement, and I certainly do my best to try and make that clear today. I still think, though, and I have to say it, that I believe there is a very large amount of quite baseless assertions about what is in this agreement. When people are asked to point to specific language—where does it say that we have made certain commitments, where is it going to lead to the undermining of the fundamentals of the PBS in the FTA—I have seen no evidence that has been satisfactorily pointed out to me as to where we as negotiators have done this. We know what we negotiated and, quite frankly, we have looked very hard at those assertions and we believe they have no substance. I am happy to try and elaborate that particularly as we go through some of the points that were made.

I would like to start on the review mechanism because, whilst there has not been perhaps quite as much discussion of that this afternoon, there certainly has been a lot of discussion about the independent review mechanism that was agreed to as part of the outcome of the FTA with the United States. This is a new commitment that Australia made as part of the final outcome with the Americans. It very much is a transparency and accountability commitment that we have entered into, and again I think there are exaggerated claims about just what this review mechanism does and does not do. The critical thing to point out is that we went into these negotiations with an absolutely clear mandate to protect and preserve the fundamentals of the PBS. That is what this agreement does, and the review mechanism as part of that. When you

look tomorrow, assuming that the legislation is tabled tomorrow, it will be crystal clear to everybody that there are no changes that all in legislation required as a result of what we have agreed to in the pharmaceuticals annex of the FTA or as a result of the side letter that clearly has to be read in concert with that agreement.

CHAIR—Can I ask you a question on that point. When you appeared before us earlier we talked about the review mechanism. I asked you whether the government would have the details of how that review mechanism is to function: what are its terms of reference, what qualifications will the people have that sit in it and those types of detailed questions. Also, will we have it in time for the parliament to consider along with the legislation? The answer was, as I recall, that you would do the best you could. You could not guarantee it but you hoped that we would have that detail. Are you now saying that will be embedded in the legislation we are about to see?

Mr Deady—No, very much the opposite. There is nothing in the legislation that will be tabled tomorrow in relation to the commitments under annex 2-C of the agreement or the side letter. There is no legislative requirement and no regulatory requirement needed to give effect to the commitment that we have entered into to the United States to establish the review mechanism.

CHAIR—That is what caused the question.

Mr Deady—To clarify, there is nothing in the legislation tomorrow on this point.

CHAIR—Okay. But—

Senator BRANDIS—Let us make that perfectly clear—

CHAIR—If I may—

Senator BRANDIS—I am sorry, I thought you had finished. I will ask the question when you have finished.

CHAIR—All right. While we are pausing at this point, it is convenient for me to ask whether the parliament will be able to see how the independent review mechanism is defined—all those questions about who sits on it and what their qualifications are—before we are required to vote on this legislation.

Mr Deady—I cannot answer the question in relation to the precise timing of the conclusion of consultations which are going on at the moment with relevant stakeholders. There were some points raised today by the AMA which I think are relevant to this very question, and they are the sorts of questions about transparency, about just how this review will operate, that the Department of Health are in discussion with relevant stakeholders about. That is quite reasonable. That is the process that is going on. I think that is the critical thing, if we are talking about the commitments that we made under the free trade agreement—which is what I believe is before the Senate select committee: just what precisely we have agreed to, just what commitment we have given to the United States in relation to this review. That is very clear in the language that is there.

There are actually two parts and it has to be read together. Dr Faunce mentioned the part of the annex that refers initially to the establishment of the review mechanism. Paragraph 2(f) talks about establishing a review mechanism. The letter makes it very clear that Australia in setting up this review mechanism will look at decisions not to list. That further narrows what we agreed with the United States. And the Americans understand that; they accepted that. They wanted more out of this commitment under pharmaceuticals than we were prepared to negotiate and give. That is a very good example. This refers to applicants being able to take decisions not to list to this independent review. That is solely what they can take.

CHAIR—Okay. Did you have a question, Senator Brandis?

Senator BRANDIS—Yes. On that point, let us just get this straight. Mr Deady, we have been referred by witnesses to subclause 2(f) of annex 2-C. I do not remember hearing any of the witnesses, at least in their oral submissions, refer us to the side letter of 18 May 2004. Can you tell us, in the first place, from a trade law point of view what the relationship is between the side letter and the agreement itself? Does the side letter have the same status as a clause of the agreement?

Mr Deady—The side letter has the full treaty status as per the agreement.

CHAIR—Just a minute—I thought you were following up my question, Senator Brandis.

Senator BRANDIS—I am. I just wanted to establish, because I am going to ask him to elaborate on the side letter—

CHAIR—Please ask him, because you are interrupting his presentation, Senator, and that does not accord with the rules that we have agreed to. Please ask him your question.

Senator BRANDIS—I will ask him my questions, and I will ask them a lot faster if I am not interrupted.

CHAIR—As long as they are relevant, you will not be interrupted.

Senator BRANDIS—Mr Deady, I take you to paragraph 2 of the side letter of 18 May 2004, which reads:

Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list.

Is it your understanding that clause (2) of the side letter is directed to the review mechanism contemplated by clause 2(f) of the pharmaceuticals annexure?

Mr Deady—Yes.

Senator BRANDIS—So, when we look at what 2(f) means, we interpret it by reference to clause (2) of the side letter?

Mr Deady—Yes.

Senator BRANDIS—You have had a look at section 101 of the National Health Act 1953—

Mr Deady—Yes.

Senator BRANDIS—which sets out the functions of the—

CHAIR—I think, Senator Brandis, you are leading the witness.

Senator BRANDIS—I am; I am absolutely leading the witness. I am directing his attention to something and I am going to ask him what it means.

CHAIR—I am asking you to ask him what it means now.

Senator BRANDIS—All right. Mr Deady, you are familiar with section 101 of the National Health Act 1953, which sets out—

CHAIR—Will you come to ask your question, Senator Brandis?

Senator BRANDIS—I will keep resuming asking my questions each time I am interrupted.

CHAIR—Senator Brandis, you will ask them if you are in order. I am not going to have this procedure descend into—

Senator BRANDIS—I have one question left, Mr Chairman, which would have been asked and answered five minutes ago if you had not interrupted.

CHAIR—I am asking you to ask the question rather than lead the witness through a presentation of a point of view.

Senator BRANDIS—Please let me.

CHAIR—Ask your question, Senator Brandis.

Senator BRANDIS—Looking at section 101 of the National Health Act 1953, which sets out the functions of the Pharmaceutical Benefits Advisory Committee, is it your understanding of the meaning of the FTA and in particular clause (2) of the side letter that the determination described there is the determination described in section 101(3) of the National Health Act?

Mr Deady—Yes.

Senator BRANDIS—And that provides for no price review mechanism—correct?

Mr Deady—That is right.

CHAIR—Perhaps, Senator Brandis, to clear up this point of procedure before we go any further, if you have a question like that, why don't you just ask it? This is not the time in this procedure where we go through leading the witnesses in a chain of evidence. We just want to

know what they have to say and we want to know what their view is. It would save us a lot of time if we would just go straight to those points. Having said that, I intend to rule that way for the future while we are in this phase of taking initial presentations. Mr Deady, please proceed.

Mr Deady—I labour this a little bit because, with the legislation coming out tomorrow, I think it is important that this is understood: that there is nothing in the commitments that we have entered into in annex 2-C or the exchange of letters on the PBS that requires legislative change. I think that is critical, because there is this great debate—Dr Faunce mentioned it again today—that somehow there is this capacity for this independent review mechanism to overturn PBAC decisions. I think it is critical that I get on the record as clearly as I can say to you and to the committee and, through the *Hansard*, to the wider Australian community, that is not the case. There is nothing in this independent review that will enable negative recommendations of the PBAC to be overturned by independent review. The minister for health is responsible for determining what can be listed and what cannot be listed. He cannot overturn negative recommendations of the PBAC. There is no legislative change which will change any of that situation, and that is what I want to say as clearly as I can today and get on the record.

CHAIR—Thank you, Mr Deady. I want you to say whatever it is you want to say as clearly and as concisely as you would. Please continue.

Mr Deady—The other point is that we have seen a number of comments in the last several months, including in the last week or so, and it came through more of the discussion today. The comments probably focused on chapter 17 rather than actually on the annex of the PBS. Certainly it is worth saying some things about article 17.10.4 because this is an area where, again, people will see the legislation tomorrow and this will be crystal clear. I cannot go into precise details today on that but this is an area where there will be a legislative change required to give effect to the commitments that we have entered into with the United States. Claims, however, that these changes will delay generics entering the market, therefore pushing up the price of the PBS—again, I will say as clearly as I can—are not true. There is no change to patent terms in article 17.10.4, or anywhere in the IP chapter.

There is no extension of the term for copyright protection of test data in chapter 17 of the agreement, and these are things that the United States pressed us about. These are things that they did want as part of these negotiations. We had a lot of discussion with the generic industry leading into the process and right through the process. They were areas of concern. Those concerns have been fully addressed. There is nothing that affects the patent terms or any possibility of extension of test data. There is one change, as I said, to the TGA, which people will see tomorrow, to give effect to the commitments on 17.10.4. These measures that are part of these commitments that we have given relate to introducing measures in the marketing approval process which will prevent the marketing of drugs that are currently under patent. That is the existing law in Australia: drugs that are under patent cannot be marketed on the Australian market. So there will be some changes there to give effect to the measures in the marketing approval process but they will not delay generic drugs onto the market. We specifically did not agree to have 30-month or 24-month stays. Again, this is something I think the Americans would certainly have liked us to have agreed to as part of these negotiations. We did not agree with those points. As I said, what we have committed to on 17.10.4 are these changes, measures in the marketing approval process, and they will be giving effect to legislative change, which people will see probably tomorrow evening.

As for some of the other points, I will just address some of the other issues that were raised in relation to chapter 17. Starting with 17.9.6, which was the first point that Dr Faunce made, this relates to two points, really. One was the capacity for the Australian generic industry to export now for the sake of seeking marketing approval in overseas markets while a legitimate patent still exists in Australia. We have maintained that ability. The Australian generic industry will continue to be able to export for marketing approval. They will not be able to export whilst a patent is in place in Australia. That is the status quo. That is the current arrangement and nothing changes as a result of that. Also, I believe very strongly that that reflects international obligations we already have under the TRIPS agreement of the WTO: prohibition on the export of patent material while that patent still exists in Australia.

Article 17.9.4 I think relates to the question of parallel importation. Again, I can say that this article does confirm the status quo. We do not allow imports of parallel importation of drugs at the moment. That remains the situation. I will hand to my colleagues in a few moments to elaborate on this more fully. But that is certainly, in the view of the government, a very significant health issue that needs to be taken into account in considering these things but, in any event, it is the status quo that we are maintaining there.

The other aspect of 17.10, as I understand it, was related to this question of the extension of patent protection for a new use or formulation. Again, there is nothing in the agreement that changes the status quo in Australia in relation to data protection and extensions of data protection for new uses and formulations. It is something that the Americans wanted; it is something that we did not agree to as part of the free trade agreement.

Senator BRANDIS—You are not being given enough credit for your wins.

Mr Deady—These issues are important and we did take them very seriously. I suppose I should not digress but there have been some comments made about aspects of certain of the negotiators in some of these various areas. All I can say, and I do want to put it on the record if I have another chance—and you have given me this chance before, Senator, and I do appreciate it—is that the professionalism, commitment and dedication of Australian officials negotiating in this area and other areas in my view should not be questioned by anyone with legitimate questions and concerns about aspects of the free trade agreement.

CHAIR—I have to say on behalf of the committee, Mr Deady, that no-one is questioning the professionalism, dedication and ethics of the negotiators. We are required to examine the outcome.

Mr Deady—Exactly. It has never come from the committee, I know that. On the question of harmonised IP laws, this is probably an issue that you have heard from us before on. If you look at that language, it talks about ‘endeavouring to work together’. It is a best-endeavours clause; it does not commit Australia. There are no obligations there for Australia to harmonise anything but rather to work with the United States and where appropriate—if future governments decide it appropriate—to work together in those areas. It is a best-endeavours clause and there are no obligations there.

Clause 17.9.7 is to do with this question of compulsory licensing. My understanding is that this reflects current TRIPS commitments of Australia. In any event, just looking at the language

makes it very clear that, despite what Dr Faunce, I think, has said, there are exceptions in the case of public non-commercial use, legitimate government use, national emergency or other circumstances of extreme emergency. There are exceptions that would allow future Australian governments to deal with these sorts of issues in an appropriate way. They are the main points I want to make by way of introduction. I am very happy to try to explain and elaborate those points more clearly.

If I can have your indulgence for one further moment, may I add that it is heartening that some of the things that have been raised in the past were not raised today. In the past there have been very strong claims about the dissemination of information, that this was something we had given away. Hopefully, it is now recognised that there is no change there to current arrangements under Australian law.

There is another element where there is perhaps some confusion. There is an allowance that is reflected again in the side letter which says that Australia will provide opportunities for the adjustment of prices of pharmaceuticals under the PBS. For the record—and it was not brought up today, so again perhaps we have managed to clarify that misunderstanding—that is the current arrangement. For drugs that are already listed on the PBS, applicants do have an opportunity to apply for adjustments of those prices annually, as I understand it. I will stop there. Perhaps Dr Lopert has some points she would like to elaborate on.

Dr Lopert—I thank the committee for the opportunity to speak. I will not cover ground that has already been covered but I will attempt to address the issues which have not been responded to thus far. I will make some opening comments. I would like to reinforce what Mr Deady has said in that the PBS text—annex 2-C and the associated exchange of letters—entirely preserves the fundamentals of the listing and pricing mechanisms of the PBS. There is no impact on the integrity of the PBS and PBS processes. What they do is improve the transparency both to the applicant and to the public, and I think that that is an important point. There are provisions within the annex that address transparency for both the applicant and the public more broadly.

There is no mechanism within the text of either the annex or the side letter that can lead to price increases. I have read all of the witnesses' statements and testimony before the committee and I cannot see how they can possibly draw the conclusion that prices will rise.

The text reinforces the primacy of the PBAC as the gatekeeper to the PBS. On the review mechanism, as Mr Deady said, without a change to the National Health Act there is no capacity whatsoever for any review mechanism to overturn a recommendation of the PBAC. The PBAC will remain the only body which may recommend to the Minister for Health and Ageing whether a drug may be listed on the PBS.

In relation to some of the specific comments that have been made, I won't make any further comments about the IP provisions except in relation to a comment that was made I believe by Dr Faunce who suggested that article 17.10 part 4 was a provision that would allow the evergreening of patents. I would strongly argue that the evergreening of patents is something which is not either provided for or supported by any of the provisions of this agreement. The evergreening of patents is something that will be pursued where pharmaceutical companies believe it is in their interests to do so. There is nothing in this text which either supports or impedes that. There is nothing in 17.10.4 that promotes the evergreening of patents.

