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TRANSCRIPT OF PROCEEDINGS

PRODUCTIVITY COMMISSION

DRAFT REPORT ON COST RECOVERY

MRS H. OWENS, Presiding Commissioner
PROF J. SLOAN, Commissioner
DR R. STEWARDSON, Associate Commissioner

TRANSCRIPT OF PROCEEDINGS

AT SYDNEY ON FRIDAY, 8 JUNE 2001, AT 9.37 AM

Continued from 7/6/01

MRS OWENS: Good morning. Welcome to the public hearings for the Productivity Commission inquiry into cost recovery by Commonwealth regulatory administrative and information agencies. These hearings follow the release of the commission's draft report in April. My name is Helen Owens and I'm the presiding commissioner on the inquiry. My fellow commissioners are Judith Sloan on my right and Robin Stewardson on my left.

The purpose of this round of hearings is to facilitate public scrutiny of the commission's work and to get comment and feedback on the draft report. Hearings have already been held in Melbourne and in Sydney yesterday. We will be holding hearings in Canberra next week commencing on 13 June. We will then be working towards completing a final report to government in August, having considered all the evidence presented at the hearings, the workshops held on 17 and 18 May with the agencies and in submissions as well as other informal discussions.

Participants in the inquiry will automatically receive a copy of the final report once released by government. I like to conduct all hearings in a reasonably informal manner, but I remind participants that a full transcript is being taken. For this reason comments from the floor cannot be taken, but at the end of proceedings for the day I will provide an opportunity for any people wishing to do so to make a brief presentation. Participants are not required to take an oath but should be truthful in their remarks. Participants are welcome to comment on the issues raised in other submissions. The transcript will be made available to participants and will be available from the commission's Web site following the hearings. Copies may also be purchased using an order form available from staff here today. Submissions are also available. I'd now like to welcome the Medical Industry Association of Australia, the MIAA, to these hearings. Welcome, and could you each give your name and position with the MIAA - and AWIN. We've got AWIN Services as well.

MS WINSLADE: Doubling up.

MRS OWENS: So if you could each give your name and position with both organisations for the transcript.

MS WINSLADE: My name is Heather Winslade. I'm a consultant on technical and regulatory issues representing both my company, AWIN Services Pty Ltd, but mostly this morning the MIAA.

MRS OWENS: Thank you.

MR VALE: Commissioners, good morning. I'm Brian Vale. I'm the chief executive officer of the Medical Industry Association of Australia.

MRS OWENS: Thank you both, and welcome again to a commission hearing. Thank you very much for your submission. We've had quite a few submissions from you both with different hats on for which we thank you. I'd like to particular thank you for drawing to our attention some problems in our appendix G, some misrepresentations there, and we will do our best to correct those misrepresentations

in our final report. So I'm grateful for that. You know, sometimes these things just slip past you and that's exactly why we have a draft report so people can provide us with assistance in that manner. Now, I understand, Mr Vale, you do have an opening address that you'd like to - - -

MR VALE: Yes, if I may, commissioners.

MRS OWENS: Thank you.

MR VALE: Well, firstly please allow me to extend our sincere congratulations on the delivery of a very sound report. I must say, even to those of us from industry who might have thought that we knew something about this cost-recovery business, the detail you have revealed in this draft report has been surprising. Again, we thank you for the opportunity to speak with you today, and perhaps to add any necessary clarity to any of the issues that we have raised or which otherwise might be in your minds.

In our response to your draft report dated 25 May we first sought to point out what we saw as a weakness with some definitional issues, and indeed you've just indicated that you've picked up on those. I hope that we have now made clear that we are a non-drug environment, at least in that definitional sense, no matter that some of our devices actually have a drug component. Our market, therefore, is quite different from that of the pharmaceutical or complimentary health care industries. We also ask that you consider specifically noting the nature of our industry as inclusive of high technology products that frequently have a very short market life. We felt that perhaps that difference did not come through clearly in the report. We feel that the importance of this recognition is that it flags that our industry needs a responsive regulatory system if our products are to reach consumers before their technology life is superseded.

We think that if the report were to address the definitional issues that we have drawn to your attention and this technology issue it would make for greater clarity and understanding. You will have noted that we did ask for that specific correction in part G.7 and you've indicated that that is being addressed. Specifically, with the cost recovery practices of the FDA, if there are any questions there then we would be happy to address those for you this morning. If I may make a couple of general observations on the report.

I would first like to again state the need for government to be alert to the numerous cost recovery practices under way that might, or do, impact a single industry sector. We believe that the parliament must be able to take an holistic view of the decisions they take with regard to fees, charges and taxes. Under present arrangements that is not possible. An additional issue within costs is the degree of notice industry requires to be able to manage cost increases. An example of this would be the intention of the Department of Finance and Administration to increase the rent payable by industry for TGA premises at Symonston. You've noted this intent within your draft report. In this instance the decision to increase the rent by 166 per cent on 1 July 2001 was first advised to industry in December 2000, no

matter that there had been discussions under way for two years before that time. That advice led to an appeal by industry to defer or not proceed to implement this increase. This was rejected in May this year and at that time the TICC process confirmed that the rent would increase with effect 1 July next month. Clearly industry budget cycles cannot accommodate such a degree of short notice with a significant change of that type.

I'd like to say something about competition. I'd like to reinforce industry's belief that the regulatory and conformity assessment functions carried out within TGA should be separated. Your draft report has noted that the TGA is not subject to competition in conformity assessment tasks and submissions to your inquiry have asserted that the TGA is thus quarantined from pressure to be more efficient. We support that view. I believe that in our last testimony to this commission we pointed out that there are private sector bodies in Australia who are enthusiastic about taking on this conformity assessment role. Some of these are tertiary institutions that would much benefit from such revenue-earning opportunity. It is thus difficult to understand why the TGA insists on holding on to this function, unlike any other agency in the world and contrary to the recommendations of the 1996 industry commission report to which we have previously referred.

A couple of words on TGA's conduct, if I could use that terminology. The TGA is clearly a public sector agency of government. As I said a moment ago, we note that it wants to do some things, like conformity assessment, that elsewhere in the world are delivered by the private sector. It may seem a small point but industry finds it upsetting that the TGA, funded by industry and undertaking some private sector tasks, nevertheless expects the privileges of the public service. A small example is that in all overseas travel, TGA personnel are apparently entitled to and do fly business class. In Australia, senior managers in the TGA - and there are many of them - are entitled to, and do, fly business class. This is in significant contrast with the practices that prevail in the industry sector who pay the TGA bills. Industry senior managers almost always fly economy class in Australia and will often be restricted to economy class travel or economy class for overseas travel when the flight duration is below four or five hours.

This is not seen by industry as the trivial matter that it might seem and effectively puts a gap between the payer and the beneficiary. A further matter that industry has noted is that while TGA personnel numbers have shown some reduction in recent years, there is clearly evidence of rank and salary creep among senior managers. Such upwards movement may be consistent with the public service trend, but unexplained this is again a concern to industry and it causes gaps to appear. There is the matter of the TGA not being prepared to commit to reasonable performance objectives. We have explained that our sector has recently abandoned efforts to have the TGA commit to a performance agreement that included incentives to perform. Looking at the last three issues, cost increases, conduct and performance measures - your draft report's observation on page 91 that:

There is sufficient anecdotal evidence about the negative incentive effect about cost recovery to raise concerns -

makes clear that these issues deserve early attention. For this reason we cannot support a recommendation of your report that addressing these issues be allowed to extend over five years. The matter is of such importance to industry as to demand early reform.

If I could just make a comment on the TGA reserves, which I think have been dealt with exceptionally well and certainly helped us understand the requirements of government and the practices that are out there. Your report addresses those reserves and the information is enlightening. But we believe the report contains evidence of confusion with use of the reserve by the TGA. In the last TICC meeting on 16 May this year the TGA announced to industry that it would proceed to reconstitute the reserves of the TGA to 50 per cent of operating costs and stated that this 50 per cent level had been agreed by TICC several years ago. I know of no documentation to support that but I am a relative newcomer. However, you will be aware that the last three audited annual reports of the Department of Health as shown in these documents show a continuing erosion of the TGA reserves. The reserve has declined as follows: in 97-98 it stood at 16.7 million; the following year 98-99 it was at 9.8, and in the last annual report, 99-00, it was down to 4.5. You will be aware that such erosion results from under-recovery of costs, or over-expenditure in a climate where government had directed full cost recovery.

At note B to table D.1 on page D.4 of your draft report you will see that the TGA claims to have discounted fees and charges to industry to offset the surpluses from earlier years. Commissioner, something doesn't jell in that testimony. We would suggest that the TGA had experienced difficulty with budget management and that was the reason for under-recovery. If so, this would tend to confirm an urgent need for external oversight and increased visibility and cooperation with efficiency initiatives. Commissioners, thank you for the opportunity to present that opening statement, and we would be happy to address any questions that you might have on that or any other issue.

MRS OWENS: Thanks very much. I think you've just actually raised some pretty interesting questions there. I'd like to go back to the issue first of the incentive effects, and I think again you've actually pinpointed something that has concerned us and I think it's reflected in our draft report that when you've got cost recovery at a hundred per cent of an agency's costs, there's little incentive on the agency then to perform well and to contain their costs. We fly business class, but having said that, I'd like to just give you one little anecdote that I heard last week. The head of Ford Australia, while he's been in this position – this is a man called Geoff Polites – he has instructed all his staff to fly economy in Australia and in any overseas trips up to I think 10,000 kilometres, which means the only time they can go business class is if they're going to the United States or Europe, and that includes himself. So I think that's just an aside for the transcript.

I think that the only way you can deal with this issue of negative incentive effects is to have appropriate scrutiny, and we've been trying to think about how do you make this work. One approach is to ensure that there's not a hundred per cent

cost recovery for an agency but there's cost recovery for individual activities; that reduces that incentive a bit and only on those activities which are deemed to be appropriate to be cost recovered, so we'd say that there's certain activities in the agency such as policy advice to government and in some cases international obligations should not be cost recovered. But the other approach that we have been thinking about is how do you provide external incentives on the agency to perform and be accountable?

We looked at the operation at the TICC and said, "Is this an appropriate body to do that?" and as it's currently constituted, it doesn't appear to be because it's meant to be a consultation body, and we're heard in our hearings yesterday that even in that context, the information that's made available is often inappropriate or there's insufficient information. The other approach that we've been thinking about, either trying to beef up the TICC so that it works more effectively and gives industry a greater say by maybe determining that the TICC has certain responsibilities and does increase accountability, or we have made a suggestion that there be a different sort of body set up, what we've called an efficiency audit committee. I don't know, Robin, if you want to progress this issue further, but we were wondering, do you have a view? I think in your submission you basically sat on the fence a bit, but would you support an efficiency audit committee? Which way do you think is the appropriate way to go?

MR VALE: Well, I'd confirm your comment that the current process within TICC does not work. It doesn't render to industry the accountability that it reasonably deserves. The issue of the EAC was first raised by the commissioner in that first evidence that we gave and I believe we supported the concept at that time, and we continue to support the concept. However, I do think there is a need to consider whether or not a similar degree of accountability and visibility might be achieved by reconstituting the TICC and externally chairing it. We have proposed to government in the past that the other department that has a significant interest, from our perspective, Industry, Science and Resources, might be well placed to perhaps provide that external perspective.

