LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN CAPITAL TERRITORY

STANDING COMMITTEE ON HEALTH, AGEING, COMMUNITY AND SOCIAL SERVICES

(Reference: Inquiry into the sourcing and supply of dental prostheses and appliances to Australian dental practitioners from overseas)

Members:

DR C BOURKE (Chair)
MR A WALL (Deputy Chair)
MS Y BERRY
MS N LAWDER

TRANSCRIPT OF EVIDENCE

CANBERRA

WEDNESDAY, 12 NOVEMBER 2014

Secretary to the committee:
Mrs N Kosseck (Ph: 620 50435)

By authority of the Legislative Assembly for the Australian Capital Territory

WITNESSES

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Amended 20 May 2013

The committee met at 2.31 pm.

HEWSON, ASSOCIATE PROFESSOR NEIL, Australian Dental Association
IRVING, MS EITHNE, Manager, Policy and Regulation, Australian Dental Association

THE CHAIR: Welcome to this public hearing of the Standing Committee on Health, Ageing, Community and Social Services inquiry into to the sourcing and supply of dental prostheses and appliances to Australian dental practitioners from overseas. Today we will be hearing from the Australian Dental Association, the Therapeutic Goods Administration, the Oral Health Professionals Association and an interested individual.

Professor Hewson and Ms Irving, could you confirm that you have read the privileges card lying on the table before you.

Prof Hewson: I have.

Ms Irving: I have.

THE CHAIR: Do you understand the privilege implications of the statement?

Prof Hewson: I do.

Ms Irving: I do.

THE CHAIR: Before we proceed to questions, would you like to make an opening statement, Professor Hewson?

Prof Hewson: Thank you. Thanks for the opportunity to present. There are more than 15,000 dentists in Australia. As the peak body representing them, the ADA is well positioned to speak to this matter.

This area is of such importance to the ADA that it has an expert committee of monitors and advisers on matters relating to dental materials, instruments and equipment. It has close liaison with the Australian Dental Industry Association and the Therapeutic Goods Administration.

The ADA provides advice to members about their responsibilities in relation to the importation of medical devices and appliances regularly through the ADA's news bulletin, a publication that is provided to every member of the ADA in both electronic and hard copy format. ADA members should be very aware that there are restrictions about the use of imported therapeutic goods. One of the most recent articles on this matter makes it very clear that, if a dental practitioner imports materials directly, they become a sponsor of that product and must comply with the regulations of the TGA. However, if they purchase the material from a supplier in Australia, the supplier is the sponsor. As a sponsor, the regulations require the prostheses to be fit for purpose, and the sponsor must provide information identifying the manufacturer of the device.

As registered health professionals, dentists have a further responsibility for all the

treatment they provide to patients, including the fitting of custom-made prostheses and appliances. Part of that responsibility is to ensure that these appliances have been manufactured in accordance with the regulations and standards.

Nearly all dental instruments, materials and equipment are imported from overseas. The ADA agrees with the ADIA that there is no evidence of increased risks for patients as a result of the increased sourcing of prostheses from overseas; nor has there been any significant number of complaints from patients recorded. In fact, this would seem not to be an issue for the public at all, despite the efforts of some to try and make it so. I can report that in my own practice, I have never been asked by a patient, or been concerned, about the origin of any material or equipment that I have ever used. And I have been around for a while.

Participating in a global economy, competition agendas are not those of the ADA but of government. Dentists are not immune to this environment, and now are competing on an international market with the advent of dental tourism. The ADA has great sympathy for the situation that dental technicians and laboratories find themselves in, and perhaps there is potential for all relevant parties to work with the ADA to promote the advantages of using local laboratories.

Accusations of dentists seeking to make excessive profits are claims we find difficult to reconcile; however, there are some facts which suggest it is otherwise. For example, the ADA practice survey and the Australian Taxation Office figures indicate that dental practice overheads are about 70 per cent. Furthermore, the ADA fee surveys indicate that dentists have maintained their fees well below the general CPI over the last few years. Finally, under the chronic disease dental scheme, a majority of dentists bulk-bill at a seriously discounted rate, and initial trends for the child dental benefit schedule show a similar trend.

In summary, the ADA believes that the current regulatory requirements on the importation of goods, combined with the accreditation of dentists, provides an appropriate safety and quality framework for the sourcing and supplying of dental prostheses from overseas. I have not repeated anything that was already in the letter. Thank you.

THE CHAIR: Thank you. Professor, do you think in the last five to 10 years there has been a growth in overseas outsourcing for the supply of dental prostheses and appliances by Australian dentists?

Prof Hewson: There has been?

THE CHAIR: Do you think there has been?

Prof Hewson: Yes, I think there has been, but it is pretty anecdotal. Also, you have the situation where you can send a job to a local laboratory and, without your knowing it, they might be sending it overseas. A lot of laboratories are actually sourcing the work from overseas laboratories themselves.

THE CHAIR: So your understanding about the extent of this is primarily anecdotal. Do you have any idea of how widespread it might be amongst Australian dental

practitioners?

Prof Hewson: No. I did read in the ADIA submission that they think it could be up to 50 per cent, but it is very difficult. You have got individual private practices sending off; you would have to do some kind of survey to find out what is happening.

THE CHAIR: One of the requirements in the UK is that dentists who source appliances or prostheses overseas are required to disclose that to the patient. That is not the case in Australia, is it?

Prof Hewson: It depends. If they are a sponsor and they directly get the appliance to their practice, they would have to. And if the lab is using overseas work, they would need to report that to me if I was using that lab. That is the way I understand it should be.

Ms Irving: Dr Bourke, could I just add to that. As a dentist, you would know that with every single thing you are using in that practice environment, it would be very hard to have something to state the source of all of it. If you are using a handpiece, the drill itself might be from Germany but the burr on the end could be from the UK and the injection of local anaesthetic could come from America. It would be quite impractical to try and have some sort of labelling system. And you would probably raise concern in a patient's mind: "Why are you telling me where everything is coming from. Surely there is a quality process that I can rely upon through other regulatory processes so that the dentist does not have to go down to that level of detail."

I think it would be something very hard either to regulate or to monitor, to make sure it is happening. And given that we do not have huge numbers of dental manufacturers in Australia, it would be just about every single thing a dentist is using, including the chair.

THE CHAIR: I think you are bringing two separate issues together there. Of course pharmaceuticals, implements and dental materials are regulated through the TGA. Overseas sourced dental prostheses are not. Is that correct?

Prof Hewson: My understanding is that, whoever imports these things, it is covered by the TGA.

THE CHAIR: If you have a crown manufactured, for instance, you think that is regulated by the TGA? I do not believe that is in their submission.

Prof Hewson: No, but declaring where it comes from is covered.

THE CHAIR: To whom?

Prof Hewson: It depends who the sponsor is. The sponsor has to declare it to whomever they are selling the product to. If I get it from the lab, the lab has to do it. If I import it directly, I would have to do that to the patient. But does the Australian public worry about things being from overseas? Just about everything we use is from overseas, isn't it? It is funny to me that you pick out this thing. We do not have a car

industry any more. Why? Because people buy cars from overseas. Just about everything people buy is from overseas.

THE CHAIR: This is a committee made up of elected representatives of the ACT public, and we have decided this is something we are interested in, so we shall pursue it.

Prof Hewson: I am just saying that I do not think the public are demanding something to be done about this. That is just my perception.

Ms Irving: Perhaps I could add to that. My understanding is that if you are a sponsor of a product, there are responsibilities that you must meet. You must apply to the therapeutic goods authority to have each dental plan included on the register; you have to ensure that the conditions placed on the device are met and continue to be met; you have to ensure that any information that the TGA require is available; and you have to ensure that the appliance continues to meet all the legislative requirements once it is on the market. If you are the sponsor importing things, you still have obligations under the TGA act. It might be a question for the representative from the TGA.

THE CHAIR: Thank you. Supplementary. Ms Lawder.

MS LAWDER: I think a different submission does say that dental laboratories registered in Australia must use TGA-registered materials, but there is no central body tasked with responsibility of analysis of the manufacturer. And another submission, from another organisation, says it is not subject to the TGA.

Prof Hewson: Just to clarify, are you saying that the laboratories here have to use—

MS LAWDER: I am not necessarily stating that, but—

Prof Hewson: That is what they are saying—but the overseas ones do not necessarily have to?

MS LAWDER: Yes.

Prof Hewson: That may be the case, but part of the responsibility of the dentist—with laboratories I use, I have gone and spoken to them, asked them and got assurances from them that they do use all the right materials. If I was to use a laboratory overseas, I would do the same thing, because that is my responsibility as a dentist. There are lots of labs now that are being accredited overseas, so you have that formal assurance as well that you can get.

THE CHAIR: Mr Wall.

MR WALL: To what extent is the ADA concerned about the use of prostheses that are manufactured overseas? Is it in the use of materials, is it the quality or is it an issue regulation or a global standard for the manufacture of the products?

Prof Hewson: The ADA believes—this has been going on for quite some time,

though it has increased—that there is no evidence that there are unforeseen or poor outcomes. We think that the current regulatory system is working. But, as I have said before, we keep reinforcing messages that "it is your responsibility as a dentist to monitor and oversee these things". We keep informing our members of any changes. And we have that expert committee to advise us if there are problems or things like that.

MR WALL: Yes.

Prof Hewson: We think at the moment it is fine. There is no reason why you cannot use a laboratory overseas that is as good as that. But people choose to do different things for different reasons.