The second point that I would like to make is in relation to a comment that was made I think by Dr Harvey—and I apologise if I have attributed comments to the wrong witness. One of the witnesses said that the way in which the independent review mechanism is established is a matter for discussion of the medicines working group, and I would argue that that is not the case. The medicines working group as agreed to under I think it is paragraph 4 of annex 2-C is a mechanism for discussion between officials of aspects of implementation of the text of the agreement but has no decision making status and cannot participate in the determination of how the review mechanism will be established. That is a matter for Australia to decide.

Finally, I would make a comment—and I am happy to elaborate if required to on these issues—on what has been repeatedly stated, and was stated by Dr Harvey, in relation to the principles that are articulated in paragraph 1 of annex 2-C. It has been suggested that these principles create obligations upon Australia or confer additional obligations or hitherto unavailable rights on manufacturers of innovative pharmaceutical products and that these rights that are enshrined are somehow inconsistent with both the national medicinal drug policy and the Doha text.

I think it is really important to recognise that these are statements of principle and they do not confer or imply any rights to any of the parties. They also do not convey any specific obligations on the parties and they are indeed consistent with the current principles and practices underlying the operation of the PBS. They are not intended to encompass all important principles to which Australia or indeed the US subscribe—they are not exhaustive. They do not prevent the continued priority being accorded to fundamental principles that are articulated in our national drug policy, particularly in relation to affordable and timely universal access to medicines, innovative or otherwise. They do not preclude the continued recognition of the importance of public health as encompassed by Doha paragraph 6. What they do is reflect two very different systems of health care and of delivering access to health care and to individuals.

Paragraph 1(d) reflects the fact that the US operates a market-driven system for recognising and determining the value of innovative medicines. Australia, by contrast, operates procedures, as it says, that determine the comparative therapeutic value of a medicine.

I would also like to address a point that was made in one of Dr Faunce's submissions. He said that these are inappropriate because the PBAC does not reward innovation and should not be required to reward innovation. I would strongly dispute that. The PBAC processes indeed do reward innovation but only where that innovation is demonstrable on the basis of well-conducted clinical trials. On the basis of the clinical evidence put before it, PBAC indeed does reward innovation and will continue to do so.

CHAIR—I think we will skip the part about clarification because we did clarify issues as we went. I now invite members of the committee to list the questions that they would like the panel to answer, then we will go around the panel quickly to get answers to those questions. Then I want to get into an interactive discussion in which members of this committee can examine the detail of those questions where they wish.

Senator BRANDIS—Chair, I want to indicate to you what I want to do, subject to your guidance regarding at what point in this process you think these questions are appropriate. What I want to do is put to Mr Deady, Dr Lopert and Ms Cobbold certain propositions which, as I

understand them, have been put by other witnesses. To a degree, they have been addressed narratively in the evidence that we have just heard. But I want to, as it were, put a series of propositions to them and ask for their short responses so that that can be there on the record for all to understand. No doubt the witnesses will wish to rejoin where appropriate. I think that is the best way of doing this, but that is just my opinion. That is what I want to do. Whether it is appropriate to do that now or at a later point in the proceedings is a matter for you.

CHAIR—The first thing I would say is that you obviously will have and should have an opportunity to do what you request. It is a procedural question—that is, in which part of this procedure do you do that.

Senator BRANDIS—That is exactly right.

CHAIR—My suggestion would be perhaps that we all do it up-front so that all of the things that are in our minds are out there for the panel to comment on. We will go around and take the comments from the panel and then, given their general answers and their replies, we may wish to go to the detail of some of those replies. It is the detail that I want to keep back a little at this stage because I think we are still at the more general propositions.

Senator BRANDIS—My questions are only to Mr Deady, Dr Lopert and Ms Cobbold, but, given that their responses will involve them commenting on things that have been said by other witnesses, no doubt other witnesses would wish, as I said before, to rejoin on what they say.

CHAIR—Yes, and they will get the chance to do that when I invite them to comment after the entire committee has put their questions forward.

Senator BRANDIS—All right. If it is in order for me to do that now, I will do it now. Please forgive me if this involves some repetition of what you have already said narratively, but I just want to get the record as clear as can be. Mr Deady and Dr Lopert, Dr Haikerwal, as I understood him, said that the PBAC is not at liberty to release the data on the basis of which determinations have been made. Dr Haikerwal, I take it that, when you say that, you have in mind determinations under section 101(3) of the National Health Act. Is that right?

Dr Haikerwal—Probably.

Senator BRANDIS—Dr Haikerwal said that it would be good if there was transparency. I think this is a question to you, Dr Lopert. What is the position now in relation to that?

CHAIR—Hang on. That is one question. What is your next question? We will get them all out.

Senator BRANDIS—No, let us do one question at a time.

CHAIR—No, we are not going to go into that. I have laid down the procedure several times already. You know it, Senator Brandis. We did this with the economists and with the intellectual property people. We will do it this way. If you want to do direct questioning, wait until we have completed this stage.

Senator BRANDIS—That is why I asked for your guidance. I want to ask one question at a time. I have so many questions here.

CHAIR—You never made it clear to me that you wanted to ask one question at a time and examine witnesses.

Senator FERRIS—That is unfair to the witnesses.

Senator BRANDIS—I have about 15 or 20 questions.

CHAIR—You will get the opportunity to ask them. Do any other senators wish to ask general questions at this point?

Senator BRANDIS—I will just wait till whenever you say I can ask these questions.

Senator FERRIS—How do we determine whether they are general questions? I have a number of questions.

CHAIR—If you were here at the beginning of the proceedings you would know the answer to that question.

Senator FERRIS—If I had not had to have whip's duty because of the censure motion from your side of the chamber, I would have been there.

CHAIR—Do not import the business of the chamber into this committee.

Senator FERRIS—I do not think that is a productive insult to make when you know that I had whip's duty.

CHAIR—I am not making an insult. It is not appropriate.

Senator FERRIS—You are so, and I am insulted.

CHAIR—It is not appropriate to bring the business of the chamber to a specialist committee. We can have an argument about this and make a spectacle of ourselves if we choose.

Senator BRANDIS—Why do we not just deal with this item by item? I can formulate these questions quite sharply, and if I can put them—

CHAIR—If you wish to formulate them sharply and do them all at once—and, as I have ruled, this is the section in which we do that—please do so. But, if you do not wish to do that, let us move on.

Senator BRANDIS—As long as I can do it at some stage, I do not mind when.

CHAIR—I have said, and I said at the beginning, that you will get the opportunity to do that. It is a question of where in the process you do that. I never understood from what you put to me earlier that you wanted to pursue a line of questioning rather than ask general questions.

Senator BRANDIS—All right. I will ask one general question. Mr Deady, just to make this abundantly clear, are you telling us—because I gather that you have seen the bills in draft form—that there will be no legislative changes whatsoever to the Pharmaceutical Benefits Scheme as a result of the free trade agreement and the legislation being introduced into parliament tomorrow?

Mr Deady—There will be no changes to the Pharmaceutical Benefits Scheme in the legislation tomorrow.

Senator BRANDIS—In particular, as I understand that the Pharmaceutical Benefits Scheme is part VII of the National Health Act, are there any proposals at all to amend the National Health Act?

Mr Deady—No.

Senator CONROY—Is there any way that a decision taken by the tribunal or by PBAC can be appealed under the FTA appeals mechanism or any other mechanism?

CHAIR—You can take that on notice. Are there any other questions?

Senator CONROY—That is my general question. I have lots of specific questions, but that is my general question.

CHAIR—Senator Ferris, do you have a general question?

Senator FERRIS—No.

Senator O'BRIEN—I want some more detail on what each of the witnesses thinks will be the exact effect of the proposed changes to the intellectual property laws on the way in which generic drugs come to market. That is, is it suggested that the changes to intellectual property laws will have no effect, or will they have a specific effect and, if so, what is it?

CHAIR—I have a couple of general questions. The Senate was assured that the Pharmaceutical Benefits Scheme was not going to be watered down as a consequence of these negotiations. The first question is: when did negotiations on the PBS commence in the negotiating round? The second question is: given the independent review, we are assured that that, in effect, has no material impact on pricing or the listing of drugs. We did not seek it. I understand the Americans did. If it does not have that purpose, what purpose does it have, and if it has no purpose why is it there?

The next brace of questions is about the FTA and the Doha declaration. Regarding the inclusion of language about protecting public health and promoting access to medicines for all, is there some reason why that language is not reflected in the FTA? If so, what is that reason? Finally, given the emphasis in the FTA on innovation, research and development in competitive

markets, which I understand from a trade point of view is language that frequently appears in trade agreements, is there a view about how this will be interpreted in the light of the goals of the PBS about cost effectiveness and equity? It is the clash of those two concepts that I would appreciate some comment on.

Mr Deady—Could you please repeat that one?

CHAIR—In the FTA, there is language about innovation, research and development in competitive markets, which is, I would say, language typical of trade agreements. In the case of the PBS, there is this equity element to it and a cost-effectiveness element as far as consumers are concerned. There is this obvious clash between those two objectives. How are the equity and cost-effectiveness elements dealt with against the agreement's commitment to emphasising innovation, research and development in competitive markets? I understand that PBS listings that cost \$10 million or more a year require cabinet approval, that ministerial intervention is not unusual and that Celebrex is an example of this. How will the provisions of the FTA affect the decisions of the minister and the cabinet with respect to PBS listings? Do they have an effect at all? What provisions in the FTA or elsewhere will make these decisions more transparent or quicker? They are a couple of general questions. There are no other general questions. I suggest we start at your end and work our way back, and then we will make the panel available for direct questions and discussion with the senators. If you are now in a position to answer generally, please do.

Mr Deady—I will start, and I might ask Dr Lopert to help me out with a couple of these. Senator Conroy asked whether there could be a challenge under the dispute settlement mechanism of a decision of the PBAC or, I assume, the independent review tribunal. No, there can be no challenge to individual decisions of the PBAC or the tribunal under the dispute settlement mechanism of the agreement. Regarding Senator O'Brien's question, there will be no effect on generics entering the market as a result of the commitments that we have entered into under the FTA. As I said before, that will be clear once the legislation is outlined tomorrow. On Senator Cook's question about when negotiations on the PBS commenced, the best answer I can give is that discussions on the PBS commenced in the first round of negotiations here in Canberra in March. However, it was not a negotiation. It was an exchange of information—very much a question and answer session. But that is where the discussion came up. What was the question about the independent review?

CHAIR—The whole question about this is: if it does not do anything what is the point of it?

Mr Deady—It is a commitment from the government of Australia. It does get very much to the question of transparency and accountability. It is a meaningful commitment. It is a process that we do not have now that we will introduce as a result of the concession to the United States, but it is about transparency and accountability. It does put an extra mechanism in the process—limited, as you know, to the negative recommendation but in that regard it is a meaningful commitment as part of a trade agreement. But at the same time it does not get to the pricing and listing. Once the review is established and up and running then it will look at these negative decisions and at evidence, and that, I think, as part of transparency and due process is a good thing.

On the Doha declaration, let me say that it is not reflected in the FTA because we do not believe that there is a need to reflect every aspect of our WTO obligations and commitments in the bilateral agreement. There is certainly an overall article that states very clearly that nothing in this agreement either adds to or subtracts from our WTO rights and obligations, and that is certainly very much how we see that. As Dr Lopert has said in relation to those principles, for example, that is not an exhaustive list and there is nothing in this agreement with the United States that would inhibit Australia taking a very robust position on these issues in Geneva.

Dr Lopert—In relation to some of the remaining questions you asked, Senator Cook, you mentioned in relation to the emphasis on innovation, R&D and competitive markets the issue of the tension, if you like, between equity and cost-effectiveness. That is a tension which exists already, with respect, in PBAC in making its deliberations, with the issue of ensuring cost effectiveness while ensuring that they maintain equity of access. You also mentioned competitive markets. The text of the agreed principles in the annex in 1D states:

The need to recognise the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.

That text is specifically intended to reflect two systems and not to reflect that we in any way do this through the operation of a competitive market. It was purely intended to reflect the US system in the reference to the competitive market, and in the reference to adopting and maintaining procedures that ‘appropriately value the objectively demonstrated therapeutic significance’, it was intended to reflect the Australian system as it currently exists. The understanding was that the agreed principles were entirely consistent with the operation of the PBS in its current form and do not oblige us in any way to change the way in which we operate.

CHAIR—Thank you. We will start with you, Dr Harvey. What I am looking for is just a brief comment on the general issues that have been canvassed and if anything has been said that you want to reply to, please do so, but please keep it brief. We want to get through this as quickly as we can.

Dr Harvey—I suppose I am still concerned that although Dr Lopert said that the principles do not preclude any broader agreement the fact remains that, when people look at the free trade agreement, the principles do emphasise one side of the issue, which is the side of innovation and looking after and rewarding manufacturers. They do not mention these broader principles. My concern is, as with my colleagues, that when people look at this agreement it appears unbalanced. Despite your saying that there are other principles, they are not mentioned. People perceive it to be unbalanced. And the concern is that, when it is being interpreted and under dispute, those principles that are there—not the broader principles you refer to—are the principles that will determine disputes and interpretation, and I would be interested in a comment on that.

CHAIR—We will not ask them to comment on that just at the moment.

Dr Harvey—That is my key issue.

CHAIR—Mr Honnor—

Senator BRANDIS—Sorry—

CHAIR—You are out of order, Senator Brandis.

Senator BRANDIS—I want to ask Dr Harvey what he meant by something.

CHAIR—You will get a chance to do that shortly. Add it to your list.

Dr Faunce—In relation to Senator O'Brien's comments on what aspects of the intellectual property chapter will most influence the PBS, our submission has been that the crucial provision is that related to the amendments about to take place to the Therapeutic Goods Act. We have been told repeatedly by the negotiators—and I am in no way questioning their integrity—that there will be no change in relation to evergreening coming in. Yet the Pharmaceutical Manufacturers Association of Australia, representing all the generic manufacturers in Australia, say:

A literal interpretation of 17.10.4 would suggest that abuse of the system through evergreening of patents will be encouraged.

They go on to say:

Under this paragraph, if the product is claimed in the use patent, then marketing of a generic equivalent is prevented. This could lead to long delays of generic equivalents not reaching the market.

This is the generic Pharmaceutical Manufacturers Association of Australia.

Senator FERRIS—It is their submission, not what Mr Deady says.

CHAIR—Order! Proceed, Dr Faunce.

Dr Faunce—In America, under Hatch-Waxman, the Federal Trade Commission, in a study of paragraph 4 certifications, which are equivalent to what is going to happen under this provision, noticed that 104 drug products came on market between 1992 and 2001. Seventy-five of those 104 involved paragraph 4 certifications with automatic injunctions. These involved the triggering, in that case, of a 30-month stay provision. In 15 of those it was not necessarily the first product that was sued—the first named manufacturer—it was subsequent ones. But a variety of different options then arose. There were court decisions in 53 per cent of those products. In other ones, the original manufacturer licensed the generic, but whatever it was there was a delay of entry.