We do not think for one moment that a TICC type committee should be chaired by industry. That would be inappropriate. At the end of the day this is a government agency. But it is just too close, too incestuous as it runs at the moment with the national man of the TGA chairing the committee in an environment where, as they say quite openly and quite reasonably, at the end of the day they don't have to be accountable to us.

DR STEWARDSON: How would you deal with a couple of issues under that situation: (1) the apparent reluctance of the TGA to give to the TICC, whatever its chairman, appropriate and timely information which the TICC can make assessments; and secondly, what we understand from, I think, you and other people that recommendations of the TICC are often ignored by the TGA? How would having an independent chairman solve those problems?

MR VALE: Perhaps it depends on who the independent chairman responds to. I

note in the report that with the EAC you explain a line of direct communication to the minister and that brings a degree of accountability that obviously is not there at the moment. Perhaps the answer lies in the way in which the chairmanship reports and I think there are opportunities then to encourage responsiveness from both the TGA and the industry players within the TICC process.

PROF SLOAN: I thought you were going to make what I think is a strong point and bring it back to this, is that one way to deal with what we might generically call goldplating - business class travel is an example of goldplating. Isn't that your suggestion, that really an organisation like this should operate on different grounds, ie there should be a separation between standard setting and assessment, and you would do that actually on governance grounds alone - you might - but secondly, that in fact by having an outsourcing model for assessment it seems to be that that is a kind of new incentive structure which would enable you to probably cap the incidence of goldplating and cross-padding, because presumably those agents who have been outsourced would be subject to, you know, certain standards and certain remuneration. Did you want to say something, Heather? You seem to be nodding in agreement with my previous - - -

MS WINSLADE: Just taking it in.

PROF SLOAN: No, I'm just wondering whether - I mean, you could argue just on governance grounds that you should really separate standard setting from assessment anyway.

MR VALE: Heather has a couple of points here and knows this area in detail, and I won't be speaking in her area. But could I just say that while we haven't put forward in this forum this concept of outsourcing we have raised a number of times with ministers the prospect that you could transition the conformity assessment function out of the TGA in a progressive way that was done first by outsourcing it, that the TGA grow confident that it can be done and then as it grows it gives industry an opportunity to see what the costs are in, for instance, a tertiary body. That then applies competitiveness to the TGA, that progressively you wean the conformity assessment function over a couple of years out of the government regulatory role.

MS WINSLADE: The FDA in its 1997-98 Modernisation Act in fact looked at exactly that. It wasn't prepared to give away its ultimate responsibility of approval. But what it said, it appointed bodies to whom you can pay money to have your goods evaluated and they oversee those bodies, and if the body says it's okay, it passes through FDA very rapidly. It's your choice. You can also send it to FDA and don't hold your breath on when you'll see the evaluation through. That is one particular model that could certainly work as well. The issue of who has got the capability of evaluation keeps getting totally overlooked and quite frankly it doesn't lie with the regulator, despite what they say.

PROF SLOAN: Or does it only lie with the regulator?

MS WINSLADE: It doesn't lie with the regulator.

PROF SLOAN: Okay, that's a different point.

MS WINSLADE: We've got such a vast range of goods that need covering. You can't expect any one group to have that level of expertise and this has been faced in Europe with the notified bodies, to the extent that what they're doing now is coming to grips with it, saying certain bodies are experts in these and they can look at those products and others are expert in those. I mean honestly, can somebody look at a Foley catheter and pacemaker and have the same level of expertise? The answer is clearly no.

DR STEWARDSON: Do we have that expertise in Australia at present?

MS WINSLADE: No.

PROF SLOAN: Do we need in Australia though anyway? Presumably there's nothing to stop it being done anywhere, except the TGA.

MS WINSLADE: It's the claim of sovereignty; you know, Australian consumers are entitled to Australian evaluation.

MRS OWENS: When we did the medical and scientific equipment inquiry, as you know, we recommended that this be freed up, but then you say, "Well, why didn't that end up happening in the way that we thought would be appropriate?" Again, it comes back to the incentives. If you've got a hundred per cent cost recovery, there's no incentive for the TGA to think about, "How can we do this more efficiently? Will it be cheaper to allow people to go to other bodies to get the assessment done?" There's absolutely no incentive for them to do that. In fact, the incentives tend to work the other way, to maintain the bureaucratic structures that we've got.

MR VALE: As your hearings are progressing, there is further evidence of this next week in Brussels, where the mutual recognition agreement between Australia and the EC is up for discussion, and on the agenda there will be, keeping out of mutual recognition, devices in the high-risk category. The TGA will insist that only it can do these. There are some areas within high risk that we would say, "That is correct, an industry would support it," and in particular, products of animal origin, bovine products, things that have quarantine implications, industry would view that Australia should always hold those and our regulators should do it. But if we're talking about heart valves and pacemakers and things that are used in much larger numbers around the world, there can be no argument that that can be done more effectively in Australia.

PROF SLOAN: It seems to me - I don't know whether you trained in economics - but I think you're on to quite an important point in your submission, Brian, in that what you're telling me really is that the beneficiary pays model is all very well, but we have to look at who is the ultimate beneficiary and the nature of the markets into which medical devices are generally sold. How I'd interpret that as an economist is that you're telling me that they're mainly sold into the public sector - who effectively

act as monopsonists. See, we have a kind of basic view that yes, the ultimate beneficiary should be charged, but many times it's impractical so we'll charge the regulator firms who then in turn will pass it on to the ultimate beneficiary. But what you're telling me is that you've got a funny market here; you're actually selling to a monopsonist who has the ability to drive down prices because they're such a big single client, and therefore your ability as an industry to pass on TGA fees is quite limited. Am I interpreting - - -

MR VALE: No, you're exactly correct. If we had to put a split between public sector and private sector sales, while it does vary quite dramatically across individual device types, the general split would be 70 per cent into the public sector. The large buyers are the states. They tend to purchase the bulk of their items on contract. They are contracts that run typically for two years with extensive provisions. It's very hard to pass on costs in a state contracting environment. It's not at all easy to sell into the increasing numbers of last private sector corporate buyers, the likes of the Mayne health care. All of these bodies are currently putting a significant price squeeze on our industry in a way that hasn't been seen in the past, and yet that comes at a time where last year we dealt with the government's new tax regime and we dealt with the TGA's 43 per cent cost increases and we dealt with the Department of Health's separate application and annual fees for a prostheses listing. So it is a very difficult environment to accommodate short-notice changes of that type.

DR STEWARDSON: The percentage increase in the rental, I think you said, 166 per cent. What sort of percentage increase does that translate into for some typical fee that you're being charged?

MR VALE: I think that is very difficult to answer with accuracy. It's \$1.5 million spread across at least four industry sectors that will be giving testimony to you. We have the best part of 4 or 5 hundred companies, some of them with up to 10,000 products.

MS WINSLADE: The real problem is we're going into new legislation and therefore the total free structure will go by the wayside. PricewaterhouseCoopers have been taken on to look at that issue, so we're going to find it very hard, except to be able to say, "Well, our annual bill at the moment is this." In future, will it be that? We don't know this. So what we've got is a huge increase coming on top of a total change in the way that the fees are going to be charged, and nobody really knows what is going to be equitable in there. That's the difficulty for devices.

I'd like to make just one comment though that's been missed: we have very, very small - maybe 1 or 2 per cent only - direct to consumer business. We're talking about in supermarkets, bandaids, bandages, condoms, tampons, that's it, in rough terms.

MRS OWENS: All the other sales are to intermediaries.

MS WINSLADE: Yes, through the hospital sector, through health care professionals, so you could almost discount that portion.

MRS OWENS: In terms of beneficiaries, do you see that your company can also be a beneficiary from the regulatory activity if it means that consumers are more confident in the products you're selling?

MS WINSLADE: No. The reason I say that is that consumers at this point in time have a confused point of view about what's regulated and what's not. They believe the government evaluates every product from go to whoa, and that's not the case. If the process was spelt out properly, they would probably feel comfortable but it's very hard to explain. They have a feeling that the government is watching everything and that's really not the case, and Australia couldn't afford a system where the government did that. We look at risk management. The concept of going through that approval process gives the consumer - the consumer in most cases doesn't know what goods are used on them. They go into hospital and they trust their doctor or their surgeon and many of these goods are used multiple times; a monitor, how many patients are attached to it? How do they know what brand of monitor they're attached to? They trust that the hospital has purchased the appropriate goods.

MR VALE: Industry has supported though the issue of increased regulation because we judged that there was a lack of regulation in some areas and I believe we made comment on this at the previous hearing. So we have been supportive because we see the value in products that are not regulated at the moment which most people would deem to be dangerous and perhaps requiring some controls, so we have supported increased regulation and I think industry does see benefit in that increased regulation.

PROF SLOAN: This is a hypothetical we often think about, that if there were not government regulation of this sub-industry, do you think the major players would move to some form of self-regulation?

MR VALE: New Zealand is an unregulated market. Singapore is an unregulated market.

MS WINSLADE: Totally unregulated for devices, yes.

PROF SLOAN: Would they have any form of - - -

MRS OWENS: And what's happening with the consumers there? Are they dying in greater numbers?

MS WINSLADE: Alive and well; very strange, isn't it?

MR VALE: Having said that though, we do support the regulation, but we take exception to the sort of comment that is made by the TGA on page D10 where they suggest that they exist only for industry. I think that's an abrogation and a failure to recognise their primary role which is to be the government's consumer protection agency, working hand in glove with industry.

PROF SLOAN: I'm pretty interested in your suggestion at page 2 of your submission that - - -

MS WINSLADE: Which submission, the MIAA submission?

PROF SLOAN: Yes. You don't have to get it out, it's just that you made the point that Australia is a very small market, so there's not necessarily great incentive to be bringing every device into Australia and that at the margin, the TGA fees could be a disincentive to bring devices into the Australian market. It would be a great help if you could give us an example or two of that. You might want to take this on notice. We've had one example of Cochlear who have - it sounded like - an extraordinarily clever device to restore the hearing of people who have had brain tumours which has not been brought to the Australian market because of the fees.

MR VALE: I'll just say that there are examples in almost every major company, where they choose on a routine basis not to bring product to Australia for reasons of the small sales and the high entry cost. But there is a great sensitivity about actually tabling product numbers and models and being seen to be a company that perhaps is not making available that technology. Would you just like to comment on that?

MS WINSLADE: In my former position with regulatory affairs with a multinational, very commonly products came across the desk, and you sent the information back to the marketing staff as to what the cost was going to be, where they needed pre-market evaluation - never heard again.

MRS OWENS: Was it the cost of actually paying a fee or was it the cost of going through all the compliance?

MS WINSLADE: No, the compliance in fact was done. It had already been done in either the US or the EU, and in fact I was responsible for Asia-Pacific and we'd happily launch those same products into those markets and put them into New Zealand, but it was the cost up-front of a fairly large payment of money that might take you five or six years to recover, and who knows if the product is still around in that period?

MRS OWENS: This was the money to get the product listed on the register?