MR WALL: The intent of the inquiry was to cover off two aspects. One, which you have discussed with us so far, concerns a professional or a clinician importing prostheses from a laboratory overseas to provide to a patient locally. The other facet of it is an individual such as you or I heading overseas to receive dental treatment and then coming back into the Australian health system or the territory's health system for what could potentially be a—

Prof Hewson: From that point of view, the Australian Dental Association, I guess, has taken a different tack. What we are trying to do is inform the public about making a good decision. Once again, there are some of those facilities that seem to be quite good. But we try to inform them that, if you are having extensive work done that needs a lot of lead-up time, to just go for a week and stuff might lead to problems. So we try to inform patients so that they can make good decisions, understanding that the way of the world is, and what governments say is, that we are in a global market and that trade barriers and things like that are not ideal. But of course that is why we have sympathy for the labs because we are having the same sort of stuff happening to us too.

Ms Irving: I guess the difference, Mr Wall, is that if you as a dentist are using material that has come from overseas and there is any problem, you will fix that work if there is an issue. If someone goes overseas and has treatment in a country where there are not the same reliable sources of materials, it is very difficult to have it fixed. We certainly are aware of cases where consumers have gone overseas, had treatment, come back, there has been a problem two years down the track and the material that was used, say, in a crown or an implant was not available in Australia because it has not met the standards to be imported and the whole procedure has to be done again. So I guess the difference is that quality backup that you have. If it is a product that turns out to be in any way faulty, then the dentist will repair the work at no cost to that patient.

Prof Hewson: I think it is much easier for a laboratory that has really good processes and uses the right materials to produce a product, whereas, in treating a patient, the diagnosis is really important and all those things. They are quite different, I think, in that sense. But it is the way of the world, is it not, today?

MR WALL: From your experience as a clinician and as a representative of the ADA, why do you think there has been a shift towards sourcing prostheses from

international suppliers, as opposed to making them domestically?

Prof Hewson: I think it is probably driven by costs, trying to keep overheads down. As I said before, with the commonwealth CDDS, a lot of work was done at a very low rate. If you had been paying Australian lab fees, you might not have been able to cover your costs. I have experienced that over the years with Veterans' Affairs, where sometimes my lab bill is more than my fee. Obviously that becomes an issue. The big laboratories have been promoting this too. It is not just the dentists. I guess it is like a lot of things: people go and source things from overseas because they can.

There are some incidences of certain processes with certain brands where they can only be done overseas because that is where they have got those labs. A lot of crowns now are milled out of little blocks of things, and that requires a very large investment. There are laboratories in Australia that are doing that where they have been licensed by certain manufacturers, and others you can only get overseas.

THE CHAIR: Ms Berry.

MS BERRY: I am probably just clarifying a few things that have already been asked. At the moment, all of the appliances that we are talking about now, like prostheses and crowns, have to be approved by the TGA?

Prof Hewson: No, not the crowns themselves but I think the materials that go into them. There are international standards for all sorts of materials. When the laboratories overseas are accredited, they have to demonstrate that they are using all those, what are called, ISO standard materials.

MS BERRY: And if a person was to complain if something went wrong with their dental work and they did not know that it was from overseas, would they necessarily complain to you, or is there somewhere else?

Prof Hewson: Usually they complain to whoever fits the denture.

MS BERRY: Yes, but is there a complaints body for dentists?

Ms Irving: Yes.

Prof Hewson: Yes, there is sort of—

Ms Irving: There are a couple. Do you want me to take that one?

Prof Hewson: There are health service commissioners, there is the national registration thing. Some of the ADA branches run conciliatory help. There are services and a lot of those things can be resolved very quickly there. Australian-made things break sometimes too.

MS BERRY: I am just saying that if you are not the person, whom would people complain to? You say in your submission that you are not aware of any problems. I was saying: is there somewhere else that people complain to?

Ms Irving: Perhaps we could just—

Prof Hewson: Patients complain if they have trouble or they just come back to you, obviously complaining, and say, "This has failed." And sometimes that happens.

MS BERRY: I think we have all spent some time in the dentist's chair.

Prof Hewson: But they normally would not know the laboratory, so they would come to the clinician.

Ms Irving: If a dentist was getting complaints regularly about something or they were finding that the work was not sustained, whatever the procedure was, they would start to question themselves about the supplier. Often if it becomes an issue and, as members, they will let the ADA know that there is a problem with a particular supplier. In terms of a patient making complaints, it does depend on what state or territory you live in but, as Professor Hewson said, the process is to report that. You can report any practitioner to the regulatory authority which in our case is the Dental Board of Australia. They will investigate the complaint or they will refer the matter to the healthcare complaints commissioner in the relevant state or territory.

The Australian Health Practitioner Regulation Agency, which is the overarching administrative body for all health professionals in Australia, have just released their annual report, and that annual report gives a breakdown of complaints against health practitioners. I am pleased to say that complaints about dentists have actually reduced in this annual report, which is nice, and it also breaks it down into the category of whether the complaint is related to clinical care or cost, which is usually one of the biggest issues people complain about with dentistry. But it does not break it down to the level of detail about a product, that the materials used were ineffective. But it is something that you could probably approach AHPRA about and ask them if they would be willing to provide some further de-identified data in relation to that. But generally there has never been anything that has pinpointed complaints down to that level of detail.

Prof Hewson: The health complaints commissioners have various names, depending on the jurisdiction. They tend to break down the complaints they have into more detail too.

MS BERRY: Just one other question was: when the dentists are purchasing or getting their equipment, whatever it is that they need, the suppliers are approved suppliers, or can they go themselves directly and source it from overseas? How does it work?

Prof Hewson: That is where it becomes, if you do it directly yourself, you becoming a sponsor. I think the stuff that Eithne was reading out was more applicable to products rather than appliances. And of course that involves an expense, does it not?

MS BERRY: But could you do that?

Prof Hewson: I could import stuff directly. I do not, because I would have to get licences and all that.

MS BERRY: Yes, but do you have to? How would you know if you were not a sponsor?

Ms Irving: So if you import anything—

MS BERRY: Could you do it illegally, if that is the term to use?

Prof Hewson: I suppose so, yes. Anyone can do something illegally.

Ms Irving: You can always do everything illegally.

Prof Hewson: It is a trust thing, I guess, too.

MS BERRY: Without being a sponsor, without having a licence?

Prof Hewson: I do not ring up the managing director of the supply company and demand that he do things in a certain way. One assumes that that is a business and that they would do those things properly.

MS BERRY: Sorry, I am not suggesting that they do; I am just trying to get my head around how it works.

Prof Hewson: It would be easy for someone to do that, unfortunately.

Ms Irving: If a dentist is importing directly and they have not applied for an authorisation under the regulations, they are restricted to only using that material for their own purposes or that of their family. They cannot use it in their clinical practice to treat patients. Does that help to clarify it a little?

MS BERRY: Yes.

Ms Irving: And they can also obtain things through a conference, through a trade exhibition, but again there are restrictions on them using it. If they want to use it in practice, they must apply to have the product registered. The other thing is—again you perhaps should seek some clarification from the TGA representatives—there are principles that have to be met. Essential principles for safety and regulation, I think they are called. Again, the dentist has to comply with them.

Prof Hewson: There is occupational health and safety.

Ms Irving: There is consumer law that protects the consumer that has to be met, and the dentists would be accountable as well if there was an issue with the product they were using. So there is quite a lot of regulation. They do not all directly apply or are specific to dentistry but they are general consumer laws and trade practices law that apply that have to be also considered.

THE CHAIR: Ms Lawder.

MS LAWDER: Does your association have a consumer reference group that you talk with?

Ms Irving: No.

Prof Hewson: No.

Ms Irving: The staff are pretty cheeky, though, as consumers.

Prof Hewson: We are like you. We are a federation. We have a national body and we have various state and territory bodies, though we do not have one in the ACT. Part of that service—we were talking about the different levels of complaints—is that most of the branches have a consumer line where there can either be a complaint or a lot of the time it is people just ring up and they get asked questions and they get given information and stuff. That is one way the association deals with the public.

MS LAWDER: Let us perhaps assume for a moment that the concern of consumers is not necessarily about the quality of the product but they may have an interest in the price. Dental work traditionally has been viewed as reasonably expensive, and the view I have had expressed to me by some consumers is that they feel that dentists may be getting in cheaper product from overseas but are not passing those savings on to consumers. Have you heard that view at all?

Prof Hewson: I spoke about that in my opening address, saying that dentists' fees have not risen with the CPI, the health and general CPI, but there was a lot of work done under the commonwealth scheme. A lot of that was crowns and it was at severely discounted fees that a lot of that work was done. It gets back to competition law, doesn't it? The ADA is not allowed to have a scale of fees. The AMA has been able to keep that as a tradition, I suppose. And governments keep saying, "You have got to be a business. It has all got to be competition."

I do not know how anyone could actually make that statement. The overheads of a practice are, as I said, towards 70 per cent. For example, when we established our practice, we had to have a body protection system in our surgery, not that anyone has ever been electrocuted in a dental surgery. It cost $15,000 extra, and that is just an example of the high overheads that are required to set up a practice and to run one. Unless someone has got everyone's books and can do that, I do not see how they could say that. The evidence is that the fees have been contained over the last few years.

MS LAWDER: Another example someone gave me was that they met someone who had a laboratory in the ACT. They met them at a marathon. This man gave him his card and said, "If you ever need a crown or whatever, ask your dentist to come to me." So this person did. When he went to his dentist, he said, "I'd like you to get my crown from Joe Blow." His dentist said: "No. I have a contract with another overseas provider. I cannot go to Joe Blow in the ACT." Have you heard that?