Essentially, our submission is that the crucial effect of the intellectual property chapter—to answer Senator O'Brien's question—will be that evergreening definitely takes place. I would like, for the first time tonight, to actually go to the text of 17.6 where these principles will take place, rather than just asserting, as we have been hearing from the negotiators, that no change will take place, and look at the actual words of 17.10.4, because I think you will see from those words that it is quite clear exactly what is going to happen. I will explain, and this will not take very long. Essentially, the key words in 17.10.4 are:

The party shall provide measures in its marketing approval process to prevent those other persons from marketing a product—

so this means TGA approval shall not be given—

where a product is claimed in a patent.

We are not talking about entry of generics where a patent is already in force and we are not talking about any particular type of patent like a compound patent or a patent over the crucial pharmaceutical substance. We are talking about the claiming of a patent—in other words, where there is an allegation or an assertion that any sort of patent is involved, any old patent, and this is what evergreening is. Evergreening is the process of claiming multiple patents over all sorts of aspects of the product at the end of its compound life in order to continue patent terms. I have shown the senators that in Canada and America, the only other two jurisdictions in the world to have these sorts of provisions, it has been disastrous for the generic industry, and Dr Lokuge will be able to quantify the exact cost of that for the PBS.

Senator BRANDIS—I would like—

CHAIR—Senator Brandis, you will get your chance to ask questions in a minute. There is such a thing as freedom of speech—

Senator BRANDIS—There is also such a thing as the efficiency of the conduct of this committee.

CHAIR—I would like to hear what these experts have to say before I start questioning. I have ruled this way and there is no argument about where it is going. You will get a chance in a moment.

Dr Lokuge—As I mentioned in my presentation at the beginning, I concentrated on the cost of this FTA on the Pharmaceutical Benefits Scheme and the cost of prescription drugs in Australia on 17.10.5. I would just like to point out again, in relation to a comment by Mr Deady, that the generic industry had been consulted—

Senator BRANDIS—Did you mean 17.10.4?

Dr Lokuge—That is right.

Senator BRANDIS—I just wanted to make sure we were talking about the same thing.

Dr Lokuge—I would like to refer the committee to the Generic Medicines Industry Association's submission to this committee, which says:

A literal interpretation of Article 17.10.5(a)(ii) would suggest that abuse of the system ...

It goes on to say:

Therefore, if generic manufacturers are forced to wait for otherwise invalid patents to lapse or are compelled to challenge for invalidity first, it is likely to delay rapid generic entry on to the PBS and drive up its cost to the taxpayers.

So 17.10.4 is critical to a discussion about the impact of the free trade agreement on the price of medicines, and I believe it has been drawn to their attention. I would like to say that we need to get this right. We are including 58 references to ‘pharmaceutical’ or ‘PBS’ in this text of the agreement. We need to make sure that they are only transparent, as we are being told, because of the cost of not getting it right if you look at the drugs that are coming off patent.

In its submission, the generic industry of Australia states that by 2008, approximately 12 of the 20 most costly drugs in Australia will go off patent. They represent 27 per cent of the PBS expenditures, or \$1.2 billion. The first of these, simvastatin, a drug for cholesterol, goes off patent in July 2005. We need to be sure that what the generic industry is saying—that 17.10.4 will delay the entry of generic competition—is not true. We need to know exactly where in the text the preventive measures are for this. We are seeing examples in the US and in Canada where these delays are leading to higher costs.

It is important to note that the calculations that I have done of the \$1.1 billion cost of this FTA to Australia over four years will be if the 10 drugs that are coming off patent are delayed, as the generic industry has claimed in its submission. I think that the negotiators are aware that after the release of the text of the FTA—the general industry has raised this and individual firms have also mentioned this in our interviews—that the requirements of 17.10.5 will impose a cost, not only in terms of uncertainty about whether or not when the key patent expires it can enter the market but also if there is a need to challenge patent infringement claims made by originated product.

By 2008, 12 of the highest selling drugs in Australia will go off patent. The generic industry is gearing to exploit this. It believes that there will be an increase of the industry from \$800 million to \$2 billion by 2008. This will represent an increase in employment of about 3,000 to 4,000 people. There are new companies entering the market to take advantage of this. I refer you to the Genepharm prospectus. Genepharm is a generic pharmaceutical company which was recently floated—

Senator BRANDIS—Dr Lokuge, before you go onto a particular point—

CHAIR—Order!

Dr Lokuge—I would just like to point out—

Senator BRANDIS—I just wanted to ask a question.

Dr Lokuge—If I can just finish, Senator. The company says a key cause of the increase in the \$2 million—

Senator BRANDIS—Mr Chairman, I raise a point of order. This part of the process, I understood, was not to remake submissions that have already been made but to respond to questions from members of the committee.

CHAIR—That is right.

Senator BRANDIS—You, without any complaint from me, have on occasions interjected questions in the course of witnesses' answers. I want to interject a question into Dr Lokuge's answer—a brief clarifying question. I do not think it is appropriate for witnesses simply to read out statements without listening to questions that members of the committee have to ask them.

CHAIR—Let me express a view about the point of order. It is a point of order that is validly raised, and I accept the point of order. The purpose of the roundtable, as I understand it, is to invite people who are expert in this field to come and express their views. I want to hear those views. I think it is important that those views be aired in public. I think that it is important that those views be aired in a forum in which, if necessary, those views can be challenged. But, in the interests of getting the views clear so we can weigh them, evaluate them, analyse them and consider what return questions we might have, it is important to hear those views in full. This, as you have rightly said, is a part of the proceedings in which we do not want to regurgitate what was said before. If that is what the complaint is, I would ask Dr Lokuge to bear that in mind.

Senator BRANDIS—But I would also like to follow your precedent of interjecting during each question.

CHAIR—I do note the point that we took questions in general, and this question that is being answered now is the question put by Senator O'Brien. I do not want to stifle the views of the committee. I want every view and every question to be pursued, but we cannot do that unless we follow some sort of orderly procedure. So, if I may, Senator Brandis, I will ask you whether you would mind just making a note of this question. In view of the reference to the text, I would like to conclude this before we go to direct questions from the committee by asking Mr Deady to comment on the interpretation of 7.4.

Senator BRANDIS—I am going to ask him that anyway, so don't worry about that.

CHAIR—I want to ask him that.

Senator BRANDIS—If you are not going to permit me to interject and ask a question, in order to clarify in my own mind what Dr Lokuge is trying to say—that is the rule, that there will be no questions by way of interjection when other senators' questions are being asked—

CHAIR—I want an orderly procedure.

Senator BRANDIS—that is fine, and I trust you will impose that on other senators and on yourself.

CHAIR—Of course. Dr Lokuge, have you completed your points?

Dr Lokuge—No, I have some additional points to make.

CHAIR—Would you please make them.

Dr Lokuge—I also ask for clarification. I point out that, in addition to the PBS of the drugs that are coming off patent, there are also costs if 17.10.4 does, as the generic industry claims in their submission to this committee, delay the entry of low-cost competitors into the market. I would like to clarify, and I believe this is not a contentious issue, that if drugs are delayed it will affect PBS prices. It will also affect PBS reference pricing mechanisms, therapeutic group premium policy, as well as the brand premium policy. It will affect the price of over-the-counter medicines and it will also affect the price of drugs in hospitals. So I think it is very important that we concentrate on and clarify the concerns of the generic industry in their submission, after seeing the text.

CHAIR—We have to suspend proceedings now because we have to attend the chamber for a division. Does that complete what you have to say, Dr Lokuge?

Dr Lokuge—It does.

CHAIR—Dr Haikerwal, you have been sitting there quietly and patiently. We will come back and conclude with you and Mr Shaw. Mr Deady, we will ask you for any further comments in view of the interpretation that has been referred to, and then we will take questions directly to the panel from the committee.

Proceedings suspended from 5.48 p.m. to 5.58 p.m.

CHAIR—You have the floor, Dr Haikerwal.

Dr Haikerwal—I will try and keep my comments brief. In short, the AMA's position in regard to the Pharmaceutical Benefits Scheme is that it is vital, it is central and it is part of the National Medicines Policy that we adhere to. We need timely access to the medicines that Australia needs at costs that individuals in the community can afford—and I stress 'can afford'. Medicines must meet the appropriate standards of quality, safety and efficacy—nobody would argue with that. The quality of those medicines must be maintained to ensure a responsible, viable medicines industry.

We see a chink of light—a benefit, believe it or not—from the Australia-US free trade agreement that could lead to greater transparency in the process that currently exists. Currently, when medications are submitted to PBAC for consideration, they make their case with data that is submitted. PBAC then says yea or nay or 'Here are some restrictions.' For us as prescribers it is extremely frustrating that we are given a story that some medications work brilliantly, based on some of that data, but we do not get the full picture to say, 'It's only part of the picture.' If greater transparency were achieved through this process and all the data that is given to PBAC were available for general consumption by clinicians, we could see why PBAC have made certain recommendations which we might find unpalatable until we have seen all the data—because we never see all the data.

Beyond that we see a problem where some of that data is fed out to the public in direct-to-public advertising campaigns or surreptitiously through advertorials, which do not give the full picture. We as clinicians wear the angst of the public because they have heard about this medication which is supposed to be so great, but we do not have the full data set to refute claims or say that they are reasonable. So there is a window of opportunity if this transparency is

grasped with both hands and we see that transparency put through. This is probably the one positive thing that we say could come through.

My general comment on the free trade agreement on behalf of the association is really to reiterate the statements that we have made and the motion that we have passed, which is before you. The devil is in the detail. We do not know what the detail is. These are things we would like to see underlined in the detail. I am pleased to hear what Mr Deady said, but at the end of the day we want to ensure that these provisions encapsulate the changes that we suggest. We want to make sure that that greater transparency opportunity is grasped and that we as a nation do not suffer the deleterious effects of this agreement.

Mr Shaw—I have a few notes to make about several of the questions. I will be very quick. With regard to your question about when negotiations started, Senator Cook, it is an interesting issue that Mr Deady responded to. There was, of course, speculation for probably 12 months before it was formally put on the table. The AMA started putting out media releases and statements calling for clarification of the issue and for the PBS to be quarantined out of the free trade agreement. They were met with denials that the PBS was part of the negotiation process. We were getting leaks that in fact it was always on the agenda, but that the Americans were simply delaying when they introduced it. I will not labour that point, but it was an interesting issue.

With regard to your question about the review process, I agree with Stephen Deady's comment that it could lead to some transparency because of the extra mechanism that it provides. From the AMA's perspective there are some circumstances where we would welcome that—for example, where we do not like a negative decision that has been made by the PBAC. I point out that the ones that we have are fairly rare. We would be concerned if the whole process became gridlocked because a sponsor company began a review process every time a decision went against it. We will be suggesting to Medicines Australia that they develop a protocol to ensure that that does not happen. Quite apart from speeding up the process—which is what the free trade agreement is supposed to do—it could lead to a real gridlock if this review mechanism is used that way or the avenues of legal appeal are used the way. Chair, is it appropriate at this stage to address the questions that Senator Brandis asked?

Senator BRANDIS—I did not ask you any questions.

CHAIR—I think you asked one question at the beginning.

Senator BRANDIS—I have been prevented from asking questions.

CHAIR—No, you have not, Senator Brandis. To the point that he has asked a question generally, by all means, Mr Shaw.

Senator BRANDIS—I asked the question of Mr Deady, who has seen the draft bill. It was a very specific question, which could only be sensibly answered by somebody who has seen the draft bill.

Mr Shaw—I meant the first couple of your list of 15 questions that you are going to ask.

Senator BRANDIS—Sorry, Mr Shaw. When eventually the chairman gives me the opportunity, I am going to ask them one at a time and expect answers one at a time. If you want to, as I say, rejoin on the answers at that stage, that is when that will happen.

Mr Shaw—That is fine.

CHAIR—But if you have some general views to put, please put them now.

Mr Shaw—I will leave that for that time. I will just make one final point in response to Senator O'Brien's question earlier on—and it also picks up a point you asked us on 5 May at the earlier public hearing where we undertook to get back to you with a more considered position on your questions about impediments to introduction of cheaper brands. I apologise for the fact that we have not gotten back to you. The reason for that is that, from our perspective, the issue is still clouded in some mystery, as it were—mystery is probably not quite the right word, but it is part of the developmental process, the rolling-out process of how the free trade agreement is going to be developed. I think some of that has been clarified today, which I welcome. We would welcome the opportunity to be part of the consultation mechanism that Dr Lopert referred to that the health department is undertaking with stakeholders on that broad question and other aspects of the implementation of the process.

CHAIR—Thank you, Mr Shaw. I think everyone has had a fair go to put their point of view to this inquiry, but I did indicate earlier that if you, Mr Deady, had any comment about what Dr Lokuge was saying on the interpretation of provision 7.4 then I would give you the opportunity to make that so I do so now. We will then go to questions.

Mr Deady—I have two or three points to make again on provision 17.10.4. Dr Faunce mentioned the Hatch-Waxman Act. We are not importing the Hatch-Waxman legislation into Australian law as a result of the free trade agreement. So I really do think that comments about 30-month stays and 24-month stays are not relevant to the commitments we have made to the United States and how we are going to give those effect in legislation. On the specifics of provision 17.10.4, I say again that that was a very tough negotiation. I say that not for any aggrandisement reasons other than to make the point that we did speak long and hard to the generics industry.

We understood their concerns in this area and we have negotiated an outcome which we believe meets those concerns. It does provide the ongoing balance between the interests of the generic medicines industry and the legitimate rights of patent holders in these areas. That is what we have negotiated. That is what the language reflects. It says that we will provide measures in the marketing approval process to prevent persons from marketing their product where the product is claimed under a patent. That is what we have to give effect to, and that is what we will be giving effect to in legislation. We believe that does not give any new rights to patent holders, but it does establish an additional step in the TGA in the marketing approval process. The TGA will have to seek something from the generics, and that is what the legislation will reflect.

CHAIR—I think everyone has had the chance to put their point of view, and we appreciate your patience in doing so. We are going to rise at 7 p.m. according to the program. It is now 6 p.m. So for the purposes of trying to manage fairness from the point of view of the committee I

will give government senators half an hour to ask their questions and opposition senators half an hour to ask their questions.

Senator BRANDIS—Mr Chair, it will take much longer than that.

CHAIR—Excuse me, I have not finished saying what I am saying. Would you just curb your enthusiasm, Senator Brandis, and allow me to finish. If one party does not wish to take up all of their time then the other party can do so. If at the end of the process we are out of time and our quorum collapses—I would hope it does not, but if it were to—and we cannot extend then we will have to find a way in which those questions that are left unanswered are given an opportunity to be asked. One of the things I want to see as chair of this committee is that the Senate can inquire to its heart's content in pursuing issues, so that no Senate can say it was not given the opportunity to do so. I also want to see that we hear a representation of the views so we can form an opinion on it. I gather from your enthusiasm, Senator Brandis, that you may wish to start. If you do, the call is yours.