MS WINSLADE: The register, yes, we're looking at registering - - -

MRS OWENS: On the ARTG, the Australian Register of Therapeutic Devices or whatever it is.

MS WINSLADE: We're looking at those that are not necessarily considered higher risk in other markets.

MR VALE: That can cost you up to \$96,000 at the moment, but you're quite right, if it's an imported product, usually the technical file and all the work behind it will have been done. But no matter that it's been done, you still face \$96,000 per product

line if it's a high-risk item to get it up, and that's hard to recover.

MRS OWENS: I was going to say it's a pity we can't get the examples because it just would enrich our report. People have been saying to us, "You've made some very good points but it would really help to have examples," so we're very aware that that is a gap in our report, because people are making statements if the products aren't coming in and, (a) we don't know what the products are and, (b) we don't know whether it's because of the small size of the market because it's compliance costs in some areas, or whether it's because of the fees, the charges, and trying to sort of uncouple all those factors and get good evidence is proving very difficult.

MS WINSLADE: I can't on a confidentiality basis with either the previous company or current customers - it's very difficult. However, I can tell you it's never been the cost of compliance. It's not having unique requirements, it's the fact that you are being put through another re-evaluation that has already been undergone, either in the US or the EU or both. It's a re-evaluation of data and it's the cost to re-evaluate that data. The data exists; the file is there. It's all there.

DR STEWARDSON: Can I just take up the subsequent sentence though in your submission. After saying, "The decreasing availability of certain therapeutic devices in Australia," you say:

The absence of these cannot always be addressed by the TGA special access scheme as product support may not be available.

One response we get when we raise this point you're making is that there is the special access scheme. Can you elaborate on this "product support may not be available"? Is the situation that most things can in fact come through under special access or is the situation that there are an awful lot of things that can't come through under special access?

MS WINSLADE: That's the special access scheme; that's the front page of a large document and I'll happily leave that with you. We note on your D29, they talk about "small niche markets can be addressed". Page 6 says:

The promotion of unapproved therapeutic goods is an offence against subsection 22(6) of the act and carries a financial penalty.

A niche market by definition is not something you can't promote in.

DR STEWARDSON: Sorry, I didn't quite get what you were saying then. There is still the special access scheme, isn't there?

MS WINSLADE: The special access scheme is available if a surgeon hears during one of his travels overseas of something, and he can go to the TGA. They will give him permission to use that product on that patient which gives you the right to supply it, but you must not go to that surgeon and say, "Oh, there's one of those?" Now, by definition, niche market means you're allowed to market, but it's an offence to

promote, and promotion is one of the four key - - -

PROF SLOAN: That's an important point, isn't it? They've not come to know of it.

MS WINSLADE: They're not relative.

MR VALE: There are two other elements to it.

PROF SLOAN: I'd like to know the figures. My guess is that there aren't too many - - -

MS WINSLADE: Of?

PROF SLOAN: That too many applications go through on the - - -

MS WINSLADE: There have been a great deal recently because all silicone breast implants have gone out under IPU because none are openly available and they really wanted to be able to track exactly where these goods are going, so the surgeons made application. But if you take out those - no, it's very limited and the rules actually forbid promotion, so we have no access to orphan-type products, and that's not a niche market by definition.

DR STEWARDSON: So are there a lot of things then that aren't being applied for under the special access scheme that are being used overseas?

MS WINSLADE: We believe that there are several really useful goods and they are niche markets, they really are, and that's the difficulty. When we talk to regulatory staff from multinationals, all of them would probably say if you had a dozen people refusing eight to 10 products a year, that's probably what we're talking about.

PROF SLOAN: Would these kinds of things go into New Zealand though which is a smaller market again?

MS WINSLADE: Yes.

PROF SLOAN: A much smaller market.

MR VALE: Because you can fly it in and use it straightaway - - -

PROF SLOAN: So that's the kind of test of the small market idea, isn't it?

MR VALE: - - - and use it immediately - not an issue, provided product support is there. You'll still run into that problem at the moment with companies. I mean, some of those devices require IT interaction and support on a routine basis and if you haven't got that in the country, it reduces your capacity to use it.

MRS OWENS: There was another issue you raised about your concern about our

proposal that the existing arrangements be reviewed within five years. What we were suggesting was that there be these reviews or all existing cost recovery arrangements over the next five years but that those reviews would be prioritised in some way by the Department of Finance and Administration. Now, what we may do - and I haven't discussed this with my colleagues - is we are saying that that responsibility should lie with that department, but we may make some suggestions about where they might start and because we've been having so much input from different groups such as your own about the Therapeutic Goods Administration, we may suggest that that may be an early cab off the rank to give some sort of guidance on that issue. Would that satisfy your concerns about that?

MR VALE: We would be keen to see some early action in the TGA's area, yes. If there was a prospect that it was going to be five years or beyond - that was really the point I was making, that we think unfortunately that's too late for many. There are going to be enormous pressures in the near term in our industry for consolidation and a lot of small players will disappear from the marketplace. It is happening right now. I think this is just another pressure for those smaller players that we need to address sooner rather than later.

MRS OWENS: One of the other things I think you supported us on was our recommendation 6.4, where we were arguing that cost recovery should relate to activities and not to agencies - no, that was the recommendation where it was the activities not for government - - -

MR VALE: Separate of those, yes.

MRS OWENS: Separation of those out. Now, we had a workshop with the regulatory agencies last month and one of the issues that was raised by the agencies at that workshop was that the work that they do, government policy work and so on, is really directly linked into their regulatory responsibilities and how can they split those off, so they should be able to charge for all those things because they're all directly related to their day-to-day responsibilities. Do you care to comment on that?

MS WINSLADE: One of the issues particularly for TGA is we have to remember that they look after things like recalls and serious safety concerns and you addressed the point very clearly that you can't charge for those sorts of processes, therefore the cost of that, if you've got a hundred per cent recovery, is being picked up elsewhere. In essence, companies may be paying for somebody else's activities. I think this is one of the reasons why we believe a hundred per cent is totally wrong, that they're very consumer-focused activities and they should stay being paid for by government.

MR VALE: My comment would be that the benefit of the regulatory activity of that type certainly flows to many parties. We are one of those parties. We do draw benefit from it, but a regulatory function, I would have thought, is principally about consumer protection and Australian governmental issues. I am not sure that the benefit that does flow to industry would mandate that we should be paying for all of that activity.

PROF SLOAN: It inevitably generates cross-subsidies though, doesn't it, in the context of a hundred per cent cost recovery?

MR VALE: It does.

MS WINSLADE: Absolutely; it has to.

PROF SLOAN: Yes, it has to. So presumably you are supportive of our idea that the cost recovery be - - -

MR VALE: By activity. That's your benchmark. The TGA almost unfairly suffers criticism for the high cost of their activity because the judgment is made against the lodgment of that application and the management of it and the annual fee and people perhaps don't immediately recognise that the fee that is charged obviously is a cross-subsidy arrangement.

DR STEWARDSON: A small point about definitions - you raised some question about definition or some comments about definitions earlier in your comments - you do make a point about the definition of "therapeutic devices" on page 2, where you say:

Therapeutic devices, as inclusive of diagnostic equipment and diagnostic supplies -

I don't know that we actually necessarily need it for a glossary but that's a partial definition and it's just saying it includes those things. I presume you have a more comprehensive definition of therapeutic devices and maybe you could perhaps subsequently give us some words - - -

MS WINSLADE: It's actually in the act.

MRS OWENS: It's in the act.

DR STEWARDSON: That's right.

MRS OWENS: I think we've defined it in our medical and scientific equipment inquiry report.

DR STEWARDSON: Right.

MRS OWENS: Yes, we've got a glossary there.

MS WINSLADE: Basically it's something for therapeutic use that doesn't achieve its effect by its own pharmacological activity.

MRS OWENS: I apologise for this terrible noise.

MS WINSLADE: The point I guess we've tried to make, we've struggled for many

years to get recognition through regulation that we're different. We've struggled with the current Therapeutic Goods Act in a few areas and at long last we now have regulation coming that is device specific. There are differences; you can't regulate both the same way.

PROF SLOAN: Yes, that was a very useful discussion, so thanks very much. Is there anything else you'd like to say before we have a break?

MR VALE: No, I have nothing further. We have nothing further?

MS WINSLADE: No.

MR VALE: But once again, thank you for the chance to be here and to present our case.

PROF SLOAN: It's always good to talk to you.

MRS OWENS: Okay. We will now break until our next participant arrives. Thank you.

MRS OWENS: The next participant this morning is Blackmores Ltd. Could you each give your name and your position with Blackmores for the transcript.

MS SAMUELS: Sure. I'm Jan Samuels, director of corporate affairs.

MS McFARLANE: And Lynda McFarlane, regulatory affairs manager.

MRS OWENS: Thank you. Thanks both for coming and thank you for yet another submission, which we greatly appreciate. I was wondering if either of you would like to make any opening comments, and then we'll just have a bit of a discussion on your submission.

MS SAMUELS: Sure. Thanks, Helen. We just wanted to say on behalf of Blackmores that we really welcome this inquiry. We think it's really important that this is happening at the moment, particularly for our industry, the complementary health care industry, which is suffering quite a difficult trading environment at present, and also the effects on our industry of the GST, which I know is outside the scope of this inquiry but does have an impact on cost recovery for both our industry and for small business and so on.

We saw this inquiry as a good opportunity to take a look at the system that we have at present and hope that there are going to be some adjustments as we're moving into a new era of trans-Tasman harmonisation within our industry, with the hope that we can end up with a more equitable and open system as we move away from just Australian regulation into a joint trans-Tasman regulatory environment.

Senator Tambling has already done quite a lot of work on his reform agenda for our industry, and we're concerned now that with the reforms that are going on we can perhaps build on what's already been done and perhaps iron out some of the problems that we have, in particular things like appropriate fees and charges that are applied to our industry, which Lynda will talk about, and the difference between service and servicing the industry, with which we have problems with the TGA in some respects. We don't believe our industry should be paying for some of the social responsibility material that the TGA undertakes, for example, in the training and networking, HR, building and services, separate investigations and that sort of thing that really have no direct impact on or relationship to our industry. Lynda, did you want to - - -

MS McFARLANE: With regard specifically to fees and charges, I guess where we're coming from is we see a lot of inequity in the fees and charges that we as a company pay. One key charge that comes up quite a lot is this annual charge which is levied on each product on the register. That money goes into the big sort of TGA pie which they use to then regulate the industry. They do all their community service activities, all their surveillance enforcement activities, out of that huge pie, but what we see is the larger companies are definitely subsidising the smaller companies. Smaller companies, if their turnover on their sales of products is quite low, have a smaller annual fee to pay and it's capped at \$10,000 per company. So we know that there are many companies out in industry who have lots of products on the market

and are relatively small companies, and I guess morally it's a really good thing to support small business, but ultimately the TGA needs to regulate for everybody and every product.

So if some companies are having to contribute much more to that pie than smaller companies, then that for us in particular is an issue. For example, in this financial year Blackmores will contribute \$160,000 in annual fees to this TGA pie, and yet a smaller company could only end up contributing \$10,000 to that pie. So we're unaware of how many companies actually are the \$10,000-capped companies and how many are perhaps even larger and pay more than us, but ultimately the TGA is regulating for everybody and yet there's definitely an inequity there of who is paying what slice of that pie.