Prof Hewson: No, I have not heard.

MS LAWDER: Do practices enter into an exclusive contract?

Prof Hewson: No. I was not aware of that. I guess, once again, it is quite legitimate to

do that, but it is interesting. I have had the same thing happen to me. When you are a general dentist like I am, you tend to use specialists or laboratories that you are comfortable with and you have confidence in. As I said, I am a person to use ones locally because I like that interaction, but I have had people come in and say, "My cousin is that." I would be happy to do that, but I guess people could enter contracts with whoever they like.

MS LAWDER: They would like to use this person that they knew locally but—

Prof Hewson: I guess they could go to another dentist, too. That is part of the competition as well, isn't it?

Ms Irving: Ms Lawder, I do not want to take you off on a tangent, but depending on the type of practice, if you are in a preferred provider agreement there is a set fee that they have to charge—by the insurance company. If you are a preferred provider for, let us say, Bupa, for the sake of argument, Bupa sets what the fees are for any client or patient who is a policyholder with Bupa and the dentist has to then charge that fee even if they think they could do it for less or if it has actually cost them more. There are a lot of factors that might be at play here that might be more than just any contractual arrangement that a dentist might have with a particular laboratory. But it would not surprise me that they would do that, because they might be getting a better price by having a guarantee of a certain volume of work going through.

Prof Hewson: You do notice that when dentists advertise a lot more—there are dentists that advertise crowns for much less than I charge. Once again, that is part of the competition. I think there is evidence that there are quite a range of fees available to people for having crowns and things like that.

MS LAWDER: The marathon runner said he spoke to his friend the dental prosthesis maker, who said, "If you get your dentist to send me the info, I'll make it and provide it at cost price." The dentist declined that offer as well.

Prof Hewson: That is their right. As I said, I have had exactly the same things, and my response has been, "If you want to do that, I am happy to cooperate."

MS LAWDER: The person said to me that the local person said, "It is because the dentist will get more money out of it when they purchase it overseas." Obviously he has an interest as well.

Prof Hewson: The dentist could also say, "Yes, I will find out what their fee is for a crown and then I will quote you." There are lots of ways you could do that, but if they are in a contract, I guess he or she was bound by that contract.

THE CHAIR: Professor Hewson, we have talked about cost differentials between the overseas manufacture of, for instance, crowns and Australian manufactured crowns. Could you give us an idea of approximately what you think that ballpark figure might be?

Prof Hewson: Could I get back to you on that, because I am not sure. I would have to go back and look at advertising material. We will happily send that to you.

THE CHAIR: Okay. If you could take that on notice, it would be appreciated.

Prof Hewson: Yes.

THE CHAIR: Perhaps you could also give us, from the most recent ADA fee survey, the range of fees for crowns, say, in the ACT and what the median or mean is, so that we can see what proportion a difference makes. For instance, if overseas labs were offering crowns at $250 a pop, the local labs were charging $900 and the average fee was $1,600, you could see that there was a substantial difference there. That is the sort of detail that we would appreciate.

Prof Hewson: I think the fee survey might indicate that the ACT has a fairly high level, but we can do that.

Ms Irving: Dr Bourke, I do not think it is going to tell us. It will give us the fees for the crown across the ACT in comparison to other states, but we are not going to be able to differentiate what the source of material was that went into that fee.

Prof Hewson: No, but we could get indicative costs from advertising and things like that.

THE CHAIR: If you are able to get some indicative costs of Australian made crowns as opposed to overseas crowns, that would be—

Ms Irving: I do not think we would be able to do that. I do not think we collect that sort of information.

THE CHAIR: Perhaps I could ask you, then, Prof Hewson, how much you pay your lab to get yours?

Prof Hewson: I am happy to do that.

THE CHAIR: Since you have already told us that you use an Australian lab.

Prof Hewson: Just for the committee's benefit, there are various forms of crowns, for example. Some of them are porcelain, some of them are new-type porcelain and some of them are precious metal with porcelain fused to them. They all vary a bit. I could do a bit of homework for you, Mr Chair.

THE CHAIR: Thank you. I will just turn to ADA policy statement 6.12, "Custom-made dental prostheses and appliances", which states in 3.3:

> The origins of all dental prostheses and appliances should be identified.

Is that an indicator that the ADA thinks practitioners ought to be telling their patients the origin of their prosthesis or appliance?

Prof Hewson: I have not got it right in front of me. I do not know whether it is saying we should be telling them, but it is saying that it should know.

THE CHAIR: Who should know?

Prof Hewson: The dentist, I think. There are a hundred and something policy statements.

THE CHAIR: Okay.

Prof Hewson: I think my understanding of that policy statement was very much that the dentist or the other practitioners placing the prosthesis—that that is their responsibility.

THE CHAIR: That does tend to be covered in 3.1, which says:

> Dentists and dental prosthetists have a responsibility to be aware that all materials … comply with Therapeutics Goods (Medical Devices) Regulations 2002 and its amendments …

I want to come to another point. We have had some suggestions and some submissions that the ADA should do more to educate its members about the complex regulatory environment for overseas sourcing and legal liability issues. Perhaps you could tell us what the ADA has already done in this area and, perhaps, what more you could do.

Prof Hewson: I mentioned that in the opening. We have had numerous articles about that, to reinforce that. As well as the news bulletins I mentioned, we have an electronic newsletter. The ADA is constantly informing its members about all regulatory responsibilities all the time. That is an ongoing process if there are any changes, if we think people need reminding when things happen. You can be spending a lot of time researching that stuff and writing the articles; we see that as a key role. I guess there is some frustration that, when you provide so much information, some of our members will not read it. But as I said, we have got this new e-newsletter as well; we are continuously trying to find more and better ways to update people.

One of the other things that we have done recently, which started in the congress in Melbourne, is start a member forum on particular issues because we have got a lot of dentists together. That was introduced for the first time last year in Melbourne. We are constantly looking at different ways that we can try and get to our members. The traditional paper magazine is becoming less and less relevant to the younger demographics. The ADA is very conscious of that and desperately tries to get as much information out to save our members and to better treat their patients.

One of the other initiatives we have had is the voluntary system of practice accreditation. Hundreds and hundreds of dentists have successfully done that. That is quite a process. All those sorts of things are very bureaucratic, so it is not a natural thing for individualistic private practitioners to do. That is another way that we are trying to reinforce the regulatory requirements that dentists have. Our practice has done that, and I found it quite useful. It puts in order the things that you are doing anyway—hopefully, it does. It reminds you of things that you need to keep your eye on. I found it a very good process.

The quality and safety of patient care is an extremely important issue for the ADA—extremely important.

THE CHAIR: Of course. If it was regulated in the same way as it is in the UK—where, with imported custom-made dental devices such as crowns, dentures and whatnot, patients had to be told regardless of whether the dentist was the direct importer or whether they were getting them from a laboratory—do you think that would be particularly onerous for dentists and dental prosthetists?

Prof Hewson: I think the origin is not relevant. It is—

THE CHAIR: Regardless of whether it was relevant or not.

Prof Hewson: Yes. To me, the important thing, if you were going to have such a thing, is that the dentist could assure the patient that the materials and the processes used are to the correct standard. You could get a bad denture or a bad crown from Australia couldn't you? So to me the origin is not that relevant. I guess it has already been said that it might get a bit strange if you say, "I have to tell you that this was made in here," or something. That seems a strange thing to do—just to do for that one thing.

Dentists keep having more and more things that they have to do. With that practice accreditation, we are meant to check the patient's name three times: when they come to reception, when the nurse picks them up, and then when they come and see me. I have just been in hospital for 2½ weeks; I was very glad of a system like that where my name is checked, because I saw about 50 different people. But when you have seen someone for 20 years, they find it a bit strange. We can over-regulate, I reckon.

THE CHAIR: Thank you. Mr Wall.

MR WALL: Just one final one. I guess this is an opportunity where you might be able to raise an issue that you think the committee should include as a recommendation in the report that we can file at the conclusion of this inquiry. Is there any area where yourself professionally or the ADA think there needs to be either some changes or improvements to the rules or regulations surrounding prostheses?

Prof Hewson: I do not think so. I guess one has to be a bit careful about one jurisdiction adding another layer of regulation on one group of people.

MR WALL: Look at it on both levels—not just locally, as the ACT as a jurisdiction, but also nationally. It is common practice for these reports to be shared amongst parliaments; if there is an issue that you believe needs to be raised or addressed, this is your opportunity.

Prof Hewson: At the moment we do not.

Ms Irving: Could we take that on notice? If there is, do we still have the opportunity to make that point within a short period of time?

MR WALL: Yes. If you would like to consider that further, please do.

Ms Irving: We have our federal council meeting over the next two days. It would be good to pose that question to the council if that is possible. We could get back you next week.

MR WALL: Excellent, thank you.

MS BERRY: Chair, can I just ask one?

THE CHAIR: Yes, Ms Berry.

MS BERRY: If a supplier is found to provide a product that has been found, through, say, a couple of dentist practitioners, to be faulty, how does it then go out to the dentist community? Where does it go? Do you go out and say, "This supplier has provided a dodgy something; we suggest you do something about that." It is like a recall, to try and make a comparison.

Prof Hewson: Yes, I understand. Is there a system of reporting unsatisfactory lab work?

MS BERRY: Yes.

Prof Hewson: I do not think any of the ADAs have such a formal system, as far as I know. There are various reasons. Sometimes things go wrong with the processing; it has nothing to do with the materials. But obviously if it happened consistently, you would imagine the dentist would stop using that person.

