



**TRANSCRIPT
OF PROCEEDINGS**

SPARK AND CANNON

Telephone:

Adelaide	(08) 8212-3699
Melbourne	(03) 9670-6989
Perth	(08) 9325-4577
Sydney	(02) 9211-4077

PRODUCTIVITY COMMISSION

INQUIRY INTO COST RECOVERY

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

TRANSCRIPT OF PROCEEDINGS

AT SYDNEY ON WEDNESDAY, 22 NOVEMBER 2000, AT 9.04 AM

Continued from 21/11/00

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 am Helen Owens, the presiding commissioner, and with me on my right is my fellow commissioner, Judith Sloan, and on my left our associate commissioner, Robin Stewardson.

Public hearings have been held in Melbourne and yesterday in Sydney, and next week we are holding public hearings in Canberra, as in the following week, and then by video in 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 near the entrance. The commission has three main tasks in this 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 Trades Practice Act 1974 as part of the legislative review required by the Competition Principles Agreement between the Commonwealth and the states and 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 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 these hearings informal we do take a transcript, as you can see, 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 persons present to make oral presentations, should they wish to do so. Now I will turn to the Association of Superannuation Funds of Australia, our first participant, and ask each of you to identify yourself for the transcript service and then to speak to your submission.

MS ANDERSON: My name is Michaela Anderson and I'm the director of policy and research for the Association of Superannuation Funds of Australia.

MR CLARE: My name is Ross Clare and I'm principal researcher with the ASFA research centre.

MRS OWENS: Good. Thank you. Would you like to make a few opening comments, and we can then open up the questions for discussion.

MS ANDERSON: Thank you for the opportunity to appear. We are quite pleased to see that somebody is looking at these issues. For us the translation of the Wallis recommendations in legislation was not an altogether satisfactory experience. Our levies are set under the Superannuation Supervisory Levy Imposition Act 1998 with equivalent arrangements applying to other entities regulated by APRA. These levies are paid into consolidated revenue, as they are technically considered to be taxes

under a standing appropriation in section 50 of the Australian Prudential Regulation Authority Act 1998, and are made available to APRA.

More accurately, as we say in our submission, the amount made available to APRA is the balance remaining after the treasurer has determined by way of a disallowable instrument how much is to go to ASIC or any other government agency for consumer protection and market integrity functions associated with the prudentially regulated industries. This potentially allows some part of the levies raised from the superannuation sector to be used for other purposes, as typically the amount allocated to agencies such as ASIC or the Australian Taxation Office forms only a small part of the overall expenditure of those organisations, and this opens up the possibility of superannuation levies cross-subsidising other activities of those organisations as there is no hypothecation of sums allocated.

As well the act doesn't require any consultation with the sector, although the second reading speech for the act indicated that this would be usual practice. We've found that since the introduction of APRA and ASIC, rather than our former regulators that in fact would have had much less - well, hardly any real consultation and this has proved to be very difficult as well. Not only is the consultation not there but the sort of information that we used to get that we could see where the levy was being spent and how it was being spent seems to have disappeared. Partly this is because of the nature of the organisations who use the levy and the way they are structured in terms of functions rather than our particular industry or industry groups. It's therefore difficult to see what part of a levy is being used for superannuation purposes. I think I will leave it at that.

MRS OWENS: Thank you very much for that. I think you have given us a very complete and very clear submission and I also appreciate getting the attachments with other details of the review of financial sector levies and your submission to that discussion paper, and so on, that you attached. It provided us with very useful background information, but I think your submission has raised some quite important issues and one is this issue about the way APRA is structured and the transparency of what's happening with the money there, but also whether there is some degree of cross-subsidisation between APRA and ASIC and the ATO, and so on. So I think there are submissions that we would probably like to tease out with you there.

One of the first things I was going to ask you was in your submission on page 5 you do mention that a number of the functions that you had considered to be public benefit functions are no longer linked with APRA and that they have gone elsewhere, for example, the public education function has been abandoned, you say, and some of the other responsibilities are now undertaken by ASIC. Given that, does that imply that you are happy to see APRA funded on 100 per cent cost recovery basis?

MS ANDERSON: I think even though there are some things there that could possibly be taken as a public good, given the nature of our industry, I think the hesitation I have is probably because of the nature of the industry, in that in fact it is the mainstay of the government's retirement income policy, so in some ways the

industry itself is performing a public good. So there is an argument, I think, that says anything that APRA does to sustain the government's retirement income policy could be seen as wider than just the industry. Having said that though, we are not really arguing that. It's when you get round the fringe areas of public education that's very clearly public education I think we would have some problems of being the mainstay of that.

PROF SLOAN: I don't want to lead you but you might have looked at APRA's submission to this inquiry, and I thought it was probably quite useful for your thinking, in the sense that it's clearly stated that they have essentially three functions, and I presume that you would have no hesitation about the levies being devoted to function (a) and (b), (a) being the formulation and promulgation of prudential policy and practice; (b) the effect of surveillance and compliance programs; but (c) - and I just want your view - they say that they undertake activities which - "advice to government on the development of regulation and legislation affecting regulated institutions in the financial markets in which they operate". Is it fair to have levies devoted to that kind of function?

MS ANDERSON: It's something that we have talked about. I think there's an argument that says when it's advice to government or when it's advice to other governments, which is another activity that they actually undertake - - -

PROF SLOAN: Internationally, yes.

MS ANDERSON: Yes - that we have some problems. Arguably you could see that making us part of sort of a global interest is good for the industry. But I think in fairness we would say that some of that advice to government or to other governments probably is not directly related to the business.

MR CLARE: Though a larger problem, which is taking a rather different tack, is that quite a few of these policy functions have moved into the treasury portfolio proper within the central treasury, and even though we may be paying for some of that policy function, when you knock on the door of APRA and want to discuss any of those policy issues you're told to go away and talk to treasury. The industry I think was reasonably comfortable with the policy role resting in the old ISC because they had good knowledge of the sector and that could help with policy development. They also had well-developed consultation mechanisms.

So a little bit of attention in terms of what the industry thinks it should pay for and what is legitimate for it to pay for and where these functions rest, and also with some of these functions, if they're done well within the organisations that we are paying levies to, that can be seen as a better deal than not funding them for that and having it done in a less satisfactory way elsewhere. But it does cut across some of the principles of what a levy should be for; paying for the policy development is a little bit odd, and paying for international aid activities by a government agency is a little bit odd as well.

MRS OWENS: But you haven't really made a big issue of those in the submission. You've said in your submission about the international organisations, that you've had some concerns, but you didn't really play up any concerns about the policy.

MS ANDERSON: In part, this is because we're not sure what's going on. To be honest, it's that lack of knowledge that's a key problem. As Ross says, sometimes when there is a regulatory policy issue that the industry is interested in it's a case of do you go to APRA and you get no feedback there; if you go to treasury it's very difficult to find somebody who's really working on that issue anyway. So there has been a distinct change in the industry's involvement, if you like, in the sort of regulatory policy, and I don't know that that's sort of as if the industry wants to take over it, but certainly I think it has a role in at least understanding what's going on and probably it can be useful.

MR CLARE: We also don't know how much we're paying for that function. They list it number C. They have been unable to tell us how much those various activities cost in relation to the sector, so we suspect it's not one of their larger items because they reduced that function and cut back on quite a few of the activities more of the public good nature though they still list them as activities. There's not much evidence of what they do there and we have no evidence at all of how that contributes to the cost and the costs allocation to our sector, so it makes it difficult, if it's a small amount of money. You don't get terribly excited.

PROF SLOAN: But that's really your theme, isn't it: accountability and transparency? In one sense that's probably your major gripe, that you really don't know how the levy is being allocated across functions and therefore it leads you to suspect that you may in fact be cross-subsidising other bits of the financial services industry. Hard to tell.

MR CLARE: Yes, and other bits of the ATO and ASIC, which is even more of a black hole.

PROF SLOAN: Yes, you don't know that split too.

MR CLARE: APRA at least is a zero sum gain for the financial sector, whereas with those other agencies the money disappears and ASIC in particular has far more revenue than it has in terms of expenditure and we would say very poor accountability. If you have a look at their annual report there's a couple of lines on superannuation activities.

DR STEWARDSON: Can I ask you two questions about that and how it should be addressed and rectified. Firstly, one of the key issues, leaving aside your ability to get information from APRA, leaving that aside for the moment, there is the question of the mismatch between the industry sector basis for paying and the risk-type nature of the assessment. You obviously must have thought a lot about this. How would you address that information problem of matching your costs to your industry? Is it simply a matter of APRA keeping fairly detailed records of what each of its staff is

doing every hour of the day? Is that the answer, fiddly but fairly straightforward, or is there some greater problem than that?

MS ANDERSON: I was immediately thinking then of the way some large consulting firms work, where they know what their staff are doing with every bit of time because it's based on billing. I don't know that we're suggesting that this is exactly what needs to be done, but I think with the sophistication of time-keeping now electronically I think we could get a little bit of a better understanding of the amount of time that's spent specifically on superannuation. I don't think it's a difficult task that would need hourly billing time sheets for staff.

MR CLARE: Many commercial organisations are structured in similar ways you could say there. They have divisions concentrating on large organisations, some are catering for small business or domestic customers. They have product lines that cut across different areas, but they develop quite sophisticated pricing and costing techniques which enable them to know which are good products and which are the dogs.

In terms of a government agency, we would say that it shouldn't be beyond the wit of the accountants and management to introduce some sort of system. At the moment they throw up their hands and say it's too hard or tell us that we should just accept that everyone should regard themselves as a specialised institution or a large diversified group and understand their plight in dealing with the accounting problem. But the structure of the levy actually doesn't relate well to the diversity of organisations within the sector, and that's the other problem.

Even if they had better accounting systems the degrees of freedom and their approach to setting the levies would tend to lead to a mismatch. So that's another concern we have, where they're trying to introduce a "one levy structure fits all", and the review of the levy structure - subsequent statements have clearly shown that was the intention, but their attempts at imposing that on the sector led to quite spirited reactions across the sector. No-one was happy from the large to the small end.

So they see the world as really developing in ways that should suit their structure, but there's still a great deal of diversity in the size and role of the financial institutions they supervise and their levy proposals don't mesh in well with that. So there are about three things that they need to consider.

DR STEWARDSON: What sort of levy structure do you think they should have for you people?

MRS OWENS: Yes, do you want them to go back into a levy structure that's just sector-specific or what are you looking at?

MR CLARE: They haven't departed from the sector-specific. They're trying to impose uniform asset rates and they've gone a certain way towards that.

MRS OWENS: But you don't want them to change the system they've got now. Is that what you're saying?

MR CLARE: We'd be reluctant to see a system where the larger superannuation fund paid the same as the AMP group of banking, insurance, superannuation, or Westpac or National.

DR STEWARDSON: But within the superannuation group sector, what sort of levy structure do you advocate? For example, do you advocate the UK system, which you refer to in your document, of a fixed amount plus a graduated amount related to assets rather than the current one?

MR CLARE: A graduated amount may be one way of dealing with it. There's a particular problem we identified with the small APRA firms where one commercial organisation was an approved trustee for about 6000 funds and for very little supervisory effort there's a \$1.8 million payment made to APRA - more than for the largest commercial bank - so at the small end, working out what that fixed charge would be and the circumstances of the small APRA funds and the use of approved trustees is one area.

Having some idea of what the minimum processing charge for a fund is would help us in putting forward a better levy structure. The \$300 minimum at the moment seems to fall out after they've set what they think the market will bear in terms of a maximum rate for superannuation funds and then moves towards a uniform per asset rate, so a few of the amounts that come out of the current levy structure tend to be more arbitrary and designed to lead to revenue for the sector that they consider is more or less right. We don't have some of the things that we would need to develop a better levy structure, like what's the proper minimum, how you deal with circumstances where there are multiple entities within a group and which are supervised, how supervisory costs vary with the number of members or the amount of assets under management.

MS ANDERSON: In the past, when we were just looking at the superannuation and insurance industry, we actually got some breakdowns of functions, of the things that they were doing and the differences between small funds, large funds and you could actually work with that to look at some form of levy that was equitable in a number of ways, but it's very difficult now, since you're working in the dark, to see how you might propose that and certainly when they're talking now about conglomerates and looking at an organisation overall that might have a number of different activities within it, one of which is superannuation, it still begs the question that superannuation funds themselves are trust based, require a certain type of supervision based on what they are, so that they are not actually completely thrown with the rest of the conglomerate's activities, so there is a point at which you can see a separation there.

I suppose what makes the industry less than happy is the fact that the kind of accountability that we are requesting, the kind of breakdown of functions, the kind of

documentation, if you like, of activity that we want, they're demanding of us under the regulatory structure. It doesn't sit well with an industry that's told to be open and disclose all, to then get nothing from the regulator and for them to see no reason why they have to behave as a good corporate citizen in the same way that they're asking us to.

MRS OWENS: Can I just come back to what APRA is doing - and I don't totally understand it yet, because we haven't spoken to APRA yet, but I can actually see it a little bit from their point of view, why they might want to move to thinking and organising themselves on a risk basis, rather than a sectoral basis. You've said that there are some differences in what needs to happen with the super funds, but there must be a lot of common elements as well between the funds and AMP and whatever and in some ways I can actually see their point about wanting to maybe treat a big super fund the same way as you might want to treat AMP, when they're actually carrying out their functions and there might be similar costs involved, so it's cutting it a different way.

MS ANDERSON: The way they've divided themselves up, is large conglomerate organisations or stand-alones, so you would have say, for example, AMP. Within AMP, there would be super funds, several. Within any other large conglomerate, there is likely to be super funds as well, so I can see that that would make sense to look across the whole lot. Separately, they would look at a very large corporate superannuation fund in their other division, but as well in that would be any very small stand-alone fund, any industry fund or any small APRA fund are all in that other - - -

MR CLARE: You'd also have credit unions within the specialised function, so you might have Australian Retirement Fund or CBUS, which is a multibillion-dollar fund, dealt with by their specialised institutions division, which is also looking at the suburban credit union, so that's the way they're dealing with it. They're not putting large industry funds in with the AMPs or the like, because typically now the retail-for-profit providers are diversifying financial conglomerates and they go within that grouping. It isn't such a risk based approach that they're dividing the market. It's specialised or diversified and within the specialised sector, we have about 3000 superannuation funds ranging in asset size from under a million to multibillion and we have credit unions and building societies all tossed in there and that's more the way they're approaching it and that's why we struggle a bit with their costing.

According to the risk, they vary their intensity of supervisory activity. I think that's quite clear and we would have no problem with that general notion. You do your cost-benefit analysis of where you put your supervisory effort.

MRS OWENS: And they are doing that in that way now?

MR CLARE: So they tell us, and there is some evidence of that. They are still developing some of their processes for getting a better feel for who are the risky ones. But it is more institutional - how they feel that you can divide up the market, and you can see in some ways why dealing with a conglomerate group makes sense, because

there are impacts from one part of their business to another. The superannuation fund may use the investment services of another part of the financial group and being able to follow the trail within the one audit team makes sense. The specialised institutions group is a bit of a grab bag of the smaller stand-alone insurance companies, superannuation funds large and small they've got from the states in terms of building societies and credit unions.

It's one approach to dividing their supervisory task. I don't think it's the only one and we're saying if they do go down that path, give us better accountability within what you're doing, which shouldn't be beyond the wit of accountants to do that.

MRS OWENS: Are they responsive when you say this or is there some degree of stonewalling?

MR CLARE: They say it's a bit hard and when ministers press them, as Minister Hockey has in some of the decisions made on the review of the levies - he says it will be done. We have seen no evidence of greater accountability. The initial promises were for greater accountability in the most recent period. There's no evidence of that in the annual reports and, if anything, the process of setting the levies for the current financial year was very much truncated. I think it was a phone call at the last minute on the basis of some summary papers circulated for another purpose and then, even later in the process, an announcement that a change was being made to the maximum levy. I'm not sure it's a complete stonewall. There's an indication they would like to do it, government says they should do it but, on their behaviour, it's not being done and there's no evidence that it will be done.

PROF SLOAN: What form of organisation do you advocate in order to have the relationship between you and them in such a way that you could get what you want but, of course, without your organisation and your peer organisations controlling the regulator, which clearly would undermine the whole purpose of its independence?

MS ANDERSON: I think the provision of information is not going to allow the industry to capture the regulator. I don't think there is any problem there. I think if you had the sort of information about where they see risk, where they're spending their money, you could in fact perhaps better assist in any calculation of the levy. I mean, it is very difficult when there is - well, there's no consultation now even required under the legislation, but it is also very difficult when you get a phone call - which is what I did - sort of at the 11th hour to make any response whatsoever. I mean, I am struggling with answering your question because it is as if you're in a dark room, trying to find an answer. If there was more understanding of their view of risk even on the part of the industry, perhaps that would be a starting block for us to - - -

MR CLARE: One thing that has been helpful in earlier rounds of consultation was that after a certain amount of information was provided and we had some idea of what the agency was seeking in total recovery from our part of the industry they provided to us a spreadsheet model, which allowed us to model various minimums and maximums and levy rates and we could have a look at different ways of achieving

what they saw as an overall funding requirement for the sector, and we could do that, and we could test what would happen if you said that a certain amount wasn't properly recoverable or if there was a likelihood of asset growth that they hadn't factored into their calculations and we could come up with an alternative levy structure. That was helpful because we could discuss minimums and maximums and levy rates with our members and they have a feel for what's right and what they think is justifiable in terms of their contact, and that was a helpful process.

MS ANDERSON: And it became more helpful because what we realised was in fact that the very small superannuation funds were at that time very clearly because of the sort of activity information we were getting from the ISC at the time were subsidising the larger ones. Now, the industry actually saw that as a real problem. We took it on board that, you know, this was something that had to be fixed. We were very willing to look at - as Ross says - the alternatives for putting the cost where it needed to be and, I mean, that issue has now departed because those very small funds - or a section of them - have now gone across to the ATO, but there's still a number of those very small funds with a slightly different structure that are probably in the same situation.

As Ross said, that million and a half or whatever it is that's going from one particular company that couldn't possibly be requiring all of that amount of fee to be regulated, is an issue there that we can see this is happening again - that there could be a cross-subsidy from the small funds to the large funds - but it's only when you get - we discovered that ourselves because we had provided some assistance for the GST with the Tax Office. We were doing some GST education stuff and we got some information about who we needed to post things to - that's how we actually discovered that this one group had all of these funds there and then when we did our sums and said, "Look, there's 300" - you know, how much it cost for each one, we could work out, so it wasn't as if we actually were given that information. We discovered it because we were actually doing another service for the government.-

MR CLARE: And APRA is quite aware of that problem - it has been raised with them - but their response is that they would prefer to raise that revenue there and go for a more uniform, overall rate on an asset. So they prefer to play with the other degrees of freedom and just impose that on those particular funds, so that is one of the difficulties we have. We seem to have some overall levy structures being driven by the wider considerations with trying to shape the sector to their preferred model rather than responding to the way things are. Perhaps in 10 or 15 years when the numbers of the small funds do change, their organisational structure will better reflect what is actually happening in the market and it would make more sense to do the direct alignment that they propose, but we do have that tension at the moment. Where they see things going isn't where things are, so we struggle with that.

MRS OWENS: I was just going to say maybe the market will reflect their organisational structure. There is another issue you have raised here and that is the issue of levy versus charges and you seem to be quite adamant in your opposition to fee for service, both in the context of the tribunal, the Superannuation Complaints Tribunal, and I think more generally as well, if I read your comments correctly. Are

there any instances where you think a fee for service or a user charge is the appropriate way to go? Like, if there was a special audit conducted would that be appropriate in that situation?

MS ANDERSON: Given the integrity of the whole system I think this is where we have said no. I think we would only see it as appropriate where a superannuation fund for some reason wanted some service for commercial reasons rather than for regulatory reasons and, I mean, if they were looking for something special, I suppose, for a commercial reason, that might be the only time when we would consider that as appropriate.

MRS OWENS: Do they ever do that? Would that be considered to be quite unusual?-

MR CLARE: I'm not sure they do things of commercial value too often. You could say that - - -

PROF SLOAN: There's a standard approval, isn't there?-

MR CLARE: Yes. In terms of summary organisations, if within the complex, financial conglomerates, they wanted to do some major restructuring and that would be helped by some sort of activity of the regulators then perhaps that's vaguely arguable. At the other end of the scale where you have a small credit union and super fund under threat the regulator coming in and making offer of another few hundred thousand dollars of the depositors' or members' money in help fees, we would struggle with. That's a strange notion of protection, where the regulator goes in and takes a bit more money and perhaps puts the last nails in the coffin.

For sure closing down some institutions that aren't viable or helping with the realisation of assets or trading through makes sense, but we do struggle with the notion of a fee or a substantial fee being charged for that. The protection really is being provided to the members and the depositors and having the sort of double imposition of whatever poor practice has developed and a charge being made for the detection, and perhaps not even the remedy of those problems, we see as a rather strange notion and I think, when pushed, APRA and ASIC aren't really seriously going down that path, though they may have flirted with it at times.

They certainly see some potential at the upper end of the conglomerates for some value-added services there, but I think they have had a few too many people in their corporate affairs area get enthused with the idea of value-added services and dynamic new corporate approaches without thinking through all the ramifications of that and when it has come down to the reality of what they can charge for it it is fairly limited and they have cut out a few of their value-added services. Their research and statistics area is less than satisfactory at the moment. I think their official line is that they've closed things down pending a review. That has been happening for a couple of years now and we've even had the situation where, because they've closed things down, the last people out the door forgot to tell them how to prepare some of their

regular statistics, so we've had delays in publication of quarterly statistics because of that. So for sure if they do offer value in those areas, and if they're game there may be some scope to sell the services, but at the moment what they're doing is a fairly limited set of opportunities.

MRS OWENS: Have they ever tried to introduce fee-for-service for their superannuation complaints tribunal? Did they ever float that idea?

MS ANDERSON: No, and that would be something that would be really frowned on by industry, and I suspect by just about everybody, because of the widespread nature of superannuation and the need for a complaints tribunal.

MRS OWENS: I think it doesn't just apply for superannuation; it applies right across the board.

MS ANDERSON: Yes.

MRS OWENS: I think there are certain principles about complaints or prosecutions, or whatever.

MS ANDERSON: Yes.

MR CLARE: We did have some complications when the constitutional validity of the complaints tribunal was in doubt and when some alternatives were being looked at funding was one of the concerns, but I think that the consistent line from the sector has been there are public goods type aspects to the dispute resolutions. It's not a commercial arbitration tribunal; it is dealing with some fairly basic consumer issues.