I guess the other key point is the TGA costing structure should be activity-based. We should be paying for the services that they provide for us, and those services above all need to be efficient and transparent. That's definitely something we see as an issue. We are just not sure how they work, how the systems could be improved. Could certain things be actually farmed out to private industry to do on a tender basis? I guess from our point of view we see a lot of that as one sort of big black hole, and while I guess you could find out this information if you really wanted to, sort of dig around and do FOI requests et cetera, I guess we don't see that that information is readily available to industry. Also their activities and their services need to have KPIs attached to them so that we know what we're paying for, what we're getting and how that performance is measured. So I guess inequity in fees is something that we see as a big issue, and then obviously the transparency of those fees as well.

MS SAMUELS: We accept that the government has imposed 100 per cent cost recovery on the TGA but, as I say, I think it's inappropriate that we don't know what percentage goes there. There really is very little accountability from the financial statements that we're able to find, and I think one of your findings in the draft report was that the policy decisions and the transparency around agencies such as the TGA really do need investigation at government level. We're not really qualified to talk about other agencies at all, because the TGA is the main one that we deal with, but as a concept 100 per cent cost recovery is clearly inappropriate for this industry, and this agency in particular.

MRS OWENS: Thank you. I see from your submission that you've supported quite a number of our recommendations, so we don't necessarily have to talk about those issues. But I think one of the issues you just raised this morning and you also raised in your submission was this issue relating to whether industry should be paying for some of the broader responsibilities of the TGA, what you've called social responsibilities, and we'd noted areas like government policy, advice, international arrangements and so on.

MS SAMUELS: Exactly.

MRS OWENS: I think it was your submission, or maybe it was your earlier

submission - yes, I think it was the earlier one that you sent us - had lots of examples of activities that the TGA got involved in, such as GMP training for Vietnamese delegates and all sorts of things.

MS SAMUELS: Yes, there's a very long list.

MRS OWENS: Yes. WHO vaccine regulators course; all sorts of nice things that the TGA does. I'm not saying that they shouldn't be involved in those activities, but it does raise the question of who pays for it.

MS SAMUELS: Who pays, yes. We've picked up some here too - staff to attend a conference in Japan, two to attend a conference in Melbourne, one for a meeting in the UK, someone for a group workshop in Fiji, a meeting in Denmark, a meeting in Strasbourg, a pesticide regulator from the TGA who trotted round Queensland courtesy of the Fruit and Vegetable Growers Association. Then you've got conferences like a six-day training course for vaccine regulators that you've mentioned for people that came from Asia and South America, a group of pharmacists who came from Vietnam for training and good manufacturing practice, and clearly outside the bounds of our industry. Those examples come from three of the TGA's newsletters over a period of about six months. Good on them for doing the work, but should it really be an industry cost?

MRS OWENS: I've decided I'm in the wrong game. I think I'll go and work for the TGA next.

DR STEWARDSON: I don't think they'll have you after this.

MRS OWENS: They won't have me, no. What I think is interesting is we had a workshop last month with the regulatory agencies. We had another one with the information agencies, but one of the issues that was raised at that workshop with us was that the agencies felt that all the things they were doing were directly related to their responsibilities as a regulator of whatever they were regulating, in the case of the TGA therapeutic goods, and that for that reason all of those activities should be cost-recovered. I think it's very useful having those examples you've given, because when I look at those I really basically come down on your side. I think that those are distinctly areas where somebody else should be paying, probably through the taxpayer through the budget of the department. There may be some grey areas.

MS SAMUELS: Certainly. There are always are.

MRS OWENS: If you're talking about government policy advice, it depends that advice and at what level that advice is. If it's more general, relating to how the TGA is fitting into the broader health system or something, that's broad; it should be budget-funded. If it's specifically in relation to, "This is the way we're going to do our conformity assessment in the future relating to these companies," I think that that is something that should be probably charged as a cost to industry. Do you see it in that way?

MS SAMUELS: Yes, I agree. The other thing I would be concerned about is - we've talked about transparency and accountability, but I'd hate to see some sort of bureaucratic system set up for putting \$5 in this fund and \$100 in that fund, you know, some sort of cumbersome accounting system to say what's industry cost and what's government cost. I think with the old system they had before, 100 per cent cost recovery that was imposed on them in 1998 was a percentage, which seemed far more practical.

PROF SLOAN: A rule of thumb really, wasn't it?

MS SAMUELS: Yes, that's right. You could almost divide it down the middle but, again, 100 per cent is just not really appropriate.

PROF SLOAN: That issue of what you perceive to be the unfairness or the distortions in the charging arrangements, does that cut two ways? One is that issue of the relative favourable treatment of small companies, which you mentioned, but is there also an issue of how complementary medicine is treated compared with the other sectors? It seems to me that - - -

MS McFARLANE: In what way?

PROF SLOAN: In the sense that in the case of the prescription pharmaceutical segment of the industry - they clearly do gain quite significant or clear commercial benefits from being approved by the TGA.

MS McFARLANE: Yes, they do.

PROF SLOAN: Do you see Blackmores being the beneficiary in the same way as - - -

MS McFARLANE: I guess with the pharmaceutical companies - clearly you would have seen the fees and charges structure from the TGA, and those companies are paying literally hundreds of thousands of dollars in some cases to get a new drug approved. The benefit that they also gain is it ends up on the PBS, so a lot of those costs for them are actually - the benefits that they gain by getting a drug on the PBS far outweigh the pretty small costs that it takes them to get that product to the PBS. We don't have that sort of opportunity really in our industry, so I guess any commercial benefit we do get out of being regulated is in the export area, and at Blackmores we do have a fairly aggressive export plan. Particularly in South-East Asia the TGA is quite highly regarded by some of those governments, so being able to send some documents up to them with the TGA all over them is clearly a benefit to us.

But, given that the bulk of our business is Australian based, I guess consumers - we don't know that they understand much about how our sort of medicines are approved in Australia, what the Austel, Austar numbers mean on the pack, et cetera. So I think it's pretty intangible, the kind of benefits, if there are any, that we do get from being regulated and for paying such fees.

MS SAMUELS: The other part of that too, of course, is that pharmaceuticals are a lot more dangerous than complementary health care products. They're comparatively low-risk, safe sort of products that we produce, and what we really want to see is appropriate levels of regulation for our industry and our products rather than the very high risk products that, say, the pharmaceutical industry does make. Again, this is outside the area of cost recovery, but it seems that the mindset of the TGA is to push complementary products into more of a pharmaceutical model that we have a problem with. Also, given that we can't ever patent any of our products, there's a greater cost to us for going through this regulatory system than, say, there is to the pharmaceutical industry, which can at least recoup some of those costs that they put into regulation and development. We don't have that same protection. So for us a lot of the issue we have with the TGA is not so much the cost part of as the mindset part of it being shoved into an inappropriate model.

PROF SLOAN: Are there wide variations in the developed world as to how complementary medicines are regulated?

MS McFARLANE: Yes. They go the whole gamut from practically unregulated which - New Zealand is practically unregulated. It does have regulation, but there's no enforcement at all, to again similar countries like Germany probably along similar lines to Australia in terms of herbal products, that sort of thing. So they go all the way from practically nothing to sort of foods, to foods, to dietary supplements, to sort of pseudo-medicines and then right into medicines, so across the board; it's the full gamut.

DR STEWARDSON: You have a separate division, don't you? You don't have it but the TGA has a separate division - is that the term - for complementary products?

MS McFARLANE: A separate office, yes - the Office of Complementary Medicine, yes.

DR STEWARDSON: Is that not adequately meeting this problem that you're talking about of successive regulation?

MS McFARLANE: Let's just say there's lots of room for improvement. We have an office, we have a full complement of staff devoted to our industry but we do have some issues with the way that we interact with them and the sort of issues that we deal with so we've got some more work to do with them.

DR STEWARDSON: On the question of consultation you indicate in your submission today that you think there's a lot of shortcomings in that. What would you recommend as an improvement.

MS SAMUELS: I think it's again the mindset. It's the philosophical approach that we have the biggest problem with in an agency that is rightly concerned with public health and safety but has a very risk-adverse way of dealing with the industry. We could talk about the Canadian model where the emphasis is more on access for the

consumer; safe, affordable products that are accessible by the consumer. Whereas here it tends to be or the perception that the industry has quite a lot is that the TGA is trying to stop things from getting to market. But that's - - -

DR STEWARDSON: No, I was really meaning - if I could interrupt you - more the process of interaction between industry and the regulator. Are you out of the TICC or do you have a separate subdivision of the TICC?

MS McFARLANE: We are members of the Complementary Healthcare Council who essentially do most of the lobbying and those sort of issues, development work with the TGA on our behalf. You probably won't find many companies who interact directly with them on that basis. They tend to go through the industry organisations and CHC is represented on TICC, I understand.

PROF SLOAN: All the segments are represented on TICC. I think there was a bit of a fight about it, but - - -

MS McFARLANE: Probably, yes.

PROF SLOAN: - - - it is true, I think, that all the different - - -

MS McFARLANE: I guess people don't know how well that process works. I guess they get together every year and they start hashing and tick-tacking about fees and charges and I don't know that it's a process that works very well. I have got for you, if you are interested, just a quick summary of the type of fees that we pay for the TGA, what the actual trend in those fees has been for the last six financial years.

MRS OWENS: Yes, we are interested in that.

MS McFARLANE: Yes, I can leave that with you. I haven't got any notes to accompany it, but it's just a table and I'm happy to give you more information if you need. But I guess originally when cost recoveries first started to go from 50 per cent and then ramped its way up to a hundred per cent, the fees were pretty reasonable. We could deal with some of the changes that were happening every year, and in one particular year from the financial year 99 to 2000, we had really no fee changes at all, and last year they took off again dramatically, so I guess we're feeling that in years to come, every year they are just going to keep going. There's just this inevitability that every year the TGA will say they need more money to do their activities and we will just have to keep paying every year.

MRS OWENS: The no-fee increase in 99-2000, it may be a reflection of swings and roundabouts because at one stage they were under-recovering and maybe now they're smoothing it out in this financial year. Would that be right?

MS McFARLANE: Could be, yes, possibly. I guess you have to look in terms of the whole pie; we're one part of the pie and we have particular charges that we pay in that pie. Perhaps the prescription drug industry actually copped a lot of fee increases that year; we may not have but they may have, so it's all about context really. But

from a corporate point of view, last year was a big increase to the year before that and this year is mooted to be not such a big increase, although we haven't seen the final sort of numbers yet. But how do we know next year that they won't start zooming up again?

MRS OWENS: But are you consulted on those fee increases? This comes back to the point Robin is trying to get to.

MS McFARLANE: That's the TICC - - -

MRS OWENS: When you go to TICC, does the TGA put in front of you a proposal, "This is what the percentage increase is going to be for this year," and do you get an opportunity to negotiate on that increase?

MS McFARLANE: Yes, the Complementary Healthcare Council will obviously look at what's been proposed and say, "Well, you need 10 per cent." "Why is it 10 per cent? Where is all that extra money going to go?" - et cetera et cetera.

