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Official Committee Hansard

SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Reference: Therapeutic Goods Amendment Bill 2005

THURSDAY, 13 OCTOBER 2005

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SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Thursday, 13 October 2005

Members: Senator Humphries *(Chair)*, Senator Moore *(Deputy Chair)*, Senators Adams, Barnett, Feilding and Polley

Participating members: Senators Abetz, Allison, Bartlett, Mark Bishop, Boswell, Bob Brown, Carol Brown, George Campbell, Carr, Chapman, Colbeck, Coonan, Crossin, Eggleston, Chris Evans, Faulkner, Ferguson, Ferris, Forshaw, Hogg, Hurley, Joyce, Lightfoot, Ludwig, Lundy, McEwen, McGauran, McLucas, Milne, Nettle, O'Brien, Parry, Payne, Robert Ray, Siewert, Watson, Webber and Wong

Senators in attendance: Senators Adams, Allison, Barnett, Fielding, Humphries, McLucas, Moore and Polley

Terms of reference for the inquiry:

Therapeutic Goods Amendment Bill 2005

WITNESSES

Committee met at 4.05 pm

BROWNBILL, Mr George Metcalfe, Consultant, Australian Self-Medication Industry

SCHOOMBIE, Dr Deon, Scientific Director, Australian Self-Medication Industry

CHAIR (Senator Humphries)—I call to order this meeting of the Senate Community Affairs Legislation Committee. The committee is taking evidence this afternoon on the Therapeutic Goods Amendment Bill 2005 and afterwards on two other pieces of legislation. I welcome Dr Deon Schoombi and Mr George Brownbill, who represent the Australian Self-Medication Industry. Witnesses are reminded that the evidence given to the committee is protected by parliamentary privilege. I would also remind them that the giving of false or misleading evidence to the committee may constitute a contempt of the Senate. We have a fairly tight timetable today, so I would appreciate members of the community who give evidence before the committee keeping their opening addresses to the committee reasonably short, after which members of the committee will be invited to question them. The committee has your submission. I invite you to make an opening statement, and we will follow that statement with questions.

Mr Brownbill—I refer you to our executive summary, which records that the Australian Self-Medication Industry accepts the need for a robust but flexible and transparent sanctions regime to ensure that consumers have access to safe, efficacious, quality medications. The Australian Self-Medication Industry represents that sector of the therapeutic goods industry known as OTC, over the counter—that is, all the things you will find in your bathroom cabinet for which you have not had a prescription. Our representation extends to that sector of the OTC market which is known as complementary or alternative medicines. It is an industry with probably a $2 billion turnover.

We accept the need for the protection of the public, and we support the bill in principle, but we are also concerned about some aspects of the bill. The particularity of some of these issues can be found in attachment 1, which is a somewhat complex legal argument. We have also made a number of points about the sanctions regime. We have a concern that the bill could provide better and more transparent due process. In that respect, we are at one with the committee's terms of reference (a) and (d). We are also concerned that the level of penalties may be quite large—indeed, in some cases on a par with penalties attached to high crimes of treason, sabotage, terrorism and so forth.

We also draw to your attention that some of the new regime's regulatory processes will incur costs for industry—in particular, the costs of bargaining with the regulator to a greater degree, because there is a greater range of outcomes. We are also concerned that there may be costs to industry of increased insurance premiums because of the personal liability clauses. Nevertheless, we recognise that that is a trend in modern legislation, but we would have liked to have seen some effort at establishing what the costs to industry were.

We also draw to this committee's attention the fact that somewhere in the pipeline there is a trans-Tasman agency for the regulation of therapeutic products. We are not entirely certain just how this legislation will fit into that new regime—and I do not think anyone could be, given the New Zealand political situation—which is due to come into effect on 1 July next year.

Turning to the committee's concerns, I have already dealt with terms of reference (a) and (d), which are about procedural fairness. We do think that either the head legislation or the subordinate legislation should define in greater particularity the processes by which the regulator will go about their business.

With regard to point (b), which is about the alleged difference between listed and registered goods, we consider that point has no substance. All medicines are required equally under the law to be safe and of acceptable quality. If you break those laws it does not matter whether your medicine is registered or listed, so we do not think that point has any substance, with respect to the committee.

With regard to local and foreign entities, we are not entirely sure that we understand what the committee's term of reference is about. However, on our legal advice we can see no difference in how a sponsor is treated in terms of the sanctions. It is really about the sponsor and not about whether it is a particular kind of company, whether it is foreign owned, locally grown or whatever.

In summing up, we do recommend that the penalties regime be brought more into line with the Attorney-General's guidelines. We do not know why they departed from them. If guidelines are departed from regularly, they are not worth the paper they are printed on and there should be new guidelines.

We think that the rights of appeal and review, especially in relation to enforceable undertakings, should be explicitly provided for in the bill or at the very least in the regulations, which are disallowable. A minor point: the search warrant provisions should be amended so that the regulators do not have to choose at the start of their investigation between eventual criminal or civil proceedings. We are happy to answer any questions.

CHAIR—Dr Schoombie, do you wish to make any comment at this stage?

Dr Schoombie—Not at this stage.

CHAIR—Thank you for those comments. I note your point that a robust and flexible regime is necessary to enforce standards in this industry. In the wake of the public perception of there being some failing in our system of enforcement following the Pan recall in 2003, I take it that you would support the view that we need to tighten the regime and provide a greater regime of options for enforcing those standards. Do you feel that there is fundamentally a need for different regimes for mainstream medicines and therapies and complementary medicines and therapies?

Mr Brownbill—No, we do not.

CHAIR—So you see that the same regime should apply in both systems?

Mr Brownbill—The same regime should apply. The regulatory regime for what is confusingly called 'registration of therapeutic goods' contains two branches, namely registration and listing. 'Listing' requires the TGA's satisfaction about the quality and safety, and it requires data on efficacy, but it does not require an assessment of efficacy.

Registration—broadly prescription and high-level pharmacy goods—are required to be assessed for quality, safety and efficacy. In either case, the rules about quality and safety are the matters on which a regulatory regime should be enforcing sanctions. We do not see that

there is any difference between ensuring the safety of the products made by Pan, for example, or those made by Pfizer or GlaxoSmithKlein. They should be safe. If they are not then those who have not made them safe are guilty and should be punished across the board in accordance with a regime which applies equally and without difference. Therapeutic goods should be regulated without difference. That is our position.

CHAIR—You just pointed out that at the moment the regulatory regime does not require listed medicines to be assessed for efficacy.

Mr Brownbill—No, but they are required to hold evidence. If they have indications, or if they make claims in advertising—and an advertising claim is very broadly defined in the law—that data is required to be provided, and it will be assessed against the claims. If you breach those codes, you are selling a product to the public which is not what it says.

CHAIR—You raised a number of points in your submission which I think we will ask the Department of Health and Ageing to comment on when they come to the table. So we will take a note of those concerns. I want to ask, though, about your comment about listed and registered goods and the need for there not to be a distinction in the sanctions regime between the two. Can you explain what you see as the difference in this legislation, in the present sanctions regime, for listed and registered medicines?

Mr Brownbill—Are you talking about the bill or about the act that is now in force?

CHAIR—You say:

The new sanctions regime should not distinguish between the two classes of listed and registered medicines. There should be one law for all.

What do you mean by that?