MS ANDERSON: Yes, and it doesn't seem to have suffered from people taking trivial complaints to it or time-wasting. Anything that goes there - although there has been a backlog of complaints because of the constitutional problems - the thing seems to be handled pretty well so that anything that's purely an inquiry or a trivial matter gets handled pretty smartly and real issues go forward. So I don't think there has ever been that question of, "Do you need to put a fee there because it makes it work better?"

DR STEWARDSON: This discussion has been quite interesting. I'm thinking to myself there are significant differences between regulators such as the Therapeutic Goods Authority and APRA, and one of the differences is that a lot of what the Therapeutic Goods Association does is to test new products. Now in the case of APRA and its prudential regulation of superannuation there isn't really, is there, any equivalent to testing new drugs. I can't think of any situation in which a superannuation fund would have that. I mean, if a superannuation fund decides - let's suppose, that investment choice for members wasn't already in existence and someone dreamt up the idea of giving members investment choice, that wouldn't be something that the fund would have to go to APRA and say, "Please, may we do this? This is a new product," would it?

MS ANDERSON: The only time when that would come - it's not a new product; it's when they're actually, in a way, testing the law, and not so much testing - I suppose in some ways they're actually testing trust law as well as the Superannuation Industry Supervision Act, and they may in fact be testing something like the sole purpose test and they may go to APRA for comfort, if you like, that they're not breaching any provision there. They could just as easily go to one of the superannuation lawyers, I suppose, and test the same thing. It's a test of law rather than - - -

DR STEWARDSON: The product.

MS ANDERSON: - - - the product, yes.

MR CLARE: And it's a bit like getting a private ruling or trying to seek some comfort from the Tax Office. I think there are some fairly difficult issues, in terms of paying the Tax Office for a private ruling. I think paying APRA for a private ruling on something can raise some similar concerns. Getting responses on some of these things is quite difficult in any event now. In terms of what they're listing as their activities, I think providing comfort to superannuation funds and new initiatives isn't high on their list. They are more likely to come in and review activities after they've been in place. ASIC has flirted with the idea of charging for registration of disclosure documents, even though they don't really do anything.

DR STEWARDSON: Registration for what?

MR CLARE: Disclosure documents.

MS ANDERSON: Prospectus. I mean at the last count the amendments to the Corporations Law that were going to - they were going to have people provide the disclosure document to ASIC and the government has now reviewed that and it would look like they're not actually going to take them because there was no point; they weren't actually going to review them they were just going to lodge them and charge. So everybody said, "Well, it has a bit of a problem too because if it's lodged people think that it's okay," so it has a sort of moral hazard problem with it as well, plus the industry sort of said, "Why would we lodge them if you're not going to look at them?"

MRS OWENS: That's a very good question.

PROF SLOAN: I'm fine. I think it's a very thorough submission, so it's very useful.

MRS OWENS: Yes, thank you. I think we have just about exhausted what we wanted to talk to you about. Have you got any other final comments before we go on to the next participant?

MS ANDERSON: No, I thank you for allowing us to be here and present our - - -

MRS OWENS: How it works out.

MS ANDERSON: Yes.

MRS OWENS: Thank you for coming. We will just break for a minute and invite the next participant.

MRS OWENS: The next participant this morning is the Australian Self-Medication Industry. Could you please give your names and your positions with the organisation for the transcript?

MR BROWNBILL: My name is George Brownbill and I'm government relations consultant with ACIL Consulting Pty Ltd and retained by ASMI as government relations consultant.

MS WILLIAMS: I'm Sue Williams and I am here as a member of the association. I am actually general manager of Boots Healthcare but I am also a member of the executive subcommittee of the association.

MRS OWENS: Thank you. Sue, this is your first public hearing of this type?

MS WILLIAMS: It is, yes.

MRS OWENS: Thank you very much for the submission. I think the Australian Self-Medication Industry has been very involved in previous inquiries that we've held and have always taken an interest and so I thank you once again for the next submission. I know it takes a lot of time and effort and it is a very clear submission but we would be happy if you made a few opening comments.

MR BROWNBILL: Madam Chair and commissioners, thank you. The ASMI appreciates the opportunity of putting its views to this inquiry, as it has done to previous ones. My principals faced a bit of conflict of timing today, as I have explained to you. Otherwise the executive director and chairman of ASMI would have been here. We regret that but that has been a very long-standing engagement for them.

MRS OWENS: We're very happy to meet Juliet Seifert in our visit, so at least we have had that discussion and I am sure there will be other opportunities throughout the inquiry.

MR BROWNBILL: Yes, and that opportunity to do some background briefing by my clients was very much appreciated. If I may now just go to the submission that we have presented, I am glad to note that you find it clear and I think that it puts its finger on what to me seems to be the central issue for this particular inquiry. We, as citizens, pay for every service that government provides to us. Some of those we pay in the form of taxation. The others are paid for in the form of fees and charges. The real question is where the difference between taxation and fees and charges is to be drawn and that, I think, is a fundamental question.

The ideologues and bean counters in the finance department embarked, I think, a few years ago on a number of experiments with the public good and one of them was the notion that you could shift that line significantly up or down - I'm not sure quite which way - but to the disbenefit of industry or business and to the supposed benefit of the taxpayers in general. I think that in some respects that shifting has been

done with regard to some of the serious issues of policy and the serious issues of administrative accountability that have arisen. It has also been done somewhat capriciously.

You'll find in the submission from ASMI, for example, that a timetable for "moving towards full cost recovery" - whatever that might mean - has been accelerated more than once and without notice and, indeed, without consultation in the true sense of the word "consultation"; that is, you ask and you take advice. Not you tell someone what you're going to do and do it. So there are I think for this inquiry - and it's very timely - some quite significant questions. I think the questions, if I may suggest, arise most painfully at the point when you move from something less than to 100 per cent cost recovery.

The reason I put that observation to the commission is that if you pay for something like all of it you expect to have, first of all, some control over price and, secondly, you expect to have some ability to influence the quality of what you're buying. I take those to be quite fundamental principles of economic theory, although I am not an economist. In the case of 100 per cent cost recovery I think that the overwhelming evidence this commission will receive will tend to the view that people do not have choice, industry does not have choice, and they do not have control over the quality. I think in the broadest terms those are the messages that come through in the ASMI report.

There are not only problems for the people who pay for services at 100 per cent - or indeed any other lower figure - there are problems for the public in general and for the governmental system, as well. The problems for the public arise because the consumer movement and individual consumers perceive that 100 per cent cost recovery ensures that a regulatory agency is captured by those who are paying the 100 per cent and, indeed, as I suggested, that's nothing more than good economic theory. The problem for the government - by which I do not mean the executive government but I mean the parliament, the government, the executive.

The problem there is that the agencies who are charged by the parliament, by statute, with the performance of regulatory functions are responsible to - and through the minister to the parliament - and the parliament is responsible for the appropriation of public moneys except that if 100 per cent is paid there is no money being appropriated. So you have a clash of responsibilities and I would suggest to the commission that this arises most acutely not at 98 per cent or 99 per cent but at 100 per cent because, at 100 per cent there is no room for a notional, as distinct from a rational or calculated division of responsibility between public good and private good, it's all private good by definition and therefore all the things that are done, so to speak, in the public interest - and you'll find a list of the ones we think are appropriate for the TGA on - I can't find it, but in the submission.

These are, so to speak, free-to-air for the public and for the parliament. Finally, commissioners, I just wanted also to draw to your notice the difficulties that the judiciary has had with some of these concepts and I fancy that the commission will

have had brought to its notice *Air Services Australia v Canadian Airlines International Ltd* (1999) 8 CA 62 2 December 1999, which was a case about the issue of whether the general costs of the air services that are provided by Air Services Australia were properly taxation under the constitution or whether they were properly levies, and their Honours at paragraph 456 made this observation:

In *Swift Australia Co v Boyd Parkinson* -

which is a 1962 case -

the court decided that fees imposed by regulation for the purpose of both defraying the expenses of providing a service for the inspection of meat for sale and carrying into effect the act -

I repeat that, "carrying into effect the act" -

under which the regulations were made were not fees for services and were excise taxes. Dixon CJ, with whom Kitto and Windeyer JJ concurred, rejected the contrary submission stating, "It is evident from the introductory words of the regulation that some attempt is made to represent the fees as a charge for services, but when the regulation is examined it appears that the fees are not payable in respect of any particular service -

I repeat that, "not payable in respect of any particular service" -

but generally for the purpose of defraying expenses.

Further, and this perhaps is fatal to the argument:

The expenses are not merely those of inspecting meat but those of carrying the act considered as a whole into effect - that is to say, for administration expenses generally.

Their Honours go on to observe that the particular case wasn't quite such a fatal effect and they go on then to turn to what they call the critical problem, and this is at page 459:

It is now necessary to turn to the critical problem which is revealed in applying the statement in *Air Caledonie* -

which is another case -

referred to above, to the present case. It is that the adoption of Ramsey pricing by the authority as the method of structuring the price or rate of the charges imposed on *Compass* severed any discernible relationship between the amount charged a user and costs incurred in providing the particular services to the user.

I've quoted that at some length. I apologise for that, commissioners. I can hand up that judgment if it's of interest.

MRS OWENS: Yes, thank you. I think that would be useful, and it was good to have that read into the transcript as well.

MR BROWNBILL: It's there if you wish. That raises I think a very substantial point and I think it's why the founding fathers in the constitution made some very important distinctions between levying taxation, including excise and customs, and charging fees for service. The constitution provides that there are different ways in which the parliament will authorise the one as distinct from the other and therefore I think it is not to be accepted lightly that the whim of some official in the finance department, rubber-stamped perhaps by a cabinet anxious to fill out the bottom line of the budget, is a sufficient way in which to establish the principle of where that line is drawn. I think some of the people who may or still will appear before you may well have contemplated whether they should have gone to the courts in order to have obtained some redress in these matters, but there are limits to the effectiveness of that approach and many of them perhaps haven't done so.

I hope that those general views are of interest to the commission. As they work through in the case of the Therapeutic Goods Administration, which is the agency my clients are most concerned with, you will see that we have made it quite clear that those things which the TGA does as an arm of government - that is, the amount charged a user and costs incurred in providing the particular services to the - not being of that kind, ought not to be funded from industry and business; in fact, there are sound public policy reasons why that should not be the case. We've listed - and I've found it now, page 15 - whole-of-government policy advice.

For example, the TGA is not only responsible for the administration of the regulations, which are complex and in some cases rather more onerous than in other parts of the world, but it also has a process within itself by which it determines ongoing policy. Shall we amend the regulations to make peppermint a prohibited substance? Yes, we might. Now, clearly raising that question and many, many more of much more significance - considering it, researching it, writing up a submission through the system, making a proposal to the minister or, if it's important enough, to the government or the cabinet, writing the ministerial letters explaining why that decision was taken and why wasn't mint, simple mint, included along with peppermint, and I'm using an absurd example - all of those matters are not germane to a benefit industry is receiving; in fact, if it is, as one regrets to say sometimes is the case with the TGA, to ban something else, it's a distinct disbenefit to industry. Now, there are costs in all of that and those are what we would call the "whole-of-government policy advice".

TGA services promoting overseas, it's a matter of record that the Therapeutic Goods Administration is highly admired in other parts of our region and the TGA under another perverse doctrine of the finance department called "commercialisation"

likes to promote its services in these parts of the world. The benefits to industry are at least indirect - at best indirect; trans-Tasman harmonisation is a branch of that regulatory policy I've referred to. Post-approval monitoring: I think there's room for a difference of view on the degree to which the person with the product on the market benefits as distinct from the public in that sort of situation, but the point here is that costs are incurred. "Product recall not arising from sponsor negligence or non-observance of rules and from extortion", extremely serious, and there's been some advertising to that in the press of recent days. Now, all of that takes time, costs money, uses up resources and general information and promotion.

I guess I would also add to that list the whole apparatus that all public authorities are burdened with of interfacing with the parliament, properly in my opinion, but appearing before senate committees, preparing annual reports - - -

MRS OWENS: Submissions to Productivity Commission inquiries.

MR BROWNBILL: Indeed, and a full range of other public policy development processes and accountability to parliament and therefore to the public. These are not costless, but it is difficult, I would submit, to argue that a particular therapeutic good which has been licensed for sale in Australia benefits, as it were, more than any other.

So I think we would end by saying that the devil lies in the hundred per cent, and then secondly the devil lies in the processes by which one can be satisfied of the efficiency and effectiveness of the resources that are used, and those resources then are costed out and the charges are levied accordingly. We gave quite a deal of background to the commission about those matters and we would be happy to answer any further questions on them.

The main point about it I think is that it is a question of management information, and there is of course a difference between management information that a public agency which has responsibilities to the parliament thinks is appropriate and the sort of management information that Sue, as managing director of Boots Healthcare, thinks is what she needs to see how the market is performing for her products and whether the expenses that she is authorising are commensurate with the profits being generated for shareholders. I'll cease there if I may, thank you, commissioners.

MRS OWENS: Thank you, George. You've raised a lot of interesting philosophical, practical, legal and economic issues in that - - -

MR BROWNBILL: Diatribe.

MRS OWENS: - - - introduction. Some of the introduction has actually answered some of my questions. I think each of the issues you've raised, however, could lead to a discussion on each of them for about an hour, and we probably don't have an hour because we've got numerous other participants coming. I could act as a devil's advocate.

On the list of what you define as public goods on page 15 there's basically two ways you could look at this: you can look at it in this way, or you could look at it in the way that maybe the Health Department looks at it and some others, and that would be - and I can't talk for the Health Department and I'm not saying I necessarily agree with this approach. But it could be that there is an industry out there that creates an impact, possibly a negative impact, on the community through certain activities, what economists call "externalities" - and you said you weren't an economist, George, but I know that you know these terms - and that the industry then should be responsible for in some way paying for those externalities, however defined and however measured, and that could be covered through the industry's compliance with requirements to minimise those negative impacts, or you might need to actually then go further and cover any charges that may be imposed by a regulator that is established to deal with those problems.

So instead of thinking of it as who are the benefits - the public versus the consumers versus the industry - you could look at it and say, "Here we have an industry that's creating these spillovers or externalities which may have a negative impact on the public. Should the industry pay to have those externalities reduced or minimised or eliminated even?" Would you care to comment.

MR BROWNBILL: First of all I don't think that ASMI would regard the availability of safe and efficacious medication that can be taken responsibly by people as a negative impact. I think that there are significant public benefits in a respected and quite rigorous regulatory regime backed by self-regulatory processes which industry cooperates with government in administering and also of course pays 100 per cent of as well.

I think, Helen, you might be referring to the last couple that I adverted to, which is post-market monitoring and recalls arising from extortion; the Health Department might have an argument in respect of those. I think that we would say that these are matters very much in the public benefit. No single industry player who has obtained all proper authorities to sell its product but who is the victim of an extortion threat should be paying a service for that - for example, different from that of a victim of crime ought to pay for the services of the police to, as it were, rescue them in particular.

DR STEWARDSON: Could I perhaps just interrupt, because I think that it would be a more useful answer if we could broaden it away from those individual items that you were just moving on to, because I think the issue that is being raised here is really this one as a very fundamental thing: should one say that the fact that this industry that you're representing exists, notwithstanding that it does a great deal of good and that its product is there to do good, nonetheless can have bad effects if the product is not properly and appropriately tested, and that therefore to avoid those possible bad effects there has to be regulation and that that regulation should be a cost of doing business for the industry to avoid there being negative externalities, albeit clearly there are also a lot of good things. Is that the sort of rationale for charging, for cost recovery by agencies like the TGA, or should one be looking at who benefits from the

TGA's activities and asking them to pay for it? I think that that was, was it not, the point you were getting at?

MR BROWNBILL: To struggle with the answer a little, again I think I would say that whatever stretch you give to the concept of externalities there will always be left what I would call non-externalities or general government processes, and it is the vice of the hundred per cent cost recovery which makes the argument about where the externalities properly end a heated issue; why we have this inquiry, perhaps.

You cannot draw a line out into infinity and say that everything happens that has the word "medicine" in it in some way is an externality for the costs for which must accrue back to the licensee. There has to be some point where that line fades so thin that it doesn't have a touch.

PROF SLOAN: I suppose the point is - and I'm not actually sure what you're saying, Robin, is an example of an externality, I mean, because it's really about saying you accept the need for some kind of regulation. Am I right in assuming that?

MR BROWNBILL: Absolutely and cooperate in it.

PROF SLOAN: Really what you're saying is that you want to pay for the direct costs of the provision of that regulation; where there are peripheral or other activities undertaken by the regulator, then you don't see that as an industry responsibility.

MR BROWNBILL: The industry doesn't see that as a responsibility and the industry sees public policy advantages in the public perceiving that there are inputs other than industry's money into the regulatory process.

PROF SLOAN: Right.

MR BROWNBILL: And among those are the parliament and the consumers.

PROF SLOAN: You don't seem to have very nice things to say about the effectiveness of TICC.

MR BROWNBILL: I didn't hear you, I'm sorry.

PROF SLOAN: You don't seem to have particularly favourable things to say about the TGA Industry Consultative Committee. I mean, is that an answer in practice as opposed to in theory?

MR BROWNBILL: It's an answer in theory as opposed to an answer in practice. The problem with the TICC, as my people see it, is that that I mentioned at the start; that is, if you pay the full price for a good you expect, as it were, to control its quality and the terms of reference for the TICC allow industry to "comment" on the budgets and the quarterly reports which are put to it. I don't want to be misunderstood when I say this, but that is that there is no industry control over it. I think secondly is the

quality of the management information itself. Of necessity because the TGA is part of the Health Department and is therefore a department of state with all the budgetary processes imposed on it from finance and from parliamentary appropriation procedures and all the rest - because of that, management information is created and flows in that way, if you like, on a cash flow basis.

That same management information, while very useful, no doubt, to the Health Department and to the boys in the back rooms and girls in treasury and finance, doesn't help an enterprise evaluation of the processes and I think at the last meeting Miss Seifert took your colleagues through the process of unrealised estimates of turnover. Now, a business enterprise will - I mean, it's like the turnover of sales is a comparable indicator to that of blood pressure of a patient on the operating theatre. You watch every flicker - I'm sure you do, don't you, Sue? - and sales - in other words, numbers of application - have perhaps not been seen as so vitally central to the management processes of the TGA. Why? Because it's an agency which does all these other things, which are ongoing and are, so to speak, costless. Why are they costless? Because you can get 100 per cent of them back from industry. I don't know whether the documents from the TICC have been provided to you.

PROF SLOAN: I don't think we have anything from - - -

MRS OWENS: No, I don't think we have at this stage. You have got some documents there that you could table, George?

MR BROWNBILL: I would like to table them in camera, subject to checking that my clients haven't done something they shouldn't with the TGA.

MRS OWENS: That would be acceptable and we can sort it out later, yes.

DR STEWARDSON: Can I just add a small question and then perhaps a bigger one? The small question is that there is reference to an interim report by PWC on the operation, I think, of the TICC, is there not?

MR BROWNBILL: Yes.

DR STEWARDSON: And is that something that is available to us?

MR BROWNBILL: I can table that.

DR STEWARDSON: Thank you.

MR BROWNBILL: It's quite humorous in a way, really. It's a template, if you like, by PricewaterhouseCoopers for the kind of information that should be routinely provided to the TICC and it says, part 5:

Feedback from industry representatives. This chapter will be developed based on feedback from TICC members and/or the colleagues they nominate.

So it really doesn't have a full representation of - well, any representation of our side of the issues, but I can table that, again subject to that caveat, if I may, which I will check on. I will check on those papers.

MRS OWENS: Thank you.

DR STEWARDSON: Can I ask you, please, for your reaction to the following: one of the issues we have is that a number of respondents, including your clients, have said that the regulatory body in question doesn't give them the information they need to make proper assessments and helpful comments and that even when they do get the information and try to assess the efficiency within which the regulatory body is doing its task and make comments about that then the regulatory body ignores them. That's a fairly widespread complaint. It seems to be one that we need to try and address. At the same time the people and organisations who are being assessed for the regulation clearly can't control the regulator because that would totally undermine the whole principle of the independent regulation and independent regulator and public confidence.

In trying to think of ways to get round that dilemma one possibility that has cropped up is the following, and I would be grateful for your response as to whether you think it would be a viable one or not, and that is that one would establish for each regulator a thing that might perhaps be called an "efficiency audit committee". It would be somewhat analogous to an audit committee of a company board, except that an audit committee looks at financial matters whereas the efficiency audit committee's task would be to look at the efficiency with which the regulator performs its task.

It would not be looking at the regulation in the sense of the standard that the regulator was assessing because that is something that the regulator is doing for government but, having got the standard, the efficiency audit committee would look at the efficiency with which the regulator carried out its assessment and it would then report on that, not to the chief executive of the regulator - he would no doubt get a copy - but that it would report above that to the minister if it's a department and perhaps to the board if it's a statutory corporation, or maybe to the relevant minister, as well. The efficiency audit committee would have some rights to get appropriate information from the regulator to enable it to do its job properly and that that committee would be composed perhaps half of members of the relevant industry, so that they would (a) have the satisfaction of knowing what was going on - which was, answer a lot of complaints - and they would be informed and knowledgeable people to help make such an assessment of the efficiency and maybe there would be a component of ultimate customers of the product and maybe there would be a component from the regulator themselves. Do you think that would in fact help to resolve this dilemma that there is between effective input from the people being regulated without them controlling it?

MR BROWNBILL: The first thing I should say is that I really need to seek instructions from the client. I think you would agree, Sue, we would want to think

through that because, in a practical sense, the option for this industry is whether by endeavours that are under way improvements to the TICC process can be made which are, so to speak, as much as one could hope for, given the fundamental dilemma that I've adverted to.

The second thing I would offer is that it's in my memory that the auditor-general used to do efficiency audits and I think in the end it was either abandoned or it fell away presumably because all the parties concluded that it was not the efficient thing to do; that I am subject to correction on. The third thing I'd observe is that you might have an awful lot of apparatus if you were to do this for every regulatory structure and I just wonder whether something like the remuneration tribunal - that is, almost a standing inquiry of your own commission - may not be modalities in which you could deploy this review process.

I do like the idea of such bodies having some recourse to ministers, but if the dead hand of the Department of Finance is able to be imposed across everything then the best processes in the world will end up on some desk officer in that department and will go nowhere, no matter whether ministers get to see the documents or not, because all they do is take advice; the advice will come from their departments, their departments will do what finance tells them. I mean, it's as old as the hills, all of that, and sad to say it's how it is - so anything that improves the quality of management information in the sense of management information not in the sense of government finance information, and anything that provides an external Court of Appeal, if you like, and anything, thirdly, that defines more accurately what is a private good, what is public good, what is an externality, so that everyone is playing by the - you know, we're all playing chess, not some of us draughts and some are playing cards and some are playing snakes and ladders. If the rules are all written the same maybe they would be all advantages flowing from the kind of suggestion you put in my view.