MRS OWENS: How responsive is the TGA to any pleas for a lesser percentage increase?

MS McFARLANE: I'm not totally sure. You'd probably have to ask the CHC.

MS SAMUELS: No, not really able to comment on that. The CHC represents the industry on that one. I gather that negotiation phase is going at the moment. It has dropped a couple of percentage points, but again, that's really the CHC's area.

MRS OWENS: But we are interested in this TICC process, and you did make the comment that the process is not working well and I think our interest is to see how we can get a TGA that is going to be more responsive to industry, because if TGA is going to be cost recovering from industry, albeit maybe if our guidelines are followed in the future at a lesser level, industry has said - all segments of industry I think that we've spoken to - that, "We want to ensure that the TGA is going to be as efficient as possible." Is TICC the right consultation forum to ensure that that happens or do we need some other process?

MS McFARLANE: It might not be the only one that we could use, given that's I guess more of a financial sort of process. Again, you mentioned efficiency, and I guess as someone who interacts with the TGA every day, we would see them - the way they do a lot of things is very inefficient and if a private company was doing the same thing, we would say, "We would never do it like that," because it simply generates more paperwork or takes more time et cetera. I don't know if TICC is the place to sort of drill down and examine specific processes and systems to figure out how they work or where they don't work and how they could be made more efficient; perhaps that's something that needs to be looked into. I don't know how much work they actually do in TICC and how often they meet and the people representing, you know, both TGA and industry, how much they actually know about the nitty-gritty of the systems and everything.

DR STEWARDSON: We made a specific suggestion as one way of trying to address exactly what you've just said about the efficiency, namely, an efficiency audit committee. Do you have any comments about that, the desirability of that?

MS McFARLANE: I think that's probably a good sort of proposal, I guess, as long as we didn't have to pay for it.

PROF SLOAN: Because in a sense I think you're expressing the frustration which we have had conveyed to us by quite a few participants, that it's really the complete lack of transparency and accountability. It may be efficient - parts of it may be efficient - but I think - - -

MS McFARLANE: It might be wonderfully - - -

MS SAMUELS: But we just don't know.

MS McFARLANE: We don't know.

PROF SLOAN: It seems to me the exploration of that model where you might outsource all market tests - at least some of the assessment processes perhaps - it's that kind of thing that people would like to see happen and perhaps have some CAQIS and performance standards imposed on the TGA.

MS McFARLANE: One area that I think has been investigated is TGAL, the Therapeutic Goods Laboratories. I pulled it off the Web site earlier on in the week - I think they have approximately 125 scientists who work just in that section within the TGA, and what they do is they test products before they go to market in their device and pharmaceutical drug area. They will do enforcement activities and surveillance, so where products are in the marketplace, they will test those and then report back to the sponsors of the product if their product passed or failed and that sort of thing.

I guess in the commercial world there are very large and very well set up commercial laboratories already who actually perform those tests already for industry. As we're manufacturing and releasing our products for sale, those tests are being done already on our products and the TGA has the same thing set up within their own organisation. I don't know if it's efficient, I don't know if it works well, I don't know how much it costs, those sort of things, but if you had to say 125 people were probably working in one area of the TGA, it is a significant resource area, and how do we know how they're tracking? How do we know how well they work?

MRS OWENS: But there's no incentive really under the current arrangements I think for the TGA to address those questions while their funding is being underpinned by industry.

MS McFARLANE: And could any of that work be outsourced at a cheaper, quicker, more efficient way?

PROF SLOAN: This issue of harmonisation, I'm not sure I fully understand what that's about. That's moving to a common regulatory arrangement with New Zealand, or is that just about mutual recognition?

MS McFARLANE: No, there's a plan in place for New Zealand Medsafe and Australian TGA to join together and become a new joint regulatory body for medicine and device regulation some time in the next four years, of that nature. There's a lot of work already going on in that area. At the moment, there isn't a lot of cost recovery at all on the New Zealand side with Medsafe, whereas over here we are fully cost recovered and that's one issue that New Zealand has raised, that once a new agency is developed and the whole thing will be fully cost recovered - that's already been mooted to industry - how do the New Zealanders feel about that as well, given they may have been actually paying no fees, nothing, for years, and then all of a sudden they're up for whatever comes with the new agency.

MRS OWENS: It's quite interesting because in New Zealand they do have cost recovery guidelines, and I presume under those guidelines, working through those guidelines, they've got to a point of saying that there shouldn't be fees charged for some of these activities. We might have a look at that to see whether that is the case.

MS McFARLANE: Yes, I think you will find even the New Zealand pharmaceutical companies, they're really paying for activity based services only. They're not, like we are, contributing other huge chunks of money into this big pie that's used for other things, which is essentially what our annual charges are for us, is just adding to that big pot of money that the TGA are using for all their other activities.

DR STEWARDSON: But is it the cost recovery system that is different to New Zealand - - -

MS McFARLANE: It could be.

DR STEWARDSON: - - - or is it the regulatory system that is different and less thorough for your products in New Zealand?

MS McFARLANE: Probably both, a bit of both. But again, once the new agency is developed, sectors similar to our industry in New Zealand will be paying fees that they've never had to pay before, so I think part of their buy into this whole process will be, well, how does the fee structure work and who decides what the fees are going to be, how efficient are these processes, before they could possibly agree to join this sort of - - -

PROF SLOAN: It might be an opportunity of course.

MS McFARLANE: Exactly.

MS SAMUELS: And I think that's the thrust of our second submission as can - - -

PROF SLOAN: Not necessarily a threat, it's actually a - - -

MS SAMUELS: Yes, it's great. Can we get it worked out from the start; as we're building towards this new regulatory environment can we learn from what you've learned out of your inquiry and perhaps apply some of those ideas and guidelines to whatever comes out of the whole process. We have no problem with being regulated and paying for industry services but we want it to be something that works, you know, well, effectively and openly.

DR STEWARDSON: What is the reason for having this move towards trans-Tasman harmonisation?

MS McFARLANE: I think Australia and New Zealand are relatively small countries. They have, I guess, limited regulatory capacity individually. I think it's also very difficult to recruit particularly trained toxicologists, people of that nature within each country and I guess when you look at the big global picture, two small countries doing their own thing at the bottom of the world probably doesn't seem like a very good idea sort of long term. So I gather that both governments think that it's a much better idea, in the way that ANZFA is now a joint agency for food regulation in Australia and New Zealand, that medicines and devices should go the same way. It's actually a very sensible sort of proposal provided that industry isn't worse off, and in fact we'd probably like to see a lot of changes that go along with buying into this new joint agency.

PROF SLOAN: Well, it makes quite a lot of sense in the context of CER.

MS SAMUELS: Exactly, exactly right.

PROF SLOAN: You're going to have a free flow of goods, you'd probably want free flow of regulatory activity - - -

MS McFARLANE: Common outcomes.

MS SAMUELS: That makes very good sense.

PROF SLOAN: I just had one other issue. Right at the end of your submission you say:

We would also urge the commission not to accept a long five-year period of review or to permit agencies with a vested interest in the status quo to stall on the grounds of future policy or bureaucratic changes.

In our draft report we have - well, not recommended at this stage - but we've actually suggested that all existing cost recovery arrangements be reviewed within five years.

MS SAMUELS: Yes.

PROF SLOAN: What we were really thinking in the back of our minds was that there be a prioritisation undertaken, not by the agencies themselves to determine when they get done but by the Department of Finance and Administration and that there be some priorities based on the size of the agency and how much cost recovery there was, and I think that the TGA would probably be one of those agencies that would be looked at fairly early on in the piece (a) because they've got 100 per cent cost recovery of the whole agency and (b) because of the degree of concern that we've been hearing from different groups about the TGA and - I don't know whether you want to comment on this but one of the things I was saying to the participants earlier this morning, the MIAA, was that possibly we could make some suggestions in our final report about that and say that if you're going to prioritise them - we'd put some principles up, I think, in our last chapter but we may be more explicit and say that we would suggest, you know, that certain agencies like the TGA be looked at earlier rather than later. Would that satisfy your concerns?

MS SAMUELS: It would certainly address them. The ideas that you've put forward in the report already are very sensible. We have a lot of support from what you're already putting forward and I think that was exactly the point of that part of our submission, was to urge that if there is going to be a review - and with trans-Tasman harmonisation looking likely - we'd very much the TGA or its equivalent to be a priority for cost recovery issues and how it even works. I mean, I know that's outside the scope of this inquiry but cost recovery is a major part of that. It's a very good opportunity to get the thing working properly and perhaps is a model for other things that are likely to develop under CER. We'd support that very strongly.

PROF SLOAN: I think the CER issue might be another lever for getting it done earlier rather than later because these issues really need to be looked at at the same time.

MS SAMUELS: They do, yes, and our point is that we'd rather have something effective in place at the start than try and patch up something five years down the track. Yes, we very strongly support it.

MRS OWENS: Did you have - - -

PROF SLOAN: No, that's fine. That was clearly presented, the submission.

MRS OWENS: Yes, it was a clear submission.

MS SAMUELS: Thank you.

MRS OWENS: And it was nice and short. I like the nice short ones that get to the point.

MS SAMUELS: We're working on it.

MRS OWENS: So thank you very much for coming this morning.

MS SAMUELS: Thank you for having us.

MRS OWENS: I think it was a good discussion. We'll now break and we will resume when our next participant arrives, which is - they're due at quarter to 12 but we'll resume earlier if they arrive earlier.

MRS OWENS: We'll now resume. The next participant this morning is the Tourism Task Force. Welcome to the inquiry. Thank you for coming and thank you for the letter that we received as a preliminary submission. Could you both please give your names and your position with the task force for the transcript.

MR ALBIN: Yes, it's Stephen Albin, deputy CEO, Tourism Task Force.

MR FLOWERS: Karl Flowers, general manager policy and research, Tourism Task Force.

MRS OWENS: Good, thank you. As I said, thank you for coming. I understand, Mr Albin, you'd like to make a number of introductory comments.

MR ALBIN: Just some brief introductory remarks. TTF would like to thank the commission for giving us the opportunity to present here at such short notice. We initially weren't going to make a submission into this inquiry but we have noticed that throughout the process of the inquiry a lot of our members and a lot of the sectors that we represent have made submissions to the inquiry, so too have a lot of the government agencies that have been responsible for levying cost recovery and user charges on the industry. What I've tabled with the commission is basically a letter outlining some key speaking points that we're going to deliver today but we want to provide a more fuller submission, if that's possible, a week down the track and we'll do that.

Our organisation, the Tourism Task Force, represents the top 200 or leading investors, developers and owners in the tourism industry. Our members come from the airlines; they come from hotels, overseas marketing for the tourism industry, inbound tour operators, major construction companies, and they all can see the value of tourism to the economy and to their business. As I said earlier, they've encouraged us to come to this inquiry to make a couple of points. The Tourism Task Force's position on cost recovery is that basically we support it and we think that with the revenues falling - or not falling but with the government having a lot more services to provide with tighter revenue constraints, cost recovery is good way to manage demand and to ensure that you can provide and fund public goods and you can ensure that the welfare state operates as it should.