Mr Brownbill—That is the present position with the law. It is a therapeutic good which is regulated, and it is regulated in a hierarchy of registration or listing. There are also things called schedules, which are about access in a controlled way by the public. Broadly speaking, the more dangerous or toxic a medicine the more restrictions there will be on it. But those are issues of access, and they are part of the regulatory system. My clients are not makers of prescription drugs but they are makers of drugs for pharmacy-only, pharmacist-only or open sale. All those medicines, whether or not they are prescription medicines—with the exception of those very top things like heroin and so on, which are dealt with differently altogether—are part of a regime under the present act which makes no distinction if you break the law. If you break the law by infringing one of the registration or listing conditions, you will then be sanctioned. At the moment, it is only by means of the criminal law. This legislation brings in a range of sanctions where the punishment will fit the crime and the regulators will be in a position to go more gradually at a perceived transgression. However, there should be no difference between any sponsor of any medicine in respect of whether a medicine is a listed medicine or a schedule medicine or any of those things.

Dr Schoombie—We feel quite strongly about it. The way we see it, the current regime allows for only criminal penalties, which clearly is inadequate and is extremely limited. The new amendment bill suggests that there will be a flexibility and a tiered system, which makes it far more appropriate and for the lower end of the risk spectrum it will therefore continue. Those more flexible, tiered penalties and sanctions will be more appropriate. We feel very

strongly about not excluding 'listed'—which includes most complementary medicines—from this new legislation. The current legislation does not distinguish between the two, and we would not like the new legislation to make a distinction.

CHAIR—Understood.

Senator MOORE—I have two questions. One is—and this is not really my question—have you seen the Health and Ageing submission that we received?

Mr Brownbill—No.

Senator MOORE—A significant component of that submission talks about the degree of consultation with all the people who are involved in your industry and the various efforts the department made to seek views, incorporate them and go back again with guidelines. It seems that the issues you have raised in your submission are quite specific. What form of consultation did your group have, either as a group or as individuals in the industry, with the department in the formulation of the guidelines?

Mr Brownbill—We are very content with the degree of consultation that the department and the TGA afforded us. I would like to think that we have a good and a candid relationship with our friends in the department. There ought to be no surprises in this submission for the department; it has all been said many times over the last several months. We have been glad to have contributed to the discussions. We have been afforded access to drafts as they have been developed, and we are broadly in support of this legislation. We think there are some things around the edges about which the department has not quite heard us enough.

Senator MOORE—You made a number of recommendations, but the clear one about the need for clarity and the right to appeal is very understandable. When you raised that with the department through the process you described, what was their response? Why couldn't those two clear recommendations be picked up?

Mr Brownbill—I think the view was that we should accept that the regulators would work in a particular way in accordance with guidelines, now called 'general principles of implementation', and that these matters would not be required. I have been around too long to say that public administration can be conducted by understandings between an existing generation of officials. If the law provides due processes then, as time goes on, circumstances for the application of those due processes will arise. I must say that I favour proper provision for access to appeals not only in this area but in many areas of government. We have made these points to the department, and the department has not seen fit to concede the validity of our arguments.

Senator MOORE—Chair, can I follow up very briefly on that last point?

CHAIR—Very briefly, yes.

Senator MOORE—You clearly said there should be an appeal process. The department believes there should be as well. It is just a matter of how clearly that right and process is spelt out in the guidelines. There is no misunderstanding about the fact that there will be appeal?

Mr Brownbill—You get to arguments—which are perhaps too much to talk of here—about who has standing. You get to arguments about whether the appeal will be entertained as

of right or whether the department, as the present bill indicates, has a discretion or not. You get to questions like whether a decision not to accept an amendment to an enforceable undertaking is a decision or not. We say—and we have cited the case from the courts—that it is, and that gives us a measure of comfort. But we do not see why there should not be an appeal on the merits about an enforceable undertaking because there is a lot of angst in business, and has been for some many years now, with the way in which enforceable undertakings are—how shall I put it?—extracted from participants or proponents of matters before the ACCC. We would prefer that this legislation made it clear that industry comes to this matter as an equal party and does have access to objective processes rather than merely me talking to one of my friends in the department on behalf of the client, and hoping they will see it my way. It is a question of objective criteria rather than internal assurances.

Senator ALLISON—Given your general support for the bill, Mr Brownbill, can you explain to the committee what you see as the general deficiencies in the current enforcement measures that are available to the TGA?

Mr Brownbill—I think the improvement in this regime at a generalised level is that the armamentarium of sanctions—

Senator ALLISON—Excuse me—I don't know what that word means. Could you rephrase it?

Mr Brownbill—The weaponry to hand can be a dagger, a knife or a rifle. The range of sanctions are close to the range of circumstances that may arise in the regulator's experience of breaches. We all sin little bits from time to time, but we do not like to think that the first thing we ever hear about it is that we are arrested by a copper and thrown straight into jail.

Senator ALLISON—Yes, but could you be specific, please?

Mr Brownbill—I can only be specific in the sense that there was merely a criminal regime. There is now to be, firstly, a criminal regime; secondly, a civil penalty regime, where the burden of proof is the balance of probabilities; thirdly, a system of infringement notices with the option for people to pay fines to the TGA rather than incur a judicial proceeding, whether criminal or civil; and fourthly, there are enforceable undertakings. Those four options are available not only to the regulator, but they are available to industry in terms of its transgressions. Whatever one thinks of the Pan matter, one can imagine that at some point prior to the events of February two years ago—or three; whenever it was—the TGA had this range of powers, and would have been saying, 'You have infringed this and you are going to be fined that, and we are giving you this order and you can have an enforceable undertaking—

Senator ALLISON—So you think it might have avoided criminal sanctions?

Mr Brownbill—It might indeed have done. But the criminal sanction is, if you like, the most serious. I do not think anyone in the industry I act for would wish to see the most flagrant and egregious transgressions unpunishable other than by criminal sanctions.

Senator ALLISON—You do point out that the penalties are very high, and you suggest they be brought in line with the Attorney-General's guidelines. That would suggest that this bill goes too far. It is a recommendation, so I suppose I am just making the point leading to

my next question, which is: what do you think this will do for Australian manufacture? With the Pan incident and subsequent actions on the part of TGA, there is a fair bit of evidence that shows that a lot of manufacturing went offshore as a result. We became an importer rather than an exporter, net.

Mr Brownbill—I am not sure that is the case. I would not have thought—and, since I am speaking under privilege, I can say—that there are not many in the industry that regret the departure of Pan.

Senator ALLISON—That was not my question.

Mr Brownbill—I thought it was, with respect. I have not seen any figures or studies about the flow-on effect to others. The reputable manufacturers in Australia that are ASMI's members have not suffered any loss of business because of the Pan affair. There was a market blip; you would have to expect that. At the time, for example, I was acting for Blackmores. They had a three-month decline in sales and then a six-month surge at levels never before experienced.

Senator ALLISON—So you would even go so far as to say that you do not think that the areas which you criticise in your submission, which were quite substantial, and the problems you identify will be issues in terms of persuading more or even some from going offshore?

Mr Brownbill—I think, if you obey the law, have a candid and sensible relationship with the TGA and the inspectors and observe good manufacturing practice, you can run an effective business within this regime. We do think that some of these penalties appear rather large and we do not understand quite why because they are departures from the Attorney-General's guidelines. But we are told that the departures are commonplace. If that is the case, why have guidelines that you depart from as a matter of regular process? That I cannot comprehend. But I think that is an issue of the punishment fitting the crime; it is not an issue with regard to the degree to which Australian manufacturers will be penalised or deterred. I have to also say that anyone who imports a therapeutic good into this country is subject to the same range of sanctions because you cannot sell a therapeutic good that is imported unless you have it registered or listed in this country—I am pretty sure I am right on that. The people in the back will tell me if I am wrong, but I am pretty sure that is correct, except in a few very special cases of permission. So I think the issues are quite separate.