Senator BRANDIS—I am having this checked by the secretary but I understand that, in fact, notwithstanding that the Senate is sitting at the moment, our leave to sit during a sitting of the Senate does not expire at 7 p.m.

Senator O'BRIEN—That is my understanding too.

Senator BRANDIS—We have to be here until at least 9.50 p.m. So if the witnesses are available after 7 p.m., I cannot see any reason why we cannot go on.

CHAIR—Let us not argue the procedure now, let us get on and see how much ground we can cover.

Senator BRANDIS—Dr Lokuge, I listened to what you said and I was trying to interrupt you to ask a short question. I heard you calling our attention to the criticisms of the generic medicines association as to the possible impact of 17.10.4. We have also heard from Mr Deady. Isn't it as simple as this, Dr Lokuge: if Mr Deady is right about what 17.10.4 means and you are wrong about it, then your argument completely collapses, and you do not have a complaint?

Dr Lokuge—That is right.

Senator BRANDIS—Thank you. Mr Deady, just to make things abundantly clear, can you tell us why it is that what Dr Lokuge says about 17.10.4 and what the generic medicines association apparently says is just wrong?

Mr Deady—The commitments that we have made in this area do relate to adding an additional step in the process of the marketing approval. The TGA will be required, as part of the marketing approval process, to establish an additional step to ensure that the generic seeking marketing approval is not intending to market that drug during the patent term. That is the additional procedural step that will be required. It does not add an additional patent right to the patent holder, but it does establish an additional step in that marketing approval process. That is what we are committed to under 17.10.4.

Senator BRANDIS—When you say ‘an additional step’, is there a minimum time for compliance with that additional step? Because it is being said against you here by Dr Lokuge and Dr Faunce that this will spin things out for 24 months, or at least for a prolonged period of time. As I understand it, you said that that is just wrong. Why does this additional step not involve any delay?

Mr Deady—It certainly does not involve any delay. It is an additional administrative question, or certification, that will be asked of the generics when they are seeking marketing approval. It will not in any way delay the normal marketing approval processes. There is no timing issue.

Senator BRANDIS—There is no timing issue at all?

Mr Deady—No.

Senator BRANDIS—You have heard what Dr Faunce and Dr Lokuge have said, and they say that there is a timing issue. Why are they wrong? Have they just misread the agreement?

Mr Deady—I think Dr Lokuge himself said they are reading the agreement in a literal way. That is certainly not the reading that we have. It is not the negotiated commitment that we have made to the United States in this area, and what we are giving effect to in good faith in the legislation is the treaty level commitment that we have made to the United States. We are establishing a measure in the marketing approval process which will prevent the marketing of a product, and that is what we will be giving effect to in legislation to meet that commitment that we have made to the United States here. As I said, it will not extend the time of the marketing approval process, and it does not add or provide any additional rights to the patent holders in that process.

Senator BRANDIS—So it is your advice to this committee, speaking as an expert on international trade law and as the chief negotiator who secured these terms, that the reading which Dr Lokuge and Dr Faunce have suggested as a possible reading of 17.10.4 is not a reasonably possible reading of 17.10.4?

Mr Deady—That is not the commitment that we have made to the United States. We are giving effect to the commitment through the legislative change. Dr Lokuge made the point—and I think he asked the rhetorical question at the end of his presentation—that, if the outcome were to delay the generics onto the market, would it impact on the PBS? That certainly is a question that we do not dispute at all. We knew that going in. That is the basis on which we negotiated this language.

Senator BRANDIS—And that is why you negotiated this language, to ensure that that did not happen.

Mr Deady—To ensure there would not and could not be such a delay.

Senator BRANDIS—And that is what it means to you.

Mr Deady—Because it was a matter that was very much at the forefront of our minds. It was not just in the area of annex 2-C, specific commitments on the PBS; there were issues in relation

to the IP chapter that we also had to get right to ensure that there could not be any way that the PBS, the pricing listing arrangements, could be impacted by any aspect of the free trade agreement. Certainly, with respect to 17.10.4, that issue and that concern was at the forefront of our minds as we sat down and discussed this issue with the Americans.

Senator BRANDIS—So 17.10.4, in the form which it now takes in its ultimate expression in the final draft, was in fact—do I understand you to be saying—the product of the Australian side successfully negotiating to avoid the very thing which Dr Lokuge has expressed concern about?

Mr Deady—Yes, to ensure that there would not be any way through any aspect of the FTA, including the IP area, where the fundamentals of the PBS could be impacted. That was what we were negotiating about, and that is what we achieved through that language.

Senator BRANDIS—Dr Lokuge, if Mr Deady is right, you do not have anything to worry about, do you?

Dr Lokuge—I am a bit unclear because I think it is important to note, firstly, that this is a big change from current practices. We are linking patent expiration with the regulatory approval of generics, which is a TRIPS-plus standard, so that is not an international standard. We are going above the international standard. Secondly, the IP concessions we make here, because of the TRIPS paragraph, are done on a multilateral basis. So every member state of the WTO gets the benefit of this change, while the concessions that we win or that the US has to give in order to get this, are done bilaterally. We are bargaining away an important TRIPS-plus standard. In obtaining a TRIPS-plus standard, the thing to note is that by including—

Senator BRANDIS—That was not the point you were making before, was it? The point you were making before was that—

Dr Lokuge—I am reiterating the fact that in terms of public health, in this case the precautionary principle should apply. If I am wrong, then we have included text and the question is: what have we gained from that inclusion? As Mr Deady pointed out, if what I am saying is even partly right, this has massive implications, not just for the Pharmaceutical Benefits Scheme, not just for taxpayer expenditures but also for over-the-counter medicines where there are no government co-payments or safety nets. It also has an impact on public hospital expenditures, so I think it is very important in the language—

Senator BRANDIS—I understand that. I do not want to be semantic about this, but if you are right, you are right. The international trade law expert and chief negotiator has explained why you are completely wrong.

Dr Lokuge—I would like to point out, Senator Brandis, that what I am presenting is, in part, the collective effort of a research group at the ANU, with Professor Peter Drahos, one of the leading experts in trade and patent law in Australia, and the world.

Senator BRANDIS—Dr Lokuge, he is not here. We have heard your side of the story. You have had a fair go to explain the grounds of your concern. Mr Deady has explained why you are wrong, in his view; and you have conceded to me that if you are wrong your entire argument

disappears. Ultimately, I suppose it is for the committee to decide whether Mr Deady is likely to be wrong about this.

Dr Faunce—Perhaps I could—

Senator BRANDIS—Dr Faunce, I am going to ask you some questions in a moment, too, but let me go about this in my way. Dr Haikerwal, can I come back to you. Am I right in understanding your point to be not that there is anything wrong with this agreement, but that this agreement could have provided an opportunity to do something that the pharmaceutical benefits registration or listing provisions in their current form do not do, and that is to enable transparency in relation to the material before the PBAC when it deals with a listing application?

Dr Haikerwal—There are two points in answer to your question. The first would be that the actual mechanism that currently takes place is that the material the PBAC is presented with is not for general consumption.

Senator BRANDIS—Yes, you have made that very clear.

Dr Haikerwal—And that is something that could be remedied.

Senator BRANDIS—Yes.

Dr Haikerwal—As far as the agreement itself is concerned, it is the detail that we are concerned over that we cannot see, and we have certain concerns—

Senator BRANDIS—It is right here.

Dr Haikerwal—The details of who is on the committee and how it is going to work and what they can and cannot do are not there, and we have got some principles that we would like to see adhered to for us to have greater confidence in the process.

Senator BRANDIS—That, with respect, is a bit like saying, ‘I have still got suspicions. I cannot tell you why but I am suspicious of what governments do.’

Dr Haikerwal—I trust the government. I think that we have to make—

Senator CONROY—You are a very brave man.

Dr Haikerwal—We have to make sure that the principles that we have are actually understood by governments and, indeed, to make sure that those things are incorporated.

Senator BRANDIS—Absolutely, and your message, I am sure, is received loud and clear by everyone. But there has been this kind of mischievous and, as it seems to me, intellectually insubstantial attempt by some to say that prices will go up as a result of the FTA. That is why I ask people to identify the actual provisions they say will produce that result, so we can hear from the people who are the experts in the field as to their response. However, if your point is an advocacy point, namely, that the PBS is very important to the Australian health system and the AMA wholeheartedly supports it, as does the Labor Party, as does the Howard government, as

does practically everybody I can think of, then that advocacy point is well made. But do you or do you not say that there is any provision of the FTA that you can point to that will cause costs to rise in a way that they do not at the moment—do you make that submission?

Dr Haikerwal—With respect, Senator, I believe that people who have made these points have not been mischievous but certainly tried to inform the committee, and I would certainly back up my colleagues, although they are not from my organisation. They are not there to be mischievous.

Senator BRANDIS—That is not a point you make, though.

Dr Haikerwal—I understand it is not a point I made, but I take offence to my colleagues being called mischievous.

Senator BRANDIS—Well, they can take offence for themselves.

Dr Haikerwal—They are members of my association and I will actually back them to the hilt.

Senator BRANDIS—That is fine.

Dr Haikerwal—The second comment is, no, I do not have a specific problem with any particular clause. I have problems with some of the generality in which things have been expressed and we have a manner in which we would like to see the things dealt with to ensure that the Australian public is protected, that they have access to medications as they need them, at a price at which they can afford.

Senator BRANDIS—As I say, that expresses a view as to what public policy should be in this country which I think is unanimously received. But just to make this perfectly clear, you are not saying to us that there is any provision of this agreement that will cause the cost of pharmaceuticals to rise?

Dr Haikerwal—There is no specific provision that shows us that way. However, once the detail is worked out, and if it adheres to the framework we have suggested, then we think that it would work well.

Senator BRANDIS—Thank you. You see, the minister for health and, indeed, the Prime Minister have declared that, as a matter of policy, the government intends that pharmaceutical prices will not rise. That is a declaration of intent by a politician, and I think you said, ‘The devil is in the detail.’ I am interested in knowing whether there is anything in this devilish detail here which you say will produce that result, irrespective of the Prime Minister’s declaration of intent, and you do not.

Dr Haikerwal—I cannot see any detail with the problem.

Senator BRANDIS—Dr Lopert, in relation to Dr Haikerwal’s point that, the way the PBAC listing procedures work at the moment, there is not transparency, he is right about that, isn’t he?

Dr Lopert—Yes, it is limited transparency.

Senator BRANDIS—But it is no more transparent than he said it is. He is right about that, isn't he?

Dr Lopert—The PBAC does release limited information about the nature and the basis of its recommendations. But, no, it does not release the detail. The reason is that submissions made to PBAC are considered by the sponsors of those submissions to be commercial-in-confidence and are accepted on that basis, and therefore there is a significant limitation on the information can then subsequently be made available in the public domain.

Senator BRANDIS—Mr Deady, am I right in understanding that there is nothing in the terms of the FTA which changes the status quo in relation to transparency?

Mr Deady—Certainly there are some additional transparency elements that we have committed ourselves to as part of the FTA with the United States.

Senator BRANDIS—You mean, to make it more transparent?

Mr Deady—To make the process more transparent. They are commitments that the government has now entered into. I think Dr Lopert is right: several of those reflect existing practice; the independent review mechanism is a new process. But they are about improving transparency. Senator Cook asked a question earlier which, in running around the table, we did not really answer. That was a question about timeliness also including cabinet consideration of issues of more than \$10 million. I should say that there again we have made some commitments to the United States to try and improve the timeliness of these decisions, including the post-PBAC recommendations; but again that is where that is possible. There is still flexibility there for future governments of Australia, certainly on a best-endeavours basis, to try and improve that timeliness also. So I think they do get to try to improve the PBS system also where that can be done.

Dr Lopert—Perhaps I could add to that. Paragraph 2 of the annex is headed 'Transparency' and articulates a number of provisions in relation to transparency. Some of those, as Mr Deady has said, reflect current practice. But, as you would be aware, the commitment to make available an independent review mechanism is an additional transparency provision. Also, paragraph 2(e) says that we will provide written information to the public regarding the recommendations or determinations of the PBAC, albeit while protecting information considered to be confidential under the parties' law. That would suggest more scope than is currently the case to put information into the public domain.

Senator BRANDIS—So it is probably not going to be as transparent as Dr Haikerwal wants, because he wants it to be completely transparent. But are you saying that, if anything, it will be more transparent and certainly no less transparent than it currently is?

Dr Lopert—It does not preclude what Dr Haikerwal is seeking, but that would have to be through negotiation; it is not mandated by the agreement.

Senator BRANDIS—As a result of the operation of this agreement, is there any possible way that the listing process before the PBAC could be made less transparent?

Dr Lopert—No.

Senator BRANDIS—Dr Faunce gave a response to questions of mine about the effect of article 21.2 on the operation of clause 2(f) in annexure 2-C. You heard that evidence. I do not think Dr Faunce mentioned this in his oral evidence, but neither do I think it is controversial: that which is the subject of the review process under 2(f) is a recommendation or determination of the kind described in clause (2) of the side letter of 18 May 2004. Is that right?

Mr Deady—That is right. It gives effect to that.

Senator BRANDIS—So 2(f) in annexure 2-C can have a meaning no wider than what is referred to in clause (2) of the side letter?

Mr Deady—I would express it this way: the articulation in the side letter clarifies how Australia will give effect to the particular clause in 2(f) and it limits the precise commitment we have given to the United States that this independent review mechanism will look at decisions not to list. It narrows what is a wider commitment in 2(f)—and that has been agreed and accepted by the United States—as to the extent to which the independent review will look at recommendations or determinations of, in our case, the PBAC. So paragraph 2 in the letter, as agreed by the United States, is the extent of the commitment we have given that negative decisions by the PBAC will be subject to this independent review. Of course, there is nothing to stop future Australian governments under article 2(f) of extending that, if they so choose.

Senator BRANDIS—We are concerned with the agreement as it has been negotiated. Any agreement can be renegotiated, but we are dealing with what we have. The point you make I think is an important one. Clause (2) of the side letter restricts the review of PBAC determinations to circumstances—I am reading from the letter—‘where an application has not resulted in a PBAC recommendation to list’. Am I right in understanding that a refusal to list or a recommendation not to list by PBAC is the only species of reviewable decision?

Mr Deady—Yes.

Senator BRANDIS—I gave you previously a copy of section 101 of the National Health Act 1953 and directed your attention to what is set out under the marginal heading ‘Functions of Pharmaceutical Benefits Advisory Committee’. Are you satisfied that what is described in clause (2) of the side letter is a negative determination made under section 101(3)?

Mr Deady—Yes.