Essentially our experience and the tourism industry's experience with regards to cost recovery is that it is not operating in a way that is transparent. It is not operating in a way that is open and the tourism industry has become the cost recovery milch cow of the government, and I've put three examples in my speaking notes. These are three very recent examples and I'll go through them one by one which sort of adds to what we've got here in the speaking points. During the last budget that was delivered a fortnight ago in Canberra, the government decided to raise the passenger movement charge by \$8. This passenger movement charge was - was amended by Michael Lee because of international concerns with regards to a charge and he changed it into a tax. My legal understanding, which is limited, is that a tax basically goes into

consolidated revenue and the government allocate funds from consolidated revenue.

In the last two examples of the price rises with regards to the passenger movement charge - and one occurred I think four years ago, there was a \$3-increase in the passenger movement charge from \$27 to take account of the increased border activity or border control activity from the Olympics, and the latest one of \$8.

Both of those examples the government has clearly earmarked the increase to go to a specific service. You can excuse me for my limited legal knowledge but I was of the opinion that that's more of a charge, not a tax, if they're doing that. That's one area of concern that we have. We don't have concern with the fact that they're putting money into foot and mouth. We don't have a concern that they're spending money on the Olympics but if it looks like a charge and smells like a charge, then it is a charge and they shouldn't be masquerading a tax as a charge. It should be open and transparent.

The second example is one that happened after the budget, where the government actually - last week the Department of Immigration advised us of the electronic travel authority, which is a free service that's provided by the government by DIMA through travel agents around the world, was going to be provided on the Internet. As a result of that, they have imposed a \$20 charge on that service. We have no problem with the charge but there was no provision in the Budget- there was no consultation beforehand and there's no provision with regards to over-recovery.

Now, in the first week that the electronic travel authority has been up on the Net, they've had 4000 applications. That more or less means that they'll be collecting - and this is very roughly - \$400,000 this year. They had advised us in press releases that they needed \$200,000 to recover the costs. They're also saying it's a pilot, so that might be a way that they can get out of it, but basically they'll be over-recovering by 100 per cent. Once again, not concerned about cost recovery; it's just that if they're going to recover the cost, it should be specifically for that service and it shouldn't be over-recovered or there should be provision in terms of refunding the over-collection or reducing the price when they realise that basically they've charged too much.

The final one is the environmental management charge. Once again, when this environmental management charge was announced by Minister Moore many years ago, the tourism industry was up in arms. I think the charge was \$6, and following lobbying the minister dropped it to \$4. Tourism operators are responsible for collecting that charge, and to be honest with the commission, there has been a problem with that in terms of the industry under-collecting. But once again, we're not concerned with - you know, time is - we've all got used to it over time, it's not a major impost in terms of the amount. It's just that the tourism industry is the only industry that's contributing to the protection and management of the reef.

I've gone through the Great Barrier Reef Marine Park Authority's submission and they have correctly pointed out that they're getting money from consolidated revenue as well, but a report from World Wide Fund for Nature that

was released during this week called the Great Barrier Reef Report Card, which shows that the overwhelming manmade threat to the reef is from run-off from farms. Now, if we are required to pay \$4 to help manage the reef and to help protect the reef, then surely others that are polluting should be made to pay as well. I'm not saying that we're paying too much or they're concerned about the level of the charge, it's just who actually pays for that. So they're our three brief examples.

We have some recommendations in here. Cost recovery requires - the Commonwealth needs to develop some clear principles. What we've been finding is that it's been very ad hoc over time, and you'll find you've got to go through the budget papers, and look at all the fine print to see where a new cost recovery charge has been applied to the tourism industry, and pretty much since I've been in it, for five years I've been noticing there's a new one every time. I've gone through the draft report here and I agree with all of the recommendations. I think it's a great report. I strongly support that where possible agencies should adopt a beneficiary pays principle and the application of cost recovery. I think that's vitally important. Sometimes that can be difficult but they should adopt that principle.

I've put in here a third point. If possible, cost recovery principles should be applied on a net spill-over basis. In a lot of instances, for instance in the Great Barrier Reef Marine Park we pay for the management and upkeep of the park but by the same token, the crown-of-thorns starfish provide a real threat to the reef. Our industry has paid up to \$2 million to protect that reef, not in terms of the \$4 fee but in terms of us realising that it's vitally important that the asset is maintained so tourists can enjoy it. We shouldn't only be looking at the negative. There are many other examples, especially with regards to national parks, where we pay a considerable amount of money but by the same token are providing positive spill-over effects as well.

There should be clear provisions for over-collection. In many instances - you'll find specifically with the passenger movement charge, the first audit report showed the government was over-collecting by \$19 million. In the second - and this puzzles me - but in the second ANAO report, they seemed to be more focused on under-collection by the airlines. Well, the major issue is the over-collection in terms of the absolute amount of the tax, not compliance. While compliance is important, there was nothing mentioned in the second report and it was obvious that there is an amount going to - still a significant amount going to consolidated revenue and a charge should not masquerade as a tax and clear policies should be developed to avoid earmarking of specific tax collections, or call it a charge and earmark the services or earmark the revenue for the actual beneficiaries of the service. So they are my opening comments. Karl, would you like to add anything?

MR FLOWERS: Yes, just a couple of things. It's obviously unfortunately beyond the ambit of this inquiry but we've seen in the last decade within the regulatory

authorities a great deal of recognition of their compliance costs in providing services and cost recovery seems to be a remarkably one-way street. When the private sector has major compliance costs associated with new tax systems or with visa applications, processing, that's clearly irrelevant in terms of cost recovery on the agencies who impose those direct regulations. There has to be within the government bureaucracy an increased recognition that it is a two-way street.

My second point is, following on from Stephen, that we have very formal budget processes in this country concerning taxation revenue and expenditure. With the decentralisation to agencies, there is a great temptation to introduce new charges and they tend to do so on the basis of their own political perceptions and, as a result, there isn't a whole of government approach taken to many of these charges in terms of regulation impact statements et cetera. They don't certainly consider the broad impact on the whole of the economy of those measures. They take a very narrow focus within the agency concerned.

We've just had with the passenger movement charge about \$500 million over the next four years raised, from the tourism industry very largely, to counter foot-and-mouth. There are a range of issues with foot-and-mouth disease. Of the total cost recovery towards foot-and-mouth, as laid out in budget paper number 2, about 85 per cent comes from passengers. Now, it would be fascinating to know that the risk is also 85 per cent associated with passenger luggage rather than freight and mail, which bears a much smaller share of the total charge. When the budget - going back into 98-99, from budget paper number 2:

The \$3-increase -

in the passenger movement charge -

will raise an estimated 77.3 million in additional revenue over the four years to 2001-02. This will help meet the additional costs arising from the movement of people and games-related equipment across Australia's borders at the time of the Sydney 2000 games.

We have temporary reasons typically being advanced for these charge increases, tax increases, but they get locked into permanent revenue sources on our industry but not on others. With the foot-and-mouth outbreak, it will hopefully be a once-in-a-generation outcome, and we would love to think that that \$8-increase is going to be taken off as soon as the foot-and-mouth emergency goes. But the farmers who have got a very interesting approach to polluter-pays in general - they think that the tourists are clear polluters and they should pay - we're waiting with, I guess, bated breath for the next instalment which will be that the tourism industry is responsible for salinity across the country and the degradation of the Murray Darling Basin.

MRS OWENS: I don't know why you should be suggesting though - - -

MR FLOWERS: No, I understand it is a real risk. But the budget papers very

clearly make links between new charge increases and new revenue measures. That's been done not just to the benefit of the tourism industry with increased funding for the tourism package for tourism promotion and development being mentioned in the revenue section of the budget as the associated expenditure measure. We have obviously, from the tourism industry's perspective, it won't surprise you to hear, we have much greater support for an increase in the charge that goes towards funding increased international marketing of Australia. We actually see that there is a link there.

MR ALBIN: The government actually also saw there was a link there too. When they increased the fee by \$3 they showed it as an outlay as a revenue measure and showed the revenue in the budget papers and had a little asterisk at the bottom of those revenue measures and it said, "See the outlay measures." The outlay measure was, "We're going to increase the ATC funding by \$10 million a year." So that's what they did when it was increased by \$3 but they haven't done it this time.

MR FLOWERS: It's also common that of course when the charges increased as occurred with, say, Visa processing charges in 98-99 or indeed the passenger movement charge in 98-99, the ratio of revenue raised to expenditure is about 2:4:1, it varies in that range. It's very rarely 1:1. So there is a siphoning that goes on between typically the Department of Immigration's submission and the final budget outcome. But the clear link in the budget papers means that these aren't taxes.

MRS OWENS: I don't know where to start. I think that the three examples are very good examples for us and I think over this inquiry there's been sort of an acceptance that the passenger movement charge is really a tax or it's become a tax almost by default, so that means that it takes the pressure off anyone to say that that charge is going to be related in any way to the costs incurred. But then you have this hypothecation taking place and as you've noted, the amount that was raised for the Olympic Games, the \$3, has never gone off; once it's there it's there. I wouldn't be holding my breath for the \$8 to be removed either.

But I think the commission tends to, like you, abhor the idea of a hypothecation of any sort, it does go against the grain. I think that your comments about the departing tourists paying for something which is really unrelated to that activity - if we were applying our guidelines to this, it probably wouldn't fall down in that way. I don't know whether Judith or Robin want to comment on this or whether you want to comment further. Judith, do you want to say anything about the passenger movement charge?

PROF SLOAN: It clearly fails our test on all sorts of grounds actually. Whether we call it a charge or a tax is clearly - that issue of earmarking is interesting. It seems to me that there is kind of good earmarking and bad earmarking, if you know what I mean. The trouble is that the movement of outgoing passengers in fact is not kind of in any sense much related to the costs of preventing the importation of foot and mouth disease. So there is really very little logical basis to the earmarking. Think of another example where CASA which is, presumably of interest to you, I mean, they have basically an earmark tax arrangement on the levy on the fuel, which

is then used to ensure air safety. Presumably you're not going to be so worried about that because there is a close relationship between those two activities.

MR ALBIN: Correct, although I have got to go back and look at the Qantas and Ansett submissions - no, correct, because there is a clear - not happy - - -

PROF SLOAN: There is a clear link.

MR ALBIN: Because there is a clear link I would be less concerned about that, about the fuel levy, than something like the passenger movement charges increases. I'm not saying that we should not be required to pay our way and that the tourists shouldn't be required in some way to contribute to boarder control activities. What I am saying is that it's sort of got a bit out of control, spun out of control, and money is flying left, right and centre.

MR FLOWERS: I think to be fair to the Department of Immigration, they have had a massively increased workload in terms of illegal migrants coming here largely by ship. Thankfully the number of overstays as tourists is quite low. Even on the department's own figures certainly not the major problem in terms of their costs of enforcement. I was going to mention - looking through your draft report I was surprised not to see it - I will pick on a state charge. It is always a little less controversial in this sort of forum. We have a lot of entry fees to get into National parks in this country. Those are levied by state governments.