DR STEWARDSON: Thank you for that. If there's anything you want to add or subtract from that response when you've talked with your clients we'd be happy to hear it.

MR BROWNBILL: I'll take advice from my client on that. They may tell me what I said is to be repudiated or whatever.

MRS OWENS: Or they can come back to us with a little letter.

MR BROWNBILL: Indeed.

MRS OWENS: I suppose what we're trying to do in this inquiry is ultimately get some rules through, develop some guidelines, which is going to be one part of that, and those guidelines may look at the whole issue of structuring charges and maybe we can think about promoting incentives for agencies to be more efficient through the actual charges. The structure of the charges is another way of getting at it. I don't know whether that will be the case yet or not until we do more work on this.

But there is this whole issue of incentives. There's the incentives on the regulator, and basically what you're saying is that there aren't very strong incentives for the regulator - ie, the TGA - to be that efficient, and I think you're implying, reading between the lines - maybe not reading between the lines - some degree of gold plating that's taking place. I think there are also the incentives that are developing on industry and consumers. So I think we're interested in what's happening at all points. But you inferred in your opening comments that something magical happens when you get to 100 per cent.

MR BROWNBILL: I think it does.

MRS OWENS: There's this expectation that you would be able to influence prices and quality, for example.

MR BROWNBILL: You're paying for it.

MRS OWENS: Yes, but you're also paying at 50 per cent or 60 per cent or 70 per cent or 75 per cent as well. What's so magical about hitting the 100 per cent point?

MR BROWNBILL: It's not magical. It forces an assessment of issues which would perhaps remain untroubled. If agencies, for example, were capped at 80 per cent I think some in industry would then feel that the public good and the externalities were more or less accounted for in the 20 per cent, perhaps, sort of, subject to sums being done.

You can haggle over whether the charge for registration or listing of a medicine is a true recovery of costs if you're looking at all the costs under 80 per cent of the costs of operation of the agency. But if it's 100 per cent then you really are paying for the lot. I don't know. I don't think that's magical. I think it's just a practical piece of market behaviour.

PROF SLOAN: But maybe there's a positive in the 100 per cent in the sense that if it's 80 per cent then the agency can say, "Well, you know, you're only paying 80 per cent. What else we do in the name of public benefit is kind of our business," whereas with 100 per cent perhaps it actually encourages greater responsiveness and so the regulated or the clients, or whatever we call them, begin to actually take a pretty active interest in what they're actually paying for.

MR BROWNBILL: But the responsiveness must be tempered by each agency's political and parliamentary responsibilities and they are not negotiable back with industry. They are only negotiable within the government structure, so to speak, the cabinet apparatus, and so I would, with respect, somewhat discount that argument.

PROF SLOAN: No, I think that's a fair response.

MR BROWNBILL: I do think that if you're paying everything for it you expect to

get it. Council rates compared with charges for building a road so that you can then pay rates for its upkeep is another good example of the difference that a buyer of a service will look at something like that, in my view.

MRS OWENS: I think we won't hold you up much longer, but you've got a very important point. I think you might have mentioned it in your opening comments as well, but on page 16 you say:

As its costs are recovered from industry, the parliamentary scrutiny of the operations of the TGA is substantially reduced.

I presume that's the point you were making about the appropriations; if there are no appropriations there's less - well, it's not just parliamentary scrutiny, but the scrutiny of the Department of Finance may be reduced because the money is coming from somewhere, so there's less scrutiny and hence maybe less pressure back on the TGA as well.

MR BROWNBILL: Yes.

MRS OWENS: Would you agree with that?

MR BROWNBILL: I think it provides a disincentive to the regulator, yes. I would want to just go back to your comments about gold plating. I think that might be an economist's term, which is perhaps for an economist somewhat colourful.

PROF SLOAN: We're colourful people.

MR BROWNBILL: I wouldn't want it to be thought that ASMI has a view of the TGA as a somewhat sybaritic operation with a great deal of luxurious extra resources available to it. I don't think that is industry's view and I don't think it's the case. I think the point is perhaps more about different approaches to what industry thinks is the regulator's mission and what the regulator thinks is its mission and those, as I continue to maintain, collide significantly at the 100 per cent mark. At the 100 per cent mark these questions become critical to be answered; before that, not so.

MRS OWENS: Thank you. We can talk over morning tea, but there are other issues related to the TGA - for example, the extent to which it does or doesn't contract out activities, and we were talking yesterday to the Medical Industry Association about conformance assessment, and there were proposals in an earlier Industry Commission report actually to set up competing conformance assessment bodies and devolve some of the responsibilities of the TGA to those other bodies, and that has been resisted and has not gone ahead.

MR BROWNBILL: I just mention on the record in relation to that - and I think, Helen, you'll be aware of it - the substantial and very sophisticated co-regulatory process in relation to the advertising of medicines and how regulations are made by the regulator which delegate to my clients the responsibilities for assessment of

advertisements and the giving of permission for them to be put to air or published in the newspapers. Of course charges are levied for that service by my clients on individual members of industry and they're on a true cost recovery basis.

MRS OWENS: Okay, thank you. One of the other things I forgot to mention was that if you've got any really good examples of the impact of say cost blow-outs in the TGA, which you also mention on page 16, or the delays in approvals for some of the member companies - I mean, I don't know whether Boots has had any problems - those sorts of examples would be greatly appreciated. We've got no further questions. Have you got any final comments you'd like to make? Sue, do you want to make any comment?

MS WILLIAMS: No, I'm fine, thank you.

MRS OWENS: Okay, well, thank you very much for coming.

MR BROWNBILL: Thank you.

MRS OWENS: We'll now break for morning tea and we'll resume in 10 minutes.

MRS OWENS: The next participant this morning is the Australian Visual Software Distributors Association. Could you please give your name and your affiliation with the association for the transcript?

MS SIMES: I'm Megan Simes and I am the chief executive of AVSDA, which is the industry association that represents video and video games distributors in Australia.

MRS OWENS: Thank you very much for that. We are very pleased to get your submission. We have been to visit the Office of Film and Literature Classification in Sydney but we haven't, as yet, talked to them in a public hearing. I'm not sure whether they are appearing before us or not, so we have a smattering of knowledge about what they do and I presume your association would have dealings with that particular office.

MS SIMES: Yes.

MRS OWENS: So the issues you wish to raise are in relation to the activities of that particular office?

MS SIMES: Yes, only in relation to the OFLC.

MRS OWENS: Good, thank you. You argue that the distributors don't actually object to the classification system but it's not really clear from your submission whether you have concerns about whether they should pay for the system that's in place.

MS SIMES: (a) the distributors are quite comfortable with complying with the legislation that requires them to have their products classified by a government organisation, but one question is the level that they pay because there were recent moves by the government to introduce 100 per cent recovery of OFLC costs, which is quite different to a user-pays idea. A lot of the activities that the OFLC undertakes are not, strictly speaking, directly related to classification. They include payments to the states for enforcement and referrals from police and customs on product that the OFLC then needs to look at and classify, and general bureaucratic functions; for example, answering ministerials or providing secretariat services for the state and Commonwealth attorneys-general meetings.

DR STEWARDSON: Sorry, could you speak a little louder, please. It is a little hard for me at this end of the table to hear.

MS SIMES: I am sorry. I do tend to speak a bit quietly.

MRS OWENS: We do have a fairly loud airconditioning system right above your head.

MS SIMES: Okay.

PROF SLOAN: So that shift though to the full 100 per cent cost recovery was in the end rejected by parliament, wasn't it?

MS SIMES: Yes, it was.

PROF SLOAN: But you think it remains on the agenda?

MS SIMES: I would suspect so and there may be instances with other agencies where 100 per cent recovery of the costs of operating an agency might be legitimate but, in the case of the OFLC, we don't believe so.

PROF SLOAN: You said you have three points, one being that - I suppose how the system works that in other countries there's a much larger group of products which are essentially exempt.

MS SIMES: Yes.

PROF SLOAN: Okay, and of course you are actually paying for them because they're not exempt at the moment.

MS SIMES: Yes.

PROF SLOAN: So that's one point. The second point seems to be that you're actually charged a relatively high fee anyway by - is it because so much more is classified here or is it also that the unit price is higher here?

MS SIMES: Apparently it is because so much more is classified to the cost to an individual company is higher. The amount they have to budget in any year for classification costs is higher than it would be in New Zealand or the UK. I mentioned that the range of product that is to be exempted is about to be broadened and that legislation should go through in the next week or so, I think, and we welcome that, but as already exists, for example, with computing games, the system is that somebody within the company can go to the OFLC and become trained to assess product and most of the assessment is done by the company. They then submit a precis of the game and video of anything that might be contentious, so the fee that is charged is quite a bit lower. I think it is \$500 for a game as opposed to close to \$1000 for a video.

PROF SLOAN: So that is kind of really a self-regulation model, isn't it?

MS SIMES: To a certain extent. It's outsourcing in a sense to the company.

PROF SLOAN: Yes.

MS SIMES: We believe that the same sort of system could well operate for video. That it would be much more cost efficient all round to do it that way and certainly you

can still retain within the legislation the discretion by the director or by the OFLC not to deal with particular companies if it is found that they're not complying or not doing the right thing, but there's a lot of streamlining that could go on.

PROF SLOAN: Because is there kind of anything that we should know that distinguishes videos from video games as to - I mean, why would you have a different approach?

MRS OWENS: Yes. Why have a different approach?

MS SIMES: The original reason was because those employed at the OFLC just didn't have the skills to play the games and in fact you know you can get up to level 30 - and very often even people in the companies here have to go back to the original developers of the game to find out at level 30 - you know, "How do I get to this bit that will show me that?" and then put it in the video.

PROF SLOAN: So it's actually nothing to do with the inherent nature of the product, really?

MS SIMES: No.

PROF SLOAN: It's a practical matter.

MS SIMES: The contentious material in games is much less than there is in video; for example, the top rating for a game is MA15 plus whereas video goes R and X, as well, or MVE, and an MA game - exactly the same content, the same visuals in that - would be an M film, so the contentious material is a lot less in games anyway.

PROF SLOAN: Right. That might be a reason, I suppose, for keeping more control over videos - if there is more contentious material in videos compared with games, although I would have thought - I mean, if you look how violent some of those games are, they're absolutely terrible. There's quite a subjective element to classification, surely?

MS SIMES: There is, although I think the OFLC would argue otherwise to a certain extent, given the guidelines they're given and the training they undergo in assessing whether something meets a particular guideline or makes a scene or whatever move the product into a higher rating product.

MRS OWENS: So is there any chance that the videos will become subject to self-assessment eventually? Is it going to move in that direction?

MS SIMES: I have heard it mooted once or twice but it has never been a subject for consultation with industry so far.

MRS OWENS: In terms of the charges - coming back to the charges - how do they line up with the charges that would be incurred by the industry in other markets?

MS SIMES: The ones that Australia is usually compared to are the USA, sometimes Canada, the UK and New Zealand. The USA is - and I think Canada - is self-regulatory, so the costs are borne - - -

MRS OWENS: And that's self-regulation for videos and games and films. Everything?

MS SIMES: Yes, everything. In the UK, which is probably the most comparable system in that a more similar range of product is classified, although games aren't classified anywhere other than Australia or New Zealand, the UK has a more broader exemption scheme. I think we're moving towards that with the broadening of our exemption scheme, but still the range of product that has to be classified is narrower; I think the charges are probably higher. But I think that that's a fairly futile exercise, to be comparing using a standard figure and saying, "Well, on today's exchange rate that would be so-and-so here." You've got to look at a huge number of other factors, the cost of living.

MRS OWENS: You're not comparing like with like.

MS SIMES: No.

MRS OWENS: If they've got a greater number of exemptions what's left is going to be the more difficult stuff, so you might expect the charges to be higher.

MS SIMES: Yes, although from speaking to people at the OFLC that's not always clear. A product that might take the most time will be something where it's borderline between G and PG or PG and M. There's a lot of product that might very clearly be G, but the borderline product is where the time is taken. So the cost is not necessarily an indication of how long it takes to do every single one - some are clearly done in a very short time - so it's an average price that you're looking at. In New Zealand there's a lot less product classified than there is Australia, largely because they accept under M or M and below, whatever the Australian or UK classification is, so it's a very limited range of product that needs to go to the New Zealand censor to be classified.

PROF SLOAN: Saying that, most of this product does not originate in Australia. Would there be opportunities for us to just accept the classifications coming out of the UK for example? Why wouldn't we do that?

MS SIMES: I think that's a political question and it's not something that our industry is pushing for, possibly also because product tends to be released at the same time in the UK and Australia and closer and closer to the US; in fact, for games it's released internationally on the same day, so it would necessarily have been classified somewhere else in time.

PROF SLOAN: Does your association have a good relationship with OFLC?

MS SIMES: I think reasonably. I think the association has - - -

PROF SLOAN: Are they a responsible organisation?

MS SIMES: I think it's very variable. One issue, going back slightly, on what the level of fees are - I know that - it's probably going back about two years - there was a consultancy engaged by the OFLC to look at the costs of the activities that they undertook and on that basis a new fee level was devised. That was not released for public discussion and the question remains, while those costs might exist, whether those costs are as lean and mean as they could be, and certainly in talking to people our understanding is that there were some - the report certainly indicated that there was room for improvement in how they were conducting their activities, and then there were cost savings to be made. I know that at one time there was resentment in the industry at the premises that the OFLC had, which was in Elizabeth Street in the city I think, and it was felt that, you know, that was a fairly expensive place to be, and they've now moved to Surry Hills. I don't know that the cost savings are there; certainly the industry seems to be happy.

MRS OWENS: Yes, we went to visit them at their Surry Hills offices and they said that they actually had made quite significant cost savings from moving out of the city. I mean, I don't know what the level is, but I suppose there is insufficient transparency for you to be able to judge that. Is that what you're saying?

MS SIMES: Yes, definitely. Reading the annual report is not information for you to gather how well the place is being run, and I think it's not necessarily that people are saying, "You're badly run", but they would like more evidence of "How well you are run," and I think that that would go a long way to making industry more comfortable about the sort of fees that they are charging. I know certainly people in the private sector are not always as well aware as they might be of the particular costs that are incurred in the public sector because of the requirements that government puts on you and the level of documentation you need to provide, etcetera. There's certainly room for better PR to make industry aware of why costs are as they are.

PROF SLOAN: You've got what from our point of view is quite an important statement at the very end of your submission, which is very clear, talking about possible changes: "This means that many titles which would not have been released because the costs of classification made it uneconomic to do so will now be released." We're very interested in that sort of thing, that in fact these cost recovery arrangements are in fact restricting consumer choice. You don't have to answer it now, but if you had some sort of examples of that, that would be extremely useful to us.

MS SIMES: Look, I do have some statistics on that that I can provide you.

PROF SLOAN: That would be great, because that's one of the nubs of our inquiry.

MS SIMES: When Ernst and Young did their review a couple of years ago and we put a submission in to that I surveyed my members and asked them how many titles in the previous year, for example, had they not released because of the cost of classification, and I do have a number on that.

PROF SLOAN: That would be very good, because presumably it's a small market to start off with and for some of these niche products it's an extremely small market.

MS SIMES: For example, an opera or something like that, there's a very limited market and the new legislation will clearly make a big difference to a lot of that niche product that just wasn't economically worth releasing beforehand.

MRS OWENS: It is the price of doing it rather than just going through the hassles of providing information for the process to go ahead.

MS SIMES: Yes.

MRS OWENS: It's the cost of doing it not the other things.

MS SIMES: Yes.

MRS OWENS: I'm not quite sure what the companies have to produce. I suppose it's just the video. They don't have to do anything extra.

MS SIMES: In the case of video it's just the video, yes.

MRS OWENS: They don't have to prepare a document; you know, a case for getting this thing into the Australian market.

MS SIMES: No.

MRS OWENS: So there's not many other compliance costs with doing it. It's just the costs of giving them a video - - -

MS SIMES: I mean, there are compliance costs.

PROF SLOAN: Delay.

MS SIMES: There is delay, and that's certainly an issue, although in the amendments that have recently gone through there is a direction to the OFLC to process product within 20 days, which is really very good. A couple of years ago I can remember around Christmas time people were quite frantic because there had been delays of, you know, two and three months on product. That's partly a function of the government appointing people to the Classification Board and they are at times very short-staffed because of delays in making appointments, because they can be quite contentious as well. While industry is aware of that it doesn't help them when

they've got to sell their product. The 20-day provision is very welcome.

There is also a provision within the legislation for people to pay a fee for a quick turnaround time. I think people are very happy with how that's working. However, if the staffing levels are low or there's a backlog or something like that, then the pressure on the companies to have to pay a high turnaround fee - - -

PROF SLOAN: Yes, it can be manipulated, can't it? Of course for everything that's fast-tracked something gets slow-tracked, doesn't it, particularly if you're not actually deploying additional resources?

MS SIMES: Yes. One of the difficulties we've got at the moment is that in the legislation that's about to come through there is a clause in the bill - at the moment with games people semi self-assess and then submit a range of documentation to the OFLC, including a video with any contentious pieces and a statutory declaration on what's in the game, etcetera. The director has a discretion not to accept that and to require the game to be submitted. This would make it extremely difficult, if not impossible, for many of the distributors because as there's simultaneous release worldwide they often don't get the game till a couple of days before the release date.

They can't get it turned around in time. There's a very high piracy rate on games - probably 20 to 25 per cent. Even with a 20-day turnaround, that's three weeks lost to them and they're the highest three weeks of sales and so difficulties like that are arising and we're trying to speak to the government at the moment because it's something that seems to have slipped through without any consultation at all. Decisions like that, where there should be much broader consultation and there should be systems in place to make sure these things can be resolved without such a heavy-handed approach before it comes to that, that does create problems. Consultation, as I said, is a bit erratic. Sometimes it's very good and sometimes there are gaps.

DR STEWARDSON: The Ernst and Young report a couple of years ago, you say, looked at the basis on which fees should be charged. Is that something that might perhaps be useful to us and of which you could give us a copy?

MS SIMES: Yes, I think so. It didn't look at actual dollars but what it was looking at was to see whether there were other ways of charging fees that might be fairer to smaller or larger companies or people with niche product and various options were suggested, most of which were rejected by Ernst and Young, and the government appears to have accepted that and stayed with the current system but moved to the broader exemptions, which seems to satisfy a lot of the fairness criteria that they were looking to work towards but I can see if it's possible. I'm sure the OFLC could give you a copy of that.

PROF SLOAN: We think we might have a copy.

DR STEWARDSON: Okay.

MS SIMES: One of the difficulties was that it would have ended up that you've got businesses cross-subsidising each other and just because you're a small company doesn't mean you are a less profitable company, and a huge range of product that's - for example in the video area that's classified by the OFLC, I think it's 40 per cent, is X-rated product, and a lot of the titles don't sell very high volume, so really you would have the distributors of The Lion King subsidising X-rated product, which didn't seem very fair.

PROF SLOAN: No. All that issue is really important, I think - that you end up having a neutral charging structure to make sure there aren't funny cross-subsidisations going on. Your submission was very clear, Megan, and it was useful because we need to hear from users as well as the agencies.

MRS OWENS: But I think we would appreciate if you've got any examples from that survey - it would be great.

PROF SLOAN: Yes.

MS SIMES: Okay. Thank you.

MRS OWENS: Thank you very much for coming. We'll just break for a minute.

MRS OWENS: We will now resume. The next participant this morning is Mr Stephen Webster, managing director, Nature Sunshine Products of Australia Pty Ltd. I actually have to ask you to repeat your name for the transcript.

MR WEBSTER: By all means. Good morning. My name is Stephen Webster, managing director and owner of Nature Sunshine Products of Australia Pty Ltd.

MRS OWENS: Thank you and thank you for coming and, as I said to you when we met, I actually found your submission a very useful one because you did set out very clearly for us details of your application fees and the annual fees for listing and regulation and the fees for the certificate of good manufacturing practice and other compliance costs and I think it was one of the - yes, it was one of the early submissions, number 3, and it was just, for me, a very useful background very early on in the inquiry, so I would like to thank you for that.

MR WEBSTER: Thank you.

MRS OWENS: Have you any opening comments you would like to make before we get into some discussion?

MR WEBSTER: Yes, I would love to. I've been in this industry now 20 years in three different countries: New Zealand, America and Australia. I have currently lived in Australia for the last 13 years and I think I probably know more about the industry than anything else, but I've seen huge changes in it, especially in the regulatory environment, and I must say that that is not a global trend. There certainly is a global trend to greater interest and dissemination of information about the products that I sell and, by the way, I sell herbs and vitamins; what you see there. I am an importer. We do have some locally made products but the majority of our products are imported.

There has been a huge growing interest in this area of complementary health care products and medicines: medicines because we are gathered under the umbrella of the Therapeutic Goods Administration and we are classed as a medicine and certainly since the introduction of the TGA - or the Therapeutic Goods Act 1991 - when it came in, 89 when it was first moved, we have seen huge changes in this industry and, I am afraid to say, increased costs every year. In fact, this past July we saw a 39 per cent increase in our costs in registrations and listings, so that the department could move to 100 per cent cost recovery.

MRS OWENS: Thank you very much. When you said "last July" this was July this year.

MR WEBSTER: This year, yes.

PROF SLOAN: Is it not true that probably quite a few of your products are overseas - I mean, they're not classified - well, they're classified as food or something else and therefore are not under a regulatory umbrella?

MR WEBSTER: That's exactly correct. In most other countries - I was nearly going to say "all" but I can think of two that it isn't - they are classed as dietary supplements. Canada does have something called "a DIN", which is short for "a drug inspection number" and that DIN is similar to our registration or our listing number that you see in these products. There are some moves in other countries to maybe register or identify but no-one in the world classifies them as medicines as we do in Australia.

PROF SLOAN: So at its most fundamental level is that a bad thing now, that we've kind of made the regulatory umbrella larger, or is that just something you have to accept now if you are working in this industry in this country?

MR WEBSTER: We certainly do have to accept it because it's the regulation. I think it's good and bad. I think it has lifted the credibility of products.

PROF SLOAN: That's a good point.