Senator BRANDIS—Dr Lopert, perhaps you might care to comment on this as well: if you read the provisions of section 101 of the National Health Act—not just (3) but all of the subsections of 101—there is no price review mechanism.

Dr Lopert—That is correct.

Senator BRANDIS—That is correct, Dr Lopert?

Dr Lopert—Yes.

Senator BRANDIS—Are you the expert in the health department that runs this?

Dr Lopert—No, I am not a lawyer.

Senator BRANDIS—No, but I ask whether you are the person in the health department who is familiar with the way pharmaceutical benefits listing applications run.

Dr Lopert—That is correct.

Senator BRANDIS—So I am right in reading section 101 of the National Health Act as not even empowering PBAC to make price recommendations but merely to list recommendations.

Dr Lopert—PBAC makes listing recommendations which may allude to the extent of cost effectiveness but, as a rule, not specifically to the price. The determination referred to in paragraph 2 of the side letter, as Mr Deady said, refers to the circumstances in which PBAC says, ‘This drug should not be listed.’

Senator BRANDIS—Therefore, under that review mechanism concerning the Pharmaceutical Benefits Scheme, the only thing that is reviewable is a refusal by PBAC to recommend the listing of a drug.

Dr Lopert—The information on which PBAC relied in drawing that conclusion, it is anticipated, would be part of that review; the actual decision may or may not be. That is a question that needs to be determined by the consultation process.

Senator BRANDIS—Mr Deady?

Mr Deady—I agree with Dr Lopert. That is the effect of the side letter read with existing legislation.

Senator BRANDIS—Some people have said, ‘Well, you can raise the prices of pharmaceuticals through this review mechanism,’ but, on ordinary, plain English reading of the words of the treaty and the statute, it seems to me that that is just not possible. Do you agree?

Mr Deady—I agree entirely.

Senator BRANDIS—I am sorry; I got diverted. I go back to Dr Faunce’s point that, notwithstanding all of that, the operation of article 21.2(c) could give the Americans the opportunity at a future time to say, ‘Well, we’re not very happy about the way this is all working; therefore we want this review mechanism made the subject of the dispute settlement proceedings provided for by section (b) of article 21 and therefore the protections that we already have’—that is, the limitation of the review mechanism to the refusal to list and the quarantining from the review mechanism of any price issue—‘could be lost.’ What do you say to that?

Mr Deady—I disagree completely with Dr Faunce’s comments in relation to what could be challenged by the United States under the dispute settlement proceedings.

Senator BRANDIS—Before you go on, I should ask you a threshold question. Is this type of dispute settlement a reasonably familiar type of machinery in international trade treaties?

Mr Deady—Yes, it is certainly a feature of the WTO agreements and all bilateral trade agreements.

Senator BRANDIS—So we are not in new and uncharted waters here. This is a pretty common form of mechanism in agreements of this type.

Mr Deady—Yes, completely. It is a feature of all of Australia's trade agreements. Probably the only exception in the world is the CER with New Zealand—it does not have a dispute settlement.

Senator BRANDIS—Therefore would it be fair to say that the scope, meaning and operation of this fairly standard machinery is well known to international trade negotiators and international trade lawyers?

Mr Deady—Yes, that it right.

Senator BRANDIS—Do you think it is possible that Dr Faunce is right that that machinery could be used in order to collaterally attack the negative listing recommendation review mechanism in relation to the PBS? If, as you understand it, you would be saying that that is not right, can you explain please just a little more fully for the record why Dr Faunce is not right?

Mr Deady—It is not right in very much, in my view. Even the structure of the commitment that we have given to the United States here, at least in my own mind, would be something that any panel would look at. If this ever did come up—and I do not believe it would ever get to a dispute, but even if it did—the panel would look at the very structure of the agreement in this area. In fact, we have a specific commitment in annex 2 which refers to this review mechanism. It is then elaborated on in a side letter and narrowed in that side letter to identify that Australia, in implementing this part of the agreement, will look at just negative findings. That is the extent of the language.

Senator BRANDIS—And Dr Faunce, being a good lawyer, would know, as all good lawyers do, that particular words qualify general words in a statute where the whole is to be read together.

Mr Deady—Yes. Any panel would look at this in normal treaty language, normal treaty interpretation. This is what they would look at. This is a commitment that we have given to establish this independent review. Again I would make the point that that letter could have gone on; it could have said a lot more about the independent review. The Americans, frankly, would have liked it to have said a lot more about how this independent review would operate, who would be on it and what its terms of reference would be. All of those things could be outlined. The fact is that that is not something that we agreed to as part of the negotiations. We agreed to establish an independent review that would look at negative findings. That is what the language says and that is what any panel would look at and say to the United States: 'Well, if you wanted it to specify that it should have 10 people on it rather than 11, or it should have a certain mixture of people, then you should have negotiated that with Australia, and that would be reflected in

this language. You certainly had the opportunity, because there was a side letter that articulated a number of additional commitments that Australia entered into.’ That is absolutely the fundamental reality of what any panel would look at if it ever came to a decision.

Senator BRANDIS—So in your opinion it is wrong that a provision like article 21.2 could be used to collaterally attack review mechanisms set up by this agreement.

Mr Deady—Absolutely wrong. If Australia did not set up an independent review mechanism then we would be in breach and the Americans may challenge it. That would be the breach.

Senator BRANDIS—What about the other point—which, in fairness to Dr Faunce, I should say that he did not embrace dogmatically but merely as a possibility—that the 21.2 procedure could even be kind of a court of appeal from a review against a negative listing determination?

Mr Deady—I think Senator Conroy asked a similar question. There is no capacity under the agreement for a particular decision of the review or decision of the PBAC to be challenged under the agreement. The dispute settlement mechanism established under the FTA with the United States is, as you said before, a common feature of trade agreements. In this case, as in virtually all trade agreements, it is government to government—the United States government would be the one that would challenge any measure by the government of Australia.

There is no provision in this agreement for what we call investor-state disputes. Quite frankly, if we had an investor-state provision in this agreement, I suspect we would be spending a lot of time this afternoon talking about what that investor-state dispute settlement might mean for the review mechanism. It would have raised a number of questions, many of which I also believe could have been satisfactorily answered, but it is hypothetical because it is not there. There is no capacity for the United States to challenge a particular ruling or decision of the review or of the PBAC.

CHAIR—Mr Deady, can I come back to the question of the independent review and what we as legislators make of this. The proposition has been put to us, I think by Mr Andy Stoller, that this is a living agreement and this agreement has embedded in it avenues of further consultation and further discussion between the parties, quite reasonably. When you look at the scope of the powers of some of those further discussions, some of them are capable of moving beyond review and actually reaching agreement on matters. Others enable a whole series of issues to be brought forward and, if the parties agree, settled.

The first question I have comes from the Senate’s consideration of delegated legislation. The Senate, as you no doubt know, has a view that if legislation comes forward that delegates key decisions to the bureaucracy without the legislature being able to influence or oversee those decisions then the general principle is that that type of legislation is by and large frowned on by the Senate. It is not always disapproved of, but it is by and large frowned on. In viewing the legislation that implements this FTA, we look beyond the legislation at the FTA itself and there are a number of issues that could be called delegated legislation. Given that the PBS is a deal breaker, as Senator Conroy has described it and I would say the same, when might we as legislators see the terms and conditions of how the independent review will operate and will we see them before we are asked to vote?

Mr Deady—I might ask Dr Lopert to also make some comments, but the discussions and consultations with stakeholders are still going on in relation to the review. There is no legislation, delegated or otherwise, in relation to the establishment of that review. It is, as I said, up to the government of the day to have such a review in place, but there is no legislation required to—

CHAIR—That is the reason for the question. Can the legislature see what the regulations governing the independent review are when it votes on bringing this agreement into life so that it is aware of what it is approving?

Senator BRANDIS—You are assuming that there will be no regulation.

CHAIR—I am assuming that there will be some.

Dr Lopert—The implementation of the review mechanism will be procedural, not by regulation. There will be no change to any of the legislation, regulations, disallowable instruments, pertaining to the way in which the PBS operates. As I stated before this committee when I last appeared, there is this consultative process which is under way. The minister has made it clear that he wishes the review mechanism to be developed through a mechanism of consultation with key stakeholders. That consultation is under way. As I said previously, it is not appropriate to pre-empt the outcome; however, it is certainly the intention that that process will be completed before the committee reports. That is certainly what we are endeavouring to do.

CHAIR—What you are saying to us is that it is highly likely, but not certain, that, when the Senate comes to consider the legislation, it will know how the independent review will work and what the qualifications and so forth are of the people required to conduct that review. Is that what you are saying?

Dr Lopert—There are obviously a number of issues that need to be resolved such as who will do the review, how many people will do the review, what the terms of reference of the review will be, who the review will report to and what the procedural rules will be. There are a whole lot of complex issues that need to be resolved. The intention is that that will be determined before the committee reports. However, because the process is dependent on the contribution and participation of a number of stakeholders, that certainly cannot be guaranteed.

CHAIR—Yes.

Senator BRANDIS—It could be—

CHAIR—Excuse me, Senator Brandis, you will allow me to ask my questions in my way, as I allowed you to ask yours.

Senator BRANDIS—I was trying to be helpful.

CHAIR—I do not need your help, thank you very much.

Senator BRANDIS—I was trying to direct your attention to section 140 of the act which might help you concentrate your—

CHAIR—I do not need your help in any way, shape or form. Please desist from offering it. The problem I have is that some things turn on this. I am not sure how much turns on it. Your view that the legislature is unlikely to have any role here, that it will be determined administratively, raises the question: if things turn on this then what guarantees has the legislature got that the actual black letter of the way in which the review is going to be conducted conforms to our understanding? That is not to question your assurances; that is for the Senate to assure itself that their understanding of what you meant is exactly as they understood it by seeing the actual terms. I realise that this is a complex question and there are a lot of stakeholders and much consultation has to be gone through but we are being asked, it would seem, to vote on this fairly quickly. The question is, for me at least, what are we in fact voting on if we cannot see all the mechanisms set out in front of us? As far as what you have said about the independent review, is the same true of the medicines working group?

Dr Lopert—The medicines working group is a government to government mechanism that will be made up of officials of relevant departments. There are no terms of reference and no timetable for the meetings of the medicines working group. The only reference in the text to the medicines working group is that it will discuss the aspects of the annex and the implementation of aspects of the annex. It is not anticipated that the medicines working group will meet prior to entry into force of the agreement. The medicines working group may only ever meet once. These things cannot be anticipated at this point. However, I will say that the medicines working group is not a decision-making body and that it will be an avenue for consultation and discussion only.

CHAIR—Yes, that is clear from the text. What is also clear from the text is that the council mechanism, where the ministers meet on a regular basis, no doubt enables those ministers to take on board the nature and weight of the discussion in such a body as the medicines working group. While the medicines working group may not be, to use this term, a legislative body, the powers of that high consultative body have the ability to change the agreement. Is the government in a position to put down a fuller explanation of how the medicines working group will function—the role and functions of the medicines working group, the scope of things it will look at and those issues that are clearly in the public mind, given the discussion here tonight and elsewhere, for the purposes of interpreting what that clause means in the Senate debate?

Mr Deady—As Dr Lopert has said, we could give the same explanation as the one we have just given in relation to the medicines working group to each of the quite large number of various working groups that are established across virtually every chapter of the agreement. They are not an unusual feature of trade agreements.

CHAIR—I am not saying that they are unusual.

Mr Deady—They are not an unusual feature of the WTO. We have these committees talking about the agreements all the time. As you say, if governments decide to amend certain of the commitments that will amend the agreement then we are into a different process that starts again with the JSCOT and other processes if we are changing the treaty and if we are changing the law it goes through the whole process.

CHAIR—I am not saying that there is anything untoward about this. I am saying that this is a matter of high sensitivity and it behoves us to conduct ourselves cautiously. The routine for general matters in areas of high sensitivity requires us to be a bit more focused, I think.

Mr Deady—This may not help but I will say it for the record. You asked about the independent review. I understand the point you are making but, and I am not the only one saying it, after tomorrow it is very clear there is no change to the legislation in relation to PBAC recommendations. So there is nothing that affects the legislation in that area. To me at least it seems that the concern about the independent review is that somehow it was going to be able to overturn these decisions, and it cannot.

CHAIR—I have heard those explanations, I have read the text and I understand all of that. I will go on to my next question. An agreement such as this marks a point in time at which the parties agree on particular issues, but interests that exist in the community that want to see a different outcome continue to push their concerns. An agreement like this should be seen as the resolution of those issues at this point in time. Pressure continues over time; there may be a different resolution in the future according to the will of governments et cetera. We know what the US drug producers want and they have said so and it is on the public record. There is no argument about what their objectives are. We do not assume, do we, that this agreement marks for them an end to their pursuit of their goals and forever and a day they are going to put their cue in the rack and walk away and say, ‘No more pursuit of those goals as far as Australia is concerned.’ We do not make that assumption, do we?’

Mr Deady—No, we cannot make that assumption. With future governments and future US governments that are reviews and committees.

CHAIR—So will the industry. Senator Brandis said it the other day: they are in business to make a profit and they want to maximise their opportunity for a profit. If there is an opportunity at some future time to press their case again—given they are on the public record, they are ardent advocates of their case and they pursue it with a degree of relentlessness—they will. We can expect these issues to be eternal almost.

Mr Deady—I agree with that but I add the point that whether there is an FTA or not that is the situation, that is the real world.

CHAIR—Of course. But an FTA opens up the question of being able to look at these things for them. The absence of an FTA means they have to look at them in the context of the WTO.

Mr Deady—I do not agree with that. They could certainly raise these issues bilaterally. Industry put pressure on government all the time.

CHAIR—Of course. I accept that correction.

Mr Deady—What the framework of an FTA or trade agreement does in my view is to, at least to a certain extent, circumscribe those avenues for pressing these things. The Americans sat down in the early days of February and said to the government of Australia, ‘Yes, we wanted more in this area but this is a balanced outcome that we can accept and live with.’ That is again the reality of what we did at the end of February. We have agreed to establish an independent review and the Americans have agreed to that. So if the pharmaceutical industry continues to press its interests, which it will, the government of the day can say: ‘There is an independent review here. Off you go and make your case to it.’

CHAIR—Your point is also true that they can press it in a multiplicity of ways. But an agreement provides a focus for them to press their objectives. We are not disputing, are we, that some companies regard the ability to ‘evergreen’ their patents as a desirable thing?

Dr Lopert—No. It is reasonable.

CHAIR—We are not disputing that that is an objective and something they pursue. So it is a legitimate question to raise, isn’t it?

Mr Deady—I think it is legitimate to ensure that the government can maintain the balance between the legitimate rights of patent holders and the concerns of others, including consumers and, in this case, the generic medicines industry. That is the challenge in front of governments.

CHAIR—But we do know that they are likely to pursue this. You have just stated what you regard as good public policy for governments in dealing with, I guess, preventing them from doing so.