MS BERRY: Yes. The reason I am asking is to compare it to a hip or knee transplant if there is something wrong with that product and then you find out and have to go and get it replaced with something else—if something like that happened.

Ms Irving: The sponsor has an obligation to report a faulty product to the TGA. Is that what you mean?

MS BERRY: I am just wondering how it gets out. If one person is using a supplier, obviously other people are using the same supplier. If the supplier is providing a product that is faulty for some reason—found to be faulty—how do you let everybody know that they are supplying a faulty product from wherever?

Prof Hewson: You would only find out if things were breaking. You used the analogy of hip replacements and things; replacing new dentures has a lot less risk and a lot less inconvenience for a patient, but it is still an inconvenience.

MS BERRY: Yes; I know it is slightly different.

Prof Hewson: I do not think there is any formal process to dob in a lab or whatever, But they are good questions.

THE CHAIR: I take it you do not have another one, Ms Lawder.

MS LAWDER: No.

THE CHAIR: We will draw to a close there. Thank you, Professor Hewson and Ms Irving. If you would be so kind as to assist us by providing the answers which you have taken on notice within 10 working days, the committee would be very appreciative. If members have other questions for these witnesses, could you notify the committee secretary within three working days. That would mean that we could have an efficient backwards and forwards of further questions if that was necessary.

KUNCA, MS ANDREA, Head of Office of Devices Authorisation, Therapeutic Goods Administration

THE CHAIR: Welcome to this public hearing of the standing committee. Could you confirm that you have read the privileges card on the table before you?

Ms Kunca: I have.

THE CHAIR: And do you understand the privilege implications of the statement?

Ms Kunca: I do.

THE CHAIR: Before we proceed to questions would you like to make an opening statement?

Ms Kunca: Yes, thank you for that. I am appearing on behalf of our national manger, Professor John Skerritt, who is unable to be here today. My office is primarily responsible for the pre-market assessment and authorisation of medical devices. I guess some of the questions that I expect I am going to be asked will relate to other parts of the TGA that do not fall within my remit. I will do my best to answer those questions but I might have to take some questions on notice to make sure that you get accurate information.

From hearing the previous witnesses, one of the things that would be beneficial—and I will not do it in my opening statement—is some clarification around the medical device regulatory framework as well as a custom-made device regulatory framework. There seems to have been a little overlap in what was being said.

Another thing that I want to draw to the committee's attention is that the government has recently announced a review by an expert panel of TGA's regulation of therapeutic goods. That includes medical devices. That expert panel will actually be conducting stakeholder engagement sessions and there will be opportunities for stakeholders to contribute to the panel's deliberations around the appropriateness of therapeutic goods regulation as well as medical devices regulation. I know that that panel is due to report by 31 March. Its work is just starting but it might be something for the committee to be aware of if you were not aware of it already.

With that, I am open for your questions.

THE CHAIR: As you correctly ascertained, we are interested, within our terms of reference, in the custom-made devices. Perhaps you could just briefly talk us through the relevant TGA controls and regulations around custom-made devices such as crowns and dentures and all of those sorts of things and how that system works?

Ms Kunca: Unlike other medical devices, custom-made devices are not required to be included on the Australian register of therapeutic goods, the ARTG. They are actually exempt from being included on the ARTG. Custom-made medical devices, as you would know, are a subset of medical devices under our regulation but what distinguishes them from other medical devices is that they are made on the request of a health professional according to their design specifications for an individual patient

or for use within the health professional's practice. Other medical devices—and we have got about one million medical devices on the Australian market—need to be included on the ARTG and there is generally a TGA approval process for those devices.

Custom-made devices would be things like dental crowns, bridges. They might be things like orthopaedic joints that were made specifically for a patient where an off-the-shelf orthopaedic joint is not good enough to be used in a particular patient due to specific anatomical needs and you cannot modify the device. It might mean making specific intravascular grafts for a patient because they might have a particular anatomical reason for that. Custom-made devices are broader than dental prostheses.

All medical devices are expected to meet the essential principles. These are the devices that are included on the ARTG and those that are exempt from inclusion on the ARTG, like custom-made devices. Those essential principles relate to the quality, safety and performance of the device. Examples of the essential principles are that the device conforms, has been appropriately manufactured, is safe to use, appropriate materials have been used et cetera. To determine whether a device is custom made or anything else, it has to meet the essential principles. It is actually up to the manufacturer of the device to determine that. There are 14 essential principles generally, and not all of them will apply to every single device. Essentially it is up to the manufacturer and the sponsor of the device to work out which essential principles apply and whether they have been met.

The requirements for custom-made medical devices are for a manufacturer to have a written statement in relation to the custom-made device, and that statement needs to provide information that identifies the device, the patient, the health professional that provided the specs for the design of the device. The manufacturer is also required to hold information relating to the design and the construction of the device so that the manufacturer of the device can be verified and contacted, essentially. They also need to have a statement that the device complies with the relevant essential principles. Where it may not comply with the relevant essential principles, they have to provide reasons why.

That statement is not required to be sent to the TGA under our legislation but we expect that the manufacturer has that information available when the TGA requests that. Additionally, the secretary, through the TGA—

THE CHAIR: Sorry, can I just interrupt for a moment.

Ms Kunca: Yes. This could go on a while but it is hard.

THE CHAIR: What if the manufacturer is overseas?

Ms Kunca: I guess that is—

THE CHAIR: It is the nub of where we are.

Ms Kunca: That is right. At the moment the manufacturers can be overseas or in Australia. TGA has got jurisdiction over Australian manufacturers, Australian

companies and Australian sponsors. What actually happens is that, under our legislation, sponsors must be Australian based. There is always someone who is supplying the product that the TGA can liaise with about the particular product. For example, if the dentist meets the definition of a sponsor, because they are supplying the product and they meet the legislative definition of a sponsor, then it would be expected that they would be the person TGA goes and speaks to if there was an issue about a device that they have supplied, irrespective of the manufacturer.

The information the manufacturer needs to keep is that information. They also need to keep post-market information and they need to notify the TGA if there are any issues with the device that emerge after the product has been supplied, any significant adverse events that have occurred with the patient or if they have had to recall their device. It is expected that they would be contacting the TGA. The other regulatory requirements would be that the secretary to the department can ask for any information around the supply of the device and the monitoring around the supply, to whom the products have gone et cetera, from the manufacturer at any time.

Ultimately, the power is over Australian manufacturers and Australian jurisdictions. We do not have jurisdictional power over overseas manufacturers unless they are licensed by us.

THE CHAIR: It is the sponsor then who is the model for, in effect, the manufacturer?

Ms Kunca: The sponsor—

THE CHAIR: Sorry, it takes on the manufacturers' responsibilities for overseas-manufactured items?

Ms Kunca: I probably would not say that. The sponsor's obligations for a custom-made device would be that the sponsor is required to notify the TGA of the details of the manufacturer and a description of the device so that it is actually apparent where the device was made, because the manufacturer's name and address will be provided. Then it would also be clear what the custom-made device was. And that information is collected administratively at the TGA because there is no formal register.

MR WALL: Is the sponsor required to notify the TGA of those details for each custom device?

Ms Kunca: Yes. Every custom-made device needs to be notified through the TGA.

MS BERRY: I have a supplementary. Does that information that is reported to you from the supplier about each custom-made device include where it is made?

Ms Kunca: Yes, because they need to supply the manufacturer's details, the address and the name of the manufacturer.

MS BERRY: Is that information publicly available?

Ms Kunca: No. Ultimately, one of the things around that would be that there might be confidentiality issues because one of the things that might be included could enable

you to link it to the patient, essentially. I do not know. Apart from the impracticalities and the cost of having to include every custom-made device on the ARTG, I presume—and I am just speculating here; I do not know for sure—that confidentiality issues might have had something to do with the fact that the information about these products is not available on the register as well.

THE CHAIR: If, as you say, manufacturers need to tell you about every custom-made medical device, how many custom-made devices a year are being provided?

Ms Kunca: One of the difficulties is that not everyone is aware of the regulatory responsibilities and dental practitioners may not be notifying the TGA as frequently as they should around the devices that they are—

THE CHAIR: If they are a sponsor?

Ms Kunca: If they are the sponsor, that is right. If the manufacturer is Australian, the manufacturer needs to tell us its name and the name of the device that it has made and the type of device it has made.

THE CHAIR: The clear situation we got from Professor Hewson was that his Australian dental laboratories, the larger ones perhaps, who are acting as sponsors for overseas manmade crowns and whatever, as sponsors, would be required to notify you as well. Do you do any auditing or following up to see whether they are actually doing what they are supposed to do?

Ms Kunca: Primarily for custom-made devices it is a post-market scheme. It is primarily aimed at picking up difficulties in the post-market space once the product has been used and supplied. Where TGA receives complaints around the failure of a custom-made medical device it will investigate but there is no compliance undertaken around which health professionals have brought in which medical device and have supplied it to a particular patient. The TGA does not do that. What we do is look at it more on the basis that it is expected that the device meets the essential principles, otherwise it should not be brought in the country and it should not be supplied.

In terms of the post-market, the TGA has investigated the complaints it has received around custom-made devices. I believe there has been a total of 14 complaints. Out of those 14 complaints, nothing has been found that required regulatory action against either the sponsor or the manufacturer at any point in time. Two of those 14 complaints were referred to a third party like the Australian Dental Association or the Dental Board. All the other investigations were closed by the TGA. My understanding is that the materials that were used were all valid materials that could have been used to make the medical devices.