Senator ALLISON—In your submission you say:

... from an industry perspective ... the new sanctions regime will involve rather more "plea bargaining" than the present, simpler, system.

Could you expand on that and indicate why you think this the case?

Mr Brownbill—It is always the case that, where there is a public regulator, those in business being regulated will seek to minimise the penalties that they might incur. When there is a range of penalties, there are more opportunities for people like me who act for clients in the industry to go and talk to my friends and say, 'We don't really want an enforceable undertaking but we will accept a civil penalty,' or whatever. I think that is subsumed under the general description of plea bargaining. But I think that is the real world. I do not know whether those from the department behind me will recognise that as a correct characterisation of what goes on, but I think it is.

Senator ALLISON—In attachment 1 to the submission there are a number of points made in italics. I am not altogether sure where they come from and how they relate to the submission.

Mr Brownbill—The italicised bits are just by way of commentary on quotations taken out of the relevant Attorney-General's Department guidelines. You will see that a guideline is quoted and then the italicised part is our commentary on it in the light of what we see in the bill.

Senator ALLISON—Okay. So when you say:

… the "Risk Multiplier"/"tiered fine system" if we understand it correctly … would give enormous, unaccountable discretion to the TGA. We know of no precedent for it or anything like it.

Is that correct?

Mr Brownbill—Yes. The TGA saw this document, with our legal adviser's letterhead on it, and has had it for many months. It is just slightly plagiarised in the form that it is provided here to the committee.

Senator ALLISON—You also have a problem with the double jeopardy, although I notice that is not one of your three recommendations for changing the bill. Is there some reason why your double jeopardy remarks are not reflected in your recommendations?

Mr Brownbill—The recommendations reflect what we see as the priorities.

Senator ALLISON—But you would still like to see double jeopardy—

Mr Brownbill—Yes. We provided attachment 1 to the committee by way of a detailed, factual, quasi-legal analysis of issues, which the committee would be at liberty to examine from its own legal advice viewpoint. We hope that the views expressed here will be helpful to the committee if it is minded to make some recommendations about the level of penalties.

Senator ALLISON—Thank you.

CHAIR—Senator Barnett.

Senator BARNETT—I note the time, Mr Chairman, and I will be very brief with just one question. I note the in-principle support for the bill. I have a question in regard to small business in the complementary health care industry, the important role that they play and the impact on them. Can you briefly describe the impact?

Mr Brownbill—If we had a regulatory impact statement, which we urged the government to make, we would be better informed on that matter. My view and the view of my clients is that anyone who observes the law has nothing to fear from strict requirements of a criminal and civil penalty type. It has not been my experience that the small traders, particularly in the complementary medicine area, are browbeaten by the Therapeutic Goods Administration. I have acted for some in that field and I have found they have received proper respect and equal consideration under the law. Small business should have nothing to fear from this, in our submission.

CHAIR—Thank you very much for that submission.

[4.38 pm]

JOHANSON, Mrs Valda Gwendolene, Johanson and Associates Consulting

SPIJER, Mr Daan, CEO, Australasian College of Nutritional and Environmental Medicine Inc.

CHAIR—Welcome. You are reminded that evidence given to the committee is protected by parliamentary privilege and that false or misleading evidence to the committee may constitute a contempt of the Senate. Would you like to make an opening statement before we ask questions about your submission?

Mrs Johanson—I am not going to go through the points in the submission. You have all seen that, and I am sure you will have some questions. I would like to make some general comments about what I believe is a unique opportunity we have in Australia, and one which I am passionate to see we don't lose. Australia has a unique opportunity to lead the world in developing and implementing a health policy based on health and wellness, rather than a disease approach to health care. Over 70 per cent of our Australian population use natural health care products or complementary medicines, as they are defined in our legislation.

Over 50 per cent of Australians have indicated they would prefer to use a natural product rather than a pharmaceutical as a first choice if it were available. Australia's regulatory system for natural health care products, complementary medicines, as it was envisaged when it was developed as a risk based regulatory system, recognising the very low risk associated with these products, was a world leader, focusing on quality and safety and then more recently on evidence. Australian health care practitioners are more and more turning to the use of natural health care as part of an integrated approach to health that does not just address the symptoms but enhances health and prevents disease. Many of our elected leaders have recognised that greater government support for natural health care has the potential to address the serious cost concerns associated with the health budget of an ageing population. This government's COAG principles of minimum effective regulation articulate its policy that the benefits of any change to legislation or new legislation should be shown to outweigh the costs and should be used as the basis of any amendments to existing legislation.

We can be justly proud of Australia's research and education standards and our capabilities in natural health care. We have a national medicines policy that supports a viable and innovative medicines industry which includes natural and complementary medicines and we have a great opportunity to partner and collaborate with Asian research and industry, especially in medicinal herbs and Chinese medicine.

I am concerned that there is very real danger that the Australian regulatory environment will strangle our natural medicine industry with compliance costs and regulatory requirements. Having said that, I totally support the need for appropriate regulation of these products. An increasing number of Australian natural medicine companies have gone, or are planning to go, offshore—that includes some of our biggest in the country—because they are unable to compete in this costly, restrictive environment. That, I believe, is not in the best interests of consumers, industry or government. I think the challenge for our government is to get it right, to make sure that the legislation is appropriate for these low risk products.

I can recall having a meeting a few years ago with the Office of Regulatory Review. They put a safety spectrum up on the board and they had complementary medicines at the very lowest end of that safety spectrum. There are so few serious adverse reports associated with the use of these products. You do not have the food poisonings, you do not have the toxic substances that you have in prescriptions for pharmaceuticals. We need to not only protect public health and safety with this legislation, but to enhance health and support and promote the use of natural health care. The regulatory system should not only ensure quality, safety and effectiveness, but encourage innovation and research and allow consumers to know what all their options are, especially for chronic and life-threatening illnesses. The regulatory system should make us cost-competitive in the global market and support and maximise our export potential. I would like to think our amendments are in line with the COAG principles. We should find out if there are other more cost-effective ways of achieving the objective that any changes are justified and that we are in step with international trends and regulatory approaches. We are a small population and a small industry, and that brings challenges of its own in terms of distance, cost and critical mass, or the lack thereof. Changes must be in line with our national medicines policy.

My plea is that we do not lose this great opportunity we have to be the best regulatory system in the world, that we have available an innovative natural medicines industry and a sustainable health policy based on health and wellness, and that consumers in Australia have freedom of choice of a wide range of high-quality, low-risk natural medicines available here and they do not have to import them for their personal use.

CHAIR—Mr Spijer, do you wish to make a statement?

Mr Spijer—Yes. I am not in any way representative of the industry. I represent more the educational arm of the whole area of what we call natural medicine. The college has been in existence for over 25 years and is the peak body in education in this area, with most of those we train being GPs but also we cover some other health professionals. Something like 18 to 20 per cent of GPs in Australia use natural medicines with their patients. So it is a very important area of the overall medical sphere.

I know that the legislation does not distinguish between orthodox pharmaceuticals and natural medicines but, in line with what has been said already here today, I feel it is important to recognise that that part of the TGA's responsibility, which is the natural medicines, the supplements and so on, has a very low risk to benefit ratio or a high benefit to risk ratio compared with orthodox pharmaceuticals. Figures usually cited show that about 1,800 Australians a year die as a result of mishaps with or adverse reactions to pharmaceutical drugs. In the last 35 years no more than five deaths could have been attributed to complementary or natural medicines.