Mr Deady—Yes, it is about having laws that get that balance right.

CHAIR—Dr Faunce, we heard Senator Brandis talking a moment ago to Dr Lokuge, Mr Deady and Dr Lopert about the Pharmaceutical Benefits Scheme and your submission to us. Do you have any comments or views about what has been adduced from that discussion?

Dr Faunce—Senator Brandis said, ‘Show me the bits of the text that will lead to prices rising.’ Today we have said that we are absolutely convinced that 17.10.4 is an evergreening provision. This is not something that we are asserting to the committee; it is something the words themselves indicate. The words are ‘a party to provide measures in its marketing approval process shall prevent’. The word ‘prevent’ cannot do anything else except raise the spectre of an injunction on marketing approval ‘until such time as the claim is worked out’. What else can that be except evergreening, if there is no definition? In America, for example, the President himself is trying to restrict these claims to one claim per drug. Here we have no restriction on the number of claims. It just says ‘claimed’. It is worse than Hatch-Waxman in the sense that at least Hatch-Waxman limits it to 30 months. Here there is no limit at all. Until this claim is worked out, there is no marketing approval. That is an injunction on the introduction of the generics. As Dr Lokuge has indicated, all you have to do is have a restriction on generics entering the market for a period such as 24 months and you have the billions of dollars of costs.

CHAIR—This is one of the issues that we are going to have to make a decision about. You have summarised the concern. Mr Deady, you answered a series of questions from Senator Brandis about this. I understand those questions, but would you mind setting out for me why you think Dr Faunce is wrong? What are the reasons for his misreading this, in your view?

Mr Deady—The key to this provision is a commitment that we will provide a measure in the marketing approval process to prevent, as you say, persons from marketing a product. So the situation will be that for a generic manufacturer seeking marketing approval, as part of that marketing approval process—there is no requirement on them now to do this; they simply go to the TGA and say, ‘We seek marketing approval for this particular drug—we will be putting in place a measure that will honour this obligation, which will prevent the marketing of a product

where the product is claimed for a patent. Where there is a valid patent then that product will not—let me start again. I am sorry. I am getting tired.

The commitment is that we will provide an additional measure in the marketing approval process to that which we have now. That is what we will be introducing as a result of this commitment. It is the patent law which determines the existence or otherwise of a patent. That is the situation now—patent holders have their rights under the patent law and that is the situation that continues; nothing changes in that regard as a result of this language and as a result of this commitment to the United States. We are putting in place a process in the measure, in the marketing approval process, which is a very simple mechanism. It does not add to the length of the time for the processes, as I said in answer to Senator Brandis, and it does not provide additional rights to the patent holders.

CHAIR—I assume, Dr Faunce, that your response to that is that the words in this clause do not make that explicit.

Dr Faunce—No, and we have checked our interpretation with members of the generic pharmaceutical industry in Australia as to how they go about normally getting approval. It is quite clear that at the moment the Therapeutic Goods Administration has nothing to do with patents. It leaves that question to be worked out. This is a radical new interpretation which links marketing approval to patent validity. There is nothing else that this can be except evergreening. You only have to start exploring the meaning of the word ‘claimed’ and the whole thing becomes transparent—the emperor’s new clothes are revealed. You only have to start looking at the word ‘prevent’ and start thinking what that means for it to become clear that we are talking about an automatic injunction until the claim is worked out.

Senator BRANDIS—There is no such thing as an automatic injunction.

Dr Faunce—In America, for example, under Hatch-Waxman—

Mr Deady—There is no Hatch-Waxman here and there is no injunction that can be applied under this article. There is nothing that is going to change in the marketing approval process that is going to lead to an injunction as a result of that provision.

Dr Faunce—How are they going to prevent the entry? What mechanism is there for preventing that?

Mr Deady—It will be clear in the legislation tomorrow. I cannot go into any more detail than that. You have got to wait another 24 hours. We are establishing a measure in the marketing approval process that will fully meet the commitments under this article.

Dr Faunce—If someone wants to come in, they are going to be prevented from coming in until the patent claim is worked out. That has to be an injunction. What else could it be? They are prevented from getting marketing approval until the claim is worked out.

Mr Deady—No, they are not prevented. There will be nothing that stops the marketing approval process proceeding as a result of the measures that we introduce under this.

Dr Faunce—To prevent them from marketing a product.

Mr Deady—They are not going to market if the thing is in breach of a valid patent. They do not do that now.

Dr Faunce—They cannot market until the claim is worked out. It is there.

Mr Deady—That is not what it says.

CHAIR—We will await the legislation tomorrow.

Senator BRANDIS—You should give Dr Faunce the opportunity, though, Chair, to—

CHAIR—Excuse me, Senator Brandis, I will conduct my examinations—

Senator BRANDIS—In fairness to Dr Faunce, you should give him the opportunity to withdraw that slip of the tongue and the reference to automatic injunction.

CHAIR—I have been very fair to everyone tonight. I just ask that you be fair to me and let me complete in my normal way. I understand, I think, Dr Faunce's position. I have got some questions here from Senator O'Brien, who wrote them out for me and who wants them asked.

Dr Harvey—Excuse me, Chair. We were meant to finish at seven o'clock and I have got a plane to catch. Would you excuse me?

CHAIR—Yes, indeed. Thank you very much.

Mr Honnor—And me, too.

CHAIR—You, too, Mr Honnor. To anyone else caught in that situation, I apologise for running slightly over. These are questions for you, Mr Deady, that my colleague has written. The first one I will not answer; it is a question for you. Have Australian trade negotiators ever negotiated an agreement where the meaning of a provision is found to be something different to that which the negotiators intended or believed to be the case? I think the answer is: yes, on occasion, but that is a matter for the interpretation of the dispute settlement provisions if there is an argument.

Mr Deady—I think that is a fair answer. The GATT has been in place since 1947 and we are still arguing about what some of that means.

CHAIR—The second question is: what do you say the term 'claimed in patent' means in 17.10.4(a)? On what is that interpretation based?

Ms Cobbold—We are not the IP lawyers here. In terms of the drafting of the legislation which we will put before the parliament tomorrow, it will become clear. I cannot explain—

CHAIR—This is quite a serious question. If, when my colleague sees the legislation, he does not feel that it satisfies his question, I will ask him to put it on notice to you. But I am also interested in knowing what that means, in your view, and on what that interpretation is based. I go to his third question. In evidence, you prefaced your description of the outcome of the negotiation of 17.10.4 with the words ‘we believe’. Why did you do this? What do the US negotiators believe it means?

Mr Deady—Let me be clear. We have negotiated an outcome in this area which will not lead to the delay in generic medicines entering the market. That was the concern we had at the forefront of our mind. As I said, in talking to the generics industry—I have read their submissions, I spoke to them while we were there and I have spoken to them since we got back—I found that they are looking at this. From what they have said and from what I have read, they accept and understand that it is the legislation that gives effect to these commitments which will be critical and that is what they are waiting to see.

CHAIR—I do not think the American side—

Mr Deady—The Americans here have a different system. They pressed us to adopt their system, but we did not agree to adopt the Hatch-Waxman system. We came up, finally, with the language that covered our concerns and that the Americans could accept. Dr Faunce talked today about some numbers; he said 75 of 104 cases. I am not sure about that. I certainly know the Americans, in having these discussions with us, also see this provision as applying very much to a very limited subset of cases. In their case, they said that about six per cent of cases would in any way be subject to this sort of provision—that where a generic believes there is a patent in place and intends to breach that patent or to manufacture before that patent comes into place, then there are a very limited number of cases where that situation applies. That was the sort of discussion we had, so they certainly see this as very much a limited subset of cases. In our view, from our discussions with the Australian industry, that subset is very small indeed.

CHAIR—In view of a disagreement between you and the Americans about all this, is it settled by the disputes panel, if necessary?

Mr Deady—Here again, if there were a situation where the United States believed we had introduced a measure which was not consistent with the commitments, that could be something that could go to the disputes panel.

CHAIR—I think I know the answer to the next question but I will put it to you. Is the legislation to be introduced tomorrow going to deal with all of Australia’s obligations with respect to the issue of pharmaceuticals and IP issues?

Mr Deady—Yes.

CHAIR—I think I have about a minute of time left. Dr Haikerwal, you have heard this discussion and you have heard the byplay between Mr Deady and Dr Faunce. Do you have any comment to make about it—or do you, Mr Shaw?

Dr Haikerwal—I think that the comments I made earlier to Senator Brandis probably still stand—that is, the framework needs to be established so that we meet the expectation of the

Australian public, which is to make sure that they get access to their medications in a timely manner, in a manner that is cost-effective. Legitimate concerns have been raised and, if we get the reassurances, I suppose we have to ensure that those reassurances are translated into the manner in which those committees are rolled out.

CHAIR—Do you need to see the details about the independent review, to be satisfied?

Dr Haikerwal—I think so, yes. That is really a very significant part of this process—the constitution and the manner in which it will operate.

CHAIR—What about the medicines working group?

Dr Haikerwal—The medicines working group I have less concern over because I feel it is a discussion group rather than an operational group. That would be less concerning to me than the operational function of the review panel.

Senator BRANDIS—On that last point, Dr Haikerwal, I can completely understand why anybody would say, ‘I can’t be reassured about what a review mechanism means until I see the details of the review mechanism.’ But we know this much, don’t we: that that which is a reviewable decision has been defined for us—it is a refusal to list. As Mr Deady has explained, that expression in the side letter can only apply to decisions made under section 101(3) of the National Health Act. That is not controversial between us any longer, is it?

Dr Haikerwal—No. I think the important thing about that process is that the decision that is going to be reviewed is about that particular item, that the evidence given to that review committee be the same evidence that was given to PBAC, and that that review decision is taken back to PBAC and it is PBAC that reports back to the minister and nobody else breaks the chain of events. One thought is that perhaps another form of words to that effect would be useful.

Senator BRANDIS—I do not want anybody leaving here thinking that this review mechanism could be a price review when it is about as plain as anything can be that it—

CHAIR—I have never said that.

Senator BRANDIS—I did not say you had.

CHAIR—No?

Senator BRANDIS—It is a review of a refusal to list on the application of a listing applicant.

Dr Haikerwal—Yes.

Dr Lopert—Can I respond to some of the concerns raised by Dr Haikerwal in relation to the specific mechanism of the review. While I have said repeatedly that I cannot pre-empt the outcome, there are some assurances that I can provide in relation to that review. The review will only consider the information that was placed before the PBAC and the appropriate avenue for any new information to be proposed would be a resubmission to the PBAC and not a referral to a review mechanism. That will remain the case.

Furthermore, there was a concern expressed by Mr Shaw that ‘we don’t get gridlock’. The resolution passed by AMA Federal Council said that the review should:

... be pragmatic, and facilitate, not delay, the PBAC approval processes for PBS listing of pharmaceuticals.

I think I can provide some assurances in that respect insofar as the review mechanism will only be precipitated or provided where a PBAC has recommended not to list. Therefore, it cannot invoke a gridlock because that application is not going any further. It is another path.

Senator BRANDIS—The triggering event is the nonhappening of something—that is, a determination to refuse an application?

Dr Lopert—That is right. We refer to it as ‘a failure to recommend’.

Senator BRANDIS—I think everybody has got their head around that.

Dr Haikerwal—May I make one clarification. One of the reasons a listing may not occur would be a company refusing to accept the cost on their product. Therefore, there is a potential for that to be an obstacle.

Dr Lopert—If PBAC recommends listing, the company’s refusal to list would not qualify under the terms which are articulated in the side letter which say that the review will be made available where PBAC has failed to recommend listing, because in circumstances such as that PBAC has recommended listing. As you would be aware, PBAC does recommend from time to time that a drug should be listed but not at the price requested by the company. The most common occurrence of that is where a drug is considered to be similar in benefit to a drug already listed and has been proposed on a cost effectiveness basis and PBAC has determined that it would be appropriate to list it on a cost minimisation basis, on the basis that there is no substantial clinical benefit over the comparator and therefore there would be no basis on which to award a price higher than the comparator. In those circumstances PBAC will say, ‘We recommend listing but on a cost minimisation basis with the comparator’ with which it has a flow-on effect in terms of the price—but PBAC has not failed to recommend in that circumstance.

Senator BRANDIS—I understand your point, Dr Lopert, that if that were the recommendation the review mechanism would have no jurisdictional basis to operate because it is not a case where ‘an application has not resulted’ in a PBAC recommendation to list.

Dr Lopert—Precisely.

Mr Shaw—Can it happen that PBAC does consult with the sponsor company, including on the cost effectiveness report, and no agreement can be entered into as to the nature of the report between the sponsor company and PBAC so in that case the application is rejected? Does that take place? That is my understanding.

Dr Lopert—I am sorry but I do not quite follow what you have said.

Mr Shaw—I am taking it back a step from your position. The sponsor company will not accept the ballpark of the price that is being alluded to and in fact there can be no agreement between PBAC and the sponsor company on the cost effectiveness report that PBAC has done.

Dr Lopert—I think that you have the process a little out of order. That would occur subsequent to PBAC's recommendation. PBAC considers the drug for listing on the basis of the price proposed by the company in its submission to PBAC. PBAC will make a recommendation that the drug should be listed because it is acceptably cost effective, in which case the price will be nominally accepted but may be reviewed by the PBPA. PBAC will suggest that the drug may be recommended perhaps on a cost minimisation basis, in which case it would be recommended for listing on the basis of the price of the comparator drug, or PBAC may say it does not believe that the drug is adequately cost effective or there is too great an uncertainty about the degree of cost effectiveness of the drug and it does not recommend that the drug be listed, in which case that would be an avenue for something to be reviewed. If PBAC has recommended that the drug be listed under certain circumstances—because, as the act says, the PBAC must recommend the circumstances in which the drug is listed—then the price negotiation goes on subsequent to that and therefore PBAC has already recommended it.

Senator BRANDIS—I think that is a good point. Let me pursue that as well. Say a sponsor company has a new drug. It goes to PBAC and it says, 'We want you to list this drug on the PBS. It has already been approved by the TGA. We want you to put this on the PBS and we want to put it on the market at \$X per prescription.' The PBAC considers the matter and, exercising its powers under section 101C(3) to impose conditions, it says, 'We think this is a good drug. We are satisfied about its cost effectiveness but we are not going to list it at \$X per prescription. We will, however, list it at \$Y per prescription'—where Y is a value less than X—and the sponsor company is unhappy about that. Is it your point that is nevertheless a recommendation by the PBAC to list, albeit subject to conditions other than what the company sought in its initial application?

Dr Lopert—Yes, but there is a whole range of conditions and circumstances.

Senator BRANDIS—I understand that, but we are sensitive to price here. So that is one among the ways in which a drug can be listed, one of the conditions that can be imposed?