I think - and you would be able to get this data from the National Parks themselves - that it actually costs them much more to collect that charge than they actually raise for all but two or three national parks in New South Wales at least. One wonders, if you went through the whole range of cost recovery - and I would certainly love to see it in your report related to visa application charges - just the efficiency of the charge collection and just how much it costs to collect these charges versus the revenue raised because we think that a whole raft of them are very inefficient taxes. We had tax reform that pushed us towards broad based consumption taxes like GST which have very high efficiency and yet we have taxation by stealth with very low efficiency.

Obviously that's a particular frustration to an industry which finds itself paying to put people on gates, to slow the traffic flow and to involve other congestion costs.

PROF SLOAN: I mean, in our diagrams that kind of charge would fail our test because we ask the question, "Is it cost-effective to levy a charge?" So that wouldn't get through but, you know, the state governments have all sorts of different guidelines.

MR FLOWERS: Are you going to actually report on the efficiency of various of these charges?

PROF SLOAN: Of the?

MR FLOWERS: Cost efficiency of the collection of these various charge because we - - -

MRS OWENS: Well, it's hard to do that because - - -

MR FLOWERS: Very hard.

MRS OWENS: What we did, we commented in the report - the other issue that we raised was this lack of transparency about actually what the charges were in the first place but then actually having to try and determine how much it is costing for them to collect them. I mean, I don't know if we actually have got that information.

MR FLOWERS: I bet that you haven't.

MRS OWENS: I mean, you made the comment that you didn't see in our report anything on this. I mean, by having these diagrams which are the question, is it cost effective to charge, we are actually I think acknowledging that administrative costs of doing this in some instances could outweigh the benefits of actually getting the revenue, so why bother? It doesn't make a lot of sense to collect the revenue if it is going to cost you more to do so. I mean, I can't recall now whether our report goes into a lot of detail about that but I think we would have had trouble trying to actually pin down, you know, how efficient is this to undertake cost recovery because we would not be able to get the data, which is a big problem we face.

MR FLOWERS: It is just that you are much more likely to get the data from the departments through your inquiry process than certainly the public or other industry associations.

MRS OWENS: Yes - the cynical yes. We actually had to go and survey the department to get information because the information that we required was just not in the public domain in any reporting, annual reports, budget papers or whatever.

MR FLOWERS: They didn't charge you for filling out the survey?

MRS OWENS: Don't even suggest that; we might get bills. Lawrence, our staff member over here, has said in the survey we did ask about the administrative costs associated with cost recovery. He pointed out that the vast majority had no idea, so they don't even know how much it is costing them but what we are suggesting, if they apply our guidelines, they are going to actually have to think about that and try and ask that question to themselves, if they are going to apply these guidelines appropriately.

MR ALBIN: Reagan had a very interesting way of stopping this or keeping it under control anyway, cost recovery. What he did was he required - I can't remember the name of the program - but he required every single new regulation, and he required cost recovery to be part of that, to go through an inordinate amount of public hearing processes and go onto a public register, which made it extremely difficult for agencies just to sort of announce that they would increase costs. They

had to go through a great deal of consultation. What it did is it actually, one, stopped a great number of these regulations that were going through that were, in a lot of instances, nonsense. Secondly, it kept a control on cost recovery.

That is obviously not necessarily the most efficient way to go either, having registered some public hearings, and that costs a lot of money as well, but it needs some sort of response like that to ensure that, you know, you can engaged industries and you can ensure that - and keep a check on the fact that the whole cost recovery bureaucracy isn't spinning out of control.

PROF SLOAN: Of course our suggestion of having - well, the regulatory impact statements are there but to append the cost recovery impact statements in addition and in those cases where the reasons aren't suitable to have a quiz type process. That is perhaps not as grand an idea but is trying to create that kind of review process. I am interested in your idea. I mean, in effect what you're saying with the environmental management charge on the Great Barrier Reef, is that you accept that there is some rationale for that because, certainly viewed over any length of time, tourists and tourism are beneficiaries of a well maintained Great Barrier Reef. I think what you're saying - and we see this, I think, as the theme in quite a lot of places - "But hang on, we're not the only ones who should be paying."

So what you're saying really is that in this case the polluters should be paying. I suppose the net effect of that might be to actually increase the amount of funds available for the effective management of the reef.

MR ALBIN: An example of that basically is with the crown of thorns issue. The run-off, there was a particular problem I think a year ago, year and a half ago, where a lot of the superphosphates and other run-off was creating problems in the reef and actually caused the crown of thorns starfish to re-emerge. The thing is that we - you know, operators up there, Quicksilver Connections and a lot of the other big operators who make money out of the reef, actually had people out there, had divers out there every day picking the crown of thorns starfish that was encroaching on their area out - you know, throwing them out. It was costing them a significant amount of money. Now, once again, we understand we have a responsibility but if this pollution is causing, you know, the starfish to come back and we have to also pay for that, we would prefer that the Great Barrier Reef Marine Park Authority had more money to look after it themselves. But, anyway, that's just our point of view.

MRS OWENS: Can I ask, with the levies, does it get imposed on all the operators?

MR ALBIN: Yes, what happens is they collect it as part of the ticket. Now, it isn't - - -

MR FLOWERS: It's only for tourists, it's not for commercial fisherman.

MR ALBIN: So it's only for tourists.

MRS OWENS: Yes, so the cost is passed on to the tourists as well.

MR ALBIN: Yes, the cost gets passed on. They collect it and give it back to the Great Barrier Reef Marine Park Authority - - -

MRS OWENS: And they can pass the whole lot back to the tourists? I mean, they're not out of pocket?

MR ALBIN: No, they are not out of pocket.

MRS OWENS: So it's really the tourists that are paying. How much does it add to the cost of a trip?

MR ALBIN: \$4, so it's a \$4 charge, so it just basically adds \$4 to the cost of - - -

PROF SLOAN: It was mooted to be a higher figure, wasn't it?

MR ALBIN: Yes, \$6 it was going to be and then the government dropped it. So the government did come up with a more reasonable response. I haven't thought about this in more detail but they should be looking at easier ways to collect it.

MRS OWENS: What proportion of a ticket would it comprise?

MR ALBIN: It is about \$94 - or just saying \$100 for a ticket - so \$4 is, what, about four per cent.

DR STEWARDSON: Can I ask a question for clarification. The World Wildlife Fund Report only just came out last week so it would be a bit unreasonable to expect the government to have responded as yet, but I take it from you said a minute ago that the problem of the run-off is one that's been known about for a long time. Is that correct?

MR ALBIN: Correct.

DR STEWARDSON: Maybe that's something you could make clear in your final - - -

MR ALBIN: I will make it clear.

DR STEWARDSON: In the case of the ETA charge, again just for clarity, this is something that's been - the ETA has been issued over the Internet for some time. It's only the charge that's new or the issuing over the Internet is new or - - -

MR FLOWERS: The issue to the public over the Internet is new. It is on a trial basis from the Department as per the press release of a week and a half ago. It struck us as very odd because even the budget papers - this year's budget papers published within a week of this press release - said that the ETAs are free. I mean, you've got an agency of the government in the Department of Immigration - and I'd like to go through their submission if you will allow me, just to comment on a couple of their

points, which imposed on a trial basis, to be fair, a \$20 charge to apply for a travel authority over the Internet. Approximately 4 million of our 5 million visitors each year use the electronic travel authority. The potential revenue from this charge is larger than any new budget revenue market announced within the week and yet - that would assume everyone applied by the Internet which isn't going to happen. Nevertheless, where is the budget discipline? We also understand - and we're waiting for questions on notice on this point - that the money is going to a private company rather than the Department of Immigration.

Now, we need to get that confirmed but it is a long-standing contractor to the Department of Immigration in terms of the ETAs. ETAs have been available for three, four, five years. They typically take about eight seconds to process. Overseas tourists go to a travel agency and they're given the opportunity, I guess, along with about probably 3000 other destinations to come to Australia, and less than 1 per cent of world arrivals arrive in Australia, but our government then has the ETA system which the agent can access. So you wouldn't have thought that it was a major step from making that available to travel agents to actually taking it to the Internet, because the airlines obviously have the same facility because they can put people on ETAs who arrive at the airport without them.

So we have this situation where this \$20 charge comes in. We're very concerned in the sense that the passenger movement charge, according to the auditor's report, over-collected passenger processing costs. In the 1989-99 budget, we had - reading from budget paper number 2 - changes to visa application charges for the non-electronic travel authority. My chief executive calls it geographic discrimination where if you apply for an electronic travel authority country which is typically European or has a European history, you are free to come to Australia without a charge. The ETAs are available free through Australian consulates and in theory from travel agents. If, however, you come from 200 of the 230 countries in the world, the original \$50 charge subsequently went up to \$60 in the following budget to apply.

That was to raise 40 million in 98-99 and by 2001-02, \$47 million per annum. Obviously that was at a \$50 rate rather than a \$60 rate. In the actual budget revenue measure, further information on this measure - reading from the budget paper:

Further information on this measure can be found in the outlays measure entitled Enhancement of Visa Processing and Border Monitoring described in part 1 of this budget paper under the Immigration and Multicultural Affairs portfolio.

Again a very clear link between the revenue measure and the expenditure measure. The expenditure measure only cost \$19.4 million in the first year of this enhanced processing and by 2001-02, 10 million.

We then come to - when you are from one of these countries, the 200 of the 230 countries in the world, they're classified as to whether they're high risk of overstays or low risk of overstays. If you come from a high-risk country you get to

pay this \$60 non-refundable charge that was meant to go towards following up overstays, in which case why is it non-refundable. We've never understood why this charge was made non-refundable when the application is refused. As the Department of Foreign Affairs had concerns with this issue, expressed quietly, so do we in terms of the damage to Australia's reputation. Not only do you have to pay to apply to come to Australia, when you're refused entry you don't get your money back. It hardly seems Australian. It certainly has damaged our place in the world in places like South America - the recent House of Representatives inquiry on trade with South America featured a lot of discussion on this precise visa question.

MR ALBIN: South Africa as well.

MRS OWENS: But do other countries have non-refundable charges like this?

MR FLOWERS: Is that a defence?

MRS OWENS: No, I just wondered whether this is common or whether we stand out from the crowd.

MR ALBIN: Our visa system is unique and I'm not saying that it's necessarily the worst in the world but our system is unique. I wouldn't expect that there are those sort of requirements, especially travelling - you see, I've got to think about countries like India and what they do and we're not across that. But the electronic travel authority is unique. You have some countries that have policies that don't require visas. Now, that's a bit of a furphy because when you get to the hotel - for instance, if I go to Germany, I don't need a visa. I go in there, go through customs, but as soon as I get to the hotel I've got to fill out a huge form. What that form is about is effectively a visa in Germany, so it's a hard way to - but they don't apply any charges.

MR FLOWERS: We actually think the ETA system is a very good system. We'd rather have people refused the opportunity to come to Australia before they left the country rather than at the airport which of course is the US system. But going back to the non-ETA nationalities - and this relates very much to the compliance costs on the potential tourist - the tourist normally relies on the local postage service to post their passport to the nearest Australian mission which is commonly out of these countries; they have to supply a self-addressed prepaid envelope for return postage. That would be far too much to ask from a \$60 charge. They need to provide evidence of funds such as personal bank statements or tax records; if over 70 years of age, a letter from their doctor that they're fit to travel; in some cases chest x-rays because of the concerns over tuberculosis, which there's a certain logic there.