It is very hard to see a trend. You have got to keep in mind that it is 14 complaints out of I do not know how many custom-made devices there might be. As I said, I think there might be difficulties with the regulatory compliance and health professionals' awareness about the regulatory requirements for custom-made devices. So I do not think we have got a full and accurate dataset. But as I said, we have a million devices out on the market; they have been around for years. This is 14 complaints out of one million-plus devices. I want to set that context, because that is the evidence that we

have.

THE CHAIR: Mr Wall.

MR WALL: Ms Kunca, could you give the committee some detail as to what role the TGA plays in setting standards for the materials that are used in dental prostheses, if any, and then what requirement would a sponsor have to make sure that any product they import meets such standards?

Ms Kunca: That goes back, again, to the essential principles. I am talking about medical devices more generally, including the non-custom-made ones. The easiest way to demonstrate compliance with essential principles is to demonstrate compliance with internationally accepted standards. Some of these standards are really quite specific for their products; there might be indications in those standards about the materials that should not be used or materials that should be used. Okay? That is how the TGA would determine whether a device has used appropriate materials: if the standard has said so, and we have assessed it, and if we have assessed an application in that respect and that has been met and it meets the essential principles, we will approve it.

We expect that the same occurs for custom-made medical devices, but the onus is on the manufacturer when they are signing or writing their declaration that they meet the essential principles—that they have adhered to the appropriate standards and used the right materials to make sure that they have complied with the essential principles—and if not, why not.

MR WALL: Does the TGA play a role in updating or maintaining the international standards? What sort of input is there from a local level to those international standards?

Ms Kunca: Broadly speaking, the TGA will get involved, but it does not have the imprimatur to develop the standards. They work with Standards Australia and other standard organisations, and participate in the development of standards, but the TGA itself does not actually initiate standards.

THE CHAIR: Ms Berry.

MS BERRY: Earlier you mentioned the review that is happening through the federal government. Will the review include the manufacturing of these custom-made devices overseas? Do you know?

Ms Kunca: The terms of reference cover medical devices, and custom-made medical devices are a subset of medical devices, but I think they are probably a very small subset of what they are looking at. Because they are looking at having appropriate and effective regulation of medical devices, I think it would fall within the terms of reference to look at this.

MS BERRY: I know you have said that there are millions of devices and there have only been 14 complaints, but do you keep information on all of that that is not available to the public? I understand that it is custom-made devices that are made

overseas. I figure that you could keep that information and know how much was made overseas of each device, which would not identify an individual.

Ms Kunca: I guess we have that information, but again, as I said, there would be difficulty with all health professionals understanding that they have a responsibility under therapeutic goods legislation when they are bringing custom-made devices into the country for a patient's use and reporting the information to us every single time they should. We have some data, but I would say that it would be very difficult to draw any conclusions from that.

MS BERRY: You said before that customers probably are not aware of the regulations around custom-made devices. How do you think that information should go to customers?

Ms Kunca: By customers, do you mean dentists or patients?

MS BERRY: I am not sure who you were talking about. Were you talking about patients or were you talking about—

Ms Kunca: I think I was talking about dentists, probably.

MS BERRY: Okay, dentists. I guess it would be both then.

Ms Kunca: Yes. I think there is probably a lack of understanding with the health professionals, and it is not just the dentists; it is probably across the board. The category of custom-made devices covers a large span of things. In terms of patients I think they would also not really know what the regulatory requirements are.

We have been working with the Australian Dental Association, ADIA and other health professionals, but primarily the dental industry, to try and educate their members about the obligations that they will have under the legislation. That really is as far as we can go. We only really have jurisdiction over the supplier and manufacturer of medical devices as a whole; we do not have jurisdiction over practice. Some of the issues are around the regulation; then you have also got other issues around practice. We can only regulate one element, and the regulation is more on a post-market-based scheme than a pre-market-based scheme.

THE CHAIR: Ms Lawder.

MS LAWDER: Continuing a bit down the same line, you have said that perhaps there is not as much awareness as there should be about the dentist's obligation to inform the TGA about these custom-made devices. Are they technically in breach of something? If so, what? An act—technically speaking?

Ms Kunca: They would be in breach of TGA legislation. It depends which part. They could be in breach of the act or the therapeutic goods regulations. It depends on what the breach might be. There are penalties and breaches for several activities. There are civil and criminal penalties around breaches and noncompliance with regulations. But ultimately, for us as a regulator, the issue around prosecuting people for breaches is a last and least preferred option.

MS LAWDER: Sure. I am not implying that you should.

Ms Kunca: We would prefer to do education in the first place. We find that most people want to comply; they just do not know that they have to. It is about that information getting out to them.

MS LAWDER: Within the TGA, do you have a sort of education area or arm that is responsible for those types of things? Where does it sit within the TGA? You said you were working a bit with the ADA?

Ms Kunca: Yes. I guess my office has been working primarily through the ADIA. They are like our conduit to the ADA at this point in time, and we have been working with them to try and inform the ADA about what the requirements are. We have put information up on our website at their request. We also review training materials that are drafted by the dental profession or the ADIA for distribution to members. So we do assist. That is an activity that we undertake.

Another activity is that we are currently reviewing all our regulatory guidelines to make them easier to understand. We have also recently finished drafting a chapter on custom-made medical devices and the regulatory obligations on that. This was instigated by the ADIA and some of the industry members. That information should be up on the website relatively soon. It is something that has not been articulated up to this point in time. We are trying to get as much information as we can in as practical a way as we can so that people can be better informed.

MS LAWDER: I presume that these types of issues are covered at some point during the training of dentists.

Ms Kunca: I cannot comment on that.

MS LAWDER: It is up to the ADIA or the ADA to talk with universities about that kind of thing?

Ms Kunca: Yes, that is right.

MS LAWDER: What if there was a change? How would that get communicated to new and existing dentists?

Ms Kunca: I would say if there was a change to existing—

MS LAWDER: A change to TGA regulation.

Ms Kunca: Yes, to TGA regulation. We would communicate that to the industry. We have regular meetings every three months. The ADIA is one of the members. We work with industry to disseminate the messages. Also, if there are significant changes that impact on the industry, we put things up on our website. We do make an effort to contact the relevant colleges to disseminate that information as well. We are quite proactive in that regard when changes are made. I guess this is one of those situations where it is the status quo and it is just trying to get the information about the status

quo out there.

MS LAWDER: You mentioned that the proportion of dentists who advise you when they bring these custom-made devices in is not publicly available. Do you collect it electronically or is it put in a filing cabinet somewhere for one day? Firstly, how do they notify you? Is it a letter or a form?

Ms Kunca: Generally it is written communication via email. One of the things that we are doing is developing a form for people to fill out so that there is standard information being provided. That will be part of the work that we are doing when we publish the relevant chapter of the guidelines about custom-made devices. At the moment, it is more of an informal communication to the TGA.

MS LAWDER: When that eventually happens, you would be able to get statistics if someone requested them? Or let me use the example Ms Berry asked of a previous witness: what if I made something up, if someone was using contaminated porcelain for some reason, and we somehow wanted to contact anyone who might have had a device made by that particular provider? If not now, at some point in the future, would TGA be an avenue to get that sort of information?

Ms Kunca: Absolutely. And ideally the manufacturer's responsibility is to contact us. In case of recalls, et cetera, the reason we want the information about who a supplier is in Australia, and who the manufacturer is, is so that we can go back and follow up if there are any post-market issues.

MS LAWDER: Thanks.

THE CHAIR: Ms Kunca, you mentioned your uncertainty about compliance levels for sponsors who are perhaps dental practitioners. What about for the laboratories? What are their compliance levels like in notifying you about these devices? Do you have the same feeling of uncertainty?

Ms Kunca: That is right. We do not know what we do not know, and we do not know how much data we have out of the total pool of data that could be coming in to us, because we do not know the volumes of devices that are being custom made and supplied. It is very difficult for us to guess, but I expect that neither the dental practitioners nor the laboratories are all 100 per cent in compliance.

THE CHAIR: Are you saying that TGA does not compile that data in a way that provides any statistics at all?

Ms Kunca: It is not about us not compiling the data in a way that—it is not about that; it is about the fact that we are unlikely to be getting all the data that we need to have meaningful statistics. If people are not reporting in to us, we do not know that they are doing it.

THE CHAIR: In other words, you do collate the data, so you will have some level of figure, but there is going to be a substantial confidence interval about whether that is actually the real number or not?

Ms Kunca: That is right. The data would probably be only useful for follow-up purposes—to see who had the device, who made it and who supplied it. That would be probably the best you could get out of that batch of data at this point.

THE CHAIR: Any more questions? I think we are all done. Thank you very much, Ms Kunca. Are you perfectly happy to take any further questions that the committee might have in writing? That would be delivered to you within three working days.

Ms Kunca: Yes, sure.

THE CHAIR: And if we could have answers back within 10 working days, that would be very helpful for us as well.

Ms Kunca: Yes; we can do that.

THE CHAIR: Thank you very much. Members, we shall suspend the hearing for 10 minutes and resume at 4 pm.

Sitting suspended from 3.52 to 4.01 pm.

ADAMS, MS CHANTELLE, Chief Executive Officer, Oral Health Professionals Association

THE CHAIR: I welcome you to this public hearing of the Standing Committee on Health, Ageing, Community and Social Services. Our hearing is being recorded for Hansard purposes and also being broadcast live over the web. It is our inquiry into the sourcing and supply of dental prostheses and appliances to Australian dental practitioners from overseas. Could you confirm that you have read the privileges card which I think was sent to you?

Ms Adams: Yes, it was. I have, thank you.