It is a huge disparity, and I feel that, in the interest of growth in proper health care, the natural medicine industry needs to be nurtured. There are a number of reasons for this. Apart from the very low adverse effects relating to it, there is a very low cost related to it and, on the Treasurer's own figures from the *Intergenerational report*, in 30 years or so this country will not be able to afford a health system based purely on pharmaceuticals. There are many non-pharmaceutical medicines that are a very cost-effective alternative to quite dangerous orthodox medicines; for instance, for the non-steroidal anti-inflammatories glucosamine is a

good alternative. The literature is there to support it and much has been said and written about that, and there other instances like that.

I feel that, in looking at this legislation, there should be some split made between the orthodox pharmaceuticals and the non-pharmaceuticals, the natural medicines. One way of doing that might be to have an arm of the TGA or some department that, while it still comes under the broad regulatory regime, has a much better expertise in the area of the non-pharmaceuticals, and that would be a way of recognising that split.

CHAIR—Can I be clear about what you are actually recommending to the committee that we should do. Are you suggesting that we should reject the bill altogether or, like previous witnesses, that we should modify the bill to pick up issues like the penalty level, the need for explicit appeal rights and so on? What exactly are you saying that we should do?

Mr Spijer—If I were brutally honest, I would say that I would like to see the bill not proceed. From my reading of what has happened even in the last 10 years in this country, I do not see a need for stricter regulatory provisions and tougher penalties. I feel that the TGA has been able to act adequately in dealing with Pan, which is the one that keeps coming up as an example. But there have been a number of examples since the Pan incident where the TGA has used its muscle adequately, from what I can see. People who breach the law and do not provide safe and properly documented products need to be dealt with but I feel that what is there is adequate. As a private citizen, I am actually quite concerned about the level of penalties that appear in this bill, both as they relate to individuals and to corporations. It seems to me unprecedented.

CHAIR—We are going to ask the department in a moment why the penalties are so high, but wouldn't you accept that in the wake of the public concern that was generated around the Pan event there is a need for a broader range of weapons, as the previous witnesses put it, in our armoury? At the moment we have criminal penalties and persuasion, I suppose, as pretty well the only things available under the present legislation. Isn't it appropriate to throw in there things like civil penalties and enforceable undertakings with a good underpinning in the legislation?

Mr Spijer—I suppose an argument could be made for that, but not as a result of Pan. I feel that the public was adequately served. My personal opinion is that perhaps the reaction to Pan went overboard as the product that was at fault was a pharmaceutical product and not a natural medicine or complementary medicine product; yet it was the complementary medicine industry that bore the brunt of what happened. Be that as it may, I suppose there are arguments for civil penalties or proceedings alongside criminal ones provided there is no danger that, if a criminal prosecution is launched and the person or company is found not guilty, civil proceedings can then be taken. That double jeopardy I think is not on.

There could be room for undertakings but I think there needs to be more transparency and there certainly needs to be provision for appeal in all those areas. I am speaking with a background as a lawyer, which I have not stated before. I feel that there is a danger of misuse of such powerful provisions. I think there needs to be more judicial overview of those procedures and appeal provisions. I go back to saying that I do not see a great need for it

because I feel that the Pan episode was dealt with or could have been dealt with adequately with the weapons that the TGA had at the time.

Mrs Johanson—In my view, and I guess from my past experience where I prosecuted in my role as head of surveillance within the TGA, it is not entirely accurate to say that the only avenue open is prosecution. Some of the other administrative procedures that are available currently under the act are also very effective. Cancellation of a product, particularly in the small business area of complementary medicine, can be extremely effective. If a product is cancelled, that will have a huge impact. It is immediately illegal to even manufacture that product once it has been cancelled. There are recall procedures and the cancelling of licences. So there is already a range of options available. I am also fully aware of the time and resource impost of prosecution, so I understand the need to look at other options. But I think we just need to be aware that it is not just prosecution available at the moment.

CHAIR—Given that you are a lawyer, Mr Spijer, can I put it to you, also as a lawyer, that the concept of double jeopardy has never been considered to apply outside criminal law? Double jeopardy in the sense of a civil penalty backing up a criminal penalty is not a concept that I have ever seen before. The concept applies to not being prosecuted criminally twice for the one offence. So this is not really double jeopardy, is it?

Mr Spijer—I take your point; that is correct. But I feel that, where a government department or instrumentality, having failed the first time, is given the power to take someone through a judicial process twice, the effect is one of double jeopardy. Although the consequences might be lesser in the civil action, I think we have to be mindful that just to defend either a criminal or a civil action puts a huge stress both on individuals and on corporations and can be very costly. My feeling is that, if a judicial process has been undertaken and failed, either because it has not been prosecuted properly or because the court has found the person not guilty of the charge, that should be the end of it for that particular act.

Senator MOORE—I will ask you the same question I asked the previous witnesses. In their submission to the inquiry the department have gone to great lengths to inform us of the consultation processes that have been put in place around this legislation and the various ways that people within the industry, such as you, have been able to raise concerns before they get to such a stage. From your point of view, how did that work? Your recommendations about what you think needs tightening are, once again, quite specific. Moving beyond your overwhelming recommendation, which is that we do not need any of this, your specific recommendations, about appeals and so on, are quite firm. Did you raise those issues with the department and, if so, what was their response?

Mrs Johanson—I need to make it clear that I am not speaking on behalf of any of the industry associations and therefore I have not been involved in the consultation. From my perspective, I am aware that there was some concern about the consultative processes. There have been some recent changes to that situation—namely, the issuing of guidelines—but I found it extremely hard to get any information on what was being proposed. Had I been a member of one of the associations, it may have been entirely different, so I feel I really cannot comment.

Senator MOORE—Mr Spijer?

Mr Spijer—My comment is that there has been no consultation between our college and the department. Actually, having spoken to a number of people from the department, that is likely to change after today's hearing. So I am looking forward to being consulted more when it comes to legislation that would affect both what we do and what our members do.

Senator MOORE—That is an outcome?

Mr Spijer—Yes, it is a very positive outcome.

Senator MOORE—So you have not yet had the chance to raise with the department the kinds of things you have shared with us today.

Mr Spijer—No.

CHAIR—I assume that a lot of the meat of these changes will be in the regulations and that that is the level at which some valuable opportunities for consultation would occur. Is that how you see it?

Mr Spijer—I would certainly hope so, and I would make myself available for whatever input I can make into that. Mrs Johanson would no doubt feel the same way.

Mrs Johanson—Yes.

Senator FIELDING—You make a comment in your submission regarding 'total over-regulation of small business in the low risk complementary medicines industry'. Is that something that you think can be overcome in the regulations?

Mrs Johanson—I think there certainly needs to be more detail in the regulations, and until we see the actual regulations it is still an unknown. But a lot of the concern is about what appear to be inconsistencies or non-clarity. There are certainly some inconsistencies between the bill and the guidelines—which I have only seen as part of the department's submission. It may not be deliberate inconsistency; in fact, sometimes I think there seems to be an error in the way it has been drafted, but it certainly has led to concern about what they actually mean, what is being proposed and what is intended.

Senator MOORE—I know you heard what previous witnesses said, and there seems to be a view that you are being asked to take things on trust. Is that how you perceive the current situation?

Mrs Johanson—From my perspective and from the perspective of many of the clients I represent, we would be much more comfortable if more clarity and detail were spelled out. That would give us a level of comfort. I also think that there are two different industries. The complementary medicine industry is very small-business oriented, which is very different from the pharmaceutical industry, and I would like to see the level of penalty concomitant with the level of risk, I suppose, recognising that it is also a very low-risk industry.