In any case you've got to show evidence of medical insurance. If staying with friends or relatives in Australia, a letter from these friends and relatives setting out how long they expect you to stay, any financial support they will provide and whether they previously hosted international visitors; a declaration as to whether you're leaving close family at home on your trip to Australia, and a letter from your employer stating your income, the amount of leave and that you will have your job

when you return. That's for high-risk countries. In a lot of cases that makes a lot of sense but there is a hell of a compliance burden on the tourist in terms of, "Gee, they want to come to Australia, \$60 to put their hand up and in many cases be rejected." The rejection rate for a lot of countries is 10, 15 up towards 40 per cent, and the Department of Immigration can give you that data. This is all on top of the \$60 charge to raise revenue in a justification for visa processing that was over-recovered anyway from the passenger movement charge.

DR STEWARDSON: I'm not quite clear about that last bit. With all that documentation from at least some countries, you said earlier it takes eight seconds or something - - -

MR FLOWERS: If you're from the favoured 31 countries - now 32 because Portugal got it last week - it takes eight seconds to check your name against the movement list, and there's an international computer system that does that. But if you're from these other countries, well, that's the process - or from the high-risk end of these other countries that's the process that you go through. The cost recovery only applies one way and yet the tourism industry is continually being hit by more of this.

Turning to the Department of Immigration submission, just a couple of points. Certainly it's interesting that from 87-88, revenue reported by DIMA amounted to 10 per cent of their budget or annual outlays; by 98-99 the revenue was 42 per cent of total outlays from their own evidence. We find that a remarkable statistic. The core operation of the Department of Immigration is migration. You have a look at their staff structure and the areas handling the short-term tourists are largely contracted out to customs at the airports et cetera. Yet the tourists are the ones paying in many senses. Also from this submission the claim that DIMA's annual budget funding is not directly conditional upon these revenues being received, that's not what the budget papers say. The budget papers make a very clear link between the two. In point 14 of their submission:

Administering the lawful entry and stay of people in Australia is a core function of government. DIMA has no direct competitors in delivering this outcome. However, in setting the rate of visa application charges, DIMA must be aware of the impact-related charge may have on Australia's competitive position in attracting visitors/migrants as compared to the rest of the world. Research by DIMA suggests that people's preferences to migrate to Australia are not driven by the level of Australia's migration charges.

MR ALBIN: That's counter-intuitive.

MR FLOWERS: Absolutely no mention of the impact on tourism of these visa application charges, yet the claim that they have to be sensitive and when quizzed (indistinct) estimate processes they acknowledge that they never did any evaluation of the impact on tourism of these charges.

MRS OWENS: So it's just an assertion. There may be an assertion about migration, maybe that's correct.

MR FLOWERS: Indeed, it may well be correct for migration but they have previously said:

In setting the rate of visa application charges, DIMA must be aware of the impact the rate of charge may have on Australia's competitive position in attracting visitors/migrants as compared to the rest of the world.

But the only research cited is related to migration, and from other forums we know that they haven't done just that work that they seemingly commit to in terms of showing sensitivity to the impact on tourism.

MRS OWENS: Has anybody else tried to do that work? It sounds like a worthwhile bit of research, isn't it?

MR FLOWERS: As you find when you get into this exercise it's not all that straightforward. I mean, obviously things like currency movements versus the - how do you assess the compliance cost burden, particularly for those high-risk countries. I would argue that's much more significant than the \$60 charge in terms of an effective deterrent. So it is a tough exercise to research. We certainly had a look at it but I think we'd accept that the analysis that we did was ballpark at best.

MR ALBIN: Yes, it's more or less anecdotal as well. The story about four 73-year-old ladies wanting to come from South Africa to the Olympics and about to board their plane and getting booted off because their visas hadn't been - didn't have the chest x-rays for instance. You'll get stories about Indian travel groups. It's all anecdotal. It's very hard to - - -

PROF SLOAN: But isn't the point from our point of view that we think there are some appropriate principles for cost recovery and in fact - I mean, because something might have relatively inelastic demand, which is something you could probably mount so that really the visa charges are not going to affect tourism - - -

MR FLOWERS: I would counter that. We get less than 1 per cent of international arrivals to Australia. We compete in a massively competitive market. It's not like (indistinct) where there may be two or three other world producers.

PROF SLOAN: But isn't the point - whether it's elastic or inelastic - that you should use good principles to cost recover, which is that you should be cost recovering according to the actual costs of an activity and you shouldn't be cross-subsidising across portfolios in an opportunistic way which is really kind of what you implied.

MR FLOWERS: That's what we assert.

MR ALBIN: That's where we agree with the commission wholeheartedly. Some of the evidence that Karl put forward then, if you actually look at the difference between revenue collected and outlays, it's \$30 million in the out years difference.

MR FLOWERS: And that's what is a fairly small charge; a visa application fee for non-ETA countries.

MRS OWENS: Can I just come back to this ETA - the new charge, the \$20. I think Stephen initially said that there was no consultation, you just found out about this.

MR ALBIN: I found out about that, yes - a press release.

MRS OWENS: You made this point I think in your comments here that there would be an over-collect, an over-recovery by 100 per cent. I don't know what period you're talking about but you say the charge was imposed to recover \$200,000 in site development. It's going to be well over 100 per cent, isn't it?

MR FLOWERS: 4000 in the first week times 50, 200,000 times 20 - 4 million.

MR ALBIN: A lot more than that, even more than that. It just goes to show I was having a bad day yesterday.

MRS OWENS: When you're doing your other submissions - - -

MR FLOWERS: We like to be over-generous in our comments to the Department of Immigration.

MRS OWENS: - - - I think we need to understand why else this charge would be imposed. I'm sure it's not just for the site development costs, there might be something else that we've all missed.

MR FLOWERS: In budget paper number 2 of this year, as of a fortnight ago there is a discussion of the revenue from visa application charges. There was actually a 5 million reduction in expected revenue over the four year period in visa application charges reflecting:

The reduction in revenue is due to the foregone visa application charge for visitor visas (currently \$60 each) in lieu of electronic travel authorities which are issued free of charge.

Page 18, 2001-02 budget paper number 2.

MRS OWENS: So that's just revenue raising - - -

MR FLOWERS: We got a budget within the last fortnight saying that the ETAs are free of charge. Within the week thereafter we have a department introducing a new charge of \$20 on ETA by the Internet.

PROF SLOAN: Are you going to recover those site development costs - in about two and a half weeks actually.

MR ALBIN: I did say that in the car the other day in Canberra but then I went through it last year - and shouldn't have gone through it again.

PROF SLOAN: Over-recovery is an issue for us; quite common.

MR FLOWERS: I mean, the Department of Immigration has a very important role and obviously requires much greater funding - or has required much greater funding over the last few years, a illegal immigration has picked up, no question. It is just that the tourism component is paying a lot of the bills for the rest of the department's costs.

MRS OWENS: They may - I mean, I'm just trying to be generous to the department. I think they might argue the \$20 is meant to be covering the incremental cost of doing this over the Internet where they were not charging before. Maybe it is meant to reflect some incremental cost of doing it.

MR ALBIN: I actually spoke to them after they put out the press release and the reason that I was given as to why they introduced this charge was because travel agents overseas were applying a charge to process the ETA. So, for instance, if you were in Japan, a travel agent might go - their commissions are tight, travel agent's commissions, but if you were in Japan, a Japanese tourist, and you wanted your travel agent to process the ETA, they might be charging you, for instance, \$A60. They may do it for free. There is no obligation on them to do it for free or to charge. They can do whatever they want basically.

MR FLOWERS: You can go to an Australian consulate and get the ETA for free.

MR ALBIN: And you can get it for free but the Department of Immigration had advised us that it was a measure that would assist keeping the costs of travel to - keeping the lid on the cost that travel agents were charging overseas. Now, I would suspect that that isn't a concern to the Department of Immigration.

MR FLOWERS: It also effectively means that every travel agent around the world can put a floor of \$20 under their charge. They say to the customer - and we're talking about four million people per year to Australia under ETAs, "Well, there is two choices you have in terms of getting an electronic visa to Australia. You can do it yourself, apply through the Internet, and the Australian government will charge you \$20 for the privilege, or I will do it for you right now for \$20.

MR ALBIN: So they are creating a floor.

MR FLOWERS: Yes, and we think that it is very poor policy from the national interest and reflects again the ignorance of tourism effects within the Department of Immigration.

PROF SLOAN: They might say, "We will do it for \$17.50."

MR FLOWERS: Yes, that's right.

MRS OWENS: Robin just said that they should get the Melbourne taxi-drivers to collect it. Just one other issue - and can we just return to the environmental management charge for a minute and this issued of polluter pays. In one of our other activities at the commission we've been looking at this whole issue of polluter pays. There is this problem of (a) trying to identify the polluters and, (b) some of the polluters may not be alive today. There is an intergenerational issue there which just complicates that approach. Now, I don't know whether you want to comment on that. It may be why the government has decided to go in one direction and not on the other. It may be just purely political. I don't know.

MR FLOWERS: I think certainly the - and we saw it again with the foot and mouth issue in terms of the passenger movement charge - that there seems to be a much greater sensitivity towards, say, the dairy industry, just to take an example, not completely at random and the tourism industry. If one is to be hit with a new charge or if one is to get \$1.8 billion in subsidies for the failure of past industry policy, we think that the dairy industry would probably be on the good end and we will be on the bad end of that particular decision-making process. There seems to be a great deal of sensitivity to the traditional agricultural industries within this cost recovery framework.

MR ALBIN: But tourists don't vote, basically. They are easy targets. You know, they have got to go through border control mechanisms typically, which will enable them to be charged at every opportunity. Also, it is easy to identify the major operators on the reef but there are significant intergenerational impacts with regards to pollution, especially of the reef. Yes, that may be one reason why the government hasn't chosen to do that. There are obviously some political dimensions to it too. The WWF report, which I haven't gone into in the detail that I would have liked because it's only just being released. It's got a lot of scientific evidence to say that, you know, the run-off from the farms is polluting the reef but then again how are you going to measure the run-off in terms of - you know, someone might be putting more run-off into the waterways than someone else. How are you going to ensure that you can tax that efficiently as well. So there are a lot of issues associated with it. You know, clearly there is some politics but also it is difficult from an economic perspective as well.

MRS OWENS: So it is complicated?

MR ALBIN: Yes, I thought that was useful and I'm glad we came along.

MRS OWENS: Yes, I'm very glad you came along. Thank you very much. I was pleased that you actually commented on the Department of Immigration, multicultural affairs' submission as well. It is good when we can get a bit of cross-fertilisation across submissions. Have you got any other comments you

wanted to make?

MR ALBIN: No, that's fine. I just know now that my bags are going to be checked on the way back into Australia when I go overseas.

MRS OWENS: Ladies and gentlemen, that concludes today's schedule of proceedings, for the record - is there anybody else. Ester. would you like to anything before we closed today? Okay. I adjourning these proceedings and the commission will resume in Canberra on 13 June at 10 am when we talk to the Australian Bureau of Statistics.

AT 12.29 PM THE INQUIRY WAS ADJOURNED UNTIL
WEDNESDAY, 13 JUNE 2001

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