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TRANSCRIPT OF PROCEEDINGS

PRODUCTIVITY COMMISSION

INQUIRY INTO COST RECOVERY

MRS HELEN OWENS, Presiding Commissioner
DR ROBIN STEWARDSON, Associate Commissioner

TRANSCRIPT OF PROCEEDINGS

AT SYDNEY ON TUESDAY, 21 NOVEMBER 2000, AT 2.43 PM

Continued from 20/11/00 in Melbourne

MRS OWENS: Welcome to the resumption of the public hearings for the Productivity Commission's inquiry into cost recovery by Commonwealth regulatory, administrative and information agencies. I'm Helen Owens, the presiding commissioner on this inquiry, and with me is my fellow commissioner, Associate Commissioner Robin Stewardson. The other commissioner on this inquiry, Judith Sloan, is not present today.

Public hearings have been held in Melbourne, yesterday, will be held again in Sydney tomorrow, and then in Canberra for the next two weeks. We are also holding hearings by video-link with Adelaide and Perth. The scope of the inquiry is specified in the terms of reference. Copies of this and other inquiry documents are available on the table just outside the entrance. The commission has three main tasks in the inquiry: to review existing cost recovery arrangements by regulatory, administrative and information agencies; to develop guidelines for the future application of cost recovery by the Commonwealth; and to review cost recovery arrangements under the Trade Practices Act 1974 as part of the legislative review required by the Competition Principles Agreement between the Commonwealth and the states and the territories.

Public submissions are vital if the commission is to be successful in these tasks. The public hearings provide the opportunity for participants to make oral presentations and discuss their submissions with the commissioners. This is an important part of the public inquiry process as the commission is also able to seek clarification and pursue particular issues in greater depth. While we try to keep the hearings informal we do take a transcript, and we hope we are taking one today, for the public record. Transcripts are normally available on the commission's Web site within a couple of days of the hearing and we will send each participant a transcript of their session's proceedings.

At the end of the scheduled hearings for today I shall invite any people present, who wish to, to make an oral presentation, and now I am turning to our first participant which is English Australia. Could you please give your names and your position with English Australia for the transcript.

MS MOORE: I am Alyson Moore and I am chair of the ELICOS association, also trading as English Australia.

MRS OWENS: Thank you very much.

MS POWER: I am Margaret Power, executive officer of English Australia, ELICOS association.

MRS OWENS: Thank you, and thanks for coming, and I am sorry about the slight delay. Technology is always what lets us down, but thank you and thank you for the submission, which is very comprehensive and we have both read it with interest and I think we are both probably surprised at all the range of potential fees and costs facing international students coming into Australia, but if you would like to make a few

opening comments and then we could ask you some questions about it.

MS MOORE: English Australia colleges are service exporters; by bringing in international students to Australia to undertake English language training English Australia colleges - and I will just call them EA colleges - earn foreign exchange for Australia. In our submission we have outlined various examples of Commonwealth government cost recovery that impact upon English Australia colleges. The costs of some of these cost recovery mechanisms have to be met by colleges themselves and are mandatory. These include DETYAs annual registration charge, the NEAS, which is the National ELICOS Accreditation Scheme, accreditation and monitoring fees, the Tuition Assurance Scheme membership fees, which comes under the English Services for Overseas Students Act 1991, the costs of administering notified trust accounts, soon to be partly replaced by subscriptions to a fidelity fund, and that's also from the same act, 1991, and state registration fees, including any increased fees which may arise from states' administration of DETYA's national code, which is also to be introduced; proposed to be introduced in a set of bills that are currently before the senate.

Some of the Commonwealth cost recovery mechanisms are not mandatory but if EA colleges are to access the relevant services the costs must be met by the colleges. These include Australian Education International subscriptions. The AEI is a subdepartment of DETYA, Austrade service fees and DIMA's proposed student packs. Other Commonwealth cost recovery costs have to be met by the clients of EA colleges, that is the students. These include student visa fees, including the student information service fees. We have referred to that in our submission as the SISFs, and the work rights visa fees.

What all of these costs have in common, whether they be paid by institutions or by students, is that they limit our competitiveness, vis-a-vis English language training and providers in other countries such as the US, the UK, Canada, Ireland and New Zealand. By doing so they limit the EA colleges' ability to earn much-needed foreign exchange. It seems to us that most of what government now does for industry or our industry is charge back to the industry on a cost recovery basis, including that which is legislated for; for example, the annual registration charges. In terms of how a taxpayer's money is spent our impression is that very little is spent on support of the industry. We would go further to say that not only is there little support given to the industry the industry is in fact taxed heavily for being in operation. This is in stark contrast to our competitors, which is the US, the UK, New Zealand, Canada, Ireland and so on.

In using the word "tax" we use it very literally, for example, the student information service fee, and also metaphorically. There are so many taxing obligations, regulations, accreditations, registrations, etcetera, made on companies in this industry that are additional to charges that government imposes on companies in other industries. Rather than going through and summarising our submission here perhaps we should just leave it there, and if you would like to ask any questions.

MRS OWENS: Good. Thank you very much for that. I think one of the things you mentioned in your opening comments and the submission is the cost; the colleges are actually having to meet a number of mandatory charges. Do you think that those colleges then are in a position to pass those charges on to the students themselves through fees, so ultimately the actual cost is met by the students, or do you think that they are in a position where they are competitive and find it difficult; they have to just wear the costs?

MS MOORE: Ultimately the student pays and I guess another part of your brief is something to do with trade practices - I just heard in your opening statement there.

MRS OWENS: Yes.

MS MOORE: And of course our competitors are the UK, the US, New Zealand and so on. In terms of passing on charges to the students, we can't do that often as an additional charge. In fact we almost never do that. It is absorbed by the college or else it's passed on to the student through the fees that we charge, and it's just fortunate at this stage that the Australian dollar is so weak that we can do that. If it were any different we would be under a lot of pressure to find other cost savings somewhere else, which, quite frankly, are pretty hard to find.

DR STEWARDSON: I wonder if I could just come in there on that point. You mentioned in your opening statement the costs charged in Australia by various regulatory agencies and contrasted that unfavourably with what happens in US and UK, with your competitors there. Would you be able to give us any examples, fairly specific examples, of cost recovery or charges and levies made, in the US and in the UK by regulatory agencies on your competitors there, and assuming that they show, as I presume they will, what you have said, that they are much lower there, do you have any commentary on why that is so and what the effect of it is? For example, not knowing anything about the answer to that question, one could imagine that there is a totally chaotic system over there where colleges can offer fraudulent packages because there's no worthwhile regulation, whereas here you may be encouraged to be very responsible in your marketing and so on.

MS MOORE: One good example would be the student visa fees that are charged to students. In Australia I think it's around about $290 per application that the student has to pay in their home country. In addition to that there would be mandatory health checks that they have to pay, to go to see a doctor to have a chest x-ray and other health checks that they have to pay out. I think that that's in addition to the 290. Compared to the US and the UK, those fees are much more than a student would have to pay for the equivalent to go to the US or UK and their fees.

MS POWER: They are approximately double, except in the case of the UK where European students don't pay anything for a visa because they don't need to have a visa.

DR STEWARDSON: Exactly, yes.

MS POWER: And the result of that is that the UK recruits many, many more European students than does Australia, because they don't have those costs to meet.

MS MOORE: No.

MS POWER: Of course they also don't have the costs of the flights.

DR STEWARDSON: And what about the other sort of charges; the fees? Not so much as the visas, but the fees on your institutions.

MS MOORE: Many of these fees are either to do with accreditation and registration or they are to do with compliance. I could say with a fair amount of confidence that Australia has the most regulations, the most accreditation of any other country. Places like the UK doesn't have an accreditation system, nothing like the one that we have here. There is more industry regulation than anything that we have seen.

DR STEWARDSON: Self-regulation.

MS MOORE: Self-regulation. I guess it's a matter of just - yes, self-regulation and whatever is fair competition.

MS POWER: In the UK institutions or English language training institutions, aren't required to be registered. They may operate without registration, so they don't have that charge. A number are registered through the British Council which is government funded and the British Council then promotes the English language training services that England can offer.

MRS OWENS: For free?

MS POWER: Yes.

MRS OWENS: They do it for free.

MS POWER: I think there are small charges for accreditation inspections and things for those institutions but they are very small.

MRS OWENS: Can I just come back to the visas again. You said it's about $290. Does that include - - -

MS MOORE: That excludes the health.

MRS OWENS: What about the $50 if you want the work right visa? Is that separate?

MS MOORE: No.

MS POWER: No, that's additional.

MRS OWENS: That's additional, but isn't there some entitlement within the 290 to be able to work 20 hours a week?

MS MOORE: There used to be.

MS POWER: No, it's an entitlement to apply with the $50 - to apply for the $50 permit to work.

MRS OWENS: So then if you want to work it's going to cost you your 290 plus 50?

MS POWER: 50, that's right, plus your health insurance and your medical examination.

MS MOORE: When you get to Australia - - -

MRS OWENS: Okay, now, let's go to Canada because that's not in Europe. Canada, they would have a visa application charge?

MS POWER: They do. I don't know the exact amount, but it's roughly half of what we charge.

MRS OWENS: Do they pay extra to be able to work there? It's a bit hard to work in Canada for anybody.

MS POWER: I don't thing they have work rights.

MRS OWENS: No, because they usually have landed immigrant rights instead. You have got to be a landed immigrant.

MS MOORE: Australia and New Zealand I think used to be the only countries where you could get a student visa and work in the country for the period of the visa. The UK has just introduced the same arrangement now, so students can come from Japan to study in the UK and also work. I don't believe that there's a charge for their work permit. In addition to that the cost of the original student visa is much lower.

MRS OWENS: Yes, I think it would be useful to just get a handle on what some of these other countries are doing, so we can see. I thought it was interesting - coming back to registration and accreditation - we seem to be doing something at the Commonwealth level where we have got the register and at the state level you have got the - - -

MS MOORE: Registrations.

MRS OWENS: - - - national ELT accreditation scheme.

MS MOORE: It's rather complicated.

MS POWER: It is three-tiered. The NEAS is the accreditation and first a college must be accredited by the NEAS. Once they are accredited by the NEAS they can be registered by the state or territory in which they are located. Once they are registered by the state or territory then they can be registered by the Commonwealth and pay each time.

MRS OWENS: Why have we got three levels?

MS MOORE: The NEAS - is a quango, something like that. It's a not-for-profit organisation set-up under licence or under an agreement to register - or by most of the states I think, excluding Victoria and Tasmania to register colleges on their behalf.

MRS OWENS: Yes, it seems like a bit of regulatory overkill.

MS POWER: Indeed.

MRS OWENS: We are not here doing an inquiry into regulation but just every now and again these sorts of issues crop up because we are interested in what it costs the industry or in this case educational institutions to actually operate in this country.

MS POWER: I think the history there, to my understanding, that was before I joined this sector, was that up until 1990 the states registered England language providers, but there was no accreditation. Then after the Tiananmen Square incident in China, a lot of institutions in Australia collapsed and the government started regulating and it was agreed that accreditation needed to be part of that and so industry itself set up the accreditation body to do that rather than have government do it because the charges would just keep snowballing as we've seen through so many of the others.

MRS OWENS: So the industry then does that through NEAS.

MS MOORE: Yes.

MRS OWENS: Which is the National - - -

MS POWER: Yes, and receives no Commonwealth funding or state government funding at all.

MRS OWENS: If you were to start again with a clean slate, which bit of the process would you retain and would you have a charge associated with it?

MS MOORE: That's a big question, but I guess that I would look at industry self-regulation and industry accreditation, so I would keep the NEAS, the National ELICOS Accreditation Scheme. I wouldn't have the states, because this is a national industry. Of course the constitution and so on is set up the way it is.

MRS OWENS: But states could delegate that.

MS MOORE: If we had a choice we would have a Commonwealth regulatory system which does provide for minimum levels of service, but other than that I think that I wouldn't bother with states or with in fact the quite heavy regulation that we have in the industry.

MRS OWENS: The charges at the Commonwealth end are based on the numbers of students?

MS POWER: Some are. The annual registration charge is, yes.

MRS OWENS: Registration.

MS POWER: It's based on the number of students, but it's a number of student heads in each institution in any year. So if a student comes in December and does English language training from December to January and then goes to university in February, in a three-month period they are counted three times because they are counted in the English college for year 1 in December and then in the English college in year 2 in January and then at the university in February.

MRS OWENS: Okay, so they get it three times.

MS POWER: A great scheme, isn't it?

DR STEWARDSON: You have mentioned that in your submission and you have also mentioned cases where the government regulatory body, whichever it was you were talking about at the time, has offloaded some of its functions but hasn't reduced its fees. In both these cases, that case and the example you were just giving about charging three times in the three months, have you complained about this to the government?

MS POWER: Indeed.

DR STEWARDSON: You obviously haven't been successful. What consultative mechanism do you have to deal with these regulatory bodies?

MS MOORE: We are always complaining to government and putting our case. Sometimes we are successful and sometimes we're not. You might see at the end of our submission we have put a section there on fee without service, which is a little bit tongue-in-cheek, but the student information service fee would be a good example of what you are talking about there where the Department of Immigration is purportedly

providing information to students and then charging back for it, but it's not going into - they are no longer providing the service for providing the information any more. It's up to the ELICOS providers.

MS POWER: In terms of our consultation with government on this, that section that we have called Fee Without Service is taken almost word for word out of letters that we have written to a number of Commonwealth ministers, including the Minister for Immigration who is responsible for a lot of these what we call fee without service.

DR STEWARDSON: But you don't have any formal consultative mechanism, other than launching to the government.

MS POWER: We participate in the affiliation of international education peak bodies which meets with DIMA and DETYA officials from time to time as the need arises or as the opportunity arises. That affiliation includes English, Australia or ELICOS associations and the Australian vice-chancellor's committee, Australia TAFE International, ACPED, etcetera, the six or seven peak bodies all involved in international education. So we do meet with them and bring up these concerns time and time again, but then it doesn't appear as though government feels any compulsion to respond to concerns of this nature.

MRS OWENS: Can I just clarify, now that we're talking about information, back on page 2, your outlining some of the responsibilities of the department, in particular the Australian Education International, which is you say a section within the Commonwealth Department of Education, Training and Youth Affairs, DETYA, and what you're really saying is some of the educational activities or information activities are now covered through ELICOS. Does the AEI still undertake some of those activities though?

MS POWER: It does, and it undertakes them mainly for subscribing institutions, but students that enrol at institutions that don't subscribe still have to pay the student information services fee to the Commonwealth.

MRS OWENS: Right, okay. Do you think it's appropriate to charge for the provision of information if you're a Commonwealth agency collecting information and then passing it on? Do you think that's an appropriate thing to charge for?