THE CHAIR: Do you understand the privilege implications of the statement?

Ms Adams: I do, thank you.

THE CHAIR: Would you like to make an opening statement?

Ms Adams: Yes, please. I just want to contextualise our comments and responses to your questions. We are the association that represents nationally dental technicians and other related fields of practice. Most of our members are actually dental laboratory owners. What your inquiry is on is directly relevant to our members and their participation in the Australian dental market.

You have read the submission, so I will open up for questions. Thank you.

THE CHAIR: Thank you very much. We just had the TGA come and talk to us about their role in dealing with custom-made dental prostheses and appliances. They suggested to us that, in relation to the sponsors, who could be either the dental laboratories in most cases or sometimes the dentists, there perhaps was not as much compliance with the requirement to notify the TGA when these devices are sent out. Do you have a feeling around that issue?

Ms Adams: Yes. We have, for quite some time, tried to liaise with the TGA on the issue of communication to our members, to the board and to the dental community. It has only really been in the last six months that that communication has become material for them.

A sponsor, just to clarify, is any participant who supplies a dental prosthesis. In the case of an Australian dental laboratory, if they manufacture all of their prostheses in their laboratories, then they are a sponsor. But if they have a mixed supply—they manufactured some appliances but imported others—they have a dual sponsor role for the international laboratories that they would contract to. If the importer is either a dental prosthestist or a dental dentist, then they become the sponsor and the purview goes outside of our member base. Within that complex chain, the communication and understanding of everybody's role and responsibility for reporting is very unclear.

As a consequence any potential interest the TGA would have in this specific subgroup would probably not be comprehensive or meaningful, and we have for sometime been educating our members on their roles and responsibilities but also then calling on

other associations to do likewise, because the whole industry is bereft of any data that we can categorically use as empirical and therefore valid when we start talking about numbers in different situations.

THE CHAIR: Do you concur with one of our previous witnesses who said there had been a growth in the last five to 10 years of overseas outsourcing of dental prostheses and appliances by Australian dental practitioners?

Ms Adams: Yes. In a 2012 survey of members and non-members, we came to an estimate that up to 60 per cent of the crown-bridge category was being imported directly, and we know, not empirically but anecdotally, that a number of other prosthetic devices are now coming in outside of that category. Many of those laboratories that were only focused on crown and bridge manufacture are either significantly diminished in their size or have already gone out of business due to the import market that has come in.

THE CHAIR: And of that 60 per cent of the Australian crown and bridge market, how many of those patients do you think would be aware that their crown or bridge was made overseas instead of in Australia?

Ms Adams: I would suggest none would know. It is doubtful that in a general practice a dentist would advise them of where they get their components or prostheses.

THE CHAIR: Why do you think that is?

Ms Adams: I would assume that they do not think it is a relevant piece of information to provide to the patient. I suggest that their conversation would be more around the treatment, what is going to happen to the patient, how they may have to adjust to the new device that is coming in, maintenance, care. Their focus would be on other issues, not where the prosthesis is coming from.

THE CHAIR: And would you have any idea of the cost difference between an Australian-made device, say, an Australian-made crown, and an overseas-sourced crown?

Ms Adams: The price variation can be significant, depending on the Australian manufacturer. If the crown in Australia has been made by a manufacturer completely by hand versus a low grade B-class crown coming from overseas, it could be over $100 in price variation. But the lab market locally, as you would have read in our submission, has split. Many large laboratories are now fully digitised in their processes and that price variation is shrinking. The issue facing large local laboratories is if they source their raw materials locally, then there is a price difference between locally sourced components and the internationally sourced components, based on global pricing from suppliers. That is way outside any of our control.

We have had a statement made very clearly to us by one very large supply house, "We have global pricing." Asia buys at a significantly cheaper price than Australia. That is set in Germany and that price is just rolled out. We have many levels of impact on an end price.

THE CHAIR: I will ask some of the other committee members to ask some questions now. I will ask Mr Wall if he has got a question.

MR WALL: You mentioned that the bulk of patients would be unaware of the origin of the prostheses that they may have had installed. Are you aware of whether or not it is common practice for the surgeons or other medical practitioners in other medical practices to inform their patients of the origin of such devices?

Ms Adams: I am not aware, no.

MR WALL: Another unrelated question is on the issue of quality of the prostheses, the crowns or bridges, that are coming in from overseas compared to those that are manufactured in Australia. Is there a vast difference in the quality of the product that is being imported?

Ms Adams: There is no foundation data on which to make an assessment on quality, because there is no way to assess any of the products coming in, nor assess the products being made here. If under the TGA regulations, as they stand today, 100 per cent of all prostheses were actually recorded and then 100 per cent of all faults were then recorded, then you would be able to get some empirical data. But we do not have any central reporting system in which to gather that data. Out of America, they have indicated that there could be some quality variations, but locally the ADA has said that they do not believe that there are quality variations. Much of the quality assertions being made are anecdotal.

MR WALL: From your perspective as the head of the Oral Health Professionals Association, what do you think needs to be considered or should be considered to make the local production of these products more viable not just in the ACT but, I guess, Australia, being a national issue?

Ms Adams: I think there are a number of areas that we could be reviewing that would help the local market. One is that the local market could better collaborate together. There are a lot of very large houses that do subcontract work and become a third-party supplier. We know from the Australia made campaign research that if patients and consumers are aware of where their products are coming from, they do choose Australia more often than they choose international. So we do support a country of origin labelling model, such as the UK's, for dental prostheses.

We would urge the TGA to more regularly communicate with participants in our dental industry to try to reach compliance in reporting, both of the volumes that come in and the issues that may have been material to any devices sold in Australia, wherever they come from. They would be some starting points that we have been advocating for some time to help bring clarity to the Australian market, because at the moment a lot of it is anecdotal.

THE CHAIR: Ms Berry.

MS BERRY: I want to ask a question about an issue that you raised in your submission about the effect on the quality of education and career opportunities for

future dental technicians. Could you please explain to us in a little more detail the effect on the quality of education and career opportunities of the contracting of the domestic market in the production of these items?

Ms Adams: What we are seeing today is that both Victoria and New South Wales have cut their funding for education of dental technicians, and at the moment on the national platform we see that this diploma is the precedent for the advanced diploma for dental prosthetics. With the cuts to funding, it has meant that the cost to the student has increased significantly and in Victoria the numbers of local students applying for the role have dropped for this course. In New South Wales this will materialise in 2015. We are working with Sydney TAFE and the department of education on the new funding structure which will mean that a course could cost up to $32,000 to get that diploma.

On the outside, when they graduate, with the contraction in the dental laboratory market, the jobs are not there for them to get, and that is impacting both on local students taking up the courses now and also on the international students who are dropping off. They also see this is as a means of receiving a visa to work in Australia. Where there is no job to employ the graduate, then that is putting funding pressure on the education sector and questioning the validity of the diploma. It becomes a circular issue within the Australian context.

MS BERRY: Is it a real possibility that this profession, because of the contracting of the market in Australia, could not exist in the future if that were to continue?

Ms Adams: I do not see it as not continuing. I think that the profession is changing because of digital technologies anyway, but it is becoming a counterintuitive issue. As technology influences how these prostheses are made, the knowledge of the technician is changing, but the future students are not receiving this education. It could be that future students that graduate will enter a market which they are not trained to participate in and we will have an increase of skills coming from overseas through the 457 visa program. We are seeing a large number of that now; people coming from overseas with the digital skills are being employed over some of the graduates.

MS BERRY: That was going to be my next question, so thank you for answering that one.

THE CHAIR: Ms Adams, I will just ask Ms Lawder if she has got some questions.

MS LAWDER: Yes, I do. I have a question relating to your submission. On pages 11 and 12, you speak about the recommendation from the Senate inquiry into the regulatory standards for the approval of medical devices in Australia. You have written that the OHPA supplies laboratories within your accreditation program with printed patient information cards.

Ms Adams: Yes.

MS LAWDER: Is that to the laboratories? Can you provide or have you also provided them to dental practitioners and dental surgeries?

Ms Adams: How our accreditation program works—sorry if I just backtrack in order to answer the question. The laboratory goes through criteria to become accredited. They then choose to use these information cards or make their own card. The cards are then attached to every prosthesis that is supplied to the dentist under that prescription. It is then up to the dentist whether they disclose or pass on that information to the patient or whether it is not passed on to the patient.

MS LAWDER: So you are not able to work, for example, with the Australian Dental Board? Or are you already working with organisations such as the Dental Board to encourage or have a bit of a survey of dentists to see how many might be passing on that information to patients?

Ms Adams: Because of the nature of our industry they are not regulated under the Dental Board of Australia. Though we can communicate with them, they have no regulatory framework with our members.

MS LAWDER: It does seem like a good transparency initiative. Thank you.

Ms Adams: It is great transparency, and a lot of our accredited labs use it as a means to communicate both TGA compliance and country of origin information.

THE CHAIR: Ms Adams, just to come back to that point, you were talking about your lack of relationship with AHPRA. I take it that dental technicians are not registered in Australia?

Ms Adams: That is correct; they are not. They were up until 2010, when AHPRA came into existence in the national board. Then there was a decision at that point not to register the dental technicians at a national level.

THE CHAIR: Does your organisation have a view about that?

Ms Adams: Yes. Our organisation lobbied and petitioned hard to not have that position taken at a federal level when the responsibility was removed from the states—at that time, each of the states did regulate and register dental technicians—but we were unsuccessful in that lobbying.

THE CHAIR: Effectively, then, anyone could set up and call themselves a dental technician if they wanted to?