Dr Lopert—PBAC does not generally nominate a price. It is generally the company that nominates the price. PBAC decides whether, at that price, the drug is comparatively effective and comparatively cost effective vis-a-vis the appropriate comparator. What does happen, as I was alluding to before, is that there are circumstances where a drug is claimed to be better than the comparator where PBAC determines, on the basis of the evidence presented before it, that the drug is in fact either not significantly better or that any benefit is not clinically significant so as to justify a higher price. The PBAC will recommend that it be listed on what is called a cost minimisation basis with the comparator and the PBAC will nominate a therapeutic relativity on which that cost minimisation will be based which will imply a price.

Senator BRANDIS—Okay. So that is where the PBAC gets into price. But a recommendation that a drug be listed on what you have described as a cost minimisation basis is not a recommendation not to list.

Dr Lopert—No.

Senator BRANDIS—It is a recommendation to list on that condition.

Dr Lopert—Yes.

Senator BRANDIS—So that cannot be a reviewable decision, because a reviewable decision can only be a decision not to list.

Dr Lopert—That is correct.

Senator BRANDIS—All right. I have a couple of other points. You may have dealt with this in your narrative response to the opening statements, but for completeness of the record I just want to put them to you again quickly and get your response. Article 17.9.6: I understand Dr Faunce to be saying that will stop the generic drug industry in Australia from exporting and he observed, which is no doubt true, that if that were to happen there would be diseconomies of scale which could drive up local prices. Is it right to say that the operation of 17.9.6 could be to stop the generic drug industry in Australia from exporting?

Mr Deady—No, it is not true. I probably did not say this as clearly as I should have before. There are two or three points here. The first one is that there is nothing in this article that stops a generic drug producer exporting for marketing approval. That is the current situation and that remains. Of course, once patents have ended there is nothing that stops the generic drug industry exporting, and that is what they do and that is why they seek marketing approval for approval in overseas markets. The one thing that is proscribed by this article is that an Australian generic producer cannot export—

Senator BRANDIS—I am sorry, did you say proscribed or proscribed?

Mr Deady—Proscribed. The one area here where the generic producer is not permitted to export is when there is a valid patent in operation in Australia. That is the current situation. That is the situation that applies that is reinforced by this article. But I would also say that under our existing international obligations we have a limit on the ability of Australia to export whilst patents are in place in this country—under the WTO commitments.

Senator BRANDIS—So it is already governed by WTO commitments?

Mr Deady—Exporting whilst a valid patent operates in Australia is inconsistent with our international obligations under the WTO.

Senator BRANDIS—So the obligation which it is said this would impose upon Australia is an obligation to which Australia is already subject under the WTO?

Mr Deady—That is certainly the view of the Department of Foreign Affairs and Trade.

Senator BRANDIS—It was said that 17.9.4 would result in the abolition of parallel importing. Can you tell us in layman's terms—

Dr Lokuge—Could I just clarify a point there, Mr Deady, in relation to the Doha declaration on TRIPS in public health, which Minister Vaile was a signatory to. Paragraph 6 of that, the compulsory licensing agreement, allows countries to take advantage of compulsory licensing—for example, a country in our region which does not have a local production capacity. That was recognised as one of the limitations of the Doha declaration. The implementation of paragraph 6, which Australia is a signatory to, allows countries to amend their domestic situation to export to countries that have issued a compulsory licence while a valid patent is in place in their own country. Is that right? And therefore are we being locked into the current status which does not recognise paragraph 6 implementation?

Mr Deady—I am confused as to whether we are talking about different paragraph numbers here. In relation to paragraph 6 and this question about exporting for marketing approval, the issue in this chapter was whether Australian generics could continue to export to foreign markets to seek marketing approval in those countries in order to take advantage of those trading opportunities once the patents ran out. That is what we have given effect to here. Under our current international obligations, we are not allowed to export while there is a valid patent in operation in Australia. That is what is reinforced by this article. We talked before about this issue, which I think was identified as 17.9.7, which spoke about compulsory licensing. I do not know whether we are at cross-purposes here.

Dr Lokuge—Has anything in this agreement that you are aware of, particularly in article 17, affected Australia's ability to export to a country that has issued a compulsory licence, given the Doha declaration on TRIPS and public health that Mr Vaile was a signatory to?

Mr Deady—There is nothing in here that has affected our existing WT rights and obligations.

Dr Lokuge—But is it true that to implement paragraph 6 the Doha declaration allows, under TRIPS, countries to address the problem with countries that do not have a domestic production capacity. So, if in our region there was a country that had an emergency and issued a compulsory licence, are we being locked out of opportunities as a result of this agreement to meet our Doha declaration on TRIPS and the paragraph 6 part of that declaration?

Mr Deady—My answer to that is: no we are not being restricted. These articles reflect the status quo in Australia. We have not taken on additional commitments with the United States as part of the FTA in this area. That is the best answer I can give.

Senator BRANDIS—It was a fairly detailed question, Mr Deady. I wonder whether I can adopt the question, as it were, and you could take it on notice from me, if you want to give a fuller written answer?

Mr Deady—I think we should. We do not have IP experts here today.

Senator BRANDIS—Okay. You will deal with that.

Mr Deady—We can certainly look at these things.

Dr Lokuge—I am referring here to a Department of Industry, Tourism and Resources paper of 2002, *Discussion paper on patent extensions and springboarding, and the effect on generic*

pharmaceuticals manufacturers in Australia. The report identified that, due to the patent extensions and the marketing approval process, the PBAC process and other things, the patent extensions were a recognition that, due to delays in Australia, the actual effective patent life was decreased and therefore there was an extension. The issue that this raised for Australia's generic export industry was that Australian patents expire after most other countries. I think it is something like 20 years for most patents in Australia compared with the US and the UK and other countries. One of the options in this paper is that Australia changes its current existing IP laws so that, while a patent is in force in Australia, it is allowed to export to countries where the 20-year patent terms have expired, given the fact that Australia has longer effective patent terms.

That was one of the issues that the generic industry has also discussed in order to stimulate the export potential. It is a \$62 billion industry, and currently Australia only has six generic manufacturers. We are not taking advantage of the export potential that is there. In order to do that, we would have to change existing patent requirements in Australia that allow us to export. Isn't it true that, by signing this FTA, we are locking in the current arrangement, which effectively prevents generic manufacturers in Australia from exporting?

Mr Deady—Whilst valid patents operate in Australia, yes. I just do not want you to say that it prevents the generic industry from exporting, because the generic industry does export, as we sit here today. But what you have said is what I tried to say before—that that is the status quo, that Australian industry is not able to export while there is a valid patent in place in Australia. In the Department of Foreign Affairs and Trade, we believe that that is an obligation we already have not to do that, under the WTO. This agreement reinforces that existing obligation.

Senator BRANDIS—Without expanding it?

Mr Deady—Without expanding it. The expansion the Americans wanted was to prohibit exports for marketing approval, which was of great concern.

Senator BRANDIS—So you argued that with the Americans and you won?

Mr Deady—Yes.

Senator BRANDIS—I will refer to 17.10.4 again. My note says that Dr Faunce also says that this will lock us into increased patent time where there are long marketing delays. I think that might already have been covered, but do you want to say anything more about that?

Mr Deady—We do allow for patent extension to provide for the time it takes to get the TGA approval of a particular drug through the processes. That, again, is under existing arrangements in place in Australia. We do reflect those —again, I cannot pull up the particular article—existing arrangements, that we do allow for patent extension, and that continues under the agreement.

Senator BRANDIS—So your evidence is that even if that is so, it does nothing more than reflect the status quo.

Mr Deady—That is right. It does specify a particular number of years that Australia is required to provide in copyright extension.

Senator BRANDIS—Dr Faunce observes correctly that 17.9.14 speaks of harmonising our intellectual property laws with those of the United States. He says that is a requirement of that article. What you say about that?

Mr Deady—There is no obligation on Australia to harmonise laws and practice. This is an article that requires each party to endeavour to reduce differences, but it is a best-efforts obligation and not one that requires us to harmonise in any particular way. This is an area where we work together in Geneva in WIPO and other areas, and we see this as a valuable additional recognition of that in this agreement. But there is no obligation on us to harmonise our law.

Senator BRANDIS—This may be beyond your area of specific expertise, Mr Deady, but it is the case that, under WIPO, there are currently rounds in which Australia is a participant for the express purpose of multilaterally harmonising, including with the United States, intellectual property laws?

Mr Deady—I understand that is right but it is not my area of expertise.

Senator BRANDIS—Dr Faunce says that the effect of 17.9.7 is that the compulsory licensing mechanism will have an effect on drug prices because it locks us out of compulsory licences in all but very restrictive circumstances. What you say about that?

Mr Deady—Again, it seems to me that the language here does provide a number of exceptions for Australia. As I recall the conversation earlier this morning, there were these suggestions that we could not operate in cases where there was a national emergency or extreme urgency.

Senator BRANDIS—Would you read us the words that assure you that that is not right.

Mr Deady—It states:

... in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency—

there is flexibility for the government to operate in these areas. The point is in so much of this IP area, in copyright and in other areas, there is the capacity for Australia to take advantage of current exceptions under the WTO—the TRIPS agreement—and many of those are reinforced in those agreements. So there is flexibility built into it and a recognition of our the strength of our IP regime by the United States.

Senator BRANDIS—Thank you. Those are my questions, Chair.

CHAIR—Dr Faunce—I actually thought Senator Brandis might ask you this question—in view of the explanations you have heard from Mr Deady, do your initial comments stand or are they modified or refuted?

Dr Faunce—I do not resile from any of my earlier comments. I think the PBS and the intellectual property chapter relating to generics need to be put into a broader context. Essentially, what is at stake in the Senate's decision tomorrow is probably one of the—

CHAIR—We are not making a decision tomorrow.

Dr Faunce—Well, soon; if it is in the House tomorrow, it is soon—

Senator BRANDIS—The Labor Party caucus might make a decision tomorrow, Dr Faunce!

Dr Faunce—It is one of the most significant public health decisions since Federation. Essentially, what we are looking at is the risk of dismantling one of the great social justice initiatives, along with Medicare, that make the Australian nation what it is—an egalitarian system that has universal health care, not a two-tiered system of health. The reason it is at risk is that it is incredibly expensive to run these social justice initiatives. We paid \$5.5 billion in 2002-03 on the Pharmaceutical Benefits Scheme. You heard evidence from Dr Lokuge that has not been controverted; in fact, Mr Deady agreed that, if we were correct that there will be a delay, Dr Lokuge's calculations are correct. There will be a \$1.1 billion increase—

Senator BRANDIS—Mr Deady is looking very cynically at you there; I do not think Mr Deady did say that, Dr Faunce.

CHAIR—Order!

Dr Faunce—in relation to at least the five drugs that he mentioned. This is going to have an enormous impact, not just on drugs listed on the PBS but also on the public health system as a whole. Certainly, as a doctor who has worked in the public health system, in intensive care, I know an enormous amount of public hospital budgets are taken up with drug expenditure. If we are locking ourselves into a system where those drug prices are set to rise by the sorts of amounts that Dr Lokuge stated today, then this could lead to the collapse of the Medicare system as it becomes unworkable in terms of the capacity of the government to fund it.

At the same time we would be undermining our public health system for no reason except to satisfy the enormous greed of the pharmaceutical industry worldwide. And we say 'worldwide' because, under article 4 of the TRIPS agreement, whatever gains the United States makes under this bilateral agreement will automatically—in fact the words are 'immediately and unconditionally'—be passed on to every other member of the World Trade Organisation. That includes the vast pharmaceutical industries of Europe and Japan. They will all gain the benefit of the clauses we have mentioned today—in particular, again we mention 17.10.4, the evergreening provision. The drug companies of Europe and Japan will gain access to those provisions.

The generic pharmaceutical industry in Australia is holding on by its toenails. Companies are mostly owned by foreign multinationals. There are a few Australian-owned companies. They have incredibly thin profit margins. Their capacity to survive into the future, as Dr Lokuge has indicated, is based around their strategy of being able to get access to these big blockbuster drugs that are coming off patent. If we lock ourselves into an agreement where that becomes impossible then we will see the collapse of the generic pharmaceutical industry in Australia.

Essentially, what is at stake is that, just as we as a country are about to consider becoming a republic with an independent voice and something to say on the world stage—

Senator BOSWELL—There is no chance of that! I must say this has very little to do with the subject.

Senator BRANDIS—Dr Faunce is coming before us as a lawyer and a doctor.

Dr Faunce—We are about to trade off—

CHAIR—You are right about the republic, Dr Faunce.

Senator BRANDIS—This is the sort of rhetoric we would expect to hear from, you know, Pauline Hanson and the back blocks of Queensland!

CHAIR—I do not think Pauline Hanson—

Senator BRANDIS—Dr Faunce, you are not doing yourself justice.

CHAIR—I do not think Pauline Hanson is a republican, but anyway.

Dr Faunce—Just as we are about to debate whether we should become a republic, we are trading off an enormous amount of our sovereignty over public health issues. We have heard Mr Dedy confirm today that none of the Doha principles are in this trade agreement. What impact does that have? The committee only has to look at the World Trade Organisation decision in relation to Canada over its stockpiling of generic pharmaceuticals. The three-person panel trawled through that agreement, could not find any justification in the TRIPS agreement for the sorts of public health and social justice measures that Canada was trying to implement and essentially ruled that they could not proceed down that track.

If we go the other way—if we say to America, ‘No, this is an unbalanced agreement; it is all to the reward of pharmaceutical company innovation; it does not reflect the unique egalitarian principles of Australian society’—I think we will be doing a remarkable service to the people of developing countries. We will be sending a signal of hope to all those people who are being oppressed by exorbitant pharmaceutical prices—and I refer to the aged. We will be protecting ourselves from the drug prices associated with the new wave of genetic pharmaceuticals. Not only that, but I think we will be doing a service to the American people. A decision to vote down these changes, particularly to the Therapeutic Goods Act, is not a decision against the American people; it supports them. They are the people who are being oppressed by the pharmaceutical industry. They are the people having to pay four times the price of drugs here and go to Canada and Mexico to get their essential medicines.

If Australia stands up at this moment in its history and makes a decision that it is not going to go down the path of signing this unbalanced agreement which trades off its unique public health and social justice imperatives, it will deserve to be a republic. It will deserve to have a strong independent voice on the international stage. If we do not do that and we roll over and become the poodle of the United States on this, as we are on so many other human rights initiatives, then we do not deserve to become a republic.

Senator BRANDIS—Dr Faunce—

CHAIR—Order! I have the call.

Senator BOSWELL—Why don't you recruit him?

Senator BRANDIS—He is probably already a member!

CHAIR—You have heard the discussion, Dr Lokuge. Do you have anything to add?

Dr Lokuge—I would like to add something, but first I would like to clarify another point with Mr Deady, if I could. I got the impression from one of your comments that maybe we were disagreeing on different things. You mentioned that, as far as you know, there are six per cent of cases where a generic company tries to market a product while a patent is in force. Is that right?