MR WEBSTER: And certainly there are more medical practitioners who are looking at these products by way of supplements and aiding. I think it's a bad thing in the way that we've been lumped in with perhaps some medicines and drugs, which don't have the same effects and we don't wish the same effects and it has brought us into an environment of regulatory control, which I think is amiss. Obviously, if you and I were not feeling well we would look very carefully at the foods that we took, so you could say foods are a medicine as well, and we would probably go onto more liquids and a bland diet and keep down on the dairy foods and maybe no milk and cream, just for that.

PROF SLOAN: Yes.

MR WEBSTER: So food could be a medicine right to the other end of the scale where, if we were feeling unwell we would go to our medical practitioner and say, "I have these symptoms" and he would say, "Look at this" - and somewhere in between our products fit. Towards the food end of the scale mainly for self-diagnosis and for supplement purposes and as an aid to just feel better and wellbeing. I must admit however, because we do sell herbs, there are many herbs that have traditional and folklore use and, if I was feeling unwell or if I wanted a particular thing to happen to me, I would turn to a herb to help that or aid that.

MRS OWENS: I would like to just explore with you your views about some of the fees that you've listed in your submission and what impact those sorts of fees would have potentially on you or your competitors; for example, you say here each product you've listed costs \$400 application fee, so if you've got lots and lots of products you've got to do this when you apply, and then you've got an annual fee for each product that you make. I don't know how many products you are carrying at the moment, but you've got an annual fee. What does the TGA do for the annual fee? It's \$350. What do you get for your money?

MR WEBSTER: To register this product costs \$400 and that is a process of critiquing the product and this particular one, because it is an L-category or a listing category, is tested for safety and quality. Efficacy is not bothered about in this particular product. If that was an R, or registered, it would. That's \$400 to have it approved or looked at by the Therapeutic Goods Act on a questionnaire with about 32 data points. At the same time - - -

MRS OWENS: So they probably earn their \$400 on that.

MR WEBSTER: That's debatable but perhaps they do, yes, and I'm not saying that there shouldn't be a form of registration or identification of products. I believe there should be.

PROF SLOAN: So that's at least - that do no harm.

MR WEBSTER: That's correct, and that's with the listing category.

PROF SLOAN: Okay, so there's no verification of any claims.

MR WEBSTER: No, no. The claims are approved. Whatever claim I make on that application I put on the label and I cannot in any of my literature deviate from that claim. At the same time I pay \$350 for the annual listing, so that's an up-front fee of \$750, and that annual fee of \$350 allows me to keep it on the register and, to the best of my knowledge, all that \$350 does is keep me on a database somewhere in Canberra.

MRS OWENS: Do you think it costs them something to maintain that database?

MR WEBSTER: Most definitely. Without a doubt.

MRS OWENS: \$350?

MR WEBSTER: In my submission I have suggested that there are 18,000 listed products on the register. At \$350 each I believe that that is just over \$6.3 million. I would question that expense in maintaining a register of 18,000 entries.

PROF SLOAN: Is there some argument though that you want to charge something - let's not figure what the fee is at the moment - so we don't have basically extinct drugs that are - whatever I call these things - products that aren't used on the list, so it's kind of an incentive for the list to be only current and for the manufacturers and the like, the suppliers, to cull the list appropriately?

MR WEBSTER: I think there should be a list maintained and I think the biggest reason for that - or the best example I can give you - is that if any of the constituents in this product were ever found to have a detrimental effect they could pull that product off the list and identify exactly who sells that product and what products they

are in. I could be notified immediately. I provide a 24-hour contact on that list, so they could say, "We have a problem anywhere in the world with this particular product. Can we take some measures against it?"

Someone could have a reaction to our product and I think there should be identification from that. Might I also add as far as fees and charges - before I can pay that \$750 annual charge for the first year, 350 thereafter, I must send an inspector from Canberra to the United States, where this is manufactured, to conduct an audit which certifies that I comply with good manufacturing practice. I receive a certificate, which at the moment lasts me 18 months. That audit took the inspector nine hours and cost me \$11,000. I have 200 products on the register, by the way.

DR STEWARDSON: Does the agreement that's been signed I gather between the TGA and the USFDA to recognise their inspection services in America solve that problem for you from now on?

MR WEBSTER: From now on it may; it hasn't up until now. In fact, that was something that we brought up at the beginning, but the inspectorate felt that they could not trust or accept that certificate. I understand there have been changes just in the last few weeks and months about that and would maybe anticipate that my next audit would be done from somebody on site, maybe even a private individual contracted to the FDA with a set of guidelines.

MRS OWENS: So that issue may resolve itself.

MR WEBSTER: I hope so. There will still be an inspection fee.

PROF SLOAN: Yes, because the \$750 is looking quite trivial compared with your \$11,000.

MR WEBSTER: It is. I've got to divide that by 200 products and 18 months.

PROF SLOAN: Okay, so it's all manufactured in the one - - -

MR WEBSTER: Fortunately it is, yes.

PROF SLOAN: That's lucky for you, because you could be up for more, couldn't you?

MRS OWENS: No, but you've paid for a lot of trips, have you?

MR WEBSTER: We're on our third one at the moment, yes. As soon as I deviate from this manufacturer or as soon as I deviate from the recipe or the constituents in this product that listing is null and void and I've got to apply for another listing. I can change one product and that combination has to have a new listing.

MRS OWENS: Do you think it acts as a deterrent for people to actually put things

on the list and maybe still have the products here? Could they get away with this without having them on the list?

MR WEBSTER: I think it acts as a deterrent to get around the system. There is no honest way you can get around the system. These people if they wish to do so would have to do it illegally, and most of that would be by the Internet or by having the source of the posting or shipping of the product overseas. So they could quite easily encourage sales over the Internet or through facsimile or through telephone and that product would be shipped from somewhere out of Australia.

DR STEWARDSON: And that would be legal?

MR WEBSTER: That would be legal. There is a personal import scheme which allows any Australian to order up to three months product four times a year. However, there are a lot of direct sales companies - there are some direct sales companies, let me clarify that - and direct marketing companies who perhaps advertise the products within the framework of the personal import scheme, but it is just a way to get around the requirements of the TGA.

DR STEWARDSON: You used the phrase "non-complying competitors".

MR WEBSTER: Yes.

DR STEWARDSON: Apart from people supplying from overseas via Internet-type orders in the way you've just been talking about, which is legal you're saying, are there many non-complying competitors within the country?

MR WEBSTER: Sir, there are a few. One of the areas of concern is the traditional Chinese medicine areas where many herbs are available in their raw form and often these find their way into Australia and some are labelled differently than they are, unfortunately; that is a method that some people use to get around it.

PROF SLOAN: You, along with plenty of others, seem to be less than enthusiastic about the TICC - the TGA Industry Consultative Committee. Would you like to expand on that? I mean, in theory this seems like a good idea, to create a liaison between the regulatory agency and the client, so to speak?

MR WEBSTER: I believe it is. What it's doing, it's adding another infrastructure, it's adding another level. The 32-point data application for this product. Because I have so many I farm out to a consultant. The consultant fills that in; I sign it, send it off. We therefore have a consultant to fill in a form to send to the TGA. Now we're adding another infrastructure. I think that classification should perhaps be broadened where they have more responsibility for the products than you see here, the complementary healthcare products. The current minister has gone some way to try to do that with the Complementary Healthcare Council, the new one that they've set up. But I must say as an industry member I have not seen that benefiting the industry or coming into its own as yet.

PROF SLOAN: That actually is a point we haven't much thought about in a way, because of course the TGA has a very broad remit and there's always the possibility that a consultative group like that might end up getting say dominated by the prescription/pharmaceutical part of the industry. When we went to speak to your association, the Complementary Healthcare Council, there was a sense in which the "one size fits all" does create problems for your segment of the industry.

MR WEBSTER: Most definitely. It wasn't so many years ago that the pharmaceutical industry was very disparaging of our products, because it really was a "them and us".

PROF SLOAN: Now they're buying it.

MR WEBSTER: Thank you. I was just going to say, "Now they are buying us." In fact, one I believe owns probably about 30 per cent. However, I'm not saying that the industry didn't deserve some of those remarks. I think we've come a long way in the last decade to know where we fit in the industry, and I think if we keep within our parameters everybody is happy. It's when we go out of our parameters or when we've got some very enthusiastic or silly people who suggest they can do things with these products which simply are unsustainable and unreasonable.

DR STEWARDSON: As I understand it your industry seems to be a bit ambivalent as to whether it really wants to be part of the TGA process or not, because in a way you're nearer to being a food and you'd prefer much less regulation and less cost of regulation, but on the other hand, the TGA allows you to say that your product cures bad backs or whatever and that this is an advantage to you. Is that correct? Have I got the story right?

MR WEBSTER: I think you've hit the nail on the head. I think that's exactly right. 10 years ago we weren't really given the option; it was the TGA or nothing. I don't think we realised where the last decade would take us. Having now been lumped in with medicines and drugs for the last 10 years I think we realise that we're in the big boys league and we are towards that food end of the scale more and could there not be a division or a department in there which looks after us and has our 18,000 registered products, of which our industry may only account for a percentage of that? Remember, that 18,000 would cover a lot of the medicines and that sort of thing.

I don't believe we deserve the same scrutiny. I don't believe we deserve the same cost structure. I don't believe we deserve the same regulatory environment. However, to protect the customer I recognise that there must be some environment regulatory that we are part of.

PROF SLOAN: Because is not part of the trouble with the "one size fits all" that there is no patient protection on, you know, hawthorn berries? You can't patent a herb or a mineral, can you?

MR WEBSTER: That is exactly correct.

PROF SLOAN: So a pharmaceutical company in exchange for submitting and getting the tick of approval, even if it's expensive, then has quite a long period - - -

MR WEBSTER: A period of time.

PROF SLOAN: - - - of protection from competition because of the patent.

MR WEBSTER: Correct.

PROF SLOAN: But your products by and large, once they're listed, there's nothing to prevent a competitor making use of that.

MR WEBSTER: That is correct. The other thing with full label disclosure, if this was a combination - ie, there were two or more constituents in it - it would actually have the percentages. So I don't - - -

PROF SLOAN: Right, so it's the recipes.

MR WEBSTER: Yes. I don't even have a chance of getting that product out before anybody does it, because the second I release it on the market everybody can see exactly the amount of the constituents in it.

MRS OWENS: So that raises a question you've mentioned in your submission. You talk about "the costs incurred by industry members to comply with and contribute 100 per cent cost recovery or anti-competitive and deny consumers access to a full range of cost effective low risk health care supplements". I've just quoted from your submission. Is it the charges that are really the block or is it the fact that you don't have the patent protection and that certainty of being able to get into the market and actually make money in that market. I mean, what is it?

MR WEBSTER: I think it's the charges. We can't patent a product which we just gather and identify and make sure it's clean and packaged and market. We can't patent that; we don't wish to. This cost structure has been increased by, just recently, the addition of goods and services tax to this industry. Prior to 1 July there weren't any taxes on this product. On some minerals and some of the products there may have been a wholesale sales tax, on some of the raw materials, but it was very, very small. Not only are we paying full cost recovery to a government department which in my view does nothing more than maintain a registry - it certainly doesn't do anything - or my money, I don't believe, goes for the public safety health or welfare, but we're now paying, or the consumer is paying an extra 10 per cent. It's almost like we're being taxed upon a tax upon a tax.

DR STEWARDSON: Can we just go back to something you were saying before that last question about your particular products.

MR WEBSTER: By all means, sir.

DR STEWARDSON: As I understand it - I think I'm right - the TGA is in the process of introducing more categories of product. At the moment the products are either listed or registered and that relates to the degree of potential risk of the product if it's not correctly prepared and I think I'm correct, aren't I, that the TGA is about to adopt the European system of four categories, the lowest of which has less registration than now. I'm wondering whether this change will in fact to an extent answer the sort of worries that you have with your sort of products?

MR WEBSTER: To the best of my knowledge that is not the case at the moment. It is something that has been rumoured. The TGA have not suggested that they're looking at - well, they've suggested that they're looking at it but there is nothing concrete there. We did suggest some years ago that there should perhaps be a classification of N, short for nutritional supplement or something like that, but at the moment there are only three classifications; exempt, listable and registrable.

DR STEWARDSON: Are you familiar with the European system?

MR WEBSTER: Yes.

DR STEWARDSON: Which they did go over to that, which I think is four - there's an exempt and a (1), (2a), (2b) and (3), or something, and (4), would that meet some of the problems that you have and give a lower, hopefully lower, cost from your point of view but a lesser degree of intensity of assessment for your products that are carrying a lesser degree of risk?

MR WEBSTER: If that was the case, yes. It's not the intensity that I have any problems about; it is the cost structure to maintain that register, and to approve or to recognise the product. I have no problems with standing behind the product that I sell. I said I think there should be some for public awareness and I think it has added credibility. It is the cost structure when you have lumped these products in with everything else which tends to blow out.

DR STEWARDSON: So it would be a matter of whether the ongoing registration and/or fee was also reduced for these lower categories, less risk categories?

MR WEBSTER: Yes.

DR STEWARDSON: You mentioned also that there's a low volume, low value provision for exemption from fees in second and subsequent years which would help small businesses. Is that issue one that helps your particular products or are you talking about other products there?

MR WEBSTER: Yes, there is a low volume, low value category. Yes, it does help our industry. Obviously a marketer of these products would not wish to introduce a

new product and put it in that category because they would think what is the use of doing it anyway. Where it does help is where if this was a combination and the constituents were changed I would simply leave that on the register and not have to pay for it in the expectation that this may be able to come back within the year or the next year. So the way that we use it is just to let it sit there and not pay a fee for it but we would never introduce a product or knowingly sell a product under that category, or at least I hope not.

PROF SLOAN: No, it doesn't sound like a very good business decision. Can I come back to this whole issue of listing these products and the incentive effects. You have this ongoing fee that you pay each year to keep the product on the list and you said before that if you vary something in some way, the label or the manufacturing process, or whatever, you've got to virtually do it again. So does that mean that there's an incentive on you not to relist, not to make those changes? Does it act as a deterrent? Does it influence how you run your business?

MR WEBSTER: Most definitely. It acts as a headache. The problem is that that decision is often taken out of my hand. Because these products are pure, grown in the field, or the climatic region where they are, I'm subject to climatic changes, to weather changes, to patterns and that sort of thing, or a crop which simply doesn't grow in one particular year. So I might be buying from one particular area, something happens and I can't get that particular product straightaway; a raw material which is used in this product is not available for a period of time.

I may have to wait until the next crop or I may have to look elsewhere. The product may be woodier or more - marshmallow is a particular product which when harvested is a bit like cottonwool. Sometimes, depending on the texture or the amount of moisture in there, you simply can't get 380 milligrams inside a double zero hard gel gelatine capsule. As soon as I vary that to, say, 320, or 380 this particular year, my registration for that product is finished.

MRS OWENS: So you have got to then pay a new application fee?

MR WEBSTER: \$400, plus \$350, and then, as the commissioner just said, I just keep this on the register in the hope that maybe if I hit the problem next season or the season after I can revert back to that one.

MRS OWENS: Yes, if it's just a one-off you want to keep the other one there and pay the ongoing fee for that.

MR WEBSTER: Yes, which then becomes low volume, low value, and then I have a degree of protection from that.

MRS OWENS: So you still do have a list that has got things - this is where we started this discussion - there are still going to be some things that you may never want to come back to.

MR WEBSTER: Most definitely.

MRS OWENS: So it's not really an up-to-date list, is it?

MR WEBSTER: No. I may market 200 products on my price list but I may have 260 applications in with the Therapeutic Goods Act at any one time.

PROF SLOAN: It's another example of one size fits all because, of course, with manufacture of pharmaceuticals, presumably, they can control their products according to the listing, whereas what you're saying is that there are things outside your control.

MR WEBSTER: Correct, because a drug or a medicine would normally extract the active ingredient and through chemical means it would be there and then put together.

MRS OWENS: What's the total cost to your company of all these activities?

MR WEBSTER: \$180,000 a year and we are a very small company.

PROF SLOAN: Presumably that doesn't include your consultant.

MR WEBSTER: Actually, it does. Let me clarify that. That includes my 200-odd registrations with the Therapeutic Goods Act; it includes my GMP bill, annualised or monthlyised, 18 months I take that; it includes the regulatory consultant that I use; and it includes my marketing manager, a percentage of her time that is just spent on regulatory affairs, so it's half a person in that area.

MRS OWENS: That's useful to know, too. Your competitors are probably having to incur similar sorts of costs, but if you were operating offshore, your costs may be significantly different. If you go to New Zealand and maybe set up there - - -

MR WEBSTER: I could.

PROF SLOAN: Yes, but you'd have to go to New Zealand.

MR WEBSTER: My competitors would have to be doing exactly the same. The only difference would be whether or not they've got more staff or less staff than me, whether or not their consultant charges more or less and how many products they have on the register. There's just no way around it.

PROF SLOAN: And there's no back-door route in through New Zealand?

MRS OWENS: Under CER?

MR WEBSTER: Interestingly enough, the closer economic relations that you're referring to, the therapeutic goods administration has been very forward in looking at

New Zealand adopting the Therapeutic Goods Act. New Zealand have said, "No, not under any circumstances because of the regulatory infrastructure that we simply cannot afford or maintain for a country this size and for the products that we've got." Products must still be registered or listed when they come in, even from New Zealand, but what we are finding is that there are materials or constituents which were used in that particular country that may have not been approved here, such as selenium, and going back a number of months before selenium was accepted here, you could bring it in through New Zealand, but not in Australia, which had the ludicrous thing of people shipping to New Zealand, getting it out of the port or even leaving it in port and then bring it into Australia via New Zealand. That's the back door and very much back door, but not something that I would want to become involved in.

PROF SLOAN: What is selenium?

MR WEBSTER: It's a mineral, it's been added to things. It's to help with general well-being. Some would suggest that it's imperative in a diet and some would suggest that in too great a quantity it will do harm.

PROF SLOAN: That's very useful, Stephen, thank you very much.

MRS OWENS: It is, thank you. Have you got any other comments before we get onto our next participant?

MR WEBSTER: I'm delighted to help the commission, any questions that you have got would be fine, but I really would like you to consider this, and given our costs and given our contribution, the size of this industry, plus our contribution now to GST, it has got to stop somewhere.

MRS OWENS: Thank you very much. We'll just break for a minute.

MRS OWENS: The next participant this afternoon is the Australian Prudential Regulation Authority. Could you please give your names and your positions with the authority for the transcript.

MR THOMPSON: I'm Graeme Thompson, chief executive officer.

MS ROSENBAUM: Thea Rosenbaum, company secretary.

MR FLAYE: Jim Flaye, chief financial officer.

MRS OWENS: Thank you very much and thank you for coming. I apologise for the slight delay. We've received your submission, which I'd like to thank you for and you've given us quite a few useful attachments, which I'd also like to thank you for. Would you like to make a few opening comments and then we'll open it up for some discussions.

MR THOMPSON: Thank you for the opportunity to come along. The only couple of points I'd like to make is that, first of all, APRA's funding arrangements are relatively new. We don't carry a lot of baggage from longstanding arrangements. The arrangements that we have were settled on by the government in 1998. They were actually reviewed again only last year and at the beginning of this year, the basic framework for the levies that fund APRA were confirmed with some modification by the government and the government has announced that there will be a further review in 2003. I think that's relevant background. We're broadly happy from the agency point of view with the present arrangements and it appears to us that industry - after some initial controversy about the changes that came with APRA, the industry on the whole has become more comfortable with them.

As I say, we're broadly happy with the present arrangements from the agency point of view. Over time, though, we would see some changes in the structure of levies, as we've referred to in the submission, and for the reasons explained there and we'd be hoping that those issues would be looked at, perhaps as part of this review, but certainly as part of the review that the government has already foreshadowed for 2003.

MRS OWENS: Thank you. As I mentioned to you before we started, my colleague, Robin Stewardson, needs to leave in about 20 minutes, so I'm going to hand over to Robin to start the questioning.

DR STEWARDSON: Thank you. I'm sorry I've got to go and miss it, but I'll read the transcript for what I miss. In the case of an organisation like APRA and other regulatory organisations in the finance area generally, where the regulation isn't so much a matter of taking a new product and assessing its chemical composition, as in others, but it's basically - as your name obviously implies - prudential and you're supervising and making sure people are doing the right thing all the time, do you feel any constraint or problem about having your income source come by a levy from those that you are regulating?

MR THOMPSON: In principle, I think it's the best arrangement, but there are some drawbacks to it. Obviously, it can be a source of tension from time to time between the regulator and the regulated, but on the whole I don't think that's a bad thing. That introduces an element of accountability for us which would not be there to the same extent if we were, for instance, funded out of general government budget funds.

PROF SLOAN: So you think it's an okay principle that the regulated pay for the regulator?

MR THOMPSON: It's a principle that applies to every other agency that I'm aware of that does the same sort of thing that APRA does.

PROF SLOAN: Around the world, you mean?

MR THOMPSON: Around the world, yes. The government adopted this structure basically on the recommendation of the Wallis committee, that favoured what it described as a "user pays approach" to funding the regulatory agencies and there are a couple of principles underlying that. One is that institutions that are regulated by us get some commercial benefit from being able to hold themselves out to the general community as being regulated and therefore - if we're doing our job well - safer to deal with than institutions that are not regulated. There is the aspect of accountability that I mentioned earlier, which would not be there so strongly with some other approach to funding.

PROF SLOAN: Do you think so, though? I mean, you're a monopolist. How accountable are monopolists?

MR THOMPSON: We have to go through an annual process of consultation with industry about our budget for the year ahead and proposals for the levy structure that will fund that budget. So while it's true that we're a monopolist, there is a good deal of opportunity for industry to tell us and to tell government that it thinks our total cost structure is too high or too low and to express views about the levy structure which would produce the aggregate amount.

MRS OWENS: But can they influence it?

MR THOMPSON: At the end of the day it's the treasurer that actually determines the levy rates, rather than us, so there is a clear avenue for industry to express a view about our funding. So I think there's a clear element of accountability there.

MRS OWENS: You've got a little bit of history now and industry has been involved, but the consultation process, has that actually led to different outcomes than you might otherwise have expected because of the industry's involvement, or has it just been, "Yes, we've listened to you and, I'm sorry, this is the way we're going to do it"? Because there's consultation and consultation.

MR THOMPSON: Yes.

PROF SLOAN: We have all been around too long to actually - - -

MR THOMPSON: At the end of the day it's the treasurer on the recommendation of treasury that makes the determination as to what the levy rates will be. I don't think - answering the question - that industry consultation has resulted in any changes to our proposed aggregate budget, but industry hasn't really made an issue of that. The consultation process has involved going to industry with two or three or four different structures of levies that will raise the amount of funds that we're talking about and industry views have certainly been taken into account in making the selection among those structures.