Ms Adams: Yes. There is an inferred scope of practice, but there is no regulatory requirement. We have no means to monitor the qualifications, or not, of a dental technician who is not a member of OHPA. At the moment, all of our members declare to us their qualification status and where they got their qualifications. But if they are not a member, we cannot advocate on their behalf.

THE CHAIR: So effectively it is the responsibility of the dentist or prosthetist to determine the capability and quality of training of the technicians that they use?

Ms Adams: Yes.

THE CHAIR: We have finished with our questions there. I would like to thank you for your time in speaking with us this afternoon. If members have more questions, would it be possible for them to be sent to you in writing and then for us to get an answer within 10 working days?

Ms Adams: Sure. You have our contact details with the submission. We would welcome any more questions.

THE CHAIR: Thank you very much. And would it be possible for you to send us a copy of your patient disclosure card?

Ms Adams: Sure, yes. Would you prefer a digital copy or—

THE CHAIR: A digital copy would be excellent.

Ms Adams: Okay. Thank you.

CLARK, DR JOHN, Private capacity

THE CHAIR: Welcome to this public hearing of the Standing Committee on Health, Ageing, Community and Social Services inquiry into the sourcing and supply of dental prostheses and appliances to Australian dental practitioners from overseas. Can I confirm that you have read the privileges card that Nicola has sent to you?

Dr Clark: Yes.

THE CHAIR: And do you understand the privilege implications?

Dr Clark: Yes.

THE CHAIR: Before we proceed to questions, I would also say that this is being recorded for Hansard and is being webcast live off the Assembly's website. Would you like to make an opening statement?

Dr Clark: Just a short one, because a lot of my information has already been passed on in the letters and correspondence I forwarded.

I could probably precis that a lot of my views are more emotive about just the general feeling that there is a wrong about what has been conducted for nearly 20 years. There are a lot more objective thoughts about the whole process, particularly in the letter that was put forward by Dr Matthew Athanassiadis about the loophole in the way in which the appliances are getting into the country. I guess that is the gist of what I would like to say. I will just respond to questions if that is okay.

THE CHAIR: We will kick off with some questions then. I think you have told us that 60 per cent of Australian dentists now source lab work primarily from China, and perhaps from Taiwan and Korea. Where does that figure come from?

Dr Clark: That figure is based on a communique with my tech and his fellow technicians as to the general amount of business that they have lost over the last 10 years. I cannot give you a precise study that gives that figure, but it is a fairly commonly mentioned value now—about 60-plus per cent.

THE CHAIR: Do you think that is increasing, or is it stable?

Dr Clark: I would think that it is increasing, because we are repeatedly getting advice of lab after lab closing, at least in the Brisbane metropolitan area.

THE CHAIR: I understand that you are still registered with the board, but you have not renewed your membership. Would you be able to fill us—

Dr Clark: With the ADA, with the Australian Dental Association.

THE CHAIR: Would you mind telling us why that is, if you wish?

Dr Clark: There are two reasons. One is just the general feeling in my view that the association has lost the plot and lost its moral compass. There is a lot of

misinterpretation by the public. They think that the Australian Dental Association actually advocates for the patient. It does not; it is an association that advocates for its dentist members. It does that very well; it protects them very well. It does make some great efforts towards trying to help in some aspects of dentistry, such as dental awareness week and things of that ilk, but it is a misnomer to think that it advocates in the interest of the patient; it does not. That is part of the problem for me straightaway.

For example, I have a colleague who also has decided not to renew his membership. The reason he decided to do that was that any sort of alternative view, new idea, correspondence et cetera put forward to the association is not allowed to run its course if it does not fall in line with the association's values and ideals. For example, this other colleague, who I believe is a member of the Dental Board and some advisory committee, wanted to forward a letter to the Australian Dental Association about his views on perhaps there being an effective way to have some sort of denti-care scheme, which would be in the best interests of the community.

There are patients who can get some degree of care through concession cards and healthcare cards through the public service, and there are those that have the financial means to effect their own care at their own expense. But there is the large bulk of people who fall in between, who do not have enough money to deal with their dental needs as required. That is why he felt that perhaps a denti-care scheme may have a way of working. The response he got from the ADA was that the letter was not going to be published, that it did not fall into, if you like, the goals of the association at the time.

There was a similar thing with me. For example, in 2011, I think, I was challenging correspondence by the then president of the ADAQ. His first letter was in response to an appearance by me and Dr Matthew Athanassiadis on a television program, trying to get publicity about the whole thing of non-consensual outsourcing. The letter that he responded in was full of what I felt were a lot of inaccuracies with regard to saying that dentists were using it because it is highly reliable, good quality and cheap.

But the thing that I really objected to, and put in my letter straightaway, was that he failed to disclaim that he had used Chinese crowns for the last 20 years and that he had introduced it at the University of Queensland but the contract had been cancelled because of poor quality—a whole lot of, in my mind, deceptive things. In response to my letter, and you have probably seen his other letter, he just continued to put out letter after letter. At the end of it, he put out his final letter that that was 'enough debate on the subject—no more letters'. Yet there had been no debate; he had just been pushing his gerrymander or his own barrow. I just felt that the profession was not acting to the level of professionalism that I hold myself in.

THE CHAIR: Some witnesses have explained to us that there is a cost differential between an overseas-made crown and an Australian-made crown. Did you have any idea of what that might be?

Dr Clark: I have got a very good idea. Before I answer that question, note that I have worked both in the public and the private sectors. In the public sector you are probably aware that in recent years there was a Medicare dental scheme. The thing that it opened up to me was the opportunity, which is something that does not happen

very often, to critique en masse the private practitioner. I regularly, as the years passed, would see these people who normally could not have afforded more expensive dental procedures like crowns, bridges and chrome dentures and the like, and I was seeing a lot of this work that had been done under the Medicare scheme. It was in most parts very bad; you would obviously see poorly made crowns, decay and periodontal disease not being attended to. What had been done with their treatment planning had been mainly just to cash in on the $4,000 as quickly as possible using highly expensive procedures such as crown work.

Anyway, getting back to the question on cost, for me to privately have my crowns made by an excellent technician here, if I was going to do what is called a VMK which is a porcelain fused to alloy metal—gold alloy, that is; and you would be familiar with this—I am looking at $400, $450 and that is a beautiful fit. I would expect it would last 20 or 30 years if they looked after it.

What was done—and I would see this all the time with patients getting care done under the chronic scheme, and the hallmark was that the dentists were using Chinese lab work—was that the crowns, the shade and fit et cetera were not normally very good. Normally there would be lots of overhangs, but price wise, for me to pay, as I said, it was $450, but for a dentist getting a Chinese-sourced VMK it would generally be porcelain on a non-precious metal frame and they are paying anywhere between $60 and $80 from the importer. The importer themselves are sourcing it for about $20, and for some people it actually could be as low as $15 from the Chinese lab.

The sad thing to remember is that these dentists are getting it done on the cheap but they then charge a normal or higher fee than what I would pay getting it made in Australia. And this continues today.

THE CHAIR: Just going back to your statement about patients suffering from decay and periodontal disease and not having had proper treatment planning, surely that is the responsibility of the dentist? It has really got not a lot to do with where the crown was sourced from?

Dr Clark: That is absolutely true, but I am just making the point that the mindset and the motivations of the dentist that sources Chinese work, Asian-sourced lab work, non-consensually, are nothing to do with patient care, quality of care. It is all about revenue and getting things done as quickly as possible.

THE CHAIR: In fairness to overseas-sourced dental prostheses, you will recall that some years ago it was necessary to have some implant custom-made abutments, for instance, made in either Sweden or Switzerland. You are not talking about that kind of stuff, are you?

Dr Clark: No, I am not. That is not the sort of setup I am talking about. When we went on TV they actually sent a television crew over to, I think, Shanghai. We are talking about closed laboratories where they have 5,000 employees. Sometimes they might have a dormitory out the back housing 2,000 or 3,000 people as well. It is a Chinese sort of mega factory setup, which is in contrast to what happens in Australia.

My tech has about three or four employees and most of the time the tech will have

considerable ownership of the whole process, beginning from the pouring up of the impression, inspecting the impression, the dye, the fabrication of the crown, the adjusting—the whole works—whereas in these mega factories you would have a production line. An impression would come in and it would be bar-coded and then the next chap or the production line might be pouring it up. Then it would go from one process to the other. So there is no continuity of assessment of the whole job in its entirety.

THE CHAIR: I will hand over to some other committee members who have some questions. Ms Berry.

MS BERRY: I have a question regarding crowns. If I were to go to my dentist—I will not say who my dentist is—could I ask my dentist where the crown was being made, and would they be able to tell me that it was being made overseas or would they only be able to say that they got it from a particular supplier?

Dr Clark: No, they are required by law to maintain a paper trail. The paper trail was normally maintained by the technician. For example, I have been working privately and all my work has been going to the one tech. So he has an obligation to use the appropriate TGA-approved materials in the fabrication of the appliance.

The biggest problem, though, is that people are starting to get a little savvy and do ask their dentist—not many but some—or check that the dentist is actually using Australian-sourced crowns. But even now people are starting to be perceptive in how they answer. There are dentists that will outright lie. They will say something like, "I use the lab next door," when they are often using an outsourcing facility. There are dentists that will say, "We use the best lab based in Australia, based in Sydney," which is again not an Australian lab; it is just the postal centre, if you like, and it is sent overseas.