MS MOORE: The information that they're providing I think is brochures of institutions. Is that right?

MS POWER: Yes. For the Australian education centres offshore they set up centres that students can go into, and the institutions not the students pay the subscription for that service. So I think that possibly is appropriate that someone pays for that, but what's inappropriate is that the institutions pay for it and then their students also pay for it.

MRS OWENS: So they're paying twice. It makes me wonder why this is a

government activity to provide that service.

MS MOORE: Particularly in places like Switzerland and lots of other countries where we recruit students from where there is no AEI or no DIMA post or no post for providing the information and yet the students are still having to pay.

MRS OWENS: And they still come even if that information is not available. They must get the information through some means.

MS MOORE: They come through agents in the main.

MRS OWENS: Yes.

MS POWER: But the institutions pay.

MS MOORE: Yes, the institutions pay through commission.

MRS OWENS: But they still have to pay - - -

MS POWER: Yes.

MS MOORE: Yes, through the student visa charge.

MS POWER: The reason that the Commonwealth provides that service mainly in the Asia Pacific region is simply to be competitive, because the British Council is doing it. The Canadian education system has a body that does it. We just would not be in business if the government did not do that, and in a lot of Asian countries unless something has a government sort of stamp or name to it they have their doubts about its authenticity.

MRS OWENS: Yes, it has no authority. Does the British Council charge for those equivalent services, that equivalent information?

MS POWER: Not to my knowledge.

MRS OWENS: What about Canada?

MS POWER: I don't know what they're doing. All they say is that they're trying to copy everything that Australia has done and do it better.

MRS OWENS: So they're benchmarking with us. So they think we're doing it right?

MS POWER: Yes, and in - - -

MRS OWENS: And you don't agree.

MS POWER: In some countries they're doing it far better than we are. There are some markets where we were recruiting far larger numbers of students than Canada was, but the table has turned.

MS MOORE: I mean, it does look a little bit murky but there's the charge of the student information service fee of $30, which is part of the 290, and that should definitely not be charged. There's no justification for that, because there is no service provided.

MRS OWENS: So it's just revenue raising.

MS MOORE: It's just revenue raising, and it doesn't even go into DETYA, it goes into consolidated revenue. There's the other Australian education international fees that you subscribe to, and you can choose whether that's good value for money or not.

MRS OWENS: But that's okay. I mean, if it's a subscription and you can choose to participate or not, I think that's a legitimate activity for them to charge for, wouldn't you agree, Robin - - -

MS POWER: Yes, and we certainly haven't included that in what we call fee without service. We do believe that there is a service provided for the fee there. But the visa-issuing posts are another perfect example of where the government has pulled out its visa-issuing posts out of some countries. It's then discovered that someone needs to be there to accept visa applications and to hand out forms to students, so they have entered an agreement with an agency to do it, but refused to provide any funding for the agencies.

So the agencies are having to charge the students for the application forms, which is on top of the 290 visa fee and on top of the health checks, etcetera. So even though in some countries they're actually accepting the applications, providing the forms, processing the visas, in countries where they're not doing that the same fee is still charged by the Commonwealth, as though it was still providing the free service.

MS MOORE: This happened in Sweden - that's a good example - where it was outsourced; the DIMA services were outsourced to a number of agencies. I know that one of the agencies, because they're also an agent sending students, they said that they had to employ an additional staff member to process the applications, but they weren't getting any funding from DIMA to do that. So they wrote to DIMA and said that they weren't going to do it any more. In fact, all of the Swedish agencies wrote and said, "That's it, we're not going to do it any more," and now DIMA has made alternative arrangements.

MS POWER: Austrade is now doing it. In Switzerland there has been no alternative arrangements made. It's still an agency arrangement and the students are still having to pay for the forms or go to Germany to get them.

MRS OWENS: Right.

MS MOORE: In our view, there is no question that that's not right.

MS POWER: When the visa-issuing post in Switzerland first closed down and before an agency was appointed, because there were so many problems with students saying they couldn't get to Germany to get the applications, DIMA agreed that they could apply by post but they had to include a self-addressed stamped envelope, which meant that they had to go to Germany to buy the stamps so that they didn't have to go to Germany to apply for the visa.

DR STEWARDSON: It sounds a bit odd in the European community.

MS POWER: Yes.

MRS OWENS: You raised Austrade just then, and you raised Austrade in your submission on pages 2 and 3, and you gave the example where the English Australia chose not to proceed with a particular project. Now, is this a concern about - what is the concern? Is it that Austrade is cost-recovering its services, or that it's cost-recovering too much of its services?

MS MOORE: This project in particular was - Austrade is now in a cost-recovery mode, but the ELICOS Association English Australia is an association developing the industry for all Australian providers, not on a preferential basis. So a normal company that goes to Austrade and says, "I want you to make an introduction for me into Hungary," or wherever, that's fair enough, it's a service. Perhaps it's fair enough. But when an association does it on behalf of the total industry and we get a cost just for their services of $17,700 to set up a couple of exhibitions for us, that seems extraordinary. That's not even renting the room for hire, doing invitations, coordinating. None of that. That's just for them to - - -

MS POWER: Their time.

MRS OWENS: So you make a distinction between what they should be doing for individual companies, and what they should be doing for an industry association. You think they should have a differential approach.

MS MOORE: What is the purpose of Austrade?

DR STEWARDSON: I think, am I not right, that Austrade does charge for industry or trade fairs, I think, to anybody, but for other market information and help with market promotion other than in fairs is where it doesn't charge. Is that not what we've been told by someone?

MS POWER: We believe that even for information there's a charge. That to get a list of agents that operate, education agents, in a particular country, for example, an

institution would have to pay a considerable amount of money.

DR STEWARDSON: That's a recent bit of information, is it?

MS POWER: I think it has always been there, but what is recent is charging the industry - they've always charged individual colleges. But when it comes to a national promotion, a generic promotion, it used to be free of charge, and they had someone in Canberra until 1996, a couple of people, who worked with the education industry, and with no-one else, for the purpose of promoting Australian education to earn foreign exchange, but since 1996 that has no longer existed; that office was closed down. I suppose our main concern with Austrade is just that - I mean, this is on top of everything else. For us, the number of different charges that are levelled on our industry for government cost recovery gets so that it reduces - I mean, the margins on which colleges are operating are becoming lower and lower all the time because government costs are cutting into them all the time.

MRS OWENS: Yes, I think I agree with Robin, that we've had a slightly different view of Austrade's charging arrangements. I think we'll just have to go and examine that a bit further. We've just come away with a different impression of what Austrade was doing, but I don't think we've probably got right to the bottom of that yet. We'll ask them exactly what their charging arrangements are.

MS MOORE: I guess our perspective is that what is in fact Austrade doing with taxpayers' money that is not being on a cost recovery basis, because it seems to us that anything that we do, even the most - you know, to develop an industry which seems to me to be one of the core roles of Austrade on a very generic level seems to be levelled on a cost recovery basis rather than as a taxpayer funded activity.

MRS OWENS: As a community. I think the challenge for us is in just about everything we're looking at, and we're looking over a wide range of activities and a wide range of agencies, it's the extent to which it is a public good or the extent to which there is some private benefit that can be got from that particular activity.

MS MOORE: Exactly.

MRS OWENS: It's quite difficult actually answering that question. I mean, it's very rarely you have got something that is purely public good - - -

MS MOORE: Yes.

MRS OWENS: - - - and very rarely will be right up the other end, because you have got to ask if it's up the other end and it's purely private, why is it that the government is actually doing it. So usually they are somewhere in the middle and the challenge for us is deciding where. Can I just come back to the impact of all these charges on students. I suppose it must be difficult to actually determine what the impact that has been on the actual market; your market for students, because you have got too many other things that have been going on. Like you have had the Asian

crisis and you have talked about the dollar and so on and some of those things have pulled the student numbers back and other things have encouraged them, so it's very hard to then distinguish all the driving factors. Is that right?

MS POWER: It is. It's almost impossible, because in the last five years there have been just so many factors. The US government eased its visa restrictions on Taiwanese students, so that impacted upon us, and at the same time the One Nation Party debate was happening in Australia and that impacted upon us. Then the dollar came down and that moves things in the other direction and it just all keeps happening the whole time. It really is quite impossible to ever isolate the exact impact of any one factor when there are so many happening. The Asian economic crisis had a huge impact. We lost more than 40 per cent of English language students in numbers in the first 12 months of that crisis and it put more than 800 people out of work just in the English language training sector in the first five months of the Asian economic crisis.

DR STEWARDSON: 800 did you say?

MS POWER: I think it was 800.

MRS OWENS: Are we very much in the same position as New Zealand in terms of trying to attract particularly the Asian students or is it different?

MS MOORE: Well, I guess that Australia is a little bit more prominent in the choice. However, New Zealand have very, very attractive visa conditions and very cheap visa charges; no compliance costs that we have. They do attract a good number of students that would otherwise come to Australia, we would contest, because they do have a very liberal and open policy.

MRS OWENS: You see, I think that's probably the one country you could almost test the hypothesis with. You could say here's Australia and here's all the charges we have got and they got to register and they have got accreditation and so on. Here's New Zealand and it is freed up a lot more. They would have been trying to attract students from the same sort of markets, like the Asian markets, for example, at the same time - you know, when the Asian crisis hit. They have got the same problems with their dollar as we have got. You are almost comparing like with like, except they didn't have One Nation. What has happened with their student numbers? What are the trends compared with our trends? It would be interesting to - - -

MS POWER: Well, again you have different impacts. Indonesia, for example. Our student numbers for Indonesia have just hit the bottom, they have completely plummeted, but that's an Australian thing, it's not a New Zealand thing. It is public perception that Australia is no longer a country that is friendly towards Indonesia. The New Zealand English language training sector does very well in Thailand, yet in north-east Asia, Korea and Japan, probably Australia is far more prominent. A lot of that is tied up in politics.

MRS OWENS: And they do well in the South Pacific as well. We don't as well.

MS POWER: Yes, a lot of it is tied up in politics. The political relationship between Australia and Japan is far more prominent than the political relationship between Japan and New Zealand.

MRS OWENS: So we can't even look at New Zealand and try and get to the bottom of it.

MS POWER: Actually Canada would probably be the closest.

MRS OWENS: Yes.

MS POWER: Because in terms of size of the industry it's very similar.

MRS OWENS: Yes.

MS MOORE: To look at your question in just another light, we have done a few back of the envelope calculations on the costs of compliance for private providers in this industry. Whilst, you know, these have never been published and so on, it does give a little bit of an indication that the charges are quite onerous. We have come up with a figure of something like around about 2 per cent of revenue is spent on the costs of compliance, which is quite a lot if you consider that the margins are now very small for private providers in this industry.

DR STEWARDSON: The cost of compliance, that's including all of these charges you have been talking about - - -

MS MOORE: It includes some of these charges.

DR STEWARDSON: - - - that you pay as distinct from the students.

MS MOORE: Mandatory costs that we pay as opposed to students, yes.

MS POWER: But only the mandatory costs that relate specifically to this industry. I mean, the colleges are also paying their Australian Securities Commission fees and their taxes, etcetera, and that's not included in that 2 per cent.

MS MOORE: So accreditation, registration and compliance with all the regulations to do with the acts and bills and the trust accounts and so on.

MRS OWENS: I still just want to clarify this. You can have compliance costs which are actually broader than fees and charges, because sometimes you have to do certain things to comply say with the accreditation and so on. You might have to have, you know, rooms with X number of windows in them and so on or whatever - - -

MS MOORE: No, we haven't included that. We have just included things like what is the cost of it getting accredited.

MRS OWENS: Just the charges, right.

MS MOORE: Just the fee for accreditation. What is the fee that you have to pay to VETAB, the state body, to be registered?

MRS OWENS: Okay.

MS MOORE: What is the cost of operating a trust account; what is the cost of the annual registration charges paid to the Commonwealth?

MRS OWENS: Of course there could be much broader costs that they could be incurring just to be able to operate here.

MS MOORE: Yes.

MS POWER: Yes, for example, in Australia and not in the other countries there is a limit on how many students can be in an English class. It's 18 students to one teacher or something like that, whereas in the other countries that rule doesn't exist, so that there ties the costs of employing teachers directly to the number of students.

MRS OWENS: We don't have these limits in our primary and secondary schools, do we?

MS POWER: No, we don't.

MS MOORE: No.

MRS OWENS: Okay.

MS POWER: We don't in our universities, where first year university students will often find themselves in a lecture with 200 other students and only 150 seats.

MRS OWENS: And a tute with 40 students.

MS POWER: Yes.

MRS OWENS: That used to be the size when I was at uni with the lecture. We are not doing an inquiry into higher education at the moment. I think we have just about exhausted our questions, but thank you very much for coming. I have found it very, very interesting and I thought you raised issues that we haven't come across in most of our other submissions so far, so that made it particularly interesting for us. Have you got any other comments you would like to make before we finish?

MS POWER: Only that I can guarantee that you would have had more submissions from education, from some of the other peek bodies, except that the ESOS Act is currently before the senate and they had to make a choice of which submission they would prepare, because there wasn't time to do both.

MRS OWENS: Okay. They get another opportunity - - -

MS POWER: The time limit for the education sector was - - -

MRS OWENS: Not good.

MS POWER: - - - not good. It was rather critical, because the senate committee has to submit its report by the 28th of this month.

MRS OWENS: That's a pity, but we do give people an opportunity early next year after we put out our draft report, so we would like to hear from people in the education sector. We are interested in other issues like the costs in the education sector of gaining access to information from the Australian Bureau of Statistics if you are doing research and so on. There are a whole lot of other educational-type issues that we could get into if we got the right input.

MS POWER: We obtained statistics from DIMA free of charge on the number of student visa issues, but they changed how they count from time to time so it closed the whole thing up and it makes them virtually useless.

MRS OWENS: Maybe if you did have to pay a fee, you could exert some pressure on them. On that note I think we might finish. So thank you very much and we will just break for a minute while we get the next participant.

MRS OWENS: The next participant is Whiteley Industries Pty Ltd. Could you please give your name and your affiliation with the company for the public record.

MR WHITELEY: Thank you. My name is Greg Whiteley. I am the managing director of Whiteley Industries Pty Ltd. We are a company who have our base in the downstream end of the chemical blending industry and we have been established as an Australian business since 1933, although my family only became involved in our business in about 1971.

MRS OWENS: Good. Thank you. I understand that you have a couple of comments you would like to make and I just reiterate on the transcript that I would like to thank you for being submission number 1, and we did read it with interest because it was submission number 1 - we do try and read all the submissions, of course - but it was, as Paul said, a palatable size, so thank you very much. Would you like to make some opening comments?