Mr Spijer—I am always suspicious when the bulk of what is going to be the effect on the public and on industry is in regulation rather than in legislation. But that seems to be the trend in this country and in other similar countries—regulation rather than transparent legislation seems to be the place where the effect of the law happens.

CHAIR—Thank you both for your evidence today.

[5.01 pm]

ECCLES, Mr Richard, Assistant Secretary, Therapeutic Goods Administration Transition Branch, Portfolio Strategies Division, Department of Health and Ageing

GRAHAM, Dr David, National Manager, Therapeutic Goods Administration, Department of Health and Ageing

LEE, Ms Terry, Assistant Secretary, Legal Services, Therapeutic Goods Administration, Department of Health and Ageing

GRAY, Mr Geoff, Assistant Secretary, Criminal Law Branch, Attorney-General's Department

CHAIR—Welcome. I think you were here to hear my earlier comments about the protection afforded by parliamentary privilege. You will also not be required to answer questions on the advice you may have given in the formulation of policy or to express a personal opinion on matters of policy. The committee has before it your submission, and I invite you to make an opening statement before we ask you questions about the submission.

Dr Graham—Our submission went into quite a bit of detail, so I will not spend too much time on an introductory statement—only to make the points raised previously that the legislation has a limited array of sanctions that we can apply, and basically covering criminal prosecution and regulatory actions such as modifying licences or taking away licences or conditions of supply by sponsors. The proposed legislation expands those options and gives more flexibility, which is to the benefit of both the industry and the regulator. It is also important to remember that these options in this legislation do not apply to those sponsors and manufacturers who comply with the legislation and the requirements; we are talking about those elements in the industry that breach the requirements under the Therapeutic Goods Act.

I also think it is worth mentioning that any medicine can cause harm. We are not talking about the fact that many complementary medicines may be regarded as low risk in a regulatory sense but, if a low-risk medicine is contaminated—intentionally or otherwise—and those chemicals are then introduced into the body, they can cause substantial harm. In that sense, in terms of regulation and breaches, we do not differentiate between listed medicines and registered medicines. The other point to make is that the array of sanctions that do apply in this legislation and represent a maximum penalty that can and often does apply, but these can be tailored for the situation. Thank you.

CHAIR—Thank you for that, and thank you for quite a comprehensive submission in a relatively short space of time. I will follow up some of the comments that have been made by previous sets of witnesses about problems with this regime and ask you to respond to those things. A comment was made about the burden on manufacturers of complementary medicines by virtue of this new regime. Dr Graham, you have just made the point that the only people who are likely to be affected by the additional burden of regulation are those who do not comply with the standards expected in the industry. Is that necessarily true? Are there more requirements by virtue of this regime on manufacturers to adhere to a set of standards

which is now being lifted across the board which would necessarily occasion greater cost to those who are involved in this industry?

Dr Graham—The answer is, no, there is not a greater burden in the sense that, at the moment, there are sanctions under the Therapeutic Goods Act which could be applied to the existing requirements under the Therapeutic Goods Act. The new legislation will provide a greater array of options with those sanctions so, in that sense, it is really not an increased burden to the industry. It is providing more flexibility.

CHAIR—You have heard the comments about the penalty regime. You may have seen the written submissions which suggest that the level of penalties provided in the legislation do not comply with the Attorney-General's Department's guidelines on the drafting of penalties. Did you consult those guidelines, and do you accept that the penalties provided for in this legislation do not accord with the guidelines? If that is the case, why is that so?

Ms Lee—We did consult the Commonwealth guidelines. We also consulted the Attorney-General's Department. The guidelines are just that: guidelines. They are not a set of rigid rules. There is scope for departure where it is warranted, and there is other Commonwealth legislation which incorporates high levels of penalties, and they depart from the guidelines. An example of that is the Environment Protection and Biodiversity Conservation Act, which also has very high civil penalties identical to the ones proposed in the bill for the protection of public health and safety. I believe that Attorney-General's believe that the sort of circumstances that might warrant a departure from the guidelines might include the protection of public health and safety.

CHAIR—So you are arguing that these are more in the nature of strict liability type provisions and should have quite high penalties associated with them because of the potential to affect the individual or collective health of the community.

Ms Lee—That is right.

CHAIR—But are we still going too far? The submission from the Australian Self-Medication Industry argues that the fines imposed are greater than those applicable for offences relating to treason; war crimes, such as genocide; and terrorist acts. I point out that 2,000 penalty units apply for a penalty equivalent to life imprisonment whereas here we have penalties of up to 4,000 penalty units. What would be the reason for such a large disparity?

Dr Graham—I might make two points. One is that in the legislation these are maximum amounts and at the end of the day a court would decide on the appropriate level up to those maximums. The other thing is that in this case we are talking about a civil fine. It is a deterrent, in effect, that if you go along the criminal prosecution route there is the combination of a sentence as well as a fine, but along the civil route the main response is a fine.

CHAIR—So are you saying that the penalties that they are referring to in the submission are penalties that could not be imposed under the criminal sanctions in this legislation?

Ms Lee—I will explain. In relation to acts of terrorism or treason, I understand that the penalties in terms of incarceration are much higher than in the case of the penalties proposed in our bill. I understand that there is a formula in the Crimes Act which translates the period

of incarceration into some form of pecuniary penalty. I gather the reason that you have that formula is there may be in some legislation provision for, for example, a sanction that only refers to imprisonment but there is no equivalent pecuniary penalty. So that formula becomes appropriate to assist the court in determining whether or not to apply a pecuniary penalty. However, in our legislation we actually do prescribe a pecuniary penalty and it is true that it is different from the formula provided in the Crimes Act.

CHAIR—I am not sure I am fully comfortable with what you have had to say. The earlier submission refers, for example, to section 14(1) of the bill, but I have not got the bill in front of me. What civil offence is created by section 14(1) for which it prescribes a maximum penalty of 4,000 penalty units?

Ms Lee—Yes, that is right.

CHAIR—So what offence is section 14(1) covering?

Ms Lee—Section 14(1) covers an offence relating to a breach of standards applying to therapeutic goods. The standards effectively provide a benchmark for establishing whether or not the product is safe, whether the quality is acceptable and whether it works. So if there is a breach of the standard and as a result the breach actually causes harm or will cause harm then the highest criminal sanction will be a maximum of five years imprisonment or 4,000 penalty units.

CHAIR—So this is a criminal sanction?

Ms Lee—The 4,000 units are a criminal, not a civil, one.

CHAIR—So it comes back to that original question: if the criminal penalty is 4,000 penalty units and if the guidelines say that the equivalent penalty for life imprisonment—for a serious criminal offence—is 2,000 penalty units, why the disparity between the two levels of penalty?

Ms Lee—I believe that there might be grounds to justify a departure from the formula because we are taking into consideration that you need to deter and perhaps sanction activity that in fact has caused harm to the public. I will refer you to my colleague from the Attorney-General's Department.

Mr Gray—To set out the position as to why we have got involved, my branch performs a scrutiny of bills role. We have performed that in relation to this legislation. The guidelines that you have referred to is a document which we have issued and which we are responsible for maintaining. As my colleagues have said, they are guidelines. The rule of thumb here or the way that we approach it is that if the legislation deals with offences, civil penalty provisions or search powers and if there is a departure from those guidelines then the question is: can it be justified in the circumstances of the case? We have supported this legislation because of the sorts of things which have already been referred to: the impact on public health, the fact that you are dealing with commercial conduct and the fact that so much of this conduct is by corporations. It really is something different from traditional Commonwealth criminal law, if I can put it that way, but it is becoming more common for the Commonwealth to regulate this sort of conduct.