Mr Deady—These were certainly numbers that were mentioned by the US side in the negotiations, yes.

Dr Lokuge—If that is the case, then under the current situation that six per cent of drugs, regardless of the validity of the claim, would be arriving on the Australian market. Is that right?

Mr Deady—I do not understand the import of the question. Let me just say a couple of things. First of all, for the record, I do not agree that anything in this agreement will lead to anything like the \$1.1 billion of additional costs that Dr Lokuge has claimed. There is nothing in this agreement that will lead to those sorts of outcomes. As I said at the beginning of this hearing—if we are into restating positions—some of the comments that have been made about the FTA in relation to the PBS that I and members of the committee pick up in talking to people around the country just reflect that sort of scaremongering. Regarding the claims that there are going to be huge costs as a result of what we have agreed, there is nothing that I have heard from anybody today that has suggested to me that there is any language in this agreement that can possibly lead to those sorts of outcomes.

I said that this was a number that the Americans quoted. They certainly do not see this area of the agreement in that way—even in their own system, with their own law and their own Hatch-Waxman legislation, as Dr Faunce has said. They are their numbers. What we are saying is that we have negotiated an outcome in 17.10.4 and in other areas of the agreement that will not lead to the delay of generic medicines into this country. We are fully honouring the commitments that we have entered into in that particular article of the agreement. We are giving effect to that in legislation which everyone will be able to see tomorrow.

Dr Lokuge—To finish my question, under 17.10.4 in the current situation those six per cent—or whatever the number is that you mentioned—would arrive on the market?

Mr Deady—The thing is that I do not know what the number is. To be clear, I am not quoting an Australian number. I think the question was: what do the Americans think about this article? My response to that question was that they themselves, under their own system, see this very much as a subset; they do not see it as affecting all generic patents applications at all. In fact the number they came up with was six per cent, so I am using that as an indication of what the US think operates in their system under their law. We are not importing their law; we are giving

effect to the commitments we have entered into through legislation which will be tabled tomorrow. I am not saying that it is six per cent in Australia by any means.

Dr Lokuge—Okay. The Centre for International Economics said that in their brief investigation they found only one case. The fact is that there will be examples where a generic attempts to market a product which subsequently a patent is claimed for. So we can debate the percentage, but it seems the debate then is about the percentage, because as long as one case exists the difference from the status quo is that the provisions of 17.10.4 require the TGA to block that generic entry.

Mr Deady—No, I disagree with that. I do not think there is anything in 17.10.4 that requires the TGA to block anything. There is nothing in the legislation that will require the TGA to block anything. That is the situation. It was mentioned that there would be injunctions imposed on the TGA in the marketing approval process. That will not happen.

Dr Lokuge—To make a concluding comment—and I thank Mr Deady—we can argue about the numbers, and I am happy to debate the numbers, but it is important that we get this right. I think we have agreed that provision 17.10.4 is a critical issue. To quote Dr Wooldridge when he introduced the therapeutic group premium pricing policy in the 1998 budget, ‘A little bit of competition goes a long way.’ The introduction of small measures affecting a few drugs to increase the amount of generic competition in the Australian market was estimated in that budget to lead to savings of \$278 million.

I hope that, if nothing else, my contribution to this discussion emphasises the fact that it is very important that the Senate is absolutely convinced that what Mr Deady says is right—that provision 17.10.4 will not have an impact on the entry of generic medicines into the Australian market and that there will not be any dynamic effects of provisions that encourage a change of behaviour from the patent owners and the brand-name industry. If we do get that wrong, it will have significant consequences. I think we are in agreement on that.

Dr Faunce—My final point is that we are being told that there is nothing in the text, especially in annex 2-C, that indicates that drug prices will rise. Yet if you go through the heading on transparency, it becomes clear on looking at the text that it is selective transparency. It is transparency of everything the Pharmaceutical Benefits Advisory Committee is doing; it is not transparency of what the drug companies are putting up. We have been told that they keep their information commercial-in-confidence—although if that were distributed around the world, it would have an enormous benefit in terms of allowing people to adjust prices and make fair prices. What we see in the transparency provision is a whole set of strategies whereby pharmaceutical lobbyists, advocates and applicants can create different pressure points on the PBAC. The entirety of that strategy is to make it harder and harder for the PBAC to take a stronger line. Already we do not see the chair of the PBAC today.

Senator BRANDIS—You do not even get to the PBAC unless there is a refusal to list.

Dr Faunce—It is no good talking about the side letter and the fact that it only talks about a refusal to list. The whole question here is: how easy will it be for the PBAC to continue to have a strong, independent voice and say, when it looks at the data it has accumulated, ‘This is a fantastic, expensive, new, innovative drug but on balance, using all our accepted techniques, we

just do not think it adds any benefit to the Australian community'? How difficult now, as a result of all of these tactics and strategies, is it going to be for the PBAC to do that? We do not know because the chairman has decided that he is unable to turn up today. It would have been very good to have asked him some questions about that. Perhaps that is something that could be put on notice.

Senator BRANDIS—I am sure that if the chairman of the PBAC is like most of the senior officers in the Australian—

CHAIR—I would now like to go to Dr Haikerwal and Mr Shaw from the AMA

Dr Haikerwal—I appreciate the committee giving us its time and allowing us to participate in this discussion. It has certainly been most lively and revealing. I am grateful to Mr Deady and his crew, on the right, for clarifying some of the points for us.

CHAIR—We usually sit here hoping that you will end up agreeing, but that does not appear likely.

Senator BRANDIS—Chair, I think there is more agreement than there was at the start.

Dr Haikerwal—Centrally, the Pharmaceutical Benefits Scheme affords us enviable access to pharmaceuticals across the world; on that count, I certainly agree with my colleagues on the right. It is costing us \$5.5 billion currently, and it is going to cost us more. That is not necessarily a bad thing, and I have said this over and over again. The mechanism by which it works is enviable, and that is why it has been subjected to this sort of pressure. It is so important that the manner in which it works is left unimpeded, that any review mechanism that is being sought through this agreement does not undermine the benefits of the PBAC and its independence, and that any review that happens has to go back through the PBAC to get back to the minister and the government. That is vital; that is central. If we were to undermine the PBAC process, we would not get any of the experts that currently sit on it to sit on it any further, and it would be very hard to recruit other people to it. The mechanism really has to be preserved because it has done an incredibly good job for Australia so far and will continue to do so. If our concerns, as listed, are taken into account, we do not believe that this is the end of life as we know it. We believe there are some benefits in the free trade agreement with the US if that transparency is not just from the PBAC point of view but also from the big pharmaceuticals. That is central. But, otherwise, we think the system may not cause the end of civilisation.

CHAIR—Thank God for that!

Dr Haikerwal—The AMA thinks today has been a valuable exercise. We are particularly grateful to Stephen Deady and Ruth Lopert for some of the clarifications, explanations and undertakings that they have made, particularly with regard to the rolling-out of the free trade agreement with regard to the PBS and in particular the most important issues: the review process and the transparency issue. It is absolutely critical how that is done, in terms of the detail, and we do rather expect to be consulted when they have some detail on that. That is a fairly important part of the conditions we have got in the resolution passed by the AMA federal council.

CHAIR—Do you expect us to be satisfied, too?

Dr Haikerwal—We will await your report/s with interest.

CHAIR—This is one of the key elements of this broader question, in my mind. It goes back to the discussion earlier about delegated legislation. What is there in this agreement that might change, without reference to the legislature, which, if we allow the agreement to go forward, could have an effect? We have to be alive to those consequences, I think; otherwise, if we naively look at these things—and I am not suggesting malevolence on anyone's part, but circumstances change and the buck stops with us, at the end of the day, when we vote on this sort of stuff—are you saying to us that we need to see the terms of the independent review?

Dr Haikerwal—Did Dr Lopert indicate earlier on that you will have concluded your consultation process before the committee's report is expected?

CHAIR—That report is due on 12 August.

Dr Lopert—We are endeavouring to ensure that that is the case, but we cannot give a concrete commitment to that effect because it is dependent on the activities of other participants.

Senator BRANDIS—Mr Shaw, I think this was uncontroversial: whatever the terms of the independent review process, it can only be a review of that which clause 2 of the side letter identifies, which is a refusal to list. That is the only reviewable decision.

CHAIR—Senator Brandis continues to assist me!

Dr Haikerwal—The decision needs to go back to PBAC, and it needs to be the PBAC that is the final arbiter of whether the review process has a worthy cause for further change.

Senator BRANDIS—It is a mechanical issue.

CHAIR—Thank you very for intervening on me, Senator Brandis! But if you do not mind, at this late hour—

Senator BRANDIS—You freely intervene on everyone else.

CHAIR—I do not notice that I actually do.

Senator BRANDIS—Well, we do. And you are supposed to be the chair!

CHAIR—I am the chair. At this hour of the night, a bit of quiet banter is fine. But I need to actually know what the AMA's position is, and that is why I asked the question. I would rather that the AMA speak for itself than have people try and lead it. I know the AMA is an organisation with a robust opinion and always does speak for itself, no matter what words people try and put in its mouth. I just want to know what you will say to us about this independent review.

Dr Haikerwal—The president stood up when this was passed and said that what was not negotiable was the bypassing of PBAC. Any decision of any review committee has to go back to PBAC.

Mr Shaw—And that is what the current agreement sets out.

Dr Lopert—To clarify a point that Mr Shaw made, whatever the procedural outcome of the review mechanism, the fact remains that under the legislation PBAC is the only body that can recommend to the Minister for Health and Ageing that a drug be listed on the PBS. For the outcome of a process to result in a listing of a drug that the PBAC had hitherto decided not to list, it would obviously have to go back to the PBAC, because unless the PBAC does recommend it for listing it cannot be listed.

CHAIR—I understand that, and that point has been made several times this evening. It is in the text, in any case. I am not disputing that that is the factual case. Nonetheless, this is a matter of considerable importance, and it behoves us to be cautious and thorough in scrutinising the meaning. I would suggest that it behoves us to look behind what is said and put what is said in a real world context to try and work out what are the implications. That is why we are here.

Senator BRANDIS—Is it? I thought it was to decide what it meant.

CHAIR—We have to form a sensible conclusion about what it means.

Senator BRANDIS—If it means what Mr Deady says it means, we do not have a thing to worry about—nor does Dr Faunce, Dr Haikerwal or anybody else.

CHAIR—Thank you for debating me, Senator Brandis! Once again you are of considerable assistance to me in making up my mind! Not always is it the assistance that you seek to provide, I might say. I am just exercising—

Senator BOSWELL—You are not going to make up your mind on spite, are you?

CHAIR—I am not going to make up my mind on spite; I am going to make up my mind on a proper consideration of the issues. I am certainly not going to come here and try and advocate a one-dimensional point of view. I am going to look at all the points of view and come to, I believe, a balanced conclusion. I do think that in some of the discussion there is an effort to try and prove a point rather than look at the implications across the board. But that is for individual senators to decide.

Coming back to you, I think, Dr Faunce, I think it was Dr Harvey who talked about his perceptions of how the pharmaceutical lobby operates worldwide. We can focus on it with respect to this agreement and we can look at it from the context of what Mr Deady has done to represent the national interest to try and preserve the institutional structure we are talking about of the PBS. I am drawn to the conclusion that the independent review means something other than transparency because, reading what is being said on the other side of this argument, in the United States it is given some credence. It is given all the credence that Mr Deady has said, and I do not in any way dispute his opinion about that. Maybe this is a question for Dr Harvey—in which case, you will tell me and I will put it on notice for him. Are you aware of any other case

where pharmaceutical schemes have operated which are similar to the PBS? Are you aware of any other case where, in pursuit of getting market rates for drugs, the PBS system has somehow been circumscribed or broken down?

Dr Faunce—One of the most remarkable things about the PBS is that really it is a world leader in this. We can scan around the world and there are not a lot of reference pricing systems that are as effective. I think that the state of Maine in the United States tried to introduce a scheme similar to the PBS and was aggressively litigated by Pharma. I guess that gives you one of the precedents that you are seeking in a sense that there is a scheme. Our group is in intense negotiations with Kevin Outterson, who is involved with the legislature in West Virginia, who is trying to model a pricing referencing scheme in that state based on our PBS. The information that we are getting back from him is that if our PBS goes under, and he sees these provisions—that have been described as neutral and not involving any teeth—as being the beginning of the process that is going to have major structural import on the way the PBS works, he sees it as a process that destroys not only a reference pricing system that lowers drug prices in Australia but also for the rest of the world. That was one of the major points that I wanted to get across. This is a decision not just about what happens in Australia but what also happens to people who are suffering under high drug prices the world over.

At the moment the data required by the PBAC is treated like gold by other countries, if they can get access to it, because it is one of the few examples still remaining whereby affordability and efficacy data are being generated. Pharma's strategy around the world is to try to obliterate that by the various strategies we are mentioning here—preventing parallel imports, restricting compulsory licensing and all those sorts of things. Another mechanism that we have identified is the property term 'ratchet' where essentially whatever gains are acquired under these bilaterals factor back into the TRIPS agreement and increase basic intellectual property rights, and the cycle just keeps going on only in an upward direction—increasing, increasing, increasing. That is the sort of context in which we see this decision.

CHAIR—I think that brings my questions to a conclusion.

Senator BRANDIS—A little earlier on I did detect a degree of disconcertedness on Mr Deady's part at a couple of things that were attributed to him when Dr Faunce was speaking. It may well be that it has all gone as water under the bridge but I think that Mr Deady is entitled, if he thinks that his position has been misrepresented, to a right of reply. Was there anything that you have heard from any of the witnesses attributed to you which mischaracterises your position and your evidence?

Mr Deady—There is one point that I would repeat: any claim that I believe there is any credibility to numbers like additional costs of more than a billion dollars to the PBS as a result of something we have negotiated in the free trade agreement is incorrect. There is no way in the wide world that I believe that is the outcome from this agreement. As I have said so many times, we have protected the fundamentals of the PBS in the annex and in the side letters. We have ensured through the commitments we have made in the IP area—and we have certainly had a lot of discussion about that today—that we have protected the interests of the generic medicines industry in this country. There is nothing that will delay the entry of generics into the market once patents appear. That is the current law in this country and that will continue to be the case. That is the one thing that I do take offence at: that there is any suggestion that I give any

credence or credibility to those claims of additional costs to the PBS as a result of anything we have negotiated in the FTA. That is not the case.

CHAIR—Well, we all know what one another thinks. On behalf of the Senate committee, I thank you all for the time and patience you have given us this afternoon and for putting up with us as well. Thank you all for your contribution. The purpose of this process was to try to put you all together in a room and start talking it through to try to get a clearer idea in our own heads. I think it has been of immeasurable use. It has not resolved—speaking for myself—all of the questions but it has helped to define them far better, and that is a big advance.

Committee adjourned at 8.05 p.m.