MR WHITELEY: Thank you, yes. First of all I would like to thank the Productivity Commission for the inquiry. It's very timely for our industry sector, and as a small Australian business we are very grateful for the opportunity and honour of being number 1 on the list, and I would like to make some introductory comments. The chemical sector that we participate in is now probably the most regulated sector of industry in Australia. As I had in my submission, there are at least 50 acts of parliaments, both Commonwealth and state, that apply to our industry. As a matter of productivity it is virtually impossible for any one member of our industry to actually understand, contemplate and hold together all those strings at one time, and that in itself becomes a very onerous issue for our industry and becomes a stifling issue on innovation.

The other issue I would like to make by way of introductory comment is our industry sector, like many, are becoming subject to considerable global forces and as globalisation affects our industry there is growing polarisation between the size of businesses and the nature of business is changing, in some case more radically in parts of the sector than most companies are able to keep up with, and so to find 100 per cent cost recovery on certain areas of our sector of industry becomes probably the most anti-competitive potential area in our businesses and has a major disabling effect when it comes to competing on a global basis.

We, as a small Australian business, have spent considerable amounts of money in resource development - not resource development, I beg your pardon, in research and development and spent a lot of money on patenting inventions. We fund various public institutions in research, particularly in scientific areas related to sterilisation and medical technology, and so we have been an active member of the community and we see on a global scale therefore how this is affecting many, many of our companies in the industry and, indeed, our small company.

MRS OWENS: Good. Thank you. I think that our particular interest in talking to you is that we have been asked in our terms of reference to take particular note of the

impact of the cost recovery arrangements on small and medium-size companies, so we are particularly grateful for you coming along to tell us about some of your experiences. Can I just ask you, as a point of clarification, in terms of, say, the regulators that you're dealing with, which ones would you have direct contact with. Would it be NICNAS and NRA?

MR WHITELEY: I think the big seven. In most companies in the downstream industry that are covered by trade associations such as ACSMA and - - -

MRS OWENS: What's the ACSMA?

MR WHITELEY: That's the Australian Chemical Specialty Manufacturers Association, which is downstream soaps and detergents, but it would include the Dental Industry Association, the Australian self-medication industry. Most of the companies compete across a number of marketplaces and most companies therefore come up against the National Registration Authority, the Australian Quarantine Inspection Service, Therapeutic Goods Administration, NICNAS, which is the National - I can never remember NICNAS - but it's the National Inventory of Chemical Notification and Assessment Scheme.

MRS OWENS: Thank you for that. We can never remember either.

MR WHITELEY: I hope I have got that correct. I apologise to NICNAS if I have got that incorrect. I would like to speak to a specific example of that, that occurred today, to the committee - I will come back to it - and I'm happy to tender as public documents the sort of things we deal with there. But it goes on through basically all of the major federal bureaucracies covering chemical industry regulations and licence and controls, and our experience is therefore more specifically with some than others but largely across all sectors of that group of government departments. We also then on top of that deal of course with the state departments, who also in many cases want individual licensing fees, and they are probably outside of this particular inquiry in that they are not 100 per cent cost recovery, but there are - - -

MRS OWENS: We are only looking at Commonwealth agencies here.

MR WHITELEY: It just goes on and on and on.

MRS OWENS: I can understand the frustration I think. I can just hear your sense of it.

MR WHITELEY: Yes.

MRS OWENS: You mentioned something happened with you today with NICNAS. Would you like to expand on that?

MR WHITELEY: Gladly. We are a small business and we are downstream, so we get involved with NICNAS as little as we humanly can, because they have been an

unwieldy group to deal with, very technically focused and beyond the limitations usually of downstream players such as ourselves. If I can actually backtrack. I would like to explain the difference between what I will call downstream and upstream, because that has great relevance, I think, to how this anti-competitive effect occurs. As the commissioners would probably know, there's not a great deal of secondary industry in Australia in the chemical industry. There are probably only two or three actual manufacturers of what we would call raw material sources in this sector of significance and several of them are actually listed businesses; they are registered on the stock exchange.

So the large bulk of raw materials come from a number of overseas sources. Then they are sold downstream and our industry sector as blenders make or manufacture, if you like, in a true chemical sense very few materials. Most materials are made and sold as products ready for use or dilutable ready for use for customers, and if I can use a very simplistic example, it's a bit like making milkshakes. One starts with a big tank, usually stainless steel, one adds the - water is usually the base vehicle - proprietary ingredients, stirs the mixture, adds whatever else needs to be done, does quality control procedures depending on the standard of quality assessment that's needed in the plant, and there are considerable variations in that area, and then once the product is ready for packing it's then packed off, apply quality controls, and then it's ready for sale. That latter group is what's called the downstream.

Our area with NICNAS is a downstream area. They have held a number of priority existing chemical reviews under their legislation and we have participated in at least two of those reviews as an applicant, which is the highest standard. In both cases - - -

MRS OWENS: Does that mean you initiate it or they initiate it?

MR WHITELEY: No, the review is actually initiated by Worksafe Australia or through NICNAS, and they then held a public review, if you like, for which 100 per cent cost recovery was applied. The first review - the chemical that we participated in was actually PEC number 3 - was for glutaraldehyde. That inquiry took some years to complete.

MRS OWENS: You may have to give the reporter over here the spelling of that later.

MR WHITELEY: Yes, certainly. I will happily do that. If you would like me to read it into the transcript, I will, otherwise I can just provide the - - -

MRS OWENS: What is it, organic?

MR WHITELEY: It's an organic material which is used for disinfecting, sterilising, and a number of other purposes. It certainly has some health impacts on users if it's handled poorly and these are well-documented. This review took place in 1994. It was subject to a - and I have for the purposes of - I know it's a literal demonstration,

so it won't appear, obviously, on the transcript, but these documents are available just to give the committee a view. Here is the first one on glutaraldehyde. This is 176 pages of documentation of review; it's very comprehensive. Industry participated and was largely satisfied with the outcome, but there were a number of very, very dangerous things that happened out of it commercially that affected productivity in particular.

The first one is that after six years, even today, I have received the latest round of information from NICNAS - six years after the event - giving a summary which does not accurately reflect the findings of the outcome; has not actually been reviewed by the applicants - so it has just come out. The first we have heard is we have got the documents and they have already been spread for publication, and in this one in particular with glutaraldehyde one of the things that happened in industry was that companies supplying materials to perform similar functions used the guise of a review under the public health and safety requirements and needs, which, as I say, we don't decry, but nonetheless they were able to use the review as evidence of the hazardous nature of this material and the relative safety of their own materials.

Of course that is not borne out by the facts. What's more, in this particular inquiry the state governments, in at least one state, picked up on the alternative materials and actually passed into law their necessity for use over and above the material glutaredehyde. The impact on companies like ourselves is we were simply unable to compete with the resource allocations needed to both submit to a federal inquiry, such as the prior existing chemical review and then have to pay the 100 per cent cost recovery and then compete with extremely well-resourced multinational competitors who were importing materials and, though they are probably more hazardous than glutaraldehyde, were not being subject to a prior existing chemical review.

One of the materials had a material safety data sheet at the time which was not made overly public in the same way as the glutaraldehyde product was, where the material, if it caught fire in a hospital, would revert to hydrogen cyanide; and yet it was promoted - which of course is quite a known toxic material - and the sort of volumes that are likely to occur in a fire would be likely to kill all those in the reasonable neighbourhood - material after six years has still not been subject to review by Worksafe Australia.

The cost to the health industry blew out from instrument disinfectant values, probably less than $2 million a year, to a cost to the health care sector of probably in excess of $50 million per year for the competitive material, which in fact was multiples of the cost. I think in 1994 the relative cost per cycle of glutaraldehyde in the health care system ran at about 60 cents per use. The relative cost of the equivalent peracetic acid material ran in excess of $8 per use. We're talking of millions of uses per annum.

So, you know, the cost benefit of 100 per cent cost recovery on a small business like ours was that we were basically disabled from being able to compete effectively.

It denuded our resource to be able to compete in the marketplace. The slowness of the inquiry led to other commercial disadvantages and then the subsequent lack of inquiry in other areas meant that we were totally unable to compete, again against a foreign corporate selling locally.

DR STEWARDSON: Are you able to tell us, perhaps in confidence if it's that sort of information, what the cost of this inquiry was to you?

MR WHITELEY: I'm happy to come back to the commission on that. I don't have the exact number here but I had better not read into transcript the exact number, but it's in the order of over $10,000 to $12,000. I have got an idea but I'm happy to come back to the commission and make that information public.

MRS OWENS: Can I just clarify, you said that this review took place back in 1994 and they have put out material in the year 2000 still relating to that review. What has happened in the six years? Did they put out an interim report?

MR WHITELEY: This document was actually published in 94 so this has been fully publicly available.

MRS OWENS: But there has been additional material that has now come out in the year 2000.

MR WHITELEY: I have a letter that is dated 17 November. They have got the date wrong. They're actually a year ahead of themselves but I'm sure it's today.

MRS OWENS: 2001, yes.

MR WHITELEY: Yes, which I'm happy to show the committee. I don't know if you want me to hand it around.

MRS OWENS: Yes, if you wouldn't mind tabling it. Can you table that? It's not a commercial document?

MR WHITELEY: It probably is.

MRS OWENS: You could table it as a commercial-in-confidence document, I think.

MR WHITELEY: I'm happy to table it as commercial-in-confidence. I'm happy to show the commission - - -

MRS OWENS: We could just write that on it.

MR WHITELEY: Yes.

MRS OWENS: And, I mean, if you could clarify the status of that later.

MR WHITELEY: Sure.

MRS OWENS: So we can keep these?

MR WHITELEY: I probably need to get a copy. That's my only copy. It's only come in today so I could not quite believe that it was so timely in its arrival.

MRS OWENS: Yes, they must have known.

MR WHITELEY: I pointed that out to them in a conversation this afternoon. I don't think they were quite as enthusiastic about my appearance as they may have been.

MRS OWENS: So what they've done is produced fact sheets which are based on that review that they carried out and you're saying that the fact sheets are not accurate.

MR WHITELEY: The fact sheets themselves - one of the issues that takes place in a competitive industry like this one where there is what I would like to call the Captain Planet Syndrome at work - that is to say, you know, "It's a chemical. It must be hazardous. We're going to kill the environment and all those involved that are probably just waiting to go to trial for some sort of criminal and nefarious act." That tends to be how these things are portrayed once it becomes an alarmist debate.

These information sheets therefore need to be worded carefully and the sort of things that therefore need to happen, and happened in the original inquiry, was that there is to be some sort of consultative process that takes place. There are some phrases here that in fact, yes, I think don't accurately represent the information contained in the reviews and they allow for portrayal of these devices - that is, these sheets - by people who are using other materials.

The anti-competitive factor therefore becomes twofold on our small business. One, we're faced with 100 per cent cost recovery with no threshold or tiering of the charging; and the other one is that having to participate in this on an ad hoc basis, there is no seeming justification for how these things proceed. NICNAS actually receive recommendations as to what should be reviewed and they go back into a room somewhere with a committee they have who are largely not involved in industry and then make some arbitrary decision about what they will do next according to their resource allocation.

MRS OWENS: So before this came out, this safety information sheet number 2 on glutaraldehyde, you weren't consulted at any stage about this. Nobody sent you a draft to say, "Do you think this is accurately portraying this particular chemical?" Is this something that only you produce or do other companies produce this as well?

MR WHITELEY: That strikes right at the heart of the upstream versus downstream. Raw materials supply glutaraldehyde. In fact, there are two global sources for this raw material. I won't name the companies because I don't think that would be fair on them, but there are two very well-known ethical sources of the material. It's then sold to downstream companies like ourselves and used in formulations to achieve end-use applications. In our case, we're using it as a liquid, high-level disinfectant. To make this even more relevant, the product for which this is being used is actually regulated by the Therapeutic Goods Administration as a medical device. So once again I have had 100 per cent cost recovery applied across the regulation of my medical device by the Therapeutic Goods Administration, who I note are now the large outsourcing body for some of the toxicology requirements of NICNAS.

So I have a lovely loop going on and once again, as a small business - and we certainly fall into the SME category where below the threshold, and I realise this is obviously in confidence - I will just say we're below the threshold for an auditable entity. That is to say, we're not required to be subject to audit so we're definitely in the SME category and, you know, it has a massively onerous cost burden upon us. To put in context too, while I'm dealing with the medical device issue, in that area, this chemical which had been subject to a full public review by NICNAS in 1994 was then subject to a new Therapeutic Goods Order in 1996 which, again, we welcome the Therapeutic Goods Order and I was and still am a participant in the TGA process to develop the Therapeutic Goods Order. Nonetheless, the cost of testing of these devices in Australia was in excess of half a million dollars Australian.

DR STEWARDSON: Do you produce the device or do you produce the chemical that's used in the device?

MR WHITELEY: We're calling it a device but it's a liquid chemical. The differentiation from the therapeutic goods point of view is that if it's a mechanical thing, it's obviously a device, but therapeutic devices also include materials or objects which will be intended to have a therapeutic benefit but are not used directly on a person. So disinfectants and sterilents fall into the category of medical devices even though they're liquid chemicals. Antiseptics, on the other hand, are regulated as drugs, basically - therapeutic medicines.

DR STEWARDSON: Can we try and separate out the issues that you've been talking about here? I understand what you've been telling us, and I can understand why it is extraordinarily frustrating for you, but from the point of view of this inquiry, some of the harm to you is the unscrupulous use that your competitors have been making of the fact that there's been an inquiry and the fact that there is now a written report, be it accurate or otherwise, about your product, whereas there doesn't happen to have been an inquiry about your competitive's product and so they're representing that as the fact that theirs is therefore not dangerous.

MR WHITELEY: Yes.

DR STEWARDSON: And you also mentioned a state government legislation saying that they're going even further than that.

MR WHITELEY: Sure.

DR STEWARDSON: Which seems to have been either ignorant or rather strange. But from the point of view of the things that we specifically have to focus on there's the cost recovery thing and we're not actually asked to challenge the fact of regulation per se, though we asked to comment on the efficiency with which it's done. One of your points is the cost to you of the 100 per cent. Tell me if I'm putting words into your mouth, but you seem to me to be saying that there is, to some extent, an inefficiency in the fact that your product is singled out for testing, whereas other equally bad or good products that are competitors aren't and, I take it, the time factor, that this all appears to have taken a long time and that this has put you at a disadvantage; that while you are now approved, subject to taking certain precautions - leave aside the fact that it has been misrepresented, but you are now approved. But I take it, it has taken quite a long time.

MR WHITELEY: It has taken a long time. I suppose I need to make the point more accurately. Just to extend that a little bit further. The point I was trying to make was, on top of the cost burden of 100 per cent cost recovery, we have to deal with the normal commercial pressures. I meant those as examples of the sort of normal commercial pressures that can arise by default, in some cases, out of things that need to be done often by government instrumentalities in the pursuit of good public health policies.