But in the past the sort of conduct that the Commonwealth has looked at with its criminal law has not been this type of conduct. That becomes relevant—and the reason I did press forward in relation to the corporate multiplier—in section 4B of the Crimes Act. Section 4B(2A) talks about the maximum penalty being imprisonment for life. The court has power to also impose a pecuniary penalty of 2,000 penalty units. Where it is a corporation that is being prosecuted and not an individual, if a penalty is imposed then, if there is no fine, the corporate multiplier is the term of imprisonment in months times five, and that becomes the number of penalty units.

The relevance of that is that the government recently announced that there would be a review of Commonwealth penalties. One of the issues that is going to be addressed is whether that corporate multiplier is still appropriate. In terms of the sorts of questions that you have raised, when you convert life imprisonment to 2,000 penalty units, that works out to $220,000. It is not a significant amount of money. One of the issues that we will be looking at is that ratio between fines and terms of imprisonment. The questions are valid and worth asking, but to see whether these are inappropriate for the modern time is something that we will be reviewing.

CHAIR—So you are saying that the 2,000 penalty unit equivalent of a life imprisonment is likely to change?

Mr Gray—I cannot predict the outcome of the inquiry.

CHAIR—But it is being contemplated at the moment.

Mr Gray—It is going to be reviewed. That will be one of the matters which will have to be considered. We were looking at some offences recently where the penalty for an individual is 10 years imprisonment. The maximum penalty for a company is a $350,000 fine. For a multimillion dollar international corporation, is a fine of $350,000 really equivalent to 10 years imprisonment for an individual?

CHAIR—That is a good point. You just mentioned a multiplier with a factor of five for corporations in the Crimes Act. The submission before us points out that the multiplier used in this legislation is a factor of 10. Are you saying that they are likely to move to a factor of 10 in this revision of the broader criminal law?

Mr Gray—No, I could not say that. I could not predict the outcome of the review.

CHAIR—How do we respond to the argument that we have a more severe multiplier effect in this legislation than in comparable serious criminal law?

Mr Gray—The position that we have reached is that the multiplier of 10 can be justified in the circumstances of this legislation. As I have referred to already, this legislation deals with public health and with corporations and commercial conduct. I think it would be going too far to say that, therefore, a multiplier of 10 should be seen as the standard. Certainly it is one of the factors that we will be taking into account in the review. We will look at the experience under this legislation and also the findings of this committee. I am informed that the multiplier of 10 is for civil, not criminal, proceedings.

Ms Lee—The maximum penalty of 4,000 penalty units has to be taken in the context that we are regulating well-resourced companies. In addition, that penalty will only arise if the

Commonwealth can establish that actual harm has been caused as a result of, or that it will in fact result from, unlawful conduct. That is an additional aggravating element that needs to be established before that high-level penalty can kick in.

CHAIR—I am not sure that you have established a case to say that the multiplier here needs to be greater than it is in any other area of the law. Have you offences relating to poisoning of the water supply, for example?

Ms Lee—There is an equivalent.

CHAIR—An individual's culpability versus a corporation's culpability should be on a scale which is pretty well common across all these areas.

Ms Lee—There is actually another piece of Commonwealth legislation: the Occupational Health and Safety Act. That also incorporates maximum criminal sanctions of 4½ thousand penalty units, which is more than we have in our bill.

CHAIR—Yes, but what is the ratio between those and the individual penalties in that legislation? Is it a factor of five to one or 10 to one?

Ms Lee—I think that penalty applies to an individual and you multiply that by five for a corporation.

Mr Gray—I am sorry to interrupt, but I would like to clarify to make sure there is no misunderstanding. The corporate multiplier for the offences in this legislation remains at five and the corporate multiplier for the civil penalty provisions is 10. I am just not sure if there is any ambiguity left on that point.

CHAIR—I am still not clear why there is a difference between criminal and civil in that circumstance. We are talking about the civil penalties. Is it only the government's enforcement agency—I assume that would be the DPP?

Ms Lee—No, with the civil penalties it would be the Federal Court.

CHAIR—That is the forum in which you would prosecute. Who would be the prosecuting authority?

Ms Lee—We would not be prosecuting as a civil action. It is in lieu of taking criminal prosecution.

CHAIR—Yes, but who would be the plaintiff in those circumstances—the TGA?

Ms Lee—We would probably initiate the action.

CHAIR—The TGA would?

Ms Lee—Yes, that is right.

CHAIR—Is it possible for an individual, who is affected by sustained actual harm because of a failure to adhere to the standards, to sue under this civil penalty arrangement or is it reserved for the TGA?

Ms Lee—I think it is reserved for the TGA. If someone wants to take an action privately, that would be on the basis of common law perhaps.

CHAIR—Okay, in which case there is no limit to how much they could sue for, presumably?

Ms Lee—That is right.

Senator MOORE—I do not think my three years on the Public Accounts and Audit Committee prepared me for the penalty discussion we have just had. We spent a lot of our time on that committee looking at regulation that imposed penalties. The question that I was asking the witnesses we had before was about the process of consultation, and your submission concentrates on the amount of consultation there has been with industry. I am sure the exchange we have just had about the penalty regime must have come up in that consultation. Do you believe, as the people doing the consultation, that the industry would fully understand the discussion we have just had, in terms of the use of the penalties and how they differ—what the difference is between the penalty regime under this proposed legislation and the TGA, as opposed to other forums?

Dr Graham—I think we genuinely tried to explain to the stakeholders what the penalties meant. As we have heard, there was some concern and some questions about the relativities, and we have explained that to them in the sense of what Ms Lee was explaining—the relativities to other pieces of legislation.

Senator MOORE—Which is public health. In a nutshell, the justification that was put by the TGA through the process to get the difference was public health. Is that fair? That is how I heard it.

Ms Lee—It is a protection of public health. In the light of continuing non-compliance with the regulatory requirements, the bill does not introduce any new regulatory requirements. It effectively provides for alternative options for addressing non-compliance with existing regulatory requirements.

Senator MOORE—And it increases the penalty.

Ms Lee—That is right. The penalties also represent maximum penalties, as my colleague Dr Graham has mentioned before. It is ultimately up to a court to decide on two matters: firstly, whether or not there is a breach and, secondly, what level of penalty should apply. It is not for the TGA or the regulator. In that context, I would like to correct something I said. It is the secretary, on the behalf of the Commonwealth, who can actually initiate an action before the Federal Court in relation to a civil penalty breach.

CHAIR—So the action would be conducted in the secretary's name?

Ms Lee—Yes, that is right.

Senator MOORE—The Secretary of Health and Ageing?

Ms Lee—That is right.

Mr Eccles—When we were explaining it to them, I think some sectors of the industry took comfort in the fact that these are maximum penalties, that there are a number of checks and balances enshrined in the legislation, that, before the TGA starts pursuing action, it needs to get independent legal advice to make sure that the action is likely to have a successful outcome and, generally, that there is no prospect of a major penalty for a minor breach. That

was one of the things that in the consultations with industry we went through in great detail, which resulted in TGA issuing the guidelines as part of almost a second round of consultation. Once we heard the concerns that were raised by industry, the guidelines were developed and put out for industry to have a look at and talk to us in the second round of discussions.

Dr Graham—And for TGA to comment and modify in light of those discussions.