There are dentists that, if the patient does not ask, what they will do is use an outsourcing laboratory. But if the patient then asks, they will then send it down to a lab that they used to use. That example came from a lab that I am familiar with where they used to do a certain volume of work for a dentist and then over the last couple of years it has crashed to not much at all. Then every now and then a patient comes down from this lab and generally they have said something like, "I am glad that they are still using Australian labs," the inference being that they are only being told if they ask the question.

In summary, dentists are required to have that data, but patients are just not aware. Did you read my comment about NIB last October raising the point about now offering or electing to send some of their work to Thailand for both medical and dental? Did you read that?

MS BERRY: Yes, I did.

Dr Clark: What is happening is really sad. On the one hand the President of the ADA stood up straightaway and said, "No, you should not do that; it is terrible," yet she hid the fact that 70 per cent or more, a large bulk, of Australian dentists are doing just that.

MS BERRY: You talked in your submission about the increase in the corporate model of dental practices and that it is driving the increase. Do you think that there are any other reasons, besides that growth in corporate model dental practices?

Dr Clark: This is a personal view. Until the advent of Asian-sourced prosthetics—and we are mainly talking about crowns here; it is mainly crowns, bridges, that sort of thing and now crowns on implants—dentistry was a profitable business. It was more of a cottage industry and people very rarely had more than one clinic. Normally they had a business, they might have one or two chairs, and that was because the revenue that they got was good. There is a history of dentists having nice houses and nice cars. But it was not a huge revenue source really.

Nowadays that has completely changed and the explosion of the use of overseas dentistry has made a massive increase in revenue and allowed for these situations where we now have large practices. Once, these were seen by investors as quite lucrative. The development of the corporate model followed, and the corporate model is almost entirely based on using foreign-sourced laboratory materials and prosthetics.

MS BERRY: We had a previous witness whom we talked with about the problems with future technicians not being able to get the training that they need because of dental labs and dental schools, the same sort of thing that you have talked about. What implications do you think that this will have on the sector? I think it is interesting that the witness that we had previously from—Dr Bourke, help me—Oral Health Professionals Association—

Dr Clark: OHPA?

MS BERRY: Yes. They talked about importing skilled labour or 457 visas from overseas because we will not have those skilled technicians here. But you are suggesting that in addition we will be sending our patients overseas to get their—

Dr Clark: I would probably disagree with your last witness with regard to the need for importing people. Right now we have a surplus of technicians being spat out of the TAFEs and there are not many, if any, jobs for them. So that is not a problem at the moment, and it is only going to get worse. Laboratories are not closing because they do not have available staff to man them; they are closing because their shelves are empty. I remember Paul's laboratory being absolutely stuffed with work—shelves everywhere would be full. Now, all the shelves would be a quarter full. So there has been a massive reduction in work for these people.

MS BERRY: Just to clarify, she was talking about future—

Dr Clark: Future?

MS BERRY: Yes.

Dr Clark: The thing that is also happening with dentistry in Australia—and Chris would probably agree with me—is that I graduated in 2002 and I still had the opportunity to fully set up teeth, and wax and process crowns and the like. But going beyond that, 20 years prior, it was even more involved, whereas today nearly all

dental schools do not have a lab. They do not know how to set teeth, they do not know how to process teeth, they do not really know how to understand impressions properly. So you are getting a largely unskilled graduate, and how skilled he or she is on graduation is very much dependent upon whether they have been within a university that had some placement out in the big, bad world to get more skills.

I will give you an example. I supervise UQ and Griffith University students. I was so annoyed at the level of the group of undergrads and it got so bad that I refused to have any more. It was not that the students did not have the smarts or the ability; it was that I was getting these students sometimes in their last semester before graduation and they had done so little. I just did not like the idea of having to put all this effort in and the poor kids were still having to fork out $25,000.

To give you an example, I once had a student who was a quiet lass—and that might have been part of the reason. It was her final semester before she graduated and all she had done at that point was about a dozen cleans and a dozen fillings. I am sure you are raising your eyebrows, Chris. I mean that. She had not done any extractions, any crown work or any endo. That was an exceptional case but the same thing is happening with UQ.

Coming back to the thought that the labs are disappearing, if you do not have the labs, if you do not have the technicians, that is a big window of skill that they are losing. So when they are operating as dentists upon graduation, if they happen to go to a facility that outsources, straightaway they are already on the back foot because not only are they going to send off an impression that may be faulty because they have not got the skills to recognise that it is faulty but also it is going to a laboratory where the guy at the other end may not be able to recognise that it has a faulty margin or that there is a bit of show-through or whatever. Because there is no quick relationship such as the one I have with my tech, there is no comeback. If I ever make a mistake with an impression, Paul will ring me up and say, "John, I'm not sure about this margin. Would you check it?" If I have stuffed up, I will redo it. But that does not happen in a Chinese scenario. They will just make what they have got in front of them and, if there has been an error on the impression which the tech has not been able to pick up because of his inexperience, that just compounds the error.

I am going to change subjects a little. When I look at the TGA act on custom-made medical devices, there is a bit that says it is mandatory for sponsors, which means the dentist as well as the importer, to report adverse events. I bet you that there has probably not been one report raised to the TGA, yet there would be literally thousands of remakes that have occurred for these devices, every one of which should have had an adverse report.

MS BERRY: Going back to how you were talking about the crowns having gold, you are saying that the ones that come from overseas do not use gold but the dentists still charge the same. Can a person still choose whether or not they have gold or another metal?

Dr Clark: Let's talk about that. With the gold crown that you see in someone's mouth, if you see gold, that is a gold crown. There are certain grades of content of gold within them. I am talking about something different, but that is a gold crown in the sense of

what you would think of in a gold ring. There is not as much of an incentive for the dentist to use a gold crown from a foreign lab because gold still costs gold. It is a lot of money. For me to pay for a gold crown it might cost $450; they are still going to pay about $250, maybe even $300, even if it is being sourced from overseas. So the incentive is not to use gold. The incentive is to use as cheap a product as possible, which is why, in all my years of reviewing all of these crowns done outside by dentists using overseas labs, I have never seen one gold crown that has got faulty margins. They are always VMK, and the VMK is a porcelain on an alloy which is not gold. The reason why they do not use gold is that it is cheaper.

The concern in the past—it has not happened in Australia yet—was that the particular material that they used, for example, was star alloy. It is very hard to adjust, whereas gold is a little malleable and it is softer, so it is easier to adjust when you are fitting it on the model at the laboratory. In the past they have put in certain elements like beryllium which actually soften up the casting when it is done so that it is easy to adjust. Obviously, beryllium is a very nasty substance, and that has been detected overseas but not yet in Australia.

The incentive for the practitioner who is using an outside overseas lab for a cheap crown is to use a cheap porcelain crown which is laid over a metal frame which does not have gold in it. If I get what is called a VMK, which is porcelain on a metal frame, the metal frame that is made locally is a type of gold alloy. It does not look like ring gold; it looks more like platinum. It has gold in it but it is a lesser amount.

THE CHAIR: Ms Lawder, do you have some questions?

MS LAWDER: Yes, thank you. When you go to the dentist, your private health insurance company pays part of the fee. Is it visible and transparent to the private insurer as to where the dental prosthesis comes from or how much it might have cost?

Dr Clark: Not immediately, no.

MS LAWDER: So the amount that the dentist or the practice might get back is the same, irrespective of where the prosthesis is manufactured?

Dr Clark: Yes, that is right. When the dentist submits his fee to the insurer—the fee of $1,500, $400, $2,000—the patient will just get back the rebate that that fund has agreed to, in whatever scheme they are on. They know nothing about the actual sourcing of the material.

THE CHAIR: What about the situation in health fund terms?

Dr Clark: I am not sure, Chris. It is worth mentioning at this point that MIPS, which is a health insurer in this country that does dental insurance, a year or two ago made the announcement that they would not indemnify anyone using any non-TGA approved material, which is interesting, because all the importers will proffer that they have TGA approval. Again, if you refer to the letter by Matthew—and Matthew is a smarter cookie than me—you will see that there is a big cloud over anything sourced from China.

I remember speaking to a DFAT guy some years ago. He was speaking to Chinese people who choose to source medical equipment outside the country because they are not prepared to take the risk with regard to sourcing things within the country. That is getting back to the emotive side of my argument; that is, it is all well and good and people are happy to source their undies, their TVs and things from China because they see them as disposable, but it is another matter when it is something that is going in their mouth. Hopefully, it is a lifetime investment.

With the dentists, they have not got a 100 per cent, ironclad guarantee that the product materially is as safe as what comes from an Australian-sourced laboratory. No matter what they say, they cannot. I do not think that the dentist has the right to make that decision for the patient. The patient should make that decision, if they are willing to accept the risk and receive the cheaper fee—which, of course, is not the case at the moment.

THE CHAIR: I think we have run out of questions. Thank you very much, John. Would it be possible, if members come up with any more questions within the next three days, to provide them to you in writing and then have a response within 10 working days?

Dr Clark: That would be entirely suitable. I would welcome that.

THE CHAIR: Thank you very much, John. We will say goodbye to you.

Dr Clark: I wish you well. I would like to leave this thought with you. When you next go to your dentist and he tells you that he wants to give you a crown, ask yourselves where you would like that crown to be made. That might help motivate you as to where you go in coming up with your recommendations as to how to handle this matter. I understand that there are massive self-interest issues with this subject. There are a lot of dentists who are doing this and knowing that they are taking a risk. There is a big consequence in the sense that if one day a litigation case arose which set a precedent, there will be a lot of dentists who will be in the poo, in plain language, because they will not have any means of defending their position.

THE CHAIR: Okay, thank you, John.

The committee adjourned at 4.52 pm.