As I say, I don't decry that, but the impost on us as a small manufacturer for 100 per cent cost recovery is that it therefore denudes our capacity to have the resources available to compete against normal competitive and commercial forces. Where you've got small numbers of resources, it really puts a very onerous burden on you, where those sort of forces suddenly come into play.

DR STEWARDSON: Can I broaden that question because there is something that you said in your submission that relates to that. You said you talked about the disadvantage, particularly for small and medium-sized companies, and you made three points: one, better buying volume from upstream manufacturers that larger companies have; and you mentioned better capitalisation and cash flow and so on that large companies have, and you also mentioned that large companies have a bigger market share over which they can spread the cost of cost recovery. The last of those is a very relevant thing to our inquiry. The first two, while they're very relevant to you, they're not part of this inquiry.

MR WHITELEY: I agree.

DR STEWARDSON: My question really is, how significant for a small and medium company is this cost recovery burden as distinct from the other economic burdens that you have, vis-a-vis a company that has got a larger market and can spread its

overheads more in all sorts of other respects.

MR WHITELEY: That indeed was the point I'm making, is to answer that question exactly. It has a huge burden on small manufacturers. The cost of bringing in a new chemical material, and that's certainly our industry, is quite enormous when one considers the process that NICNAS makes you go through. Frankly, our view has been to avoid it at all costs. We try and push it upstream - that is, to try and make the upstream suppliers do the work for us. The advantage for them is they then can sell across the wide range of my competitors, but I accept that. What's happening in the global economy is that more and more materials - well, no, let me rephrase that.

There are less materials coming through, and those that are coming through are more frequently being made available to a smaller range of companies upstream and, as most of the development of these materials is outside of Australia in terms of the chemical entities, and this is something obviously outside of the domain of the Australian marketplace - it's just what's happening globally. What it means is that the larger company, particularly the foreign corporate players, are able to get access to those materials and conduct that research at an earlier stage. Then when it comes time to bring them into Australia, if they do bring them into Australia and do choose to go through the inquiry, they're already spreading their costs across a very large basis, and obviously the Australian marketplace is much smaller. So it means that we don't get the materials because of our limitation on wanting to go through the costs of bringing new materials in.

DR STEWARDSON: Are you saying "we" small companies or - - -

MR WHITELEY: Small companies in our sector, I beg your pardon. We will avoid trying to bring in new materials because the cost is so onerous on us and when we get it here we can't guarantee it's going to actually work or the market is going to accept it; whereas for larger companies where they can see they've got a global opportunity, they're able to do their research sooner, bring it to market much sooner and make a much more accurate assessment as to whether they're going to succeed or fail on the application to bring the chemical entity in and, of course, even if they do fail, their ability to withstand that failure and the costs associated with bringing it in is able to be spread across a much larger basis.

Whereas for smaller companies, this is our marketplace and, in the global market, how that affects our industry is that even the upstream suppliers to us are becoming bigger and bigger corporations. A couple of public examples: Dow is just in the process of buying out Union Carbide Corporation. You've got two very significant raw material suppliers who are amalgamating in a foreign jurisdiction and that will have global implications, and it means that the ability for us in Australia, as small businesses with small market volume purchases to gain leverage to bring a new material in, is extremely diminished. To then have to go to 100 per cent cost recovery makes it very difficult.

DR STEWARDSON: You've got the spreading of the costs for the bigger company

that you've talked about but when a larger overseas company wants to bring a particular chemical into Australia, is its costs of preparing the material that needs to be submitted greatly reduced? Will it already have got the paperwork or whatever is involved done for approval in its overseas home country and just sort of photocopy it and pass it in?

MR WHITELEY: I would say that it was in the second part of that but, no, it's not. Often there is new testing that needs to be done or other testing that needs to be done that is peculiarly Australian. In some cases that, I think, has good technical justification. We're an island continent. There is good justification for certain testing being unique to Australia, particularly in the environmental area, but largely the costs are borne again. They're asked to redo certain things that probably are not necessary. The cost recovery issue means that when it lands in Australia it's more expensive and then you have the situation where, even if it becomes available for a local company or local companies to actually now purchase and do some research and development on it, to develop new technologies, to make our products more efficient and effective and compete.

The foreign corporates that have already had access to the material and have worked it out are already buying it at bigger volumes, at an overseas pegged rate usually, so they're buying out the US dollar or a European Euro rate on the basis that they're global volumes and then bring it to Australia, whereas the Australian marketplace is having their price backed in with the 100 per cent cost recovery on top of that. So the biggest penalty is to the small company sector. It means, therefore, that our biggest problem and inefficiency in getting new materials to market is getting them through the regulatory burden.

MRS OWENS: Can I just cut in there? Is there a case then to have no cost recovery, or partial cost recovery? Or is it a case of saying, "We want a different set of prices for the smaller companies"? What do you want to see happen?

MR WHITELEY: We get the vexed issues of trade practices as the latter part of that, and I think we can all assume we're going to avoid the problems with regulated pricing. I really don't have a clear answer on that because I'm not absolutely clear of what NICNAS's charter is, and NICNAS is not the only issue here. One must remember that anything that is a prescribed medicine or a medical device is actually exempted under the NICNAS Act, so TGA are also involved in this. TGA are in fact the primary assessor for medicines coming into the country, first time entities, and their cost burden is different again from NICNAS.

I would suspect that there ought to be some means testing or shielding of the smaller business, particularly in the SME category. If the Australian government decides that it wants to have a healthy small sector in this area, and there is certainly a justifiable economic need where we're contributing to the gross domestic product considerably, we're providing a lot of employment, we provide competition so that sectors are not dominated by foreign corporations. It's well within our capacity to produce these materials, particularly in a downstream sector. We have no trouble

competing in terms of quality and a research and development situation. Our patenting is good.

In fact, the biggest cost in a lot of products these days is the transport costs, so competition in terms of pricing is very good. The biggest burden, and biggest problem, is getting these materials quickly and economically to market where there can be competition. As I made the point in my submission, it therefore is really an anti-competitive effect that is taking place. There is a diminishment of competition because small companies simply will not lift the regulatory burden required to bring these materials in and just have to sit by and wait or let time go by. Of course, as time goes by the likelihood is that other companies will get in in foreign corporations, develop patents, make the discoveries first and lock out Australian business from being able to compete effectively. Is that clear?

DR STEWARDSON: Yes, that's perfectly clear. So the big overseas company will do it. It's not that the product won't eventually get to Australia, it's who brings it to Australia.

MR WHITELEY: Absolutely, and the time limits of it. I've got another example: there is a new material coming into particularly the American marketplace that uses a synthetic organic material. It's a relatively good material; it has been around for quite a number of years. No-one has actually ever brought it into Australia. We could fly in a sample to play with, as it would turn out, when we finally found out about this material from an upstream supplier. We were allowed to bring in, I think, 600 grams. You know, we ran out before our research proceeded very far and the cost of bringing that in for ourselves, if we're their only customer in Australia, is just prohibitive.

Now, the only player that actually has patents in the area, or the two players that have patents in the area at this stage, are a very large global conglomerate and the raw material supplier themselves. The raw material supplier is obviously only putting the patents in place so that they can safeguard their own technology to stop it being copied by cheaper other players. On the other hand, the conglomerate involved are going to bring the product into Australia. They're not going to make it in Australia, they're actually going to import it into Australia. So even if we were to go ahead, we would still potentially be the only customer in Australia. We would therefore have to co-fund with our upstream supplier, if you like, and one way or another we're going to fund it, to bring this material in.

MRS OWENS: But then it's going to have to go through the hoops.

MR WHITELEY: It's going to have to go through the hoops, and because the upstream supplier is a big company they're going to pick it up as 100 per cent cost recovery. But their response is that that will then be passed on to us as the purchasers, which puts us at a competitive disadvantage against the global conglomerate who can then piggyback on the application through NICNAS to bring the material in, but they're buying it off a benchmark global rate out of the US.

MRS OWENS: So you could put up the application to NICNAS to have this product approved for the Australian market. Then you're saying that the big conglomerate could come in and just piggyback. Once you've got the approval, then there's - - -

MR WHITELEY: Sure.

MRS OWENS: Because they've got the patent anyway.

MR WHITELEY: The raw material is made by, if you like, an upstream company who have some application patents. Their biggest customer, globally, is this multinational company. I don't decry them: this is good, competitive advantage for them. I mean, they're using their competitive power commercially well. To make matters more complicated, what they can do with their particular situation is bring their product in actually as a therapeutic good, which means the registration for their product can be under TGA. Because their patents would lock us out of that area, we would then have to bring it in under NICNAS. So they would still be buying the raw material off of a global benchmark, but we would still be paying 100 per cent cost recovery.

The only way that we can see that this inequity can be dealt with is there has to be some sort of tiering system or means testing to allow smaller Australian businesses not to have to yield to the burden of 100 per cent cost recovery, because it's frankly beyond our capacity to do it. Again, it just means that we cannot compete. In our area of business we have now over 15 patents, both national and international, against our business which, for our company size, is quite high. We know some of our multinational competitors, who are in the billions of dollars of turnover US category, who have got literally only three or four times the number of patents that we have. So we are investing heavily in research, but in one of our key areas we are now limited completely against the next level of competition because we can't get the raw materials in. Again, we come up against this 100 per cent, to bring it in, and there are shielding limits so you can bring in little bits at a time, but it really is very, very difficult.

The outcome of that is that in one of our latest proposals we're considering moving our research to America. We actually have an arrangement with a global partner that we have had to find - they are a foreign company, and that research will be lost to Australia. We'll still consider Australia as our base, of course. We're an Australian company but we're going to have to do the second-tier - I'd call it - research; the applied research offshore, whereas previously we would have funded it through Australian universities.

DR STEWARDSON: Can I be clear about that? The reason is because you need to bring in chemicals to do that research, and you have to have them assessed in order to bring them in for the research. Is that the point?

MR WHITELEY: You can probably bring in enough to get the research done at a fairly low level, but to really move on in these things it's difficult. What tends to happen is, for small companies, we can go to our upstream supplier and ask them for samples. Usually they won't provide the samples because (a) it's not approved in Australia and (b) even if it was, in some cases, they want us to buy huge volumes. Well, because of our reputation - this is specific to our business - we've been able to get around that frequently by saying, "Look, we've got a number of international patents in such and such an area, so please give us a sample because we're doing more work. There is a global benefit for you." They hear language like that, that's fine, because they understand that there is going to be potentially global opportunities come out of it.

My peers in the industry usually don't have that sort of competitive advantage that I have. Nonetheless, when it comes to some of the work that we're involved in, the existing materials simply cannot get the job done, so we're looking for new materials to achieve the outcomes. An example: we're involved in looking at cleaning and sterilising of medical devices, and I have to be careful here because this is a public forum that's a critical area. The US government has nominally said that 98,000 people a year in the US die from hospital-related injuries or incidents. I think that's probably an overly high figure, but you relate that back particularly into what are called nosocomial and iatrogenic infections, that is they're hospital-acquired or device-acquired, and cleaning the instruments becomes absolutely critical. It's a public health problem that needs to be dealt with. For certain types of procedures the incident risk is higher than for others.

Cleaning is implicated, but the current cleaning materials that are available, in terms of the chemistries, have got problems: they are either too corrosive for the instruments, they are too harmful for people using them or they are too damned expensive. We need to obviously get things done effectively and efficiently. We're finding now that we simply cannot obtain the next range of materials in Australia. The raw material upstream suppliers simply don't bother to tell the Australian marketplace what is their latest developments. We've had a number of examples of that where we've found materials through our contacts or via the Internet that are not made available to us through our normal sources, because it's all too hard. The market is not big enough. So the impact effect on us is that we are likely to find that competitor, who is probably not as well focused as we are, may basically beat us to the competitive advantage of patentable technology. We're locked out of the competitive advantage that we would otherwise gain if the materials were available to us.

DR STEWARDSON: But is it that the market is not big enough per se or that the market is not big enough to bear the cost of the testing?

MR WHITELEY: It's the latter. The market is not big enough. Remembering that some of these materials - can I give you an example? A hospital detergent to clean floors, it has probably got no more than 3 per cent of active materials in it. 97 per cent is water. That is a standard government contract item in the state of New

South Wales. The next advantage may be material that is in that 100 per cent may be less than half a per cent but that may be the material that contributes to the key advantage. When you multiply that out it is still not a large market volume, considering the Australian population size, but when you put 100 per cent cost recovery and the difficulties of bringing it in, that just rules out Australia as an opportunity market.

MRS OWENS: So you're saying that that's enough to tip the balance?

MR WHITELEY: Absolutely. We are seeing it regularly now in raw material supply and it is getting worse because the global upstream players are coming together and are merging and are accumulating their size rather than devolving their size.

MRS OWENS: Okay. Thank you very much for that. That was I think very informative for us. We will have a break now and we'll discuss what we do with these tabled documents. We will just have a very short break now because we're running a bit late and we'll resume in 10 minutes.

MRS OWENS: We will now resume. The next participant this afternoon is the Medical Industry Association of Australia. For the purposes of the transcript could you each please give your name and your affiliation?

MR VALE: Commissioners, thank you very much. I am Brian Vale and I am the chief executive officer of the Medical Industry Association of Australia.

DR CORNELL: Bruce Cornell. I am the chief scientist and the senior vice-president of Ambri Pty Ltd, a medical device company.

MR RYAN: My name is Warren Ryan and I am the managing director of Medtronic in Australia and I am the honorary treasurer of the Medical Industry Association.

MS HIDES: And I am Rosemary Hides, the technical and regulatory affairs manager for the Medical Industry Association.

MRS OWENS: Thank you and thank you all for coming. I am sorry we are running a little bit behind time but we'll try and make it up a little bit but I don't want to necessarily cut off the discussion this afternoon because I think you have given us a particularly important submission and there are a number of issues that have been raised in your submission which, I think, we would like to pursue, and I was particularly interested in your attachment 2, where you have given us some very useful information about other countries - some international comparisons - so I was wondering - I think it is Brian Vale who will be giving us some introductory comments. Would you like to do that?

MR VALE: Yes, commissioners, if that is okay. You are aware from our submission of who the Medical Industry Association is and the type of industry that we represent and the member companies, so I will not go through all of that. I would just say though that this industry is characterised by high technology and fast-moving devices. It is the case that many companies in our industry have products that are in the marketplace for less than two years and some companies - and I think Medtronic would be one of those - have a product range of which some 75 per cent frequently have been in the marketplace for less than two years and what that tells us is that we need a responsive regulatory system to be able to continue the flow of that type of technology in the process of health care delivery.

We, as an association, have flagged two key areas of concern in our submission. They are, first, the issue of TGA fees and charges and these are a taxation. They have been defined as such by senior counsel. That advice is paraphrased in Corrs Chambers Westgarth legal advice which I would like to leave with you today, indicating that the two acts that levy these fees and charges on our industry do in effect constitute taxation. The advice goes on to say that the parliament is not made aware of changes to the levels of taxation - as these fees and charges are - when such changes in fee levels occur, and that means that the parliament does not give due consideration to the holistic impact on industry when TGA fees and charges rise - for

instance, concurrently with the introduction of a GST this year and changes to FBT and other company taxes - and we think that that is a problem because it escapes the usual parliamentary scrutiny.

Our second area of concern is with CSIRO cost-recovery practices. We flagged those in the study and Dr Bruce Cornell will say a little about that in due course. One lesser area of concern, again raised in our study, is new departmental fees that have been applied to just our industry sector for the maintenance of the prosthesis benefits default list. A set of fees that industry has thus far willingly paid, I believe - well, in the absence of, I believe, an appropriate regulatory environment to prescribe the payment of that. That is a developing concern because - for reasons that others can speak to - at the moment we do not see the promised dividend for that investment that industry chose to make.

I would like very briefly to say something about the nature and the size of the Australian market - to say that devices and diagnostics - the Australian market is but 1 per cent of the world market. It is essentially an import market. Some 90 per cent almost - it's between 85 and 90 per cent on the best available figures - of the products and devices and diagnostics that are used in Australia are imported and the bulk of those come from the United States. There has been a manufacturing sector in Australia in devices and diagnostics. One continues, but it is diminishing in size. Some four factories have closed their doors and gone offshore - some of those quite significant concerns. Four in the last year, I should say - the likes of Smith and Nephew with two plants closed in Victoria. Johnson and Johnson, here in Sydney, in the suture manufacture area, and Tuta Laboratories with the blood bag production.

They move offshore for reasons that are not - and I need to make this clear - related to high costs of TGA fees and charges essentially. Rather it is an outcome of a multinational environment where rationalisation of manufacturing in this global industry sees that it is more profitable and more effective to manufacture offshore. There is an impact of high fees and charges but it is not the driving factor in this. It is unlikely that there will be a resurgence of manufacturing in Australia other than in niche industries, and there are some excellent examples of those.

I have mentioned the TGA fees and charges of taxation. Industry also has a concern that TGA today acts effectively as the law maker because, as the regulatory authority, they prescribe the standards. They then act as the judge and jury as they go through the conformity assessment process, and then at least in the first round of appeals they act as the appeals court. That is a most unusual set of criteria or a most unusual operating procedure, not really parallelled easily in the western world. There are some limited examples of where conformity assessment and regulatory control do occur in Europe - that is without doubt. This is arguably - and it has been said internationally in the last year - that this is not best practice.

I have been concerned that there has been a lack of submissions to your inquiry from our industry members and I would like to flag that as best as I have been able to gauge there is a genuine fear held by some of our smaller and mid-sized companies

that to raise issues in a public forum such as this about concerns with TGA potentially is like putting one's head above the parapet. Now, they may be quite unjustified fears but I think it is reasonable to raise the fact that companies have raised this with us and pointed out that that is why they will not in this forum, where they are no dependent upon a responsive TGA, be prepared to raise their hand and raise their concern with these issues.

In the opening remarks I would like to conclude by saying that the regime we face at the moment where we have experienced slow approval times to get to market, we have seen and we have demonstrated I think in those costs and others that we can leave with you today unacceptably high costs. The outcome we are seeing is that Australia is becoming increasingly an unattractive marketplace. It's unattractive to manufacture, and Bruce will say a little more about that in a moment, and it's unattractive to market products. So particularly for products that are at the high end of technology, that are regulated in today's environment and therefore attract up-front fees in the order of $76,000 for an application for a high level registered device, and you may only sell a handful of these in a year, the ability of companies to recover the capital outlays in the short time in a small marketplace is such that we are unattractive.

There should be no doubt that Australia does not see a full range of high technology medical devices today and it is simply because we are small and we are unattractive. The long term outlook, if we continue on this path, is that health care must suffer from a reduced availability of high technology medical devices and consumers will suffer as a result. Perhaps that might serve just to introduce the subject, commissioners.

MRS OWENS: Thank you very much. I appreciate your frankness in telling us about your members' concerns about appearing or writing submissions to our inquiry. I think that may be a real problem maybe in other areas as well, but one solution may be if they have particular concerns to maybe direct their concerns through you like in a series of case studies where you don't name the company, but it may be possible for the regulators to identify them. I am not sure, but there may be ways of providing us with information without identifying the actual companies.

MR VALE: In the figures that we have provided for you and others that we have here today we have specific company data, but it is unidentified, and some companies have certainly contributed to confirming the data that we have. So we do use that methodology, albeit that one or two have also put individual submissions forward.

MRS OWENS: Thank you for that. I think one of the other things I would like to thank you for is the - I understand as you said in your comments that you are tabling this legal advice.

MR VALE: Yes.

MRS OWENS: I will be very interested to actually read it. I don't know whether

it's worth sitting and discussing their actual arguments as to why the fees may be considered to be a taxation at this point, but we could take it away and look at it and maybe come back to you if we have got questions.

MR VALE: We would be happy to do it on that line. In essence - and I am not legally trained here.

MRS OWENS: No.

MR VALE: It is that one of the two acts under which fees and charges have been levied - and there are two acts that have to be considered here - has not been identified to the parliament as an act that imposes taxation, but in effect it acts as one. That is where there is an element of deception about this. The real outcome is obfuscated from the parliament.

MRS OWENS: There are usually arguments relating to whether a fee or a charge is a tax - it's related to whether it's disconnected from the actual costs incurred and exceeds the costs incurred and then it could be deemed to be a tax under the constitution, so we would have to look at the actual legal arguments there that they have used in this particular case.

MR VALE: I think this document gives enough reference to the High Court judgments, in particular the Air Caledonie case, to be able to form a first view. If we can assist with further information - as I say, we haven't tabled senior counsel's advice at this stage because that could be the basis for a Federal Court challenge if the industry chose to do so. However, this advice would make clear that it is a relatively easy process for the government to re-present an act and have it therefore legalised, so to speak, in the event that it was clear we were going to go down that path. So we have just been cautious with the senior counsel's advice.

MRS OWENS: Okay, thank you.

DR STEWARDSON: You said at the conclusion of your opening remarks, and you also said somewhere in your submission, that there were a number of products not introduced into Australia because of the regulatory cost of getting approval within the small market, the two together. Can you give us, please, some examples of those products? I don't really mean that we should do it right now, but I think it would be very helpful if you were able to follow up with some specific examples.

MR VALE: We could do so in both the diagnostics and the devices area. I think in a confidential way it might be that - Warren, would you be prepared to say anything about your company's attitude?

MR RYAN: Well, yes. We generally will bring in everything that the company makes. However, there are smaller specialty items that we would definitely not - you know, given the high cost of evaluation fees. An example of that was an epicardial pacing lead that had a steroid-alluding tip. The market for this would probably be 10

to 15 units a year and if memory serves me correctly, the evaluation fee was somewhere around the $50,000 mark. We deemed that that was just a waste of time. There is a system in place called the IPU system which would enable us to supply that to a patient if that patient actually presented, so it's not as though we are withholding devices back from the public; it's a case of you wouldn't freely market it because of the high cost of evaluation.

I might say that one has to question the evaluation process, because the company does exhaustive testing to get it to a condition to be represented in the marketplace anyway. I cannot think of any instance where the TGA has said, "You cannot allow this into the country," because they simply do a paper evaluation. If an issue eventually occurs it is after it has been implanted in a patient for two or three years. You can't assess from just the data that comes in, you know, in the paper form. It has to go into a person's body before any of these other issues come to the fore. So that begs the question of the role of the TGA more as a policeman to stop something coming in. It would be better if they were to then act as the post-market surveillance body to make sure that over time and the performance of what came into the country was in fact absolutely appropriate.

MRS OWENS: Could I just ask, with their paper evaluation, does that involve looking at how that device has actually been used in other markets?

MR RYAN: Yes.

MRS OWENS: So they might say that that's almost like, you know, an evaluation; a post-market evaluation.

MR RYAN: I think you can do an evaluation to make sure that the company has taken the appropriate steps, but it doesn't need to take eight months and it doesn't need to cost $73,000.

DR STEWARDSON: Thank you for that example that you gave. I do think that if, you know, as an organisation you were able to give us other examples - - -

MR RYAN: Sure.

DR STEWARDSON: I mean, it's better for us if they are not commercial-in-confidence because they are reports public, but at least if there are some that have to be that way, commercial-in-confidence, so be it; but I think it would be helpful if we could have some more examples, please. I think also it could be helpful if we could take up your offer in attachment 2, which I think is a very useful attachment with those international comparative costs of testing, but if we could take up your offer of comparative examples on a commercial-in-confidence basis of costs of making the tests by the notified bodies overseas, that would be very helpful if we could do that.

MRS OWENS: Is that sort of information available?

MR RYAN: Yes, I have two particular examples here which we have dated around 30 September last year. Well, that's when we accumulated the information. We had an implantable defibrillator which in Australia costs $32,265 and took seven months to evaluate. In the US there was no fee and it took six months to evaluate. Canada, $12,500, it took three months to evaluate. The European body, $48,000 and two months to evaluate.

DR STEWARDSON: Can you just remind me of the Australian cost?

MR RYAN: 32,265 and seven months.

DR STEWARDSON: So it's a bit more expensive in the UK, but much quicker.

MR RYAN: Yes. Now, there could also be some structural difference in the way they work out the fees. Here in Australia they tend to - because of the number of models that you have in a particular group they tend to give you a fee for each of the models, which in my view is only a fund-raising activity. It doesn't help any evaluation process at all.

MRS OWENS: Are they fees that are based on different levels of risk?

MR RYAN: No.

MRS OWENS: What are they justifying then?

MR RYAN: If you have got 50 models you will get $50,000; if you've got 10 you will get $10,000.

MRS OWENS: There's no difference for the workload for the TGA?

MR RYAN: Not that I'm aware of. I won't say that that would be an emphatic response but I can't see that there would be a huge difference in the workload. I will give you an example. Recently we had a change of the packaging of one of our implantable leads. We rang up and got a quote for $5000 for the evaluation, which in itself is a bit ridiculous because you are only changing a piece of plastic and the peel-away top, and we were told that that would cost $5000. Fine, we said, so we sent in the application. We got back an invoice of $46,000; $5000 of which was for the total evaluation, plus $1000 for every single model that was in that group, and there were 41 of them.

I have written an objection to the TGA and I have been told that they're looking into this on an urgent basis, and I'm yet to hear what the outcome of that is, but what I think is occurring there is that there's probably a practice within the TGA that's saying, "Well, whatever we can charge we will do that as a multiplier for a number of different models."

MRS OWENS: For a revenue raising device.

MR RYAN: It would appear so.

MR VALE: Commissioners, if I could comment.

MRS OWENS: Yes.

MR VALE: Rosemary Hides that sits across here has fees and charges in detail and can certainly provide - if I can put words in Rosemary's mouth - details of some of the notified body arrangements in Europe, but our judgment industry-wide is that the TGA is unable to be cost comparative and cost effective here when lined up against these international agencies as a direct outcome of the 100 per cent cost-recovery regime. It's for that reason that in this transition to 100 per cent cost recovery that we have suffered those increases of 30 to 50 per cent in 97-98 and 43 per cent in this current calendar year, with a projection and a warning on my desk now that we're about to face another series of increases, and that's just not tolerable by an industry that is facing pressures that are pushing prices downwards and pushing the industry more offshore and reducing choice.

DR STEWARDSON: I don't quite understand something you said then. You said that the TGA was not competitive in its prices, or with its prices with the overseas bodies because of the 100 per cent cost recovery, but the notified bodies, I take it, are recovering 100 per cent, indeed plus, presumably a profit margin of their costs, so they are comparable in that respect. Why is it that the TGA is not?

MR VALE: I can tell you in the one example there, attachment 2, that for instance, the notified body costs, even in that particular example given, bring in the total cost of applications and assessment in Europe below the Australian standard. Rosemary might say something about how organisations work with the notified bodies to establish a relationship which means that such things as good manufacturing practice are certified up-front and then costs are negotiable thereafter.

MS HIDES: Basically I mean there are two things. The first thing that I think I should point out is that you can't compare the TGA with a notified body because the notified body indeed recovers all its costs and makes a profit, yes, but the TGA is not recovering only evaluation cost. It's recovery all the other costs. Like the cost of training overseas regulatory authorities and the public interest costs, and those sorts of things, which a notified body of course is not doing. If a notified body went to train another notified body they would of course charge them for it, whereas we are covering those fees and charges.

With a notified body, from what I have learnt from organisations, it's like any other business. I mean if you can volunteer that you will go through a notified body with all of your business, and you have a large organisation, you can negotiate of course on the costs that you will pay, because first of all if they have evaluated your plant in the first instance then they do a sort of review of the evaluations, the auditing

system. They already know it. They don't need to totally audit your system again, and, as I say, a large organisation can offer all their products going through and therefore negotiate a lower cost for themselves. A small organisation can't do that and so they're in a similar position as they are with the TGA. With the TGA there is no negotiation.

As far as the different products are concerned the TGA does come to the party, I must admit, if you have a lot of products of a similar type. You can - - -

DR STEWARDSON: Sorry, did you say "dissimilar"?

MS HIDES: Of similar type. If you have a lot of products of a similar type you can negotiate with them to reduce the cost of the evaluation overall, but they are very specific on what they consider to be similar. Different sizes, for example, of the same product sometimes will each be evaluated separately because they feel there might be some difference. In other instances they say, "No, it's okay." For example, an electrical lead - they say that an electric lead of different lengths needs to be evaluated because there might be a difference in them; a difference in the resistance, or something like this. A lead is a lead, some people say. I mean it's very subjective how the TGA will charge and quite often it's not necessarily comparable

You can ask you a question and they will say, "Yes, we will charge you X." You put it in and actually that's not what happens. Somebody else looks at it and looks at it, again subjectively, and you really have no basis - I mean the regulatory affairs managers with whom I deal come to me and say, "Look, you know, I can't necessarily work out how much this product is going to cost," because I have one product with a number of small minor variations - "What is it going to be?" - and you don't know.

MRS OWENS: I was just going to ask of the notified bodies, you can choose which notified body you can go to?

MS HIDES: Absolutely, yes.

MRS OWENS: So again there's competition there between the notified bodies.

MS HIDES: Yes, there is.

MRS OWENS: That also is a means of promoting efficiency within each one.

MS HIDES: Yes.

MRS OWENS: There's an incentive for them to be efficient and then to compete with each other when they are negotiating with you.

MS HIDES: Of course, because I mean especially with the larger organisations you do wield a lot of power. If you are going to give them a lot of business over a year

of course they will come to the party and especially for multinationals, for example, where they not only have one manufacturing plant, they have quite a number. If they can offer those - you know, evaluate all our products, evaluate our various plants, of course they are going to get a better deal.

DR STEWARDSON: You don't see that as a bit of a risk?

MS HIDES: In what way?

DR STEWARDSON: That if I'm the person that's going to be evaluated and I can offer a whole lot of them that the regulator may be induced to perhaps be a little marginally lenient on me not to lose my business?

MRS OWENS: No, you accredit the regulator.

MS HIDES: You have to be accredited, and the other thing is there is the review system for the notified bodies. I mean they do go through a review and if there are any complaints - and comparative agencies, like the TGA, for example, has gone back to the EU and said they've had some difficulty with a couple of notified bodies. They will go back and they will look at those notified bodies physically to see whether they do indeed meet the standards. I mean to lose business altogether, you don't do it.

DR STEWARDSON: Do we have qualified organisations that could do this in Australia? Your suggestion is, in effect, that there should be the equivalent of notified bodies here. Do we have the capacity and sufficient firms to do a competitive thing?

MR VALE: Perhaps if I could pick up on that. I think it's wider than just our suggestion. I mean our industry will judge that this industry commission study that was developed in 1996, and with which I think the commission has obviously had some detailed knowledge, is probably the most comprehensive look there has been at the whole issue of regulatory requirements and conformity assessment, and yet the recommendation here to separate the functions between setting the rules and then judging by them the conformance assessment function is something that appears to have been discarded with the federal cabinet decision for the shape of the new legislation which is currently in the drafting stage.

Having made that point, this report acknowledges that that capability would have to build. Clearly we already have notified bodies that operate in Australia. They come here and they actually do work on behalf of their companies, and these are the European notified bodies, and our association has been approached by the likes of the Monash University biomedical engineering element in conjunction with Latrobe to be able to compete for work in this area; in a tertiary environment where they are begging for opportunities to deliver skills and actually earn income. It's not there in a mature form today and it won't be there if we don't give it an opportunity to develop, and at the moment there's no intention to create an opportunity to allow it to develop because the key findings and the key recommendations in this report are to be disregarded and the intention is to leave the regulatory function embedded in the TGA

alongside the conformity assessment function.

MS HIDES: Could I add a little to that. That is assuming the TGA actually does have the capacity to actually evaluate or devise this. I don't think capacity as in a number of people but I mean as in expertise, and they actually don't have expertise in all the areas that medical devices cover. It's such a broad range, they have to farm work out as well. They have to get information or get technical expertise, so there is no reason that an independent organisation can't buy in a certain expertise.

MRS OWENS: Presumably, you could buy in some of that expertise from overseas if you need to, if you were talking about a particular device that was very very unusual.

MS HIDES: Yes, or any new technology.

MRS OWENS: I mean we are in a global economy now.

MS HIDES: That's right, so I don't think that that could be used as a genuine argument there, because you can buy in expertise if you need it.

DR STEWARDSON: Leading on from that, you've said somewhere in your submission that the planned new legislation allows for some recognition of overseas agencies here. Can you explain that to us, tell us what is planned?

MR VALE: The thrust of the new legislation is to allow the TGA to become more of a post-market vigilance surveillance organisation, somewhat akin to what Warren was saying before, and we think that that's very appropriate, because again we would judge that their skill sets are not always the most competent to do device evaluation, the point Rosemary has just made. But their strength would seem to be in the ability to track devices and see how they're performing in the marketplace and be a good policeman in that regard. To do so, they first have to align the Australian standard with an appropriate European standard and that's the path we're going to follow, a European standard, not the United States standard, and then recognise the notified bodies overseas.

That's in place now under a memorandum of agreement or a mutual recognition agreement and we're in a confidence-building period, where we look at the lower-risk medical devices being assessed overseas and coming through for a quick five-day evaluation and entry to the Australian market, a really promising outcome, quite frankly, something that is attractive to industry and presumably will bring down costs. But it's hard to see, on the other hand, how it will bring down costs when, at the end of the day, the TGA doesn't relate the cost of the service to the actual cost that's related to the need to recover 100 per cent of its budget and if you look at the figures of the department for the last two years and see that they have had to draw on reserve funds in the last two financial years to stay head above water at the $50 million or thereabouts expenditure, it's clear that they cannot go on drawing out of a diminishing reserve fund; their fees must increase.

DR STEWARDSON: Can we just look at this risk business. You said that it was low-risk products - I think that's the term - where there was this arrangement of mutual recognition being introduced. Again, really a question for information, what categories of risk versus intensity of testing does the TGA have at the moment? Is it simply the two categories of what are called "registered" versus "listed" or is there a finer categorisation of risk versus intensity of testing trade-off and where do your low-risk categories that are going to be mutually recognised overseas fit in in comparison with the answer?

MR VALE: If I may, I'll ask Rosemary to answer that, but just preface it by saying we currently have two categories, listed and registered, and registered picks up about 12 categories of higher-risk products. There is a lot of material in what you might generically say are in the low and high that are not picked up under the regulatory system today, but will be in the expanded system, and we endorse that because it brings greater safety for us and for the consumers. Rosemary could explain just how that shift is occurring from the two categories to effectively four.

MS HIDES: Currently, you have registered products, which are the high-risk products; you have listed products, which are generally lower in risk; and then you have exempt products as well. What is happening first of all, is we're going to four different classes and that is the same as the European system basically. We're going to have the very low class 1 products which currently are not listed products, they are electrical equipment and things like that, some surgical equipment. They are going to be class 1 products, where the manufacturer is just going to certify that they are doing the right thing, if you like.

MRS OWENS: They just self-certify, anyway.

MS HIDES: They just self-certify, yes. But they are going to be picked up, so there's actually going to be a recording of those products, which currently are not. Then there's the class 2A, 2B, a class 3 and then the active implantable medical devices, which are of course the highest-risk products. That is the way it's going to go into the new system. There are going to be a number of changes. There are a few products, actually, which are going to be increased in category from what they are now. In other words, they now might be listable, but the level will go up, but there will be other products that are considered a lower risk in the EU and they will change category as well.

DR STEWARDSON: Do you regard this - was it four altogether - that that categorisation is an appropriate one or is it fine enough in other words?

MS HIDES: Yes, and it's really of value to us, because it means that we are then compatible, basically, with the EU and it means, too, that it will simplify the system, because our products will be categorised the way the EU are and a lot of our products, as Brian has said, come from the US and most US manufacturers, of course, sell in the EU anyway. When the new system comes in, they will already have

products that they have in the EU that are approved and they will come in the same category into Australia, so that that's going to simplify the system.

DR STEWARDSON: Which category is it that's going to have the mutual recognition?

MS HIDES: The mutual recognition is currently in place. There are a couple of problems with the mutual recognition agreement. The low-risk ones can come in and have a five-day turnaround, but I honestly haven't heard of anyone doing it yet. The higher-risk products are coming through. They're going to be in the process of 18 months of evaluation period where the EU and the Australians will both evaluate the products and make sure that they are comfortable with the result. That hasn't started yet. The EU keep putting it off, but what they are doing at the moment - the reason they are not willing to do very much is because under the mutual recognition agreement the EU countries are evaluating to Australian requirements as they are currently and vice versa. When we change the system, the system will be the same, so the evaluation will be the same. Currently Australian requirements are not the same as the EU requirements.

The mutual recognition agreement only works for products which are manufactured in the EU anyway and the majority - you know, a vast percentage of the products currently are manufactured in the US so that they don't fall under the mutual recognition agreement anyway.

DR STEWARDSON: Is it category number 3, the top one, where there is not going to be mutual recognition?

MS HIDES: No, everything is covered by the mutual recognition agreement, but the mutual recognition agreement only covers products which are manufactured in the EU. The high risk products currently though are - well, t he process of agreement hasn't actually started yet as far as agreement on evaluation results are concerned.

MR VALE: Could I comment that it's an area that we have to watch, because if we were consumers we would think perhaps that those high risk products in particular would want an Australian level of evaluation applied, but in fact if you think that many of those products we see very low volumes, they are very sophisticated devices, the likes of which Warren's company sells. We don't have much expertise here. It's arguably the area where you really don't want to get into evaluating them, but rather draw on the skills of people who see lots of them in specialised notified bodies in Europe. An industry would argue that that's one where TGA shouldn't be tempted to try and hang onto that, because at the end of the day the volumes and such that go through there don't suggest that we would necessarily do it well.

DR STEWARDSON: Can we, just picking up on that point about volumes, come back briefly to attachment 2 again. You gave us these very interesting figures of an example of this particular product, whatever it is, where the assessment fee was 76,000 in Australia and you worked out for us the size of sales that would be required

to recoup that on certain assumptions about tax and so on. Can you give me a bit of a feel for a typical size of the Australian market for products? I mean, are we typically - is that sales figure that you have calculated there something that is very high or very low by comparison with your sort of normal product?

MR VALE: I will give a specific example in a minute, but do you want to make any first, Rosemary?

MS HIDES: No, go on.

MR VALE: I think on the public record in submissions, Cochlear is one of the companies that has submitted a response. I think their figures make very clear - and certainly their annual reports reflect this - that while they are an Australian based manufacturer, only 5 per cent of their product is sold in Australia. I think they have demonstrated in their figures - and they are paralleled here - the number of units that have to be sold in Australia to recover the outlaid costs in Australia versus outlaid costs for registration and annual fees in Europe and the United States. I think those are some concrete examples that are before you.

MRS OWENS: Yes, we will be seeing Cochlear. Yes, they have got a very useful little table in their submission which shows that.

DR STEWARDSON: It's useful information. What I am trying to get at is how many of the products of your industry pass this hurdle, if you like, of having a big enough potential sales to clearly recoup the cost and how many are marginal. That's just a rough feel - - -

MR RYAN: I think you could safely say that implantable pacemakers, defibrillators, more than cover the hurdle. The issue that our company has is not just the price for the work done, but it's the relative cost compared to overseas bodies and the time taken to achieve that. Getting back to your point about class 1, 2, 2A and so on, currently a coronary stent is a listable device in Australia. In the European scene I think it's a class 3, isn't it, which means it will have to be evaluated.

MS HIDES: A coronary stent.

MR RYAN: Coronary stent. You can't get any more implantable than a coronary stent. It has always been something of a farce in this country that for $125 and a photocopy of the label on the box you would get this thing approved, yet the device itself ends up in the coronary arteries to keep them open. Now, one would have to question the commonsense of that, so getting back to the need to go down the European path, that path makes much more sense than the existing one we have in Australia.

MR VALE: But across the board I think your question is unable to be answered by us, because the product range is so diverse. I mean, I have to cross the spectrum from bandaids to those defibrillators.

MR RYAN: That's right.

MR VALE: And that's very difficult to see. You know, it almost goes back to your earlier question of can we provide examples of products that don't potentially have the ability to return the capital outlays. Without trying to sound alarmist, in New Zealand, an unregulated market, there are examples for instance of HIV detection kits that are far superior in terms of the recognition of the disease than you can get in Australia and you won't get them in Australia because of the high costs of registration and the short market life of the product. But in an unregulated market they are available.

DR STEWARDSON: Well, that sort of example which you have just given us is on record is useful.

MR VALE: I am loathe to put that one and we haven't, because they sound alarmist in nature, but it's a fact of life.

DR STEWARDSON: No, if you have got examples, that sort of thing is a relevant one.

MRS OWENS: That's an excellent example.

MR VALE: We don't want an unregulated market though. We don't like the New Zealand market. It's not a safe market, in a sense.

MRS OWENS: Can I ask you about the TGA's accountability back to the industry? Does the TGA discuss your concerns with you. Have you got an opportunity to talk to them about their attitude to risk, about their costs, about the pricing, the price increases in the future? Is there a process that you get involved in? We have got other examples of other groups that do have industry consultative committees, for example, the pharmaceutical industry does. Do you have an equivalent body and does that give you any joy? Do you get an opportunity to express your concerns about the recommendations in our previous report not being fully picked up?

MR VALE: Is there a form; yes, there is. It is called TICC which stands for the TGA Industry Consultative Committee and the pharmaceutical groups and the nutritional food groups and such are part of the TICC process. TICC meets twice each year - - -

MRS OWENS: I didn't know you were involved with TICC as well.

MR VALE: - - - and we are a part of that, so I will say nothing further on that, except that the terms of reference for the TICC have been revised several times. The current draft of the new terms of reference is on all desks at the moment, including my own, and it makes very clear that the TGA remains a government instrumentality, not any outside agency in the form of - what is the word I have lost again?

MR RYAN: Statutory - - -

MR VALE: A statutory authority which was one of the things obviously recommended here, and that as a government body it is accountable to government and not industry. Therefore there are clear limits in terms of how accountable they see themselves to industry. My judgment is that industry will continue to have an extremely limited ability to influence expenditure and accountability, no matter that we pay 100 per cent of the costs of the TGA, whether they are parliamentary, public industry or industry-related. With regard to discussion over fees and charges and safety issues, I would point out that the TGA is receptive at all times, in my experience, to sit down and talk with us on those issues beyond the TICC meetings. However, at the end of the day they have to recover 100 per cent of their costs.

While we were prepared from our industry sector to talk about 5 and 7 per cent fee increases which were above those that by and large our products were able to win in the last 12 months, we were offered 71 per cent fee increases. Were it not for the personal intervention of Senator Tambling that probably would have been the outcome. We had 43 per cent handed to us.

DR STEWARDSON: Can I ask your reaction to an idea that somebody floated? I should say this is not specifically a Productivity Commission thought at present, but it's an idea that has been floated. You have got this problem of the TGA, the efficiency of the TGA, the time it takes to do things, the sort of problems that you mentioned much earlier about charging an extra $1000 for all the different models and so on.

Some people have said to us, "Well, yes, there's the TICC, but they don't give us enough information for it to be an effective body. They give it to us too late and even when we do make comments they don't take any notice of us." You have a problem, that if the TICC had real authority over the TGA then the people who are being assessed would be in control and the assessor would no longer be an independent body. So you have a problem of how to reconcile these two things, of people such as yourselves having an effective input on the efficiency and so on, without having control.

If you had a thing that we might call an efficiency audit committee analogous to an audit committee on a company board, the audit committee of course is just looking at finance, but if you had an audit committee that looked at the efficiency of the operation, not looking at what the standard set was, but how it was applied and done - if you had a body like that that had representatives such as yourselves, maybe the ultimate consumers, maybe some of the regulator - and if that body just like an audit committee reports to the board of the company, if that efficiency audit committee, if it's a statutory body, reported to the board of the body, or if it's part of a government department it reported to the minister, so that it was reporting not to the chief executive officer of the regulator, but to the person above that who actually does have control over the regulator and who could then receive the audit committee's

report and say, "Yes, I think that's a good idea, I will tell the regulator to take notice of it," or could say, "No, I'm not going to take notice of that," do you think that would be a practical and effective way of trying to resolve this issue of balancing the useful input from people like yourselves without you having the undesirable control?

MR RYAN: I think, off the top of my head, that would be a very desirable approach. One of the concerns I have, having reviewed the accounts of the TGA, is the enormous amount of money that gets spent on things that one would have to say, "Do you really need to spend that money to achieve the outcomes that you are there to achieve?" I think that the creation of something that you've just described would probably go a long way to say, "Are you spending the money in an appropriate manner?"

MR VALE: I agree. I think that would be a significant lift in level of accountability without in any way, abrogating government's responsibility, at the end of the day, to manage the government agency, but to be listening to the people who are the prime users and the funders for it. The additional measure that could be considered, and one that we have put forward is that we thought there might be an opportunity to actually chair that process of TICC from another related government department such as Industry Science and Resources that has a - - -

DR STEWARDSON: You say to chair it?

MR VALE: To chair it - having a fundamental relationship with the pharmaceutical and medical devices industries, and I think some of the other industries who were there at the table, but are, to some extent, seen as impartial from the hands-on processes that the TGA is bound to deliver. We thought that that still left control with government and yet would bring that degree of impartiality to it.

DR STEWARDSON: If that could be considered, perhaps, with the efficiency audit-type approach.

MRS OWENS: We might think of a number of different approaches. I mean, one of the arguments that is always put forward for cost recovery is that it potentially can lead to the agency being more responsive to industry, because if they're paying 100 per cent then the agency will be responsive, but I am yet to see what the link is between paying the money and being responsive if the agency is a monopoly and you've got no choice but to go to that agency. I have a little bit of trouble with that particular logic, so maybe we have to introduce some other way of getting that responsiveness.

Can I just change the subject, because I think we're going to run out of time soon. I want to leave just a few minutes to talk about the Zyro issue, because, Dr Cornell, I think you mentioned that you wanted to discuss this. You raised a couple of issues in the submission: one is an issue that was around years ago when we did the R and D inquiry, and that is the problem for particularly small cases facing Zyro charges to get to their 30 per cent cost recovery target. The other one is an

issue which I hadn't confronted before, which may be getting a bit beyond our terms of reference, which was this proposal to adapt the START grant so that it could cover the costs of using Zyro infrastructure and staff.

DR CORNELL: Just very briefly, talking to this: MIAA, the organisation we're representing here, covers both a range of large importing companies, but also a group of relatively new start-ups, which are aspiring and very much need encouragement of the Australian government and the rest of the population - aspiring to try and put in place a high-value industry which addresses this market, obviously not only for a domestic market, but also for an international market. Having been through the process of being involved in, firstly, the securing of patents, then the gaining of money and now the actual setting up of an independent company with no support from government at this stage, the thing that is so very apparent as the big disadvantage of trying to have high-value industries in Australia, going this path, is the fact we not have, as we were discussing just now over the tea break, a DuPont, we do not have a 3M, we do not have the myriad of support industries that a similar-sized company in America would have, or in Europe would have.

So it means we are at a very big disadvantage in Australia trying to have the next level beyond the start-up. Of course, we all know the amount of encouragement that is being given now to academics, government scientists and the like to go out and try their hand at being entrepreneurs. No sooner do they do that than they run into the brick wall of the fact that there is no life support system, in terms of engineering and technology, to allow them to go forward. Whereas that life support system has traditionally been invested in Australia, certainly over the last 30 or 40 years in terms of massive government funds being directed towards technologies and engineering, it is within our major research organisations of which CSIRO is the premier.

So the point I would raise would be the fact that CSIRO was, scientifically, very rich in skills and a very excellent organisation in terms of its engineering and technology base, and yet the very products of this push within the Australian population to try and grow such an industry is barred access to CSIRO by virtue of the pressure CSIRO was under to charge at the level they are obliged to charge, of times three the base salary, that you would ordinarily be paying to a person, or the base contract fee that you would ordinarily be expecting to pay in the open marketplace, because they are under pressure to get cost recovery.

It's a bizarre situation in which you have - admittedly it's a statutory body, it's not directly a government organisation, but it is attempting to operate in part as though it was a commercial organisation, and it is not, which means that you get overheads which are unreasonable and not at market levels being addressed to anyone who tries now to access that which has been set up as this missing infrastructure by public money. For our company we find it both cheaper and faster to actually go to North America, to access much of the infrastructure that we could access only a kilometre up the road with a range of CSIRO divisions who have excellent scientists and excellent facilities available.

Now, realising that this is something which probably is at a more in-principle level than would be fairly directed to this inquiry, it's an issue that I've felt strongly over for a number of years, but something that practically, I think, could be done if it was raised with Ausindustry to have one of the boxes that you ticked on something like a START grant that says you could get access to the staff, facilities and equipment within CSIRO for the period of a project. I think that if indeed that was available to you, rather than getting money which you then had to go back and give back into CSIRO at some inflated rate to get access to those capabilities. If indeed you had access directly, I think that it would solve the other issue which Australia is facing in terms of trying to grow a high technology high-value industry, and that is this question of job mobility in the science and technology area.

The fact that there is not the kind of free-flow between industries in Australia as you would expect to have on the west or east coast of America. If indeed CSIRO staff were now contracted out with the ticking of the appropriate box, in say a START grant as an example, I think this would now introduce them to a world outside. It was not perhaps quite as foreign or as inaccessible to them as might be imagined whilst remaining within the organisation.

MRS OWENS: It probably would be a good thing, if you haven't done so already, to talk to the new director.

DR CORNELL: I've not yet had an opportunity of talking to the new head of CSIRO. I've submitted these ideas to Rob Battam, as part of his review, and also indirectly to Senator Minchin as part of a backbencher inquiry into science and technology in Australia.

MRS OWENS: Yes. I think the dilemma we face is that we are meant to be looking at administrative information and regulatory agencies, Commonwealth agencies, in this inquiry and that's what our terms of reference tell us to look at but at the same time we'll be developing a set of government guidelines relating to cost recovery and, as we see it, those guidelines could have broader application than just those particular sorts of agencies, so although we may not look at the CSIRO directly the outcome of the inquiry may have some indirect impact back onto that agency because we may, for example, have guidelines that say, "Thou shalt not" or, "Thou should not have revenue targets, cost-recovery revenue targets." I don't know. We haven't got to that point of deciding that yet, but that may be one of the outcomes.

DR STEWARDSON: Can I just ask a small question of detail? You said - and I think with a critical implication - that CSIRO was charging by the formula of three times basic salaries. That's not an unusual formula in quite a number of industries where there is a good deal of service component. Was your implication that overseas in the scientific area that that was not an appropriate formula?

DR CORNELL: For the period of time for which that salary would be asked, for the manner in which the project would be administered, overseas we can indeed for a fraction of the money get a much more responsive direct answer to the inquiries we

would make with it. The formula is very much - because of the say we see Australia structured - is that one would be looking for a major chunk of time - be it six months or 12 months - to pick up the overhead essentially for a full-time staff member to address the problem you are asking me about, and furthermore that that staff member would be given the problem, would go away and address it.

I think the formula - just pursuing this model - that would be appropriate is the fact that the allocation of resource would indeed now have the resources made part of the project for the duration of that allocation; that is, that the staff would work within the administration of the company and that there would indeed be access by the company directly into the facilities and equipment of the CSIRO. It is a question of efficiency, of timeliness, as well as cost, but one starts with cost.

MRS OWENS: I think we probably need to move on to our last participant for the day because it is getting late, but I would like to thank you all very much for coming. Have you got any other comments you would like to make before we close this particular session?

MR VALE: I think we have addressed all of the issues but we would hope that somewhere in this there is an opportunity to, I guess, redress this really unacceptable level of charging at the moment and the government's intention to step away from what appeared to be a very sound set of recommendations that potentially offered competition in the marketplace, which seems to be denied in the model to come.

DR STEWARDSON: If you could perhaps follow up some of those examples that would be helpful.

MR VALE: Sure.

MRS OWENS: Thank you very much for that.

MR VALE: Thank you very much.

MRS OWENS: We will just break for a minute while we have a change of the guard.

MRS OWENS: The last participant today is AWIN Services Pty Ltd. Welcome. Could you please give your name and your affiliation for the transcript.

MS WINSLADE: My name is Heather Winslade and I'm the managing director of the company. I thought it was useful to add some discussion. I'm part of the MIAA group and have been for a long time, but having been employed for many years by one of the US multinationals that does import into this country, in April this year I moved out of there, mentally semi-retirement that somehow hasn't worked, and I'm very actively involved in consulting and I'm being faced for the first time with entrepreneurial people who are entering this market, or trying to, for the first time. They're not members of the industry group, because they don't even know there's an industry group, and it's been quite a learning curve and I thought it was important to talk about some of those issues that are coming up for them.

Whilst we're very familiar with the sort of issues that the major MIAA people are faced with, to see someone who doesn't even know there's a regulator, let alone one to whom you have to pay money and then wait several months, is quite a revelation, and they're the things I wanted to look at with you.

MRS OWENS: Thank you, and thank you for the submission. I think it's really useful for us to talk to people who see these issues from all different sorts of angles and I think it was very useful just to have the MIAA in here and they could talk about some of the issues relating to the members more generally, but I think these very small companies who may never have had to deal with the regulator - it might be a new start-up trying to get into an industry and make sense of it all, it must be extremely difficult, and, as we did with the last participants, any real-life examples are always particularly useful for us, aren't they, Robert?

DR STEWARDSON: Yes.

MS WINSLADE: I hope you'll appreciate I am bound by confidentiality to these companies to some extent, but I can certainly talk about types that may help you.

MRS OWENS: Yes. You talked about a company that chose to manufacture overseas because of the problems with the TGA, but you weren't particularly specific. I presume that is because of the confidentiality question.

MS WINSLADE: Yes, I had two that are quite different in case studies. The one that has gone overseas has a product that is what you'd call a "consumable", a single-use type item, and the second one that hasn't yet gone overseas, but I'm not sure of the outcome, is a piece of equipment and they're really quite different in backgrounds. In the first case, it's actually quite interesting technology that they've come up with. It's quite innovative, actually, and I was quite impressed with the product. One of the problems is that, like it or not, it falls into a high-risk group and it doesn't matter which market you go to, it's classified as a high-risk product. It's going to be implantable, it's going to be permanently implantable. It has animal origin

in it, which adds an additional dimension, especially for Australia. The source of the animal is not the problem, because it's the type of animal that isn't at BSE risk. Mad cow disease is not going to be a problem.

MRS OWENS: Was this product developed here in Australia?

MS WINSLADE: With some help from New Zealand. But, yes, absolutely, from one of the universities and somebody with a bright idea and they contacted me wanting to know where to go and how to go about it. What happened for that particular company, when we looked at the markets and the available markets, in Australia it was probably considered that in year one you may look at, say, 30 implants and grow over a five to 10-year period to probably maybe 500 a year.

MRS OWENS: Is this just in Australia?

MS WINSLADE: Just for Australia. We then looked at the TGA costs and, unfortunately, there is this compounding thing that was discussed earlier, whereby if you have additionals and the variables considered, there would be additional charges, although there is no additional evaluation and this, unfortunately - we recognise the TGA has been told to recover its costs, and it comes in to obliterate then - what's a fee for service? None of it is a fee for service because, quite blatantly, when you charge a flat amount for one and then an extra 3000 for every other size and there's no additional work, very clearly this is not cost recovery. When we measured that, we figured we were probably up for a bill in the $90,000 mark, payable up-front. You pay an application fee which fortunately has now been capped to $7000. It used to potentially go on forever, but once you hit 7000, it stops.

You wait a month; if it's accepted, you then pay the next amount and you pay the full amount. Then, assuming the product is approved at the end of it - now, that approval TGA tell us they're running at roughly 120 working days, but we're not necessarily seeing too much evidence of this, so there's an unknown factor coming out the other end. Added to this, to manufacture here in Australia is the additional cost of a TGA licence, which is $6800 per annum. The set-up costs are no different in Australia to anywhere else and the standard expected is no different to anywhere else and it's a commendable standard, and I don't think it should be less. Nonetheless, it carries a cost. That cost does include auditing, that's built in.

MRS OWENS: That's auditing the manufacturing facilities?

MS WINSLADE: Yes.

MRS OWENS: GNP.

MS WINSLADE: GNP. You're not allowed to say that for devices now, you have to say "quality systems".

MRS OWENS: Okay, I'll try and remember that.

MS WINSLADE: However, assuming that you are of an acceptable standard, you don't pay repeat charges. The repeat charges only turn up if you're somebody who is not doing the right thing and they have to keep coming back and that's reasonable. Nonetheless, it adds another dimension that goes onto the cost. In this case, the decision was made when they looked at what was available in Europe in a market of 390 million people and what was available in the USA in their market and the USA had no charges, and the notified body charges in fact were looking like they would come out to be a good deal less in that particular case. The decision was made that Australia can just go hang for now. We may come back to it later, but it's not worthwhile.

DR STEWARDSON: Can you just remind us, please - because with all the different organisations, it's not easy to remember it - what degree of protection - you know, exclusive production patenting type thing - is given, if any, by the approval by the TGA?

MS WINSLADE: Patent? There is no link.

DR STEWARDSON: So the organisation would have taken its patent out, but approval by the TGA doesn't give any additional monopoly production rights?

MS WINSLADE: No, it means nothing at all, has no value in any way, shape or form. In reality, when you look at start-ups, what they've got are the two biggest markets in the world, North America and the USA, and logic says if you've got a way into those, wouldn't you take that rather than pay big money to get into a small market, because by paying the big money to get into the small market, there was no presumption of that taking you into the larger market.

DR STEWARDSON: Do you see it as being realistic to think, given the dramatic size difference of the market that you've just been highlighting, that in fact a manufacturer in the situation you've described would choose Australia under almost any circumstances - 50 per cent cost recovery, 25 and even zero cost recovery - given the other markets are so big?

MS WINSLADE: Surprisingly, there are Australian people who'd like to be in Australia. In fact, I think for them it was a wrench to make that decision. I think that they probably would have liked to have been here.

MRS OWENS: With this mutual recognition, these changes that are taking place at the moment, if they'd paid their 70,000 to get into the Australian market, wouldn't the mutual recognition mean that they would get into Europe?

MS WINSLADE: No, it would fall outside the mutual recognition agreement. The mutual recognition agreement - - -

MRS OWENS: Because it's too high-risk?

MS WINSLADE: It's only the registrable groups or animal origin or human-animal origin goods fall outside the MRA. They don't come into it at all. There is a confidence building period to be set to look at just the registrables. Forget the animal origin, they will never be part of it, and can I say I think that's probably sensible. I think Australia has a record second to none in animal origin goods and I think we need to maintain that. We are a closed herd in our own right. We don't have the nasty diseases that we're seeing in Europe in cows and sheep, and it would be good to stay that way. The consumer in me says, "Keep it up, guys." But excluding that, the MRA, the group in Australia called Registrables, are under a confidence building 18-month period. That hasn't begun because Europe won't start it, and that's Europe going, "Oh, TGA, we like you," and TGA going, "Oh, we like you too."

MRS OWENS: But they are just circling and eventually they will come together; they will marry.

MS WINSLADE: Eventually they have to. It's written into the MRA.

MRS OWENS: Yes.

MS WINSLADE: But Europe won't start it. They won't begin, so it's dragging on.

DR STEWARDSON: Who has the highest standards, TGA or the European authority?

MS WINSLADE: I wouldn't say one was higher than the other; they vary. For example, in our current group of registrables they're evaluating goods that historically had issues, rather than goods that basically can be shown to necessarily have risk, and some of those in fact the rest of the world says aren't risk and will fall out of that high risk group when we get our new legislation. The risk management that has been applied to come up with those classes is actually very good and quite a serious categorisation, which is why we're happy as an industry to accept it.

MRS OWENS: But it doesn't help your particular company because they have the animal product and it wouldn't have applied anyway.

MS WINSLADE: No.

MRS OWENS: So what you're arguing is really that it is that charge that helps. Is it the charge that tips them or is it the size of the market that tips them, or is it a bit of both?

MS WINSLADE: It's both. They would be happy to go into the Australian market if they didn't have to pay a huge amount of money up-front with an unended period. At the same time the data that has been generated can be used to get into both Europe and North America, and therefore that's where you would put your priorities, and that was their decision. The second one is a piece of electromedical equipment which was

quite interesting because they have venture capital. They are paying money to CSIRO as part of the development; it was an idea again generated from a major teaching hospital, it's a worthy generation. They have done a few clinical trials from modifications of existing equipment that is showing it very capable of working. Now they are being faced with the same problem, "Where do we spend the money?" And the venture capitalists are in there going, "What do you mean, you pay a regulator that sort of money?" And to add insult to injury we're caught up in the states having some unique additional prescriptive requirements on standards.

MRS OWENS: The Australian states, not the United States?

MS WINSLADE: Yes, the Australian states, sorry, with some unique vertical standards for compliance, in this case. So where this one is going, I don't know. Again the data that is being generated will take us into any of those markets but the tendency at the moment - the lean is to say there's a nervousness about getting involved with a regulator as a conformity assessment group, and I can't overcome that. I'm certainly not blocking that. In fact it is one of the rare areas where I think TGA has got good expertise but it's their decision. I can only make suggestions.

MRS OWENS: What's their nervousness about the regulator doing the conformance assessment? Is it the intellectual property, they worry about secrecy, or they just don't trust them?

MS WINSLADE: Intellectual property is one, but if I tell you the venture capitalist is American and there the FDA is the overriding body whom you don't openly approach; you provide what you must do under duress, and you do it. To actively approach them and say, "Would you become" - when you make a relationship with a notified body it's a very close commercial relationship, and I think this is what has been missed. That's why it is hard to get figures, because companies - it's a commercial decision. They're not going to tell you how much they are paying their notified bodies, thank you very much, because it's a competitive type thing, but also you build a very strong trust relationship. It's a relationship where they come in, they audit, but they're trusting you to do certain things, and for you to generate the data - it's a relationship that I'm not sure you could ever build with a regulator. I don't know that that level of trust could appear between the two. I'm not sure.

MRS OWENS: As the previous participants pointed out, we did do an inquiry in 1996 looking at this whole issue, or that was part of the inquiry.

MS WINSLADE: Yes, I know.

MRS OWENS: We did make some recommendations on that issue.

MS WINSLADE: We were very much a part of that and of course it was disappointing to find it was ignored.

MRS OWENS: I was disappointed too because I was involved in that inquiry.

DR STEWARDSON: I'm still a bit uncertain, and I know the implication of your reply to my last question was that I was taking a rather unpatriotic view, but - - -

MS WINSLADE: Not at all, no.

DR STEWARDSON: No, you were. It's quite reasonable. I'm still not clear why the Australian company is going to choose to develop this product in Australia when the market is so much bigger in either America or England, if it gets the go-ahead there.

MS WINSLADE: The first single use, they're not. They're now saying we have gone as far as we can go; we are going offshore.

DR STEWARDSON: Sorry, what I meant was even if the cost recovery regime were much less stringent in Australia than it now is. Even if there wasn't that up-front cost, you've still got such - a larger market to defray your development costs.

MS WINSLADE: You can still reach those markets by exporting into them, and they would have been happy to do that. It became a matter in order to proceed further quite significant clinical data needed generating, and that certainly could have been generated in Australia, and they were getting ready to do that, and it was felt to make decisions at this stage - and a lot of it was based on that very high up-front regulatory cost that said, "If we need to put - where do we need to spend our venture capital," and one of them was in data generation and ongoing data generation. For example, they approached the US and got what's called IDE status, which is the status which says it's an investigational exemption, therefore the product could go under clinical trial, and that is then generating data that FDA is really comfortable with.

FDA will certainly accept Australian data but they like to come out and audit you before they accept it. It's little jaunts for the boys sometimes, but that's a fact of life. So when all those factors were looked at the decision was made that the commercial realities were going overseas and one of the critical factors was that very large up-front bill. It played quite a significant role, I think, in their decision. I mean I can't swear blind to that because I wasn't completely a party to it but that was the impression I got.

MRS OWENS: Another issue that you raised in your submission, right at the end, was about the microbiological laboratories for testing and you said that manufacturers can only use laboratories that are TGA licensed. What about the TGA run laboratory in Canberra? They can use other laboratories or is that - - -

MS WINSLADE: No, if you're a manufacturer part of routine manufacturing is you have to have testing done on your environment. This is basic microbiology.

MRS OWENS: So it's not testing the initial product that has been produced?

MS WINSLADE: No.

MRS OWENS: I misunderstood that, because I understood that the TGA laboratory basically had a monopoly on testing products.

MS WINSLADE: No, but the fact that they insist on licensing - now, they don't audit them, they reserve the right to audit, because they know NATA is doing the auditing, but it does restrict your ability to choose a laboratory. We were actually having to send goods to Melbourne, believe it or not, when there are quite good test houses here in Sydney that could have performed the tests when wanted. They said, "No, we're not going to have another licence, thank you."

DR STEWARDSON: You talked about the TGA being now regarded or classified as a conformity assessment body which, I take it is, in effect, a notified body, but an overseas one from the European point of view?

MS WINSLADE: Yes, you can't be called a notified body if you're not based in Europe.

DR STEWARDSON: And you said that it wasn't very well regarded in this role. Are you able to expand a bit on that? Has it been shown to be inefficient or expensive, cost comparisons with notified bodies or what?

MS WINSLADE: I'm not sure that I can say that it's not well regarded, but it comes back - what the MRA was about was to say that a very select group of notified bodies from Europe can approve goods to Australian standards, and that's the five-day acceptance rule here, unless they are registrable and then the confidence building comes in, or animal origin, in which case they will never come in. The TGA conversely was given an appointment as a conformity assessment branch, which enables them to CE mark goods for Europe. I'm not sure how many people they have actually undertaken this for, I think it's fairly limited to date, but this was the concern that I had, that companies won't see them in that light, they won't accept them. This was the problem I was faced with. They said, "No, they're the regulator. We're not going to them to form a commercial relationship." They felt that there wasn't a confidence available to be able to do that.

MRS OWENS: So it really wasn't about the internal workings of the TGA or its efficiency? It was just this perception that the regulator - - -

MS WINSLADE: I think they're all part of it. If there's not an efficiency now that would be acceptable from a commercial relationship, is there a guarantee that under a commercial relationship it will be? The notified bodies, in fact, move quite quickly with their big customers. They know it's competitive; they know getting products to market, especially where models have a very limited life span, is really quite critical. I don't think we've seen that sense of urgency as a regulator, so the suspicion is would we see it as a notified body or a conformity assessment?

DR STEWARDSON: So I take it that you're in favour of farming out, if you like, the assessment work within Australia?

MS WINSLADE: Yes, absolutely. I think, as we've said, we see in manufacturing that production and QC never report to each other. Why? Because one is checking on the other and you can't check yourself. So why is a regulator making the rule and checking the rule? It's the same issue. That's why Europe chose to have the notified body scheme, they came up with that idea. We've now seen, in fact, the FDA accepting similar where they have appointed bodies. Admittedly you have to pay for them, but if you go to these approved bodies they will scan your product and once they have given an okay it then goes to FDA who almost rubber-stamp it. So you pay for it. You make a commercial decision, but it gets you to market very quickly and they have approved certain bodies to do that.

DR STEWARDSON: Can I just get a little more detail on what you said a moment ago. By analogy with the production department and the quality control department you shouldn't have the same body making the rule and checking the rule. But what are we meaning there by "make the rule"? Are we talking about setting the standard or are we talking about that initial assessment of the product?

MS WINSLADE: The assessment is the testing, the QA part. The making the rule which, in theory, is the consumers saying, "We want this level of protection," and a regulator sets out the expected standard to be met. For the regulator to then be testing it to see if it has met that standard in a manufacturing sense would not be accepted, because the QC people are the ones who test to see if it has reached that point.

DR STEWARDSON: But is that fair comparison with production and QC in manufacturing?

MS WINSLADE: Why not?

DR STEWARDSON: I mean, production is the actual doing it and QC is the testing it.

MS WINSLADE: Yes.

DR STEWARDSON: Whereas in the other it's testing versus setting a standard. It's not the actual doing it, is it? I would have thought that the comparison was if you asked the manufacturer to also test.

MS WINSLADE: They're setting themselves up as a government analyst, as the final arbiter, and that's a QC role. They're also setting the rule which you meet. In production they set up a specification and QC test to see if you've met it. The role of production is to have a specification.

DR STEWARDSON: I must read that document that the Productivity Commission wrote.

MRS OWENS: Yes, I don't think we sort of set up a principle like that. I think our principle was more based on just the efficiency arguments that with a number of conformance assessors out there competing you're more likely to get more efficiency. I don't think we actually tried to pin down a point of principle, like Robin is trying to pin down, because I think I agree with Robin that they're not strictly analogous to the production quality control. I mean, I can envisage that you could have a regulator setting standards and then testing against those standards, but I think we'll think about that one.

MS WINSLADE: Sure, let that one through to the keeper.

MRS OWENS: Yes, we'll let that one through. It's getting a bit late in the afternoon.

DR STEWARDSON: We'll think about it. That's why I was asking you, to get a bit more information I can be thinking about.

MS WINSLADE: Yes.

MRS OWENS: Have we got any other issues?

DR STEWARDSON: I think we have covered most of it.

MRS OWENS: I'm always surprised when we do these hearings, how we can get a lovely short submission of two pages and we can still talk for so long. But I think that's just an indication that we are interested in the subject matter and we were interested in what you had to say. So, thank you. Have you got any other final points you would like to make?

MS WINSLADE: Am I allowed to make a brief comment on something that happened earlier today?

MRS OWENS: Yes.

MS WINSLADE: I was really interested in the girls who spoke about the English Australian, because 18 months ago I tried very hard to help one of the girls from our office in China who was desperate to take on a university degree here in Australia. She spoke English reasonably well. She actually stayed with me for three months towards the end of her visa, and was accepted to go to Macquarie University Graduate School, but couldn't pass the ALTS test. Now, it was a borderline failure problem. Part of the difficulty is that in China they are really not taught to write essays. You don't teach people to think if you - the last thing you do if you want to control a population is teach them to think. Whilst we tried to spend time with her, it was difficult.

Her sister, whose English was about the same, conversely, was accepted and is currently studying in a university in the USA where they said, "Provided you have reasonable English we'll decide if you need additional training or not." She didn't have to meet TOFL - - -

MRS OWENS: Which is, sorry?

MS WINSLADE: TOFL is the American version of the ALTS test.

MRS OWENS: ALTS is English as a second language?

MS WINSLADE: Yes, which is used in Australia. TOFL is the American test. Part of her problem is that by going back up into Beijing she had nowhere she could really learn, and this is all still going around in circles. I thought, "How crazy that the others have got the idea" - she has got the money, she is prepared to pay quite large sums of money. She's really keen to do it. The university was accepting her. The graduate school was accepting her, the university is the one that actually gives them the degree and says, "You pass the test or you don't." She had to leave.

She was prepared to pay money to the school to do some English training and she did, but her visa was running out. They would not renew her visa. She could only get that renewed in Beijing, no matter what, despite the fact that I went along and said, "You know, I'm born and bred in this country and I would be quite happy to" - I know her parents. I mean, I know her stability situation. I thought, "How anti-competitive our universities are." I would also just like to mention that I can tell you from experience that one of the reasons they don't like New Zealanders, the New Zealand degrees aren't all that recognised in China.

MRS OWENS: Right.

MS WINSLADE: I hope no New Zealanders are sitting here listening.

MRS OWENS: We've got one in the audience.

MS WINSLADE: But that's the reality. When these Chinese guys look for a degree they look for a country where it's recognised and Australia is certainly a recognised degree, so they like to have a degree from Australia. But I thought how much cleverer the Americans were in - - -

MRS OWENS: Being flexible.

MS WINSLADE: Yes.

MRS OWENS: The degree of flexibility. I think it's probably going a little bit beyond our terms of reference, but it's a very interesting point.

MS WINSLADE: Yes, well, I thought it was anti-competitive what Macquarie did in light of - I think this absolute regime of blocking was crazy.

DR STEWARDSON: How long ago was that?

MS WINSLADE: 18 months. She actually was ready to be accepted, and in fact they keep writing every three months, "Are you coming into the next intake?" because their course is in modules. It goes for 18 months, but it's modules, and you can pick up anywhere you like, but she just can't get a pass to the English. So I thought that was a little anti-competitive and just wanted to throw that in.

MRS OWENS: Thanks, Heather, for that. I think, if you don't mind, we'll now close. We will be resuming tomorrow morning here, in Sydney, again, and we will be resuming at 9 am. Thank you, very much.

AT 6.03 PM THE INQUIRY WAS ADJOURNED UNTIL
WEDNESDAY, 22 NOVEMBER 2000

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