Senator MOORE—The second point that came up in the area of penalties, which has come up pretty regularly not just in this area but others, is the issue of appeal rights. In terms of the methodology and openness of the appeal process under the proposed legislation and yet-to-be-seen regulation, what is your understanding of the right and process of appeal?

Ms Lee—This is for infringement notices; is that right?

Senator MOORE—My question relates to appeals across the whole process. My understanding is that there should be appeal rights to each part of the process.

Ms Lee—You normally have appeal rights in relation to regulatory decisions, whereas the provisions provided for in the bill are the sorts of sanctions that the Commonwealth could apply to a court for. Generally speaking, those sorts of actions are not decisions that are suited for merits review or appeals. A decision to prosecute someone, for example, is not a decision that should be reviewable. I think that might be recognised under the Administrative Decisions (Judicial Review) Act. Likewise, in relation to the issue of infringement notices, I recollect that one of the Australian Law Reform Commission's reports—I think it might be report No. 95—likened infringement notices to a settlement out of court, because an infringement notice is in lieu of taking someone to court. Therefore, because it is an agreement between parties, it is not a decision which is imposed upon another party that should be the subject of any kind of review. This is the reason why we have not provided any review mechanisms in our bill. There could be some, but I am not aware of any review mechanisms in relation to this in any other Commonwealth legislation.

Senator MOORE—I am having trouble coming to grips with someone or some company being assessed as not meeting requirements—or whatever the formal term under your legislation is—having a penalty imposed and not having a formal appeal process within that. I heard what you said, but I am still having great difficulty with it.

Ms Lee—Generally, if you make a decision to take someone to court because you think that it warrants some sort of judicial sanction because of activities that the party undertook, the issue that needs to be resolved is one that should more appropriately be dealt with by that court and not be the subject of any additional review process. The whole purpose of going to court—

Senator MOORE—So there is no internal review under your process.

Ms Lee—Not in relation to decisions to take someone to court, no.

Senator MOORE—Can I ask the Attorney-General's Department: is that common practice in the way our law operates? It is not my experience.

Mr Gray—I do not have the ADJR Act in front of me—

Senator MOORE—Neither do I.

Mr Gray—This is subject to that and we have to check. You would not expect there to be a judicial review of a decision to prosecute or a decision to commence proceedings, because that decision takes the matter before the court. If you want to then contest the proceedings, the forum in which to do it in this case would be the Federal Court or the Criminal Court, if charges have been laid. I do not see a policy problem with there being no rights of judicial review. I have only just become aware of appeals as an issue, but these will be civil proceedings before the Federal Court, so I do not see why the normal rules of appeals that apply in civil proceedings would not apply if an order was made. If you are dissatisfied with the outcome of the proceedings, then you have the appeal rights which apply in civil proceedings.

Senator MOORE—Can you take that on notice? I would really like to have the civil process clarified, because it is not clarified in the submission. So far we have had two witnesses who have both raised the issue of appeals to the committee.

Mr Gray—I have just seen some notes in relation to that. I was not aware of that as an issue until now. We can certainly look at that and give a considered answer.

Dr Graham—There are a number of options for a person if they receive an infringement notice. They could come back to the TGA, which is the issuer, and provide more information to review the infringement notice. They could decide to pay the fine. They could decide to offer an enforceable undertaking and, in that process, rectify the situation. Or they could proceed to the judicial outcome and test it in court.

Senator MOORE—Is that spelt out somewhere so those steps are clear? It is not in what we have in front of us. You can take that on notice. I have one more point on the communication process. I thought, from reading the preamble to this legislation, that this was all about making things more flexible and open so that we would achieve a more effective process. I am interested, from the review appeal process, in what you can do before you hit court because, once you bring in the court, that is where the high-level costs come in. That is certainly my understanding. From the submissions we have received, whilst people have faith in the process, they are concerned about what is going to happen step by step through that process. I take the legal argument about what constitutes civil action and how it goes to court and what happens once the decision has been made to take it to court. What I am trying to find out is what protection there is in the new proposals to make sure that every step is available before you reach that level to try and resolve the issue so that you do not get to court. You can take that on notice too.

Ms Lee—Generally speaking, before we can initiate a civil proceeding before the Federal Court, we are obligated to seek independent legal advice to establish whether or not we have genuine grounds to do so. That is a requirement under the legal services directions and is enforceable against us. In instances where, for example, as a result of breaches of regulatory requirements, we believe that some form of sanction or deterrence in relation to future noncompliance is appropriate and we make a decision that judicial sanction is the way to go, we would probably approach an independent law firm or the Australian Government Solicitor to establish that we do in fact have grounds to proceed down that line. If they come back and say yes, then that will enable us to bring an action before the Federal Court.

Senator MOORE—But that would be well down the track in the process, wouldn't it?

Ms Lee—That would be the usual process, yes. At the moment, when we prosecute someone, there is no review process. If we decide we have enough evidence to prosecute a person, we take the brief of evidence to the DPP and they make a decision as to whether or not it is sufficient for us to initiate charges.

Senator FIELDING—Dr Graham, I have just been thinking through some of the statements that have been made to some of the complexities. The comment was made that penalties have gone up a fair bit. I think it was mentioned that, for larger businesses, it is not much, and I appreciate that. I am thinking about small businesses. On the other hand, we want to make sure that families are safe and secure. Your submission was quite extensive when talking about whether there is such a thing as low-risk products and whether they can be harmful. Are there some types of goods in that category that are low risk, which really cannot be taken out of context in any way, that can be categorised to try and protect some of the smaller businesses? I can well imagine that some of those penalties would make small businesses really think but, by the same token, we do want to make sure that people are really protected and safe. Can I get your thoughts on that?

Dr Graham—Earlier on, I mentioned that it is very hard to differentiate between low-risk goods and high-risk goods when we are talking about contamination or other problems or breaches of the legislation that in fact may escalate what might be normally a low risk therapeutic good into a very high risk public health hazard. That is the difficulty. Many of these provisions are really to deter people from breaching the rules in the first place. There may be on occasion inadvertent breaches of the rules. Probably on 90 per cent of occasions we will negotiate with the individual to rectify that and to respond. But in those cases in which a person does not want to rectify it, or has an intent that risks public health, there need to be substantial penalties to respond to that situation.

Senator ALLISON—Ms Lee, you said earlier that actual harm needs to be demonstrated in the current arrangement and that that is a problem for compliance.

Ms Lee—No.

Senator ALLISON—Did I misinterpret what you said?

Ms Lee—This was in discussing the high level of pecuniary penalty in relation to the criminal sanction that we have introduced for certain unlawful activities. I was mentioning that, in order to be able to apply that high maximum penalty, you would have to demonstrate that actual harm either has already occurred or would occur, so there is an additional element that you would need to establish beyond reasonable doubt in order to secure a conviction.

Senator ALLISON—Unlike the Pan recall.

Ms Lee—Recall actions are administrative actions. There is a separate process to—

Senator ALLISON—I understand that. But you did not have to demonstrate actual harm in the case of the Pan recall.

Ms Lee—No. Recalling products and withdrawing products are actions based on criteria in the legislation. We looked at that criteria and established that the situation met the criteria and

that formed the legal basis for us to then recall the goods or seek the assistance of the companies to have their goods recovered.

Senator ALLISON—Under this new regime, would the Pan recall have been avoided? If so, how?

Dr Graham—It is very hard. What we are hoping is that with this new regime we would not get into that situation because the penalties would be sufficient to make the manufacturer or the sponsor aware of the consequences.