The other element, of course, which I referred to at the beginning, is the review that the government conducted of the framework commencing at the end of 1999 and resulting in a statement by the minister at the beginning of this year. Industry certainly participated in that review and industry views were certainly influential in the outcome of that review.

DR STEWARDSON: In terms of your charging, and related to that in terms of the mismatch between charging by industry basis, whereas your activities and costs are really generated by risk basis - two questions really in those areas. (1) are you yourselves internally happy that you have a handle on the allocation of costs by risk and by industry within that? What we're hearing from others is that some of your clients are not aware of that, so what I'm wondering is, is this costing a problem for you yourselves, from the point of view of management when you're operating on a risk basis but that you've got a number of industries and you're trying to allocate costs on two criteria, if you like, or is it a problem for you, or is it simply a problem of communication from you to your clients?

MR THOMPSON: I might ask Jim to say a little bit more about the detail of how we are collecting cost information at the moment, but we are intending to conduct supervision in a way that we describe as risk-based, which means identifying areas of greatest risk in the financial system, and that may be activities in the financial system, it may be products, it may be groups of institutions, and allocate our supervisory resources more to the areas I've identified, higher risk and corresponding less to areas of lower risk. That's our goal. We have only begun in the past year or so to feed that philosophy very strongly through into the way we actually conduct supervision. So that's more a statement of intent and a philosophy rather than a description of exactly how we are organised at the moment.

We collect information on activity basis, and by activity I mean policy advice, front line supervision activities, collection statistics, corporate support, and we collect information on an industry basis, which is obviously unavoidable given the structure of the levy acts that we are currently operating under and which require us to estimate a cost allocation on the basis of industry groups. Perhaps Jim might like to say just a little bit more about that process of cost allocation on those different bases.

MR FLAYE: Yes, it comes partly down to a matter of degree in this particular case. I mean if you go for a very micro approach with a tremendous amount of detail it comes at a cost, and that would increase the cost that we would in total be allocating to industry. By micro I mean we're measuring hour by hour what our people are doing versus a higher level of measurement, where we would take a time period and ask for the people involved in supervisory activities to give us their estimate of how much time they spend on that activity. We can do that relatively cheaply and we get a good basis then for providing an allocation across the industry sectors.

If you wanted to go down into a micro sense and then break that apart and say, "We could go further," yes, we could, but that will come at a cost of measurement, also for what purpose. I mean if we can prove that, an institution, potentially we would have spent less time than the charge that we actually gave them, bearing in mind we have to do it prospectively. If you imagine what we're going to have to do for next year: we are going to need about \$50,000,000, we are going to need a crew of people that are trained, that have been hired and are ready to do the work, and we were to move to some very strictly user-pays basis based upon exactly how much time we would have spent on supervising them, we would then be into a whole business of rebating what we might have initially charged them at the beginning of the year, and then we would be into a number - the volatility in that process is another factor which would mean "this year you've charged me \$200,000 and next year you've charged me \$110,00 and the year after you've charged me \$300,000". So institution by institution the variability I think would become a real factor if we got down to the level of precision that a very detailed time allocation basis would come up with.

DR STEWARDSON: Sorry, by institution there are you meaning the actual individual superannuation fund or are you meaning the whole group of, say, super funds?

MR FLAYE: Yes, we tend to look at it as an industry group. I mean even within that group you can argue how much time did we spend on the big guys; how much time did we spend on the smaller guys. Then there is the amount of work that we do in policy research consulting. If you looked at the amount of overhead that we would have to allocate, I mean that of its own nature cannot be that precise, because if you are doing a program that is common to all, like we are doing, for example, the statistical project at the moment, you have to allocate that across all industry groups. So the allocation itself is quite a significant part.

PROF SLOAN: But why would you allocate that at all, because that's a public good, isn't it? The Productivity Commission produces public goods research and we don't charge anyone.

MR FLAYE: This is the actual returns upon which all the supervision itself requires - as a database, as a starting point.

PROF SLOAN: But you've called it Policy Research and Consulting Division. That

sounds like a classic public good to me, so why would you be wanting to charge industry for that?

MR THOMPSON: Under the present arrangements we have got no choice. Our legislation requires that it be collected from industry.

PROF SLOAN: Okay.

MR THOMPSON: That's the answer under the present arrangements.

PROF SLOAN: But your point is not really quite right, is it? First of all the idea that there are a lot of costs associated with getting an accurate financial management system which is activity based, that is not an extremely expensive thing to do because firms are doing it all the time. You would only have to go to a big law firm and big accounting firm - - -

MR FLAYE: They charge that cost on.

PROF SLOAN: Yes.

MR FLAYE: It's an integral part of the cost.

PROF SLOAN: Yes, but I mean to say we couldn't do it because the cost is too high. I think in fact the costs are pretty much sunk and you could easily go and get a consultant and achieve that quite easily. It seems to me that you do have to have a system where the regulated have some greater degree of comfort in relation to transparency, accountability, and the fact that cross-subsidies across industry sectors and size of firms and stuff are kept to a minimum. It seems to be one of the complaints that we're hearing, that they really feel it's very opaque.

MR FLAYE: Historically it came from the past of being industry based; what we want to get to is risk based, and the measurement of risk of the number of assets in the financial system, well, that's currently what we're using. In an ideal world we would have one rate applied to all industries across all assets and that would reduce to a minimum then - there would only be potentially a cross-subsidy between the big and the small argued in that mechanism.

MRS OWENS: Sorry, why in an ideal world one rate, or is it one rate per risk category?

MR FLAYE: The best measurement or contribution to assets within the system or overall risk in the system, if you had to use just one measure rather than a cocktail of them, is the assets that are actually within the system, the assets that you have, if you had to come up with a generic measurement, which is a better measure than say a flat fee.

MR THOMPSON: We would prefer to keep the system reasonably simple and

using assets is probably the best proxy for the sort of thing that we're interested in. It's not the only - - -

MRS OWENS: Is a proxy for the costs of supervising a particular institution directly proportional to the assets?

MR THOMPSON: It's roughly proportional. The present legislation is based on the idea that the costs of supervision are roughly proportional to the size of an institution, subject to a minimum, because no matter how small the institution there is some basic amount of fixed cost associated with supervision, and the legislation also provides for a maximum on the basis that beyond a certain size the institution probably doesn't require additional supervision, certainly not in proportion to the increase in size of the institution. Coming back - - -

MRS OWENS: Sorry, can I just interrupt there. So the assumption is that the level of risk is also proportional to the size of the institution: the bigger the institution the higher the risk.

MR THOMPSON: I'm not saying that's a thought that the legislation is based on, but if we were talking about a system of charging based on risk, then I think assets is probably the best single indicator of risk that you could come up with. You could come up with much more complicated measures which - I doubt that the gains you'd make would be worth the additional complexity.

Coming back to a question that was raised earlier about whether these arrangements are a source of friction or tension between ourselves and the industry, my feeling is that the more complicated the levy calculation is, the more likely that we will have tension with industry, because we would have a more complicated methodology which people could pick at bits of. Undoubtedly that more complicated methodology would produce greater volatility I think for individual institutions and for industry groups from one year to the next than a fairly simple broad-brush measure of the kind that we have now.

On the question of transparency, industry has been provided every year with our costs broken down by industry groups. We've made the point that the sort of allocations that are involved in producing those numbers involve some arbitrary assumptions and some approximations, but I think that's always going to be the case when you're allocating corporate infrastructure and other costs. But subject to that caveat, each of the industry groups has been given each year a dollar figure for the amount of our expenditure on each of the sectors. We have to produce an estimate of that because the legislation requires that we have an estimate of costs for each industry sector, and then there's a rate of levies and a minimum and maximum amount which is struck for each of those groups. When industry talks about more transparency I'm not sure exactly what they're referring to in that context.

PROF SLOAN: I'm only relaying back - you can read the submissions yourself.

MR THOMPSON: Yes.

MRS OWENS: We're really only talking so far about the superannuation industry, because we spoke to the Association of Super Funds this morning and we haven't spoken to other industry groups yet, so they may have a different perspective. But often when people come and they talk about these things, if there is some unease either you haven't got the message across about the simplicity and the advantages of simplicity or it may be just part of a settling down process, a transitional process which eventually will settle down.

PROF SLOAN: There seemed to be some specific criticism about the most recent round of consultation and that it was very eleventh hour.

MRS OWENS: Yes, in terms of the maximum rate I think there was a feeling that that just popped up.

MR THOMPSON: There was a last-minute increase in the maximum rate for superannuation funds that was not related to APRA. You have to remember the levies that we collect not only fund our own operation but also fund - - -

PROF SLOAN: Yes, there's more criticism about that other bit actually.

MR THOMPSON: - - - some of the costs of ASIC and of the ATO. I believe the last-minute increase they may have been referring to in the maximum was related to funding of the Superannuation Complaints Tribunal, which is not part of APRA.

PROF SLOAN: Yes.

MR FLAYE: Could I just add a couple of points on to that, Graeme. If you have the same rate though across all industries the actual separation of costs then becomes less of an issue.

PROF SLOAN: Yes.

MR FLAYE: Where you have the differential, then that's a problem. So we have moved, for example, superannuation from four basis points to two basis points in a period of a year. All industries are on the same rate now, two basis points, with the exception of the ADIs, which are on 1.2 basis points. So the more we can treat them as one common group the less there is a concern around, "Have we got the right allocation in this industry or this industry?" But then of course there is a legitimate discussion about whether the big should be paying as much as they do compared to the small, but then to come up with complex arrangements for trying to mottle that adds complexity which flies in the face of what Graeme is saying.

The second point is that when we moved from the prior regime, the ISC into APRA, there were some catch-up costs. There was the establishment of APRA and in addition there were some revenues that came to us which were for past catch-up,

because we moved from a cash base to an accruals base approach in APRA, so that we got some incremental revenues and we have been able to return those to industry. So the most important thing I think that we've done for industry is that inasmuch as all of the levies coming into APRA are very transparent within our financial statements; they don't go anywhere else; they're spent entirely upon the activities that we describe. It is more the sort of partitioning of this between various sectors that I think there is a current concern, but the more we move towards one common rate the less and less relevant that becomes.

MRS OWENS: Who do you think benefits from APRA? Is it just the deposit holders and the members of the fund, or do you think the community more broadly benefits from APRA?

MR THOMPSON: There's probably no adult member of the community who is not a bank depositor, a life insurance or general insurance policy holder or a member of a superannuation fund, and we supervise all of them.

PROF SLOAN: So the public at large.

MR THOMPSON: The public at large, yes.

PROF SLOAN: But they also bear the cost, would you not agree? It's one thing to levy the thing on the funds and the institutions, but ultimately the costs are borne by the members, deposit holders, etcetera.

MR THOMPSON: Yes, that's why I don't draw a sharp distinction between our present funding arrangements and one which is funded off general government budget, because at the end of the day - - -

PROF SLOAN: It's much of a muchness.

MR THOMPSON: - - - the general community will bear the cost anyway.

MRS OWENS: One of the other issues that the Association of Super Funds raised was the moneys going to ASIC. You may not want to respond to this, but they were basically saying that they couldn't see really what ASIC was doing for their industry, or they felt that the involvement with industry had diminished over time and I think they were somewhat concerned about - I think there's still 3 or 4 million. That's outside the money going to the tribunal that was being directed that way.

MR THOMPSON: I think it's about 11 million going to ASIC.

MR FLAYE: It was 11 and a half and then they wanted one further half.

MR THOMPSON: Yes, there was a bit more for the tribunal.

MR FLAYE: Yes, 12 and a half.

MR THOMPSON: I mean, ASIC really should respond as to how they're using the money.

MRS OWENS: Yes.

MR THOMPSON: But it is certainly the case that ASIC was given additional responsibilities for disclosure standards and other regulatory matters as a result of the Wallis Committee reforms. The old Insurance and Superannuation Commission was basically divided up, abolished, and its responsibilities divided up between APRA and ASIC. The bulk of them came to us. Certainly some went to ASIC. That's what that funding is related to.

MRS OWENS: I think there is still some suspicion that there may be some duplication or overlap between your responsibilities and ASIC's responsibilities.

MR THOMPSON: In principle they are distinct and we're concerned with the prudent management of funds by the trustees and ASIC is concerned with the clear disclosure to fund members of - the rules of funds, how their funds are being invested and so on, so in principle it is clear but, in practice, they will bump up against each other from time to time and, for that reason, we need to work closely with ASIC to make sure that we're not overlapping unnecessarily or certainly not doing anything that is inconsistent, one with the other, and we do that. I think we do that.

PROF SLOAN: Monopolists tend to get kind of slothful and unresponsive over time. What are the mechanisms you put in place to make sure that doesn't happen?

MR THOMPSON: There are a number of mechanisms.

PROF SLOAN: And you might like to include the role of your board in that.

MR THOMPSON: As a senior member of management I report to a board, which has external directors. Our members are people with experience from the private sector. Some of them have worked for regulated institutions in the past and have an eye for excessive regulation and slothfulness. Coming back to a point we touched on earlier, I think the process by which we are funded by the industry and go through an annual process of having to talk to industry and justify our budget is important and there is also the element that at the end of the day it is the treasurer rather than we that makes the final determination as to what the levy rate should be. We are also subject to scrutiny by senate estimates committees, by the House of Representatives Committee on economics, finance and public administration. We have performance audits by the ANAO.

PROF SLOAN: Do you benchmark yourself against overseas regulators?

MR THOMPSON: We are aiming to develop some benchmarks. The art of developing benchmarks for prudential supervisors is not well developed. There are

one or two other agencies in the world that have thought more about it than we have and we're talking to them but, yes, we are intending to develop some benchmarks. The government has said it will conduct a thorough review of all of the Wallace reforms in 2003 and the creation of APRA is one of those, so we need to be prepared with some meaningful benchmarks and measures against those benchmarks for that review. The government created the Financial Sector Advisory Council, private sector group, as part of the Wallis reforms, to advise the treasurer about the effectiveness or ineffectiveness of supervision of the financial sector, and that group will be leading this assessment that is to be conducted in 2003. I don't think we're subject to any shortage of accountability.

PROF SLOAN: Do you hold all your activities in-house?

MR THOMPSON: In what sense, I'm sorry?

PROF SLOAN: You don't contract out some of - - -

MR THOMPSON: Not our core supervision work, no.

PROF SLOAN: No.

MR THOMPSON: Some of our support functions were outsourced but, no.

MRS OWENS: Sorry, I can't hear.

MR THOMPSON: We don't have the power to delegate our - or contract out our core function of prudential supervision.

MRS OWENS: One other way of providing incentives on organisations - I am not just talking about regulators - is to structure charges in a way that provide incentives for greater efficiency - I don't know whether that was considered - rather than having charges that basically that just met your costs and when your costs go up the charges go up. Having charges that actually - I am thinking for example output-based funding arrangements where the charges are actually linked to output measures rather than to the inputs - the costs of the inputs.

MR THOMPSON: Yes. The difficulty - going back to the previous question - is identifying exactly what the outputs are in an objective way. I mean, at the highest level for APRA is a well-functioning, safe financial system that the general community has confidence in. In developing performance benchmarks we're going to have to try to operationalise that high level objective, that high level outcome, in some way, and that's not easy to do. There are measures such as, how many financial institutions have failed. That's an element probably in assessing our performance, but financial institutions fail for all sorts of reasons other than poor supervision. It obviously could be one reason but it may not be the only one or the main one. I agree with you that it would be desirable in principle for there to be some clearer output or outcome measures than we currently have and we're hoping to develop those, but there aren't

any that you can easily latch onto at the moment.

MRS OWENS: And it's even more difficult to try and link the moneys back to those measures.

MR THOMPSON: It would certainly be difficult to link it back to how much you would collect from individual institutions, yes.

MRS OWENS: Another issue that has been raised, not just in this area but more so in other areas, is the extent to which you may or may not be subject to the scrutiny of say the Department of Finance or, more generally, to parliamentary scrutiny because of your being underwritten by industry rather than through appropriations - you get money through appropriations, but you do get your moneys initially from industry and so that reduces the incentive for government to actually look at the costs and the efficiency of your organisation. Would you care to comment?

MR THOMPSON: It's true we don't make a net contribution, either positive or negative, to the budget deficit, so for that reason I guess you could argue that the treasurer or the finance minister may take less interest in the size of our budget than for other agencies, but the treasurer is brought into the arrangements through having to set the levy rates each year and industry can make direct representation about those to the minister. As I said, we are subject to senate estimates questioning notwithstanding the fact that we don't make a net contribution to the budget one way or the other. We are audited by the ANAO as if we were a budget agency each year. I mean I can see in principle the government may take a little less interest in us than one that has the capacity to blow the budget deficit, but I still think there are a number of mechanisms there that make it most unlikely that the government will just let us carry on without any scrutiny at all.

MR FLAYE: And in addition to that, treasury takes an intense interest in what we're doing. I mean, to date we've been taking cost out and they are keen to see progress in that sense, but if we then were to come up with measures that required an expansion of cost I think we would have detailed conversations with them about why, what it was for, and it would spark off a detailed discussion about what our future needs were.

PROF SLOAN: No, I'd just like to compliment you on your submission. Quite a lot of the agencies have been what you might call less than forthcoming at this stage and I think - I mean, it seems to me a lot of our users are saying they want greater transparency and accountability, and I get the impression that you have got no problems with that but you've got to add simplicity, feasibility and stability into the equation, too.

MR THOMPSON: I believe so. I mean, I think industry would not - well, it's not for me to speak for industry but I suspect that industry would not want a system that had the potential for volatility in levy rates or total amounts to be collected from one year to the next. I mean, industry likes to be able to plan with some certainty about

how much it is going to cost to fund APRA, and I really don't think at the end of the day that they would want us to adopt a very costly and detailed activity-based costing system because I think at the end of the day the answers that would come out of it would probably be not much different from what we get from the fairly broad-brush and simple system we have now, and there would be some additional cost in producing that information.

MRS OWENS: Yes. As I said earlier, I'm really not sure what other industry groups would say about your particular arrangement. So I suppose, given that say the banking sector I don't think has yet put in a submission, they may be quite relaxed about the arrangements and it might be just one sector and it may be just, as I said - - -

PROF SLOAN: They got out of all those nasty things that had to do with the Reserve Bank, remember, we learned at university and that has now all gone by the by - the LGSs and the SRDs and all that stuff.

MRS OWENS: That's right.

MR THOMPSON: That's right.

PROF SLOAN: They were paying for it, actually. That was a worse system.

MR THOMPSON: I can't comment on that.

PROF SLOAN: Definitely it was a worse system. It didn't even work.

MR FLAYE: We do have other fees and charges which, I mean, we can introduce some of them - - -

PROF SLOAN: Yes.

MR FLAYE: - - - but they are only ever going to be minor.

PROF SLOAN: Yes.

MR FLAYE: And they are prospective, because we don't know how many acquisitions there are going to be next year - mergers, demutualisations - and it tends to be cream. But we have the mechanism to return it to industry, albeit it will be in the following year. When we have made a surplus, we set about returning it.

MRS OWENS: Yes, I think, going back to the super funds, they made a fairly strong case to continue with levies and minimise or have no direct fees, user charges on industry - - -

MR FLAYE: Yes.

MRS OWENS: - - - including to the tribunal, and I think we accepted the argument about not charging specifically for the complaints tribunal. I'm not sure what the arguments are for industry-specific fees other than for specific things you might be doing for them, and that comes back to the statistical and other research services and whether you are thinking of introducing new fees that aren't there now.

MR THOMPSON: We're certainly looking at a fee for processing licence applications. That's probably the service which is most commonly charged for on a fee-for-service basis in other prudential regulators. I think the concern that industry groups will have with fee for service would be that they would likely be regressive so that they will impact more severely on the smaller institutions than on the larger. So there would be an anti-competitive aspect to them. But one of the recommendations that came out of the review the government did earlier this year was that we should look at what opportunities there were to charge more on a fee-for-service basis and we're certainly intending to do that. But as Jim said, it's likely ever to only be a minor portion of our aggregate revenue.

MRS OWENS: Yes.

MR THOMPSON: Could I just come back to one of the questions that was raised earlier?

MRS OWENS: Yes.

MR THOMPSON: I think you asked about the extent to which we can outsource or contract others. Thea reminds me there is provision in a number of our acts for us to appoint investigators or administrators to financial institutions which are in serious difficulties.

MRS OWENS: Right.

MR THOMPSON: So in that sense we can draw on outside expert assistance to help with the administration or liquidation of an insurance company or a superannuation fund that needs intensive care, I guess.

PROF SLOAN: I mean, the reason I asked that I suppose is that that kind of is potentially a device to test the market, as it were, and to make sure that the kind of activities you're doing are at least at the same kind of costing as equivalent activities done in the private sector.

MR THOMPSON: Yes. I think we would always find that - - -

PROF SLOAN: You're cheaper?

MR THOMPSON: - - - we would be paying more for those services than the private market - - -

PROF SLOAN: In the financial services industry, you're probably right.

MR THOMPSON: - - - than we would do internally. I don't think there's much doubt about that.

MRS OWENS: And I think it just comes back to satisfying the community that there is a regulator there that they can trust and they may feel that standards or whatever may be diminished. It may be a purely incorrect perception but, you know, community perception is important. Although there are other areas in other industries where there are contracting out, if you like, to other bodies. In the European union, if you're regulating medical devices, the actual conformance assessment is not done by the notified bodies, the regulators, they're done outside - or the notified bodies - they're done by bodies other than the regulators. There's a division there.

MR THOMPSON: Yes.

MRS OWENS: So certain activities are, you know, basically contracted out.

MR THOMPSON: Yes. I doubt that that would be a cost-effective alternative in our sector. We actually do some work for state governments on a contract basis. They've contracted us to oversight some small sectors of industry which it doesn't - there's no economic case for them to have their own resources because they're quite small.

MRS OWENS: Yes, and you negotiate a price?

MR THOMPSON: We do. I mean, our act requires us to charge on a cost-recovery basis for those sorts of services, but no more.

MR FLAYE: It's very small, isn't it? It's so tiny that - - -

MR THOMPSON: Yes, they're quite small.

MRS OWENS: Okay. I think we've just about exhausted those questions that we had and I'm very - - -

PROF SLOAN: Yes, a lot more than you anticipated.

MRS OWENS: Thanks very much.

MR THOMPSON: Thank you.

MRS OWENS: We weren't really giving you a hard time.

PROF SLOAN: No.

MR THOMPSON: Thank you. If there's anything further we can help the commission with in this inquiry we would be more than happy to.

PROF SLOAN: That would be great; you have been very helpful.

MRS OWENS: Yes. Thank you for your help and thank you for coming. We'll now break for lunch and we're resuming at 1.45.

(Luncheon adjournment)

MRS OWENS: The next participant today is the Australian Transaction Reports and Analysis Centre. Welcome to the inquiry hearings. If you wouldn't mind giving your name and position with - what do we call it, Austrac?

MS MONTANO: Yes.

MRS OWENS: For the transcript.

MS MONTANO: I'm Elizabeth Montano. I'm the director of Austrac, so I'm the chief executive.

MRS OWENS: Thank you and thank you very much for your submission. I didn't even know that there was such a body as Austrac before today. Excuse my ignorance.

MS MONTANO: It's quite deliberate that you may not know about us.

MRS OWENS: Maybe you could explain that in a minute. I actually found the submission very interesting, just learning about Austrac, and you raised some very important issues and you actually raised quite a number of points as to why you believe that cost recovery from what you've called "partner agencies" may not be appropriate, so what I think it would be useful to do - you don't want to make opening comments, I understand. Is that right?

MS MONTANO: Given your comment about you didn't know we exist, perhaps I should.

MRS OWENS: Let's start there and then we can come back to the questions.

PROF SLOAN: We assumed you existed.

MRS OWENS: I don't think I'd ever thought about it.

MS MONTANO: That is actually, I suppose, part of this process, in the sense that Austrac is a support agency. Its job is to make other organisations more effective and more efficient in how they use their resources and helping them to achieve their outcomes, which is why we do talk about "partner agencies". They are not clients. "Client" has a certain connotation which, in our context, is not appropriate. They are our partners, we are their partner and we are part of a process of trying to help revenue and law enforcement agencies become more sophisticated in the way in which they approach their jobs, to be more strategic in the way in which they approach the issues and to look at the way in which all these activities that as a society we do not like, such as serious crime, major tax evasion, offences to our national security; how the financial system is in fact used by people who do those things and how to be smart, government has to realise that and to act accordingly.

The reason why not many people know about us is that that is quite a deliberate

strategy. Many cases that we are involved in, many cases that we actually initiate, we are never present at the press conferences. We are not referred to, nor do we want to be. Our accountability processes are such that those who need to know and I'm quite happy to have a discussion in camera about that, but in relation to our public role, our public face is actually as regulator and even that is a fairly low-profile face, given that the organisations we work with are the financial sector bodies. The public has a very small interface with us. When you fill out your customs form when you're coming in and it says, "Are you carrying fruit, leather goods or cash?" the question about cash is about Austrac and when you go out of the country, similarly, you will see signs saying, "Are you carrying out \$10,000 or more?"

That's about people walking the proceeds of crime out of the country and there are penalties in relation to that, so that's why people don't know a lot about us, but particularly the objective is to make others work better and, to do that, we have to do it in the way in which we do it now.

MRS OWENS: Thank you. I think I've gleaned from your submission, you've basically got two types of functions; you've got a regulatory function and an information function, so there are the two arms.

MS MONTANO: That's right, and they are complementary. As a regulator, we try to make the environment hostile to crime. Things that were thought to be quite significant weaknesses in the way in which the financial sector worked before the introduction of the Financial Transaction Reports Act, where you could in fact have a whole series of false-name accounts which were not illegal per se and which meant that money trails often stopped because there was no way in which the investigating agencies knew where the money had been put, that is now an offence under the Financial Transaction Reports Act; people have to be identified, which is a smart thing to do anyway. The FTR Act initiated the 100-point check. Now, when you go to a video shop to hire a video, they ask you for so many points of identification.

This legislation is where it all came from, so that's the regulatory role. The product of our regulation, which is not only that environment, but also the reports we get is, as it comes in, interesting, but not necessarily earth-shattering and not necessarily amazingly useful either, but when you add the analysis that we do and the way we disseminate it, the way we make it practically available to partner agencies, that where we add the value and we make those other agencies more efficient, so if they're looking for someone's money, there are numerous banks in this country and there are numerous other ways in which to move value in and out of it. To look on our database of over 50 million transactions, to see whether in fact they're there - and in many cases, I can tell you they are - gives them the first lead as to where they go.

So even at that point in the process, they are far more efficient, let alone the actual analysis we do where we identify what's happening before the agencies know that it's happening.

MRS OWENS: That's very clear. What I'd like to clarify early in our discussion is

this question about whether what we're doing should apply to you and, in particular, the guidelines development that we'll be undertaking. We are required as part of our terms of reference to develop some guidelines relating to cost recovery and you've said right at the end of your submission that you think it would be more appropriate to be excluded from those guidelines. I think there's another way of looking at this which is that the guidelines should be, if they're done properly, set out very clearly which agencies would be covered by the guidelines and which agencies wouldn't be covered by the guidelines, so to the extent that you say that you should be excluded, you probably come into that.

MS MONTANO: Yes, a branch on the tree.

MRS OWENS: You're a branch in a decision tree. Once you have a set of guidelines, then we would probably, after we discuss these issues with you today, think that you have made some valid points. We would hopefully, if we're doing this correctly, and we'll be doing a set of draft guidelines in our draft report. You would find yourself at the end of a decision tree which says, "Go no further," basically, so don't look on the guidelines as being a threat, but more as an opportunity to maybe clarify this particular issue, so you don't have to worry about it again.

MS MONTANO: Obviously the comment in relation to exclusion was on the basis of it wasn't the name Austrac per se. It was if an agency is doing the sort of things we do, then as a matter of principle, one would have thought that cost recovery was not an appropriate way in which to make us a better organisation.

MRS OWENS: There are agencies and other activities where it may be obvious that you do exclude, for example prosecutions - or we've been talking this morning about complaints bodies where it may not be appropriate to fund a complaints body. A person taking a complaint to a complaint body should not necessarily have to pay to put in a complaint, for example. If you're down the prosecution path, should you have to pay to go through that process? Maybe yours is another example of something that should not be considered. I haven't thought it right through and that's why I think this discussion today should be useful for us, but actually when I went through your submission, I counted up nine reasons why you might not want to cost-recover from your partner agencies and I thought it would be useful just to clarify a few of those.

The first one I came to was that you said partner agencies, if they were being charged, would not feed back how they're applying the information you're providing and at the moment, you've got this very useful feedback loop and you feel that the charge would act as a deterrent to that cooperative arrangement that you've got.

MS MONTANO: Absolutely. I suppose you have to understand the way in which these agencies work to understand why feedback is not something you turn on like a tap. When these agencies do these jobs, whether it be the Tax Office or an investigating agency, often the role that Austrac plays is at a very early stage in the process or it might be used at various points through the process, so when they're

actually at the end of it and they can say, "And now we can give you feedback," it may be three years later and this is part of the overall drive to be more intelligence oriented. There are a lot of intelligence lessons that are often prone to be lost at the end of the job, particularly if you have a perspective that a measure of success is how many people do you lock up, how much sort of nasty stuff do you get off the streets, how much money do you recover in relation to that naughty taxpayer?

There are in fact a whole range of other outcomes. There is the deterrent effect, there's the intelligence you learned, there's the consequences for regulation. What allowed these people to do these things that could have been avoided had you had good regulation? All these sorts of things that naturally they do not think about. Part of our job in educating them is to try and get that feedback, so that we actually try to be invited into situations where you can actually ask questions which aren't necessarily - the answers to them are not automatically produced, so you have to go in and actually ask the questions and it is sometimes like pulling teeth in the sense of saying, "But what do you think about the environment made these people able to do these things for so long without being detected? Could we have had another provision in the FTR Act about how people are identified when they buy a particular kind of monetary instrument or could we have done something else that would have made this not happen?"

That really relies on goodwill and at the moment, it is a moral suasion sort of argument. Austrac is a small agency. I do not have the resources, nor could I ever envisage being given the resources, to go in and be amazingly coercive in the sense of saying, "I am giving you this feedback now. I will follow you up every month for the next five years until you tell me the value of this individual piece of information." It wouldn't happen; we couldn't enforce it properly. We rely on the goodwill of the liaison officers, both the ones we have in their offices and the ones they have in our offices, to go out and beat the trees for the feedback. Some are excellent at giving feedback. We have 26 partner agencies and, like all human endeavours, there are some that are good at it, some that are so-so and particularly good when they get prompted and they feel morally obliged, and there are some who are very bad at it.

Our job is obviously to try to get the most out of the ones that are good and make them better and try and get the ones that aren't performing to understand that it's in their interest to be cooperative and to think about the issues, because perhaps we've thought about something they haven't. In that sort of environment and in this sort of culture, if they have a cop-out, in the sense of, "Well, we've already paid you for it. What's your problem?" then we will not get the level of cooperation. We might get a little form filled out, "Was it helpful? Tick the box yes. Provide detail," and they won't. You really have to be one of them to actually get the best out of it.

MRS OWENS: Be on the same team.

MS MONTANO: Absolutely. That's exactly the environment and if you're not, you don't get much out of it and you don't the insights. You don't have the people from my organisation sitting there listening to the debriefs, thinking from their perspective,

"What are the angles for us? What are the regulatory issues? What are the analytical issues? What do those people do again? You just said they often do X," and you think, "Okay, what could we do in our analytical profiling to write a clause to deal with the X, particularly X coupled with something else, when they happen together. Is that significant? Is that a pattern of behaviour that we wouldn't have known about and, more to the point, you didn't realise was even there until we asked a question?" So it's a roundabout way of saying that to have that sort of interaction, you have to be more than a provider; you have to be a partner.

We have thought about cost recovery, as you know from our submission. It's been considered a number of times and we've thought about what is the best way to achieve this? If it would be really successful, obviously it would be something we'd want to think about, but I just don't think it would work in the environment and that's a view that has been held over 10 years, considered by lots of people, and I think we've come to the same conclusion on numerous occasions.

PROF SLOAN: I suppose if you took a broad enough view, you would say that even if you were to cost-recover from your partner agencies, on consolidation, it's all a zero sum because they're government agencies themselves.

MS MONTANO: That's exactly right.

PROF SLOAN: There are book entries involved, and there can be advantages to book entries, but it seems to me that your main game is much bigger really.

MS MONTANO: It is much bigger. It is all about making - - -

PROF SLOAN: And the potential costs of not doing it are very high, so for the sake of charging 10 or 20 thousand dollars, you might have a chilling effect on that arrangement which is aimed at solving some pretty nasty activities.

MS MONTANO: Absolutely.

MRS OWENS: I think the whole idea of cost recovery is to promote greater efficiency, is one objective, so there has got to be an appropriate incentive effect, both on you as a regulator and your partner agency. What you're really saying is that those sort of incentives are probably diluted.

MS MONTANO: They're already there, but they're already dealt with. My best performance indicator as an efficient and effective organisation, particularly a small one, which does not have a high public profile - and I can assure you there are lots of parliamentarians who come out of a briefing saying, "We didn't realise what you did or who you were," so it's very common, and my greatest performance indicator is that when I ask for, for example, additional funding or I ask for some priority in the legislative program for amendments - my performance indicator is when the partner agencies say, "Yes, give it to them." That's my success. The other success we have is the feedback we get. Our annual reports in the past few years have some really

impressive results in them that are not identified as particular cases, for obvious reasons, but which show that we are really important to those people, but we're important to them in a sense of the way in which they do their work.

We give them the kind of support they need. When we go and ask for representation in relation to briefings, we now have a system where I get consulted in relation to briefings to the minister at the end of big investigations when they're doing their, "This is what happened, minister, and these are the lessons."

We now get asked, "I'll just check if you've got anything else to add," and a very public - well, public in that context - statement, "And we couldn't have done it without Austrac." They're my performance indicators. That's why my minister takes the view that we're a worthwhile organisation.

PROF SLOAN: I'm not even suggesting that you'd agree with me, but some other government agencies might take the view that their kind of bread-and-butter output - yes, no costs recovery, but for value-added services; something tailor-made to - well, they would probably call it a client actually. Would that model not work to you either, because - - -

MS MONTANO: It's actually the opposite for us.

PROF SLOAN: Is it? Yes.

MS MONTANO: Because our whole point is that a piece of information of its own may have value, may not have value; it may mean something significant to someone or it may not. When you're the specialist that actually does say what it really means then you're adding value. We build some things thinking about particular clients in the sense of clients. For example, we might start an idea with one agency. For example, we now have data warehousing which we started with the Tax Office a few years ago, because we have over 50 million transactions on this database. They obviously have a lot of work with cash economy. They do a lot of work with risk profiling with particular groups. Out of that 50 million how do you actually build the patterns and how do you do it in a way which is most useful to them?

We already had the architecture there for a data warehouse because we knew that was where we were going to go in the future anyway, but we developed some tools. We trial it with them; it's really useful. Then we go to some of the others and say, "We've been doing X with them. Why don't we do it with some of the people you're interested in?" So Tax might be interested in the fruit and vegetable market, because that's an area of lots of cash economy activity, but customs might be interested in particular kinds of importers who perhaps have the vulnerability of doing particular things in relation to the sorts of declarations they make for duty purposes, goods coming into the country, and there are some things that are more amenable for a few little fibs on the forms than others. So you actually end up with a product that you might have thought about as being of interest to one but it ends up that the more we learn about it the more applications we see for the others.

So we don't know where some of these things are going to take us - that's the R and D aspect - and we might find that something we've developed for a particular purpose is actually useful for a whole range of other totally different things that we didn't even realise at the beginning until people started to play with it.

MRS OWENS: I'd like to just come back for a minute to the other reasons you gave for not charging at all. I may have misinterpreted this point that you've made on page 19, which was a point you made after the discussion you had on feedback under 4.2.5. You say, "Another consequence would be that rather than continue the currently successful model," etcetera, "paying agencies may wish to influence what is reported". Are you seeing that as a negative?

MS MONTANO: Yes, absolutely.

MRS OWENS: Because often you may actually want to get some feedback on what is reported from the paying agencies.

MS MONTANO: Can I explain what we do and why, then you might understand why we make that statement?

MRS OWENS: Yes, that might help.

MS MONTANO: Under the legislation, the Commonwealth legislation and the state and territory legislation that we also rely upon, the obligation under the institutions is to report whatever they think may be of use in relation to or relevant to a contravention of a Commonwealth, state or territory law. It's drafted amazingly widely because when someone comes into a bank or goes to an insurance company or goes to whoever and they're going to money-launder - that is, deal with the proceeds of crime, proceeds of major tax evasion - you don't know. So when someone walks in the door and they've got money, cash for example, you don't know what that's the proceeds of.

So the way we do it is that the institutions report it and they just report, "The transaction happened. Someone came in with X. It didn't seem appropriate, given the cash flow of that kind of business," or "was nervous", or "asked us about the reporting limits", or did something or other. They will report a suspicious transaction. They will make some comments of what they think it might be, but they don't know, and when it first comes in we won't know either. It's when we combine that with other information and other material about those people that you might take a view as to what it is.

So if you actually said to them, "Well, folks, the Tax Office is really keen on you all reporting tax evasion," they won't know - they don't know - what it is. That's one problem. The other thing is that what the Tax Office might think and why it is often a really established way of doing it, criminals use other techniques and once they realise something has been recognised as a way in which it's done they will find other

ways to do it, so they'd go round looking for the other gates through the fence.

So if we're saying to those institutions, "You should be reporting X, because we know X is a way to do something," and they don't report Y, which is the new way to do it because we haven't told them that that's what they should be reporting, "because that's what the Tax Office really wants you to report, guys", we may well lose all that intelligence they give us which we often don't know the significance of until we have a number of banks, for example, saying the same thing: "Someone's come in and done something a bit different," and then we find there's a lot of them doing it a bit different, "Let's see what we know about them from other sources and feed it into multi-agency task forces." We find out that this is in fact the flavour of the month with these sorts of people.

If you actually try and dictate what kind of intelligence the institutions will give to you, you sort of distort their natural ability to work out what's odd. The view is that the best people to know what is a weird sort of financial transaction are in fact the bankers or the insurance companies - you know, what sort of people normally come in and then buy an insurance bond and then two weeks later come back and ask for their money in cash - fairly unusual, but when would it be unusual to them? So if we say to them, "Well, actually agency X wants this," that's what we'll get and we'll get nothing else.

MRS OWENS: There would be a degree of rigidity that would set in.

MS MONTANO: Absolutely, particularly in those institutions where - and a real problem the institutions have, and we try to help them with as much as possible, is that the traditional banker is a dying breed in the sense of a banker who totally knows their customers' business and can tell what's odd is not usual. These days in branches, where you can find them, the tellers work on a really quick processing thing. They're all part-time people. They don't necessarily know a lot about financial transactions. What they know as unusual is in their personal experience, and that may well be, "I've been on the job three months."

So we have guidelines for what we suggest, "This is one kind of behaviour. That's another kind of behaviour. Here's another kind of behaviour." But we also ask them to report anything they think is odd, and that includes people who don't even make transactions; people who come in and ask questions obviously trying to work - - -

MRS OWENS: How to do it.

MS MONTANO: - - - how to do things, and then when they decline to make a transaction that can be reported and is reported, because it doesn't have to be a completed transaction to be reported. It can be an attempted transaction.

If we actually said to them, "Well, banks, the ATO is our biggest client. We know what side our bread is buttered on. Would you like to produce lots of nice

things that you might think are revenue evasion and forget the people you think are pushing drugs, because they're small agencies and they're not paying as much, whatever?" Then our problem is we may not even get what the Tax Office really needs. We'll get what they might think they need this week, but we may not get what really is happening next week, so that's why it's trying to work out from what we get what is relevant, and that often takes a lot of expertise and time over years, and people's perceptions and what they think they want is often - and actually listen to that sometimes; it's actually counterproductive for what they really need in the future.

MRS OWENS: I presume that your international counterparts don't have charging arrangements. There's no - - -

MS MONTANO: No, and I refer to that in the submission. No, they don't at all. The whole theory is that you work on a cooperative basis. We have MOUs in place with seven now. Monday the minister for justice and customs signed a new MOU for us with Italy, so we'll be doing a lot of exchanges of information with our counterpart there, and there is, I can tell you, a lot of money that flows, and a lot of it is not paying for pasta either. There's never any suggestion of cost recovery either between us or them domestically with their other agencies. It's just not the way it's done.

The quid pro quo is always cooperation with the other agencies, that they work on feedback arrangements, that they work on other kinds of support. We do a lot of international work. I'm head of Australia's delegation to the OECD group that works on this, which is the financial action task force. It sets the international standards for what national systems have to have in place to be effective, anti money-laundering systems and all that sort of stuff. We don't get funded for that. We actually do that out of everything else and I have to call on those other agencies to help by providing another person to come or help from DFAT, sending people from the post or other agencies providing us with intelligence analysis or foreign policy advice about particular issues we're going to talk about, about possible members of these groups. It's all done on a, "This is all for the benefit of all of us at the end of the day, chaps."

Me having an MOU with Italy, for example, will benefit all those agencies. So I had the AFP liaison officer in Rome running around like a mad thing for the past couple of weeks, because the fax machines don't necessarily work very well sometimes - they turn them off at night, not thinking that anyone else is awake in the world - and so you do end up with relying on a lot of cooperation from the people in other organisations, and it is based on cooperation and saying, "Please will you help me, because you know at the end of the day I'm going to help you." That's beside the point, but certainly it's the same thing with the international - - -

MRS OWENS: It's a question of other countries internally not charging.

MS MONTANO: No, they don't.

MRS OWENS: And they don't charge between countries.

MS MONTANO: No, they don't, and we went out and asked a specific question of a whole lot of our counterparts just so we could specifically say to you, "We have asked the real question," even though we already knew the answer, and the answers all came back, "Definitely not." In fact, a couple of them wrote back and said, "Why on earth are you asking?" because in the context in which this works it's just alien really.

PROF SLOAN: I think that's very useful, Elizabeth. You really put a lot of thought into your submission, and as Helen - there's nothing to fear from the guidelines. We've clearly recognised that they're activities which you could regard as pure public good and should be funded accordingly, and so I think you'll find some branch on our tree.

MS MONTANO: Thank you. All these ideas have not been thought about for you, in the sense that these are all issues, particularly the issues - well, the relationship issues, how it works, how you get the best out of people, how you do the best for them, is what our business is about, and so thinking about how we best influence their behaviour or how they can best influence our behaviour and all those things is our job all the time. So it's a really important thing to look at all the time for us.

MRS OWENS: I think we accept your arguments. I can't speak for my other colleague who's not here, but I think in terms of the way we look at it we see that what you're doing has a significant public good element, community benefit if you like, and I think the challenge for us with all the agencies that we're looking at is to determine the extent to which there is this public good element and the extent to which there may be other private benefits or there may be other benefits to industry or whatever. I think in your case it is such a unique body that you probably don't fit easily into any other category as far as I know.

MS MONTANO: No, well, this is all secret. It's all subject to the 60 provisions of the FTR Act, so there's no potential at all for any private usage; even giving people back information about their compliance behaviour, I can only ever do it in the most general of terms, "In relation to your counterparts, your reporting levels are within the range of norm" or this or that, and we really can't go any further than even that, so there's certainly no research benefit in it.

PROF SLOAN: Thanks very much, Elizabeth.

MRS OWEN: Thank you very much. That was very interesting.

MS MONTANO: Thank you.

MRS OWENS: We'll now just break for a minute and we'll call our next participants.

MRS OWENS: We will now resume. The next participant this afternoon is Cochlear Ltd. Could you please each give your name and your position with the company for the transcript.

MR BRINCH: My name is Johan Brinch. I'm the general manager quality assurance and regulatory affairs.

MS NASH: My name is Lyn-Sharon Nash. I'm senior regulatory affairs associate for the Asia-Pacific region, which includes Australia.

MRS OWENS: Thank you, and thank you for coming, and for the submission. As we were saying before we resumed, I think that the submission was a very useful submission because it contained some, I think, information we probably couldn't have got from another source, and that is the international comparisons of the costs of getting the same device into different markets, the regulatory costs, and I think it's a particularly useful table for us. You also made a couple of other very useful points which we can come back to, but I know you have some slides to show. So you may want to make some introductory comments and then we could get into the slides, or do you want to go straight into the slides?

MR BRINCH: I think I might go straight to the slides. I think first I would like to express our appreciation for being able to come and present our view, and I know that the Medical Industry Association has been here yesterday, and probably some other people from the industry.

MRS OWENS: Yes.

MR BRINCH: So what we will do is probably present a Cochlear view which is in support of what MIAA already has done.

MRS OWENS: Good. Thank you.

MR BRINCH: What I thought we would do is just give a little bit of background on Cochlear, some comparative regulatory costs, and then the arguments in the end in terms of why we think things should change. Cochlear is a publicly listed Australian company and we design and manufacture Cochlear prostheses for the restoration of hearing sensation of the profoundly deaf and the severely hearing impaired and we market our products worldwide. Our history: we started in 1981, based on research in Melbourne, and have grown since 81 on this curve in terms of the beneficiary system, so the recipients on this axis amount to about 30,000 worldwide. We established an American office, European office, and Japan fairly early in the piece and were therefore involved with the regulatory bodies in these countries prior to TGA actually being established in 1992.

MRS OWENS: The vertical axis number of recipients is the number of recipients in total?

MR BRINCH: Cochlear as a total worldwide, that's right.

MRS OWENS: Not per annum?

MR BRINCH: No, this is the total accumulated. So in that sense, in terms of world volume, we still are a low volume manufacturer compared to others. We're established with a main office in Sydney. We have three offices in Europe, and Denver in the States, Tokyo and Hong Kong. So that's our offices worldwide. We distribute through distributors and direct in more than 50 countries. That's just a picture of our profit growth from 94 till now. We have gone from a \$55 million turnover to 144 and a substantial amount is spent in R and D. There's a little bit of a dip here when the tax rules changed from 150 per cent to 125, but we consistently have been putting quite a high per cent into product development.

As a company now I think we are - we may have dropped down a couple of places - about number 70 in Australia with a capitalisation of \$1.4 billion. In terms of what we're here for, it's really to talk about our regulatory environment, and we're dealing with the main five, being the Therapeutic Goods Administration in Australia, the Food and Drug Administration in USA, Medical Advice Bureau in Canada, Medical Health and Welfare in Japan, and the European Commission, which is represented by notified bodies and competent authorities in Europe. There are others, such as Korea, China, and so on, that are merging at the moment and that's certainly an issue for us in terms of managing our regulatory affairs.

These are the figures that I've put in the submission which basically show relationship between TGA charges, the Canadian, the European charges, which is done by a notified body that are representing the regulatory authorities in Europe, FDA and Japan, and you can see if you look at the present charges the big differential, 76,000 versus 19,000 in Canada, 12,000, which is a very conservative European figure, and Japan at 1100 and zero in America. When you compare those charges against the actual medical market you can see that the Australian market is about 1 per cent of the world market in devices, and we've got 3, 26, 41 and 18, and that's an interesting exercise if you then do a ratio between the market size and the cost. You can see a relativity factor in terms of where Australia sits compared to Canada, Europe and Japan, for instance, and it's almost 200 times as hard to recover the charges in Australia compared to Europe, given all of the competitive factors being equal, and this pie chart sort of shows that ratio. So really the key here is Australia's charges are very high. They have gone up disproportionately quickly compared to other changes as well, and it's becoming a real burden for industry. Go to the next, please.

PROF SLOAN: Have you got competitors?

MR BRINCH: Yes, we do. We have an American company that has made quite an inroad in the market in the States and there's an Austrian company that also has taken market share in Europe. In Australia we are the only supplier.

MRS OWENS: When did it come up patent?

MR BRINCH: I think some of the original ones are in 81, so I think maybe 17 years, so some of them probably are lapsing fairly shortly but we are very active in creating new patents as we go to protect the new technology.

PROF SLOAN: The question I was going to ask is that it's not as if you're just kind of facing that cost once, are you? You've got like refinements to devices.

MS NASH: Every time there's a new product - - -

MR BRINCH: That's right.

MS NASH: - - - or a change to a product, significant change to a product, it has to be resubmitted to the regulatory authorities and the criteria are different for different countries.

MR BRINCH: The first slide I showed was really the regulatory, an extract from the regulatory bodies; what they charge for a new high-risk device. This shows what actually has happened to us. The bottom pie chart - again I haven't put in any numbers there because they are really proprietary, but I think the relativities are still showing their share. This is the relative registration of implants in Australia, Europe, Canada and USA. So you can see the American registration number is about 50 per cent of the total. The European is next to it, 4 and a half per cent, and then - my hands are shaking too much for this. Australian, and then Canada. So that's sort of a relative market picture.

These are the relative costs that we have been given, basically encountered since July last year, covering the same range of products in the four regions. So you can see Australia quite outstrips Canada and Europe. Interestingly Canada is lower than Europe, even though in the first table I showed the Canadian charges were higher than European, and that is because Canada has a relationship with the FDA. So some of the products that get approved in the States don't need investigation in Canada. So that's the reason why the Canadian costs have dropped.

PROF SLOAN: But these are just the direct costs. These are the costs imposed by the agency, so they are not the indirect compliance costs.

MR BRINCH: These are just directly charges against registration of products. There are some others, like audit costs and so on.

PROF SLOAN: Yes, sure.

MR BRINCH: Again FDA doesn't charge audit costs. We have audits from Europe and TGA and we've combined those. We've been working very closely with TGA to reduce duplication of those costs.

PROF SLOAN: Where are your devices manufactured?

MR BRINCH: Here in Sydney. Then a final chart is the - - -

MRS OWENS: Before we get off the middle one, you said that Canada has got a relationship with the United States, so it's like a mutual recognition agreement, is it?

MR BRINCH: It's not quite an MRA but it's more a direct agency recognition than a formal agreement.

MRS OWENS: Is it a bilateral sort of arrangement?

MR BRINCH: No.

MRS OWENS: Just an agreement.

MR BRINCH: It depends on the devices as well. Our standard Cochlear implant is classified in the second highest risk area in Canada, whereas we had a brain-stem implant that was classified the highest risk and the Canadian did not accept that American approval. So it's a bit variable there. Then again this last one is a division between this one and this one to see that Australian cost per sale, if you like, is three times that of Canada and about 20 times that of Europe, in terms of the application and registration charges.

In terms of effect on Cochlear, we have basically decided in terms of product offering that we have two implant models that we will not market in Australia. These are special. The brain stem one I mentioned, and a double array, it has got two electrodes, and the market for those is so small that we can't justify the regulatory registration cost. That doesn't mean that if there really is a need surgeons can't still implant under an individual-user provision.

MRS OWENS: The compassionate use process that the TGA have in place.

MR BRINCH: That's right, but we will not market it as a product. We obviously are adjusting our prices to recover some of the costs.

PROF SLOAN: Do you do that on a country-by-country basis?

MR BRINCH: There is some variation in that due to marketing costs and regulatory cost and so on, that's right.

MRS OWENS: These two models were actually developed - the R and D was done in Australia; they were developed in Australia?

MR BRINCH: That's right.

MRS OWENS: But we're not going to be marketing them in Australia?

MR BRINCH: No, they are approved; one of them in the States, both in Europe, and one in Canada at the moment. We will get the second one in the States and Canada but we don't intend to make it available as a marketed product in Australia. I think that sort of ties in with anecdotal evidence from other companies, that they basically are selective in terms of putting product on the market because of the entry costs.

MRS OWENS: So basically the consumer, in this case profoundly deaf people - these two products are still relating to devices for the deaf?

MR BRINCH: Yes.

MRS OWENS: They are missing out.

MR BRINCH: That's right.

MS NASH: They are not missing out totally because a physician or a surgeon can go to the TGA and say, "I have a specific clinical need. This device will fulfil that. I want to implant it," and then they are taking that responsibility because it hasn't been evaluated by the TGA. So it puts a lot more onus on the surgeon to make that decision.

MRS OWENS: So in those marginal cases presumably they don't do it.

PROF SLOAN: So some people could miss out.

MRS OWENS: It's restricting consumer choice.

MR BRINCH: You would think so, because I mean it depends on how transparent our offering is to the medical community.

PROF SLOAN: Exactly, they wouldn't know.

MR BRINCH: Because certainly we can't. It's illegal for us to actually market the product. I think probably in general the Australian community is fairly transparent. They would know what we had, so if the issue arose - - -

MS NASH: The number of surgeons are quite small. It's a very specialised area, so they would be familiar with the product range, but that's coincidental rather than deliberate, so to speak.

MRS OWENS: It is just another barrier really, isn't it?

MR BRINCH: Yes.

MS NASH: The surgeons are uncomfortable about the fact that it's not approved in Australia, even though we've explained that the process is not because the product is not approvable; it's just the fees, and we've discussed it with the TGA. They are happy that the market size is of the size that they anticipate, this individual patient usage process being applicable to it.

MR BRINCH: But it certainly puts direct onus and responsibility on the surgeon, physician. The last point is really it's our position that we are in a somewhat privileged position, because we did get into the market early, and we got established prior to some of these price rises, so we actually can afford going through it, but even so we are discriminating and then selective.

PROF SLOAN: Yes, it makes life hard for a start-up, doesn't it?

MR BRINCH: Yes, and that's on the next slide. Yes, definitely.

PROF SLOAN: Because you don't actually know whether it's going to succeed in the market.

MR BRINCH: Yes, so basically what we're saying in that is in terms of the result of the policy and implementation we feel that the charges really are a barrier to trade. We think that they potentially starve our competition. I think they create an undue burden on start-up companies and also prevent the public from access to medical devices and high-quality health care. So those are pretty much a direct result. It's hard to scale it and say how severe it is but I think it's a real effect. And I think basically business and the public are losers, whereas in terms of the government it's probably fairly neutral because, yes, they get their cost in but then the costs go up and then Medicare reimburses or there may be less tax revenue and so on. It all comes out in the wash. Okay?

So we really think that the charges and fees should be dramatically reduced, certainly to be competitive if not better than the rest of the world because of our small market, and that should help to remove some of the negative effects that I mentioned before, to stimulate our industry here and benefit with better access to high-tech devices and health care. And I think that would actually be a win for industry, the public and the government.

PROF SLOAN: I suppose if you were a start up in Australia too, given you had that chart about the size of the market, I mean, you may as well kind of bypass Australia really - - -

MR BRINCH: There's a lot of people do.

PROF SLOAN: - - - and, you know, head straight for America - - -

MR BRINCH: Yes.

PROF SLOAN: - - - because that's where the market is anyway.

MR BRINCH: Sure. But from our perspective in high-tech medical care Australia is a sophisticated market, and it's protected in the sense that it's away from the rest of the world so you can develop here and you can test the market and try out your ideas and have that as a springboard to the rest of the world. And in terms of clinical trialling that can still happen, because that is a relatively low-cost exercise. But to actually do the marketing and go through the hurdle, that's where the problem is. And even though you say, "Well, let's go to the states and let's go to Europe" then you have an establishment cost, you've got the distances, you've got all these other things to be concerned about.

PROF SLOAN: Sure.

MR BRINCH: So it is not a simple situation for an Australian company to start up, and I think that's part of the reason why some of these ideas get sold rather than actually being developed.

PROF SLOAN: Yes.

MS NASH: The other thing, the Therapeutic Goods Act says that you can't export a product unless it has some degree of approval by the TGA, and you either get approval for supply in Australia, which gives you the right to supply overseas, or to export you need to show the TGA evidence that the accepting overseas company has approved the import of that product. So it's basically to stop dumping of unacceptable medical products and things like that, but again it's a little bit of a rigmarole to go through to get approval to export by demonstrating to the TGA that, say, the FDA has approved import. And so, you know, it's one of those - and I appreciate in the context of the dumping of unacceptable goods why it's designed that way, but it is again a complexity that as an Australian manufacturer we have to be aware of.

PROF SLOAN: Right.

MRS OWENS: You see, I find that's like an export licence, which really went out with the Dark Ages.

PROF SLOAN: So you can't avoid going to the TGA.

MS NASH: In some way or another. The fees for that are very low. They're only \$300 for that export licence, but again it's - I mean, the TGA nevertheless has that position.

MR BRINCH: Again, I don't think that's a restriction in terms of setting up medical trials overseas and getting to the point of submission and approval, but it's just the actual exportation that has to be - - -

PROF SLOAN: What about your actual dealings with the TGA. You know, pay the fee, but are they responsive, high quality, on time?

MR BRINCH: It's an interesting one because I sort of I suppose purposely stayed away from that.

PROF SLOAN: I know, and it's a bit hard for you. I understand that.

MR BRINCH: Yes, I think, because our argument hasn't really been with TGA. We have a very good relationship with TGA and they are certainly very helpful. In terms of resources, availability and time I would say that they're not particularly efficient and effective. We have had product approved in the States and in Europe already which is now in submission after five months and still not approved in Australia. We've been approved in two months in the States and Europe.

PROF SLOAN: I was going to ask that.

MR BRINCH: So there is a - well, it's hard to say - efficiency issue - - -

PROF SLOAN: Is there a benchmark going?

MR BRINCH: - - - but there is certainly a benchmark and there is a question to what level of detailed scrutiny and questions are being raised.

PROF SLOAN: Yes. I was going to say, like, the FDA mightn't actually charge you anything directly but if they take two years to certify something then that's actually more costly than paying \$50,000.

MR BRINCH: Sure.

PROF SLOAN: But you're saying - - -

MR BRINCH: That's the situation in Japan. In the US it used to be very time-consuming. I know that we had a change to a device because of a field issue in 91 and it took one and a half years to get that through on a very minor obvious change. So FDA, due to a lot of commercial pressure, has changed their ways and we are now getting things through quite quickly. So a new system that we had applied to them in 97, that took seven months, whereas in Australia that was nine months, I think (indistinct) 24. Subsequent devices of similar nature have taken two to three months, whereas Australia still after five months has not completed. And then they have had minor changes that FDA is basically approving now on a phone call, a real time review, which we've been quite successful with, and that is a system that's not in place in Australia.

MS NASH: And the FDA also have had the annual report of minor changes, whereas the TGA don't have that flexibility. It's either approvable or some very minor

things are notifiable, but you then have got to get in a queue and pay your fees. So there's no middle ground of - having a quality system that has been audited you can then put in place corrective actions and report retrospectively.

PROF SLOAN: Is there greater scope for mutual recognition across the oceans? I mean, if something has been approved by the FDA should that not actually - - -

MR BRINCH: This is what is going on at the moment and sort of my last slide is alluding to that.

PROF SLOAN: Okay. You've got that?

MRS OWENS: Yes.

MR BRINCH: No, I'm just saying that in terms of changes we think the time is ripe because the TGA regulation is in fact changing as we speak and they are harmonising with the European model and a model that is set up by what's called a global Harmonisation Task Force, whose members are FDA, the US, Canada, Australia, Japan and Europe. I happen to be on one of the study groups for that. But it certainly then will make the regulation very similar and therefore there is no particular reason why European-accepted devices shouldn't come straight into Australia and vice-versa. And that's part of a mutual recognition agreement between the commission and TGA. That agreement is still in the trial phase for high-risk devices but the end point of that, as long as it sort of works out properly, will be that European devices will go straight into Australia and we can have an Australian review and go straight to Europe.

PROF SLOAN: So on balance you probably don't mind that. I mean, there's probably more competition for you here.

MR BRINCH: Yes, there probably will be.

PROF SLOAN: But a small market.

MR BRINCH: That's right. And another thing for us is that because the agreement I believe is recognising product registered in Europe that is not originating from Europe per se, we could get our product approved in Europe and coming in, which put a lot of pressure on TGA to be competitive in their evaluation.

MRS OWENS: Yes.

MR BRINCH: So we see some potential there, but TGA still has the right to not necessarily recognise the level of scrutiny in Europe. And some of the critiques by TGA have been in some of their clinical trial evaluation, their clinical evidence. So we're not quite sure where it's going to end up. But I think in the longer term, with all the harmonisation of regulations and the mutual recognition agreements, there has to be a competitive evaluation body in Australia, and if TGA is going to take that role

they may have to branch out a section that does that, because otherwise there just won't be any pressure.

MS NASH: Be bypassed, yes.

MRS OWENS: When we did our inquiry - it was the Industry Commission at that time - into medical equipment and scientific industries back in 1996, we recommended that there be a division splitting off from the TGA of conformance assessment and setting up just competing conformance assessment bodies out there, and that recommendation hasn't been accepted by government. I don't know if you have any views about that, but at this stage it looks like it's just going to all stay with the TGA.

MR BRINCH: I don't have any particular sort of feelings against that as long as it becomes on a competitive footing with the rest of the world, and I suppose the danger is that if TGA in the end end up with some specific criteria that they don't quite think is up to speed in Europe and they reserve the right to still investigate, then you may have still this issue of fees and charges and time limits and so on. So the preference I suppose would be if Standards Australia or some other body that has some medical background as well, other than just technical, will be a competitor to TGA as an evaluation body.

PROF SLOAN: The TGA holds it in-house, but in the case of the NRA, which is basically agricultural chemical, they are a tiny little group themselves and they have accredited laboratories and accredited groups that basically do the testing and standard-setting for them. So there are models around.

MR BRINCH: The European model is that way, too.

PROF SLOAN: Yes.

MR BRINCH: So we deal with TÜV Rheinland but there is Product Services and then you've got the BSI in the UK and, you know, you can basically have your pick in Europe.

PROF SLOAN: Yes, and the accreditation system is important as part of that, but you don't have to actually hold it in-house, which can be very costly of course, depending on the fluctuating demands.

MR BRINCH: Yes, that's right.

MRS OWENS: I think there was somebody yesterday said that with the notified bodies they set themselves up to specialise in particular sorts of devices, so that with your products there may be one or two that you would automatically go to because they've just got the experience with dealing with your product and would be able to do it quickly and efficiently and cheaply.

MR BRINCH: We have dealt with TÜV Rheinland from day one, since 1993, so

we have a long relationship with them and in terms of costs I can give you the number for the last two implants. That was 4500 Swiss francs, which is about the same as the Australian dollar, and the TGA charge for the same - like \$40,000.

PROF SLOAN: That's a good point, Helen, that you build up a - because of course presumably with TGA there's the potential - or whenever I deal with public servants they're never there for more than three months, so you've got this passing parade - - -

MR BRINCH: Yes.

PROF SLOAN: - - - that you're kind of in a sense retraining every time you interact with them.

MRS OWENS: And they're spread very thinly over a very, very wide range of products whereas - I mean, that can happen in the US but there's a much bigger market and they can afford a much bigger FDA.

MR BRINCH: We have the same issues there. Just in the last year or so there has been quite a lot of changes in the ENT division of FDA and a re-education program. So it happens everywhere.

PROF SLOAN: Yes.

MR BRINCH: Japan I think is probably famous for it, because they seem to rotate each year or two as a matter of principle.

PROF SLOAN: Do they? I think that's very useful, yes. Are you above the list of Pacific Dunlop now, the four companies that sold you off?

MR BRINCH: I don't know if we made it. I think we're very close, very close.

PROF SLOAN: They're about three billion dollars in sales, I think you'll find, Pacific Dunlop.

MR BRINCH: When we broke loose, if you like, or before, - - -

PROF SLOAN: They floated you off.

MR BRINCH: - - - they were certainly up to three or four billion - - -

PROF SLOAN: That's right.

MR BRINCH: - - - and I think we're just about there, but not quite.

MRS OWENS: No, I've watched Cochlear with some interest because many years ago - I think it was back in about 93, 94 - we did an inquiry into R and D, research

and development, when it was the Industry Commission, and I think Cochlear at that stage got involved in that inquiry.

MR BRINCH: We did.

MRS OWENS: That's when you were right down there on the left side of the graph. Then we did the Medical and Scientific Equipment Inquiry and you'd sort of crept up the graph, and now - you know, the next time we do a relevant inquiry you never know where it will be.

PROF SLOAN: You just never know. They could be down the bottom.

MRS OWENS: They could go anywhere, really, so long as we don't have regulatory barriers.

MR BRINCH: Yes. In the big scheme of things the barriers here are not significant for us because our biggest market is overseas anyway. But I think we're still - - -

PROF SLOAN: But in a sense it's kind of the people who won't appear at this inquiry that we might worry about - - -

MR BRINCH: Yes, that's right.

PROF SLOAN: - - - who have good ideas but are kind of essentially completely put off.

MR BRINCH: I think there are people out there that may be thinking about it. They don't even know what the barriers are and they don't know what they are actually going to face.

MRS OWENS: Have you - - -

PROF SLOAN: No, that's actually fine.

MRS OWENS: Okay. Thank you for that. Have you got any other comments you'd like to make?

MR BRINCH: No, I think that's all we can add.

PROF SLOAN: Can we have your slides?

MR BRINCH: Yes, I have a printout.

MRS OWENS: Yes, we've got some copies of the slides and we're very grateful for those, so thank you, and I think the charts are very - they say a lot, those charts, as well as the table. So thank you for coming.

MR BRINCH: Okay.

MRS OWENS: And hopefully we'll continue to have some discussions with you or, if we need to clarify anything - - -

MR BRINCH: Sure. We certainly will be around if any questions eventuate.

MRS OWENS: Thank you. We'll now break for afternoon tea because I don't think our next participant has arrived yet.

MRS OWENS: The last participant for today is the Chemicals and Plastics Action Agenda. Welcome to the inquiry and welcome again, Ian Swann. Could you please give your names and your affiliation with the action agenda - I don't know if that's the right terminology in this case - for the transcript.

MR HECTOR: Certainly. Good afternoon, commissioner. My name is Donald Hector. I'm managing director of Asia Pacific Specialty Chemicals Ltd. I'm a member of the Chemicals and Plastics Action Agenda, which is an industry based steering group chaired by Kate Abrahams and I'm chairman of the regulatory reform working party which is one of four working parties formed at the first meeting of the steering group in March 2000.

MRS OWENS: Thank you.

MR SWANN: Ian Swann from the Plastics and Chemicals Industries Association. Our association is part of the process for the Plastics and Chemicals Action Agenda and I'm a member of the regulatory reform task force that Don is the chairman of.

MRS OWENS: Thank you, and thank you for this submission as well. I will be particularly interested to hear about any progress with the action agenda in this particular area, but in the meanwhile, if you wouldn't mind, I think Donald was going to make some opening comments.

MR HECTOR: Perhaps I could briefly summarise the submission that we've made. First, the regulatory reform working party fully supports an efficient effective regulatory environment. We believe the community expects it and the industry has a responsibility to work within it. The industry primarily interacts with the following agencies: the National Industrial Chemicals Notification and Assessment Scheme or NICNAS, the National Registration Authority or NRA for agricultural and veterinary chemicals and the Therapeutic Goods Administration or TGA.

PROF SLOAN: Which would be the most important, NICNAS, or does it depend on the sector?

MR HECTOR: I think it would depend on which part of the industry you work in. All of these agencies currently fully recover their costs through a mix of company levies and new chemical or product assessment fees. There are three basic points we make in our submission. The first one relates to public good. The policy of full cost recovery fails to recognise public good benefits provided by regulation. The full benefit flows through to the wider community and we've given some example of that in the detail of the submission. The benefit is not confined to the company, so therefore we believe that the company should not pay the full bill of compliance. The second point is the impact of full cost recovery. Because of the cost of providing data in the unique NICNAS format, up to hundreds of thousands of dollars in some cases, many new chemicals are not introduced into Australia or the introduction is substantially delayed while overseas technology is constantly changing and this causes local industry to lose competitiveness, and we've given an example in our submission

relating to that.

We believe that recognition of overseas data and in some cases, such as for example materials of low concern, recognition of overseas registration would lower the cost of registration in Australia. In some cases, Australian authorities have unique rulings on particular products, which is substantially different to Europe and North America and in some cases that can add quite significantly to compliance costs. The third issue relates to efficiency. From the industry perspective, there appears to be little incentive given to the government agencies to ensure that regulations and the administration of such regulations is efficient. We believe that provision of services from external providers should be encouraged, with the final approval remaining with the authority.

We also believe that there should be internal efficiency targets set so that services can be delivered at a lower real cost, and I think that really summarises the thrust of our submission.

MRS OWENS: Thank you. I don't know whether Ian wants to make any comments.

MR SWANN: No, I'm happy with that.

MRS OWENS: I was particularly taken with this proposal. We might go backwards from what you've just said, but this idea of having some sort of internal efficiency targets that need to be met, our colleague Robin Stewardson, who is not here this afternoon and apologises for not being here, has been thinking aloud over the last day or so about the slightly different proposal, which maybe actually links in. He's been thinking about having some sort of efficiency audit committee that would be connected, not a consultation committee, but an audit committee that could be connected to the regulator, which would have industry representation on it which possibly could be, I think, using these sorts of efficiency targets, would be reporting not back to the regulator, but to the department in which the regulator sits or, if the regulator is a statutory authority, to the minister, so it would have some teeth.

It would not be able to influence the decisions of the regulator, but would be there to just keep a check because there are few checks and balances on regulators to the extent that they're monopolies and there are few incentives for the regulators to be efficient, apart from there are governmental processes, like there is an auditor-general and there are various other processes in place that can be implemented, but I probably have not explained Robin's idea as well as he would explain it himself. Have I covered everything?

PROF SLOAN: I think so.

MRS OWENS: Is that something that would appeal to you as a mechanism? If you're going to have these targets, they need to go somewhere.

PROF SLOAN: And need to be established by some process.

MR HECTOR: I think that would be very attractive to us. There is some mention, not quite in that framework that you've just described, in the detail of our submission. But I think it's important nowadays in a low-inflationary environment, such as the one that we currently have, that the costs of doing business are increasing and we've got to try and contain those costs as much as possible if we're going to maintain global competitiveness and the plastics and chemicals industry is probably one as an industry globally that is undergoing more change than most in terms of rationalisation, companies rearranging their structures to be more competitive on a global basis and I think we've seen that reflected in Australia, very much in the last decade particularly, with the amount of value-add in Australia in the plastics and chemicals industry dropping quite dramatically and I think we need everything that we can to enable us to be more cost competitive with global or regional players.

MRS OWENS: That was one of the issues, the efficiency one, and I think the idea of setting these sort of targets is an idea that is worth exploring. Another way of getting a similar result may be to implement charges that have the right sort of efficiency incentives within the charging structures. It may be more difficult for a regulator than it may be in other areas. In other government arrangements, say with funding hospitals, there are output based funding arrangements where the hospitals get funded on the basis of what they do rather than the inputs into what they're doing and that may not work in this situation, so we need to think inventively about other approaches. You also mentioned this whole issue of compliance costs and providing data in NICNAS format and unique Australian rulings all adding to the compliance costs of the industry and the idea of recognising overseas regulation.

What do you think is the barrier to doing that? Is it a lack of trust in what's happening overseas or is it this view that seems to be around that in some way Australia is different and we need to have our own systems in place? What is it that stops us doing it?

MR HECTOR: I think it's more the latter. I think there is very definitely a view that there's some sort of uniqueness and that we know best about this environment and our own particular safety and occupational health issues, whereas in actual fact I don't think it really stands to substantive analysis. About 1 per cent or a little more of plastics and chemicals globally are manufactured or processed in Australia and the level of sophistication of the Australian industry is not great compared to Europe or the United States and, generally speaking, when we want specific expertise, we have to go to Europe or the United States to get it, so I'm not suggesting that we should unquestioningly accept data which is generated in other countries, but I think we should judiciously select material which is expensive to generate - and many of the tests that are done are very expensive to do.

We should have recognised international standards that the data should be presented in and the presentation of that material, if it's from an accredited organisation overseas or an accredited laboratory overseas, should be acceptable in

the Australian format.

MRS OWENS: So maybe it's reversing the onus. You accept that unless there's some concern that could be proved; rather than assuming that you shouldn't accept it, but do our own thing. I'm not explaining this very well either, I think it's the end of the day, but it's a problem of saying, "We don't accept that because we think we need to do it here; because we don't think that that would be appropriate because it's coming from offshore."

MR HECTOR: I think there's almost a supposition that we shouldn't accept it, whereas I think there should be a supposition that we should accept it unless we can demonstrate why it's not acceptable.

MRS OWENS: Yes, I think you've explained it better than I did.

MR HECTOR: If I could just add a point there, too. I think one thing that complicates it a little is that there is quite a difference between North American regulatory approach and European regulatory approach and from my experience of working at an American multinational, it was an issue we came across quite often that the European regulators would want a particular approach and North American regulators would want a different one and it was often quite difficult to find where the common ground lay.

PROF SLOAN: They obviously need to do something, too.

MR HECTOR: In fact, I think there's some competitive issues there between North American and European from an economic standpoint that encourages that, too.

MR SWANN: Yes, and they also have recognised that through some transatlantic dialogue that they've been conducting, but that's been ongoing for many years and the results have been found few between, so it is very difficult, as you say, because of the competitive issues between the two countries, to get a commonality. But Australia actually has been quite fundamental in helping to identify some common ground in some of the international negotiations, so I think if we take a very forward approach and push some of these initiatives through, we can actually help to proceed the international harmonisation and recognition efforts as well.

MRS OWENS: Does a lack of international harmonisation make it more difficult for us to accept overseas data?

MR SWANN: Yes, it does.

MRS OWENS: Because if it's European data, America might not have accepted that.

MR SWANN: It also gets down to the level of the formatting; the difference in the formatting between the two countries means that some elements are highlighted, as

Don said, in Europe, and others are highlighted in the US. The differences there when you're trying to introduce it into Australia raises the problem of not having a complete package. Therefore more data and more requirements are then necessary to pick up. Our philosophy is that recognition will lead to harmonisation; ultimately, through the processes of recognition and getting countries to trade, we then start to break down a lot of these perceived barriers and start to get everyone working towards having a common framework within which all of the substances can be assessed and managed.

PROF SLOAN: Really what you're saying in a sense is that different regulations can become a barrier to trade, but I wonder whether even within Australia the regulatory arrangements as well as the different charging arrangements also become a kind of factor affecting the market. I'm worried that some of these might be to the detriment of smaller players, particularly smaller players who sell perhaps a large number of chemicals but in small volumes, compared with a very big operation which has only got a small number of lines but very high volume. These arrangements aren't actually very neutral in that respect.

MR HECTOR: I think there's also the issue relating to the bigger companies too. If they have got to undergo a unique registration in Australia, Australia generally being a small part of their turnover, they will say, "We won't do it because we would rather put those resources somewhere else," and I think we are missing out on technology from multinationals because registration costs seem to be too high.

PROF SLOAN: We would really like examples of that, I think, because I think one of the themes that's emerging is that the combination of regulation plus charges is limiting consumer choice in quite important ways, and if what you're saying is that they look at the regulatory arrangements, they look at the charges, and they think, "Well, we won't bother" - I mean that's quite an important conclusion.

MR HECTOR: We could send you greater detail on this, which is contained in the material that we are submitting back to the action agenda.

PROF SLOAN: That would be great.

MRS OWENS: Thank you. We are trying very hard to collect as much of this sort of evidence as possible. In this case we're actually going to develop a case study looking at the health and safety issues, which won't just cover the chemicals, plastics area. It's going to cover a wider range of areas, but we're going to be comparing and contrasting, and any evidence we can get would be, I think, extremely useful for us. I think the other really important issue was the very first thing you raised, which was the question of the extent to which there may be some public benefit, public good aspect, from the activities of this industry, or the activities of the regulator that impact on the industry. That's often the hardest thing to pin down because you can say that the public benefits from having a reassurance of safety and so on but how you pin that down and how much of the activities of the regulator you can say are going to be benefiting the public more generally versus the industry, or the customers of the industry, it's difficult to make that judgment.

MR HECTOR: There's a reference in fact in our submission to an Industry Commission report done in 1995 that suggests that the social rate of return on research and development spending in Australia was as high as 50 per cent. So it is quite substantial.

MRS OWENS: I was actually involved in that inquiry as well.

PROF SLOAN: So she agrees with it.

MRS OWENS: As well as the Medical and Scientific Equipment Inquiry and various others.

MR HECTOR: I'm pleased I quoted the reference then.

MRS OWENS: Yes, it was a very good reference.

PROF SLOAN: But it's kind of an important point because in a sense a lot of this is quite basic. You can say, "Why does NICNAS, NRA, TGA exist really? What are their basic objectives?" If you say, "Well, basically they're there to protect the users of the products they're regulating," maybe you can kind of charge the companies because you know the companies will pass on the charge to the users, but there are kind of two aspects. Maybe they're not just there protecting the direct users, today's direct users, there's kind of a broader brief. I would have thought particularly in the chemicals industry there is a broader brief because you're worried about contamination, long-run effects and the like.

MR SWANN: Public health safety and environmental aspects of all of the agencies have been clearly noted in a lot of their charters, so it is a very significant part. As you say, it's a broader brief.

PROF SLOAN: It's a bit hard to just say the beneficiaries are the users really - are today's users particularly.

MR SWANN: That's right, yes.

PROF SLOAN: The second part of the argument is that if you actually then look at what these agencies do, of course a lot of it is - it's hard to slate home those activities to the companies anyway because they're very much of a public goods nature. They might do research, they might be formulating policy, giving advice to ministers writing questions for parliamentary question time, and the like. It's a bit hard to see why industry would pay for that sort of thing.

MR SWANN: It is very hard.

MR HECTOR: I would agree. I think the other issue relating to full cost recovery too, which I can understand is desirable in terms of optimising government

expenditure, but unless you're careful a cost centre becomes a profit centre for the government and it's really seen as a source of revenue and I think that would appear to be, I think, a distortion that has come through in, particularly NICNAS, where the fees have just kept on going up really quite dramatically.

MRS OWENS: Yes, I think we're not just interested in government budgets and cost centres, and so on. I mean our charter at the commission is to actually look more broadly at the impact on the broader community of all these activities and what might benefit government in the short term, in terms of getting in more revenue, may have adverse effects, and you've raised some yourself, the consumers are not getting access to a full range of products. So that could have important impacts downstream. You've got a range of other broader impacts that need to be taken into account. So we need to think more broadly about what the impact is on the whole community of this particular cost recovery arrangement for this particular regulator, or that particular regulator can have much broader impacts and incentive effects. That's what we are really trying to get a handle on, that much bigger picture.

PROF SLOAN: The size of the chemical and plastics industry in Australia is quite small and you were suggesting it's probably shrinking relatively.

MR HECTOR: In terms of value-add, definitely.

PROF SLOAN: I mean, that's another thing we kind of have to think about, is the kind of both the nature of the regulation and the costs imposed on users, such that it may have the impact of sort of sending it offshore, shrinking the industry in relative terms.

MR SWANN: What happens with that is that it then sends the downstream manufacturing industries offshore as well because they don't have the access then to the substances and the imports to the manufacture of those goods. So the only way to get them in the country then is to have them imported.

PROF SLOAN: You had some good examples, didn't you, like bringing in the car tinting.

MR SWANN: Yes, the windscreen tint.

PROF SLOAN: You had to get approval for the small amount of chemical that was needed to make the car tinting for the windows and as a result of that you just imported it.

MR SWANN: That's right.

MR HECTOR: Exactly.

MR SWANN: So, as you say, with the shrinking market those examples will become more and more prevalent.

PROF SLOAN: Even though it's a regulated industry presumably the view is that in net terms this is a positive industry, because we're not banning you. We are not trying to tell you that you're the - you know, you're not the marijuana growing industry.

MR SWANN: That's right. We are a very important part of society and add to the value of the lifestyle that we enjoy here in Australia.

PROF SLOAN: So there's an attempt to minimise any risks associated with your activity but in net terms there's clearly a view that it's very positive.

MR SWANN: Yes. Could I raise one other issue from the submission, if I may?

PROF SLOAN: Yes.

MR SWANN: If you look at the last page of the submission, the third paragraph down, it talks about the requirements of the regulations from the agencies increasing prices for - higher cost prices for certain activities and certain substances. That's talking there about pool chemicals, marine anti-fouling paints and those sorts of substances. A good example of the need to ensure that the cost recovery mechanisms are targeted towards those substances where a service is truly going to be delivered comes through from the pool chlorine issue, where under the National Registration Authority they had set an annual fee based on turnover for all substances that were registered with the National Registration Authority.

Pool chlorine is a very basic chemical. It is a very high volume chemical and as such it attracted quite substantial revenue back into the National Registration Authority, but when you looked at and queried what value was being delivered towards the registration of that particular substance it was non-existent in a lot of circumstances and it really raised a lot of issues from industry with regards to the relevance of the agency and its role.

PROF SLOAN: That's the issue I think both of transparency - this quite large sum of money is being raised but where is it being spent, where is the hypothecation - isn't it? That's really your point, which then kind of leads people to believe that there's a whole lot of cross-subsidisation going on.

MR SWANN: Yes.

MRS OWENS: Or revenue raising.

PROF SLOAN: Or, yes, pure revenue.

MR SWANN: That's right.

PROF SLOAN: That does tend to undermine industry support for these regulatory agencies.

MR SWANN: Yes, it does. Therapeutic Goods had similar experiences with the disinfectants legislation when disinfectants were captured under the Therapeutic Goods Administration. It increased quite significantly the cost price of a number of those household disinfectants, yet the similar sort of material could be used in other aspects without those added costs to it. So there are a number of those examples out there as well, which we can gather some more of if you require it.

PROF SLOAN: Yes, I think the more examples the better really, and I think if you can give us examples where costs kind of drive - I mean didn't you have that interesting story about you could say something was antibacterial because that's not kind of a regulated statement, whereas to say "it kills germs" that is a regulated statement.

MR SWANN: Yes, that's correct.

PROF SLOAN: So of course everyone vacates "it kills germs".

MR SWANN: And they change their labelling too.

PROF SLOAN: And go off to antibacterial. It's a bit hard to see that that's much in the public interest really, because actually to me antibacterial sounds like a stronger statement than "kills germs", but I think examples where behaviour has clearly been driven by - and presumably one of the reasons you didn't want to keep with "kills germs" is because you had to kind of pay a fee to get that validated.

MR SWANN: That's right, and it also led to a number of flow-on effects in terms of good manufacturing practice within the facility, the nature and the requirements of the establishment that could manufacture those goods. So it may be that the classification and the capture of the substance under the system has an impact on - firstly on the fees, but then there's a whole raft of hidden impacts back into its manufacture and assessment.

PROF SLOAN: I think if you could give us that. I mean I can kind of see a box coming on - like that kills germs, because people could relate to that story.

MRS OWENS: We like that story.

PROF SLOAN: I think that's a good story because that goes back to the point, what is the purpose of this regulation? Perhaps the regulation is, I suppose, to protect public health ultimately, and I mean that seems a kind of bizarre story really.

MRS OWENS: Can we just come back to the pool chlorine for just a minute. Was there an attempt at any stage to get some sort of legal opinion to see whether these charges that are being imposed there for pool chlorine, or some of these other chemicals, are indeed taxes?

MR HECTOR: Could I answer that?

MRS OWENS: Yes.

MR HECTOR: Until about a month ago APS, the company that I work for, was the major supplier of solid chlorine chemical into Australia, which we imported from various countries. We were paying registration fees in six figures a year. The cost of that, as explained by Ian, was an important issue but we also found that the regulations were not being applied fairly and some of our competitors were not complying with the NRA's rulings. We were going through the stage actually of taking that to the Administrative Appeals Tribunal to ensure that the NRA did their job properly but we never really got to that stage because we decided, for different reasons, to sell the business. Our interpretation was that the NRA saw APS as a fairly large company that could afford the fees and it was too difficult to go after the small backyarders who are packing and not complying with the rules.

PROF SLOAN: There are some kind of technical legal issues in this area and it looks as though there's kind of serious over-recovery of costs. It's potentially illegal what they're doing because it needs to be a tax and there needs to be special legislation and probably if you took it to court you probably would have won.

MR HECTOR: I hadn't thought of it on those lines actually. We were going along the administrative one rather than the legal one.

PROF SLOAN: There's a legal ruling about what's a fee and a charge.

MR HECTOR: Yes, I understand the point you're making certainly.

MRS OWENS: It's one of the things we'll be thinking about, because there are quite a few examples where regulators are just charging to keep something on a register, which is very little to do with the actual costs that they're incurring in maintaining the register, and you've got to say - - -

PROF SLOAN: That's through these three agencies there are kind of registration fees.

MR SWANN: That raises a lot of issues in those areas, but also with the company registration system for the NICNA scheme for the existing chemicals review.

PROF SLOAN: When people feel that basically what's being done is a kind of pretty cheap database on the Excel spreadsheet they're going to think, "Well, you know, what are the real costs associated with doing that?" Some of them will argue that they don't want frivolous retention of whatever on their database, but that's probably right.

MRS OWENS: I'm interested in this point you made about not applying the regulations fairly, your example you gave before about possibly you could have gone

to the AAT. How can the regulators actually not apply the regulations fairly? What sort of things can they do?

MR HECTOR: The main issue was the labelling of the product, and the NRA set specific guidelines for - well, not guidelines, regulations - as to what has to appear on the label, and they change from time to time. We were packing quite a wide range of products, so to make a label change is expensive and some of our competitors were not changing labels and their labels were not in compliance with the NRA rules.

MRS OWENS: They weren't in compliance?

MR HECTOR: Correct.

MRS OWENS: The NRA was able to just overlook that?

MR HECTOR: They never took any action on it. That's my understanding of it, but I wasn't personally close to that case. That's my understanding of what was happening, but it's included actually I think in the material that I'll send you from the working party.

MRS OWENS: Good, thank you. That would be something to look forward to.

MR HECTOR: I could certainly send you a great raft of detail on that if you would like me to from ABS's perspective, but that would be - - -

MRS OWENS: It may be getting a little bit off what our topic is, which is the charges. But I think we're also interested just on the impact of - it's very hard to divorce the charging issues from the regulatory issues and just the impact of the regulation on the cost of doing business in Australia. They're all so intertwined it's very hard to divorce the issues. We can't get into the issue of labelling per se, for example. We did have a packaging and labelling inquiry a few years ago which probably looked at some of those issues.

MR SWANN: The issue I suppose that this ties in with is once again one of allocation of costs and appropriate enforcement to ensure that if companies are required to undertake a registration system and pay costs into that there should be an adequate and appropriate enforcement policy and presence behind that to ensure that all companies are participating on a level playing field.

MRS OWENS: So in other words, if they're paying for a service they should be getting that service and it should be efficient and fair and all those other things.

MR SWANN: That's right.

PROF SLOAN: Or consistently applied.

MRS OWENS: Consistently applied.

PROF SLOAN: I think all of these - NICNA, NRA, TGA - have kind of boards, don't they? Do you think they do much?

MR SWANN: They operate in different ways. We don't have a lot of experience. We can get some information for you on the Therapeutic Goods Board. I'm not sure whether you can, Don, but I can't talk a lot on that one.

MR HECTOR: No, I can't.

PROF SLOAN: Do they have anything beyond the TICC?

MRS OWENS: Who, the TGA?

PROF SLOAN: The TGA.

MRS OWENS: I think it's just the TICC.

MR SWANN: The National Registration Authority - - -

MRS OWENS: They do have a board, yes.

MR SWANN: - - - has a board and it's of multi stakeholders. It's unclear whether or not they have a strong ability to influence the process in terms of administration or structures within that full cost recovery or any of those issues, but a number of our members have expressed a strong desire that the model of the National Registration Authority Board is a good one to look at. We also feel that the Industry-Government Consultative Committee, which is the forum used with NICNAS, is a good model of industry and government coming together to look at the issues. How that information is used could well be strengthened I think by maybe restructuring that a little bit towards your comments about an efficiency audit committee. That may well then start to divorce some of the process issues away from the administrative issues.

PROF SLOAN: I think that's quite a good - yes. It's interesting, because I sit on quite a few boards. Of course I think if I got on a board I'd kind of be wanting to maximise revenue and I'd be thinking, "What else can we" - you know, you might get people with the wrong kind of mind-set and you would lose sight of the fact that, "Hey, you know, what are we here for?" I'm not absolutely convinced having a board per se is - - -

MRS OWENS: It has to have the right sort of set of instructions as to what it's there to do.

PROF SLOAN: It does, yes.

MR HECTOR: Yes, its terms of reference have to be pretty clear.

PROF SLOAN: But it can't be seen to be undermining the independence of the regulator either. Yes, I think maybe a more narrowly focused audit committee which doesn't actually report to the CEO is probably not such a bad idea really.

MRS OWENS: We're going to think about it further. We're still pondering this idea. I think you raised some good points in the submission about the administrative efficiency and the arrangements, and some of Robin's thinking may have come from this particular submission and from the other one.

MR SWANN: True.

MRS OWENS: Have you got other issues?

PROF SLOAN: No, that's absolutely fine. But as I reiterate, those examples I think are very useful. Even at this early stage, some of the themes are emerging particularly from the users and the cry for transparency and for accountability and for some acknowledgment of the split between public and private production in what they do. It's good that there are some clear themes emerging, but I think also that issue of what is the effect on consumer choice, what is the effect on the size and nature of the industry, that's all important for us too.

MRS OWENS: Have you got any other comments you'd like to make?

MR HECTOR: No, I think we've covered everything, thank you.

MRS OWENS: Good, thank you. I'll now close the hearings today in Sydney and we will be resuming in Canberra on 27 November at 10 o'clock in the morning, thank you.

AT 3.51 PM THE INQUIRY WAS ADJOURNED UNTIL
MONDAY, 27 NOVEMBER 2000

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