Ms Lee—One of the very reasons we have this regime is because it will either sanction or deter. Where we take regulatory action—such as, for example, suspending or cancelling a licence or withdrawing products from the marketplace—we often take that measure because we consider it to be appropriate in order to reduce risk to public health and safety. Taking someone to court does not necessarily address that issue. Judicial sanction is about sanctioning and deterring. We are hoping that this regime—

Senator ALLISON—Some might argue that withdrawing a licence and then recalling products—such as happened with Pan—is a sufficient deterrent. What are the processes associated with withdrawing a licence? Is that something that can be done quickly in order to protect the safety of people?

Ms Lee—It depends on the criteria in the legislation. If there is an imminent threat of death or injury, then you could, for example, withdraw a licence immediately. If not, then there is a process whereby you need to notify the licensee of your intention to withdraw and provide an opportunity for the licensee to respond to the concerns that you have raised. After taking that into account, you make a decision as to whether or not you will then remove the licence. That decision is subject to first of all internal review and then merits review.

Senator ALLISON—That sounds like a very appropriate process. Why do we need such extensive criminal and civil penalties? What are the shortcomings of the arrangement whereby recalls and withdrawal of licences are not meeting—

Dr Graham—It is not a desirable situation where you have to react after the event and recall products from the market or change a manufacturing licence because of evidence that they are not manufacturing according to requirements.

Senator ALLISON—What do you mean by 'after the event'?

Dr Graham—To recall a product after the product has been manufactured, put out into the marketplace—

Senator ALLISON—What about a licence? You can withdraw a licence if there is evidence of malpractice or unsafe conditions, surely?

Dr Graham—That is still a regulatory response that is available under the legislation.

Senator ALLISON—Why is it inadequate? That is my question.

Ms Lee—Because we want to prevent it from occurring in the first place, to minimise the risk to public health and safety.

Senator ALLISON—I see. So the penalties are huge and the powers—

Ms Lee—It is preventative.

Senator ALLISON—The powers are amazingly extensive in this legislation and it is a deterrent. That is the main argument you are putting?

Ms Lee—Yes. And they represent maximum levels of penalties. We have to take into account the full range of clients that we regulate, including the multinational companies that are very well resourced.

Dr Graham—We still expect a regulatory response in most situations and we have the ability to carry out criminal prosecutions at the moment. But this gives more flexibility in terms of the various options we might have, as it does for the industry to respond to an issue where there is a breach of requirements.

Senator ALLISON—You say this bill is necessary because the very tight time frame for effecting the amendments in May 2003 did not allow you to do this. It would not be because the government has control of the Senate that these amendments are now being brought forward, would it?

CHAIR—You are asking the officers to express an opinion.

Senator ALLISON—All right. I will put it another way. Can you explain why there was a very tight time frame at that point and why these amendments did not follow if they were, at that time, assumed to be necessary?

Ms Lee—At that time the only amendments we introduced related to a better way of identifying who the manufacturer was, to increase a number of penalties that were already in the legislation and also to introduce new offences relating to the destruction and falsification of records that, under the legislation, are required to be maintained and kept. They were considered to be urgent, so we introduced those measures as quickly as we could on the understanding that we would have to look at the entire sanctions package at a later stage to ensure that there was uniformity with the changes we made in April 2003.

Senator ALLISON—I do not recall that being said at the time, but you say that it was—that there would be a subsequent package?

Ms Lee—I am not sure that we said anything in the second reading speech—I cannot recall whether we actually said that in the second reading speech at the time. However, that was certainly the intention.

Senator ALLISON—But not necessarily expressed.

CHAIR—Mr Eccles, do you want to add something to this?

Mr Eccles—There are a couple of things. I just want to go back to the focus on deterrence. The focus on deterrence is obviously an important part of it, but one of the principal aspects of the new arrangement is to enable the regulator to better calibrate the response, depending on the nature and severity of the breach. That is why there are new aspects, including enforceable undertakings, infringement notices and a range of other things. I do not want the senators to be of the view that the sole goal of the bill is deterrence. It is also about being able to calibrate the response more appropriately.

Senator ALLISON—That is why, Mr Eccles, I asked what difference this would have made if it had been in place prior to the Pan recall.

Mr Eccles—I am certainly not an expert on the Pan recall. If the legislation gets passed it will enable the TGA to react differently from the way it did in response to the Pan activities.

Senator ALLISON—How?

Mr Eccles—Maybe my colleagues can go through the different approaches, ranging from the lower ends and the more subtle approaches right the way through. The discussion seems to have been focusing very much on the high end of the penalties, and that is understandable. But they are very much focused on when there is a catastrophe or when there is human harm involved. There are also some far more subtle aspects in the legislation to enable the regulator to take early action.

Dr Graham—In terms of a company such as Pan, where there might be a serious breach, under the new legislation we would have other options to implement. For instance, the manufacturer may offer an enforceable undertaking in some situations. We could then have some expectation that those breaches would be met. We could, in fact, introduce an infringement notice against the manufacturer or the sponsor, so it does give us greater flexibility. And, under the new legislation, we also have other powers against the directors of the company.

Senator ALLISON—Is an infringement notice a more effective tool than a notice that a licence might be withdrawn unless compliance is guaranteed?

Ms Lee—It would prevent a licence from being withdrawn at a later date.

Senator ALLISON—I am sorry?

Ms Lee—It could prevent a licence having to be withdrawn at a later date.

Senator ALLISON—How does that work?

Ms Lee—If, for example, you discover that there are recurring breaches, as in the case of Pan, and you decide that you want to issue infringement notices or apply for a civil penalty order for a fine, it may be that the company might then take stock of what it is doing. That might then perhaps act as a deterrent in terms of continuing breaches, so that it does not escalate to a situation where noncompliance is so bad that you have no option but to withdraw their licence.

Mr Eccles—I think the submission from the department refers to the fact that this is very much a tiered approach. Right down at the very subtle end, in the early phases, or the lower end of difficulties that may be discovered by the TGA in a manufacturer's premises, for example, there are options, such as the enforceable undertakings, which were not available to the TGA, or which are currently not available to the TGA.

I hope we are not losing sight of the fact that the whole intention of this is to have very much a staged or a tiered approach. I guess the intention is to prevent the response not befitting the nature of the breach, and to make sure there is no prospect of a major penalty for a minor breach of the act. The new legislation is designed to better enable the regulator to do that, through things like the enforceable undertakings. For the more severe activities,

infringement notices may be able to be issued. Again, there are also checks and balances so that the TGA cannot just act on a whim. Before issuing infringement notices, they need to have independent legal advice, as we have said before, that indicates that there is going to be a significant prospect of successful action.

Senator POLLEY—In relation to the current legislation, how many breaches have there been over the last three years, and can you give me a summary of the types of breaches and the penalties that have been applied?

Dr Graham—I would not have all that information, but breaches are relatively commonly found. They come in different degrees. In most cases, we would discuss with the manufacturer or the sponsor how to rectify that breach; we certainly would not go through a regulatory route or a route where we are applying sanctions. I just do not know the number of those, but they might be breaches of labelling or breaches of packaging, or they might be something fairly inadvertent, of a fairly minor nature. Where it is a minor breach, one that is probably not intended by the sponsor or the manufacturer, we deal with it in a bilateral way.

Where it becomes more substantial—and this is where this legislation starts to kick in—we have a number of levels under the new legislation with which we would be able to tackle that. To answer Senator Allison's earlier question as to why we do not just take away a manufacturer's licence, that may be one of the options under the current legislation. We might have to do that because we do not really have other options at the moment, and that may not be in the best interests of the community at large in the longer term. But if we can put in place something like an enforceable undertaking, where we have confidence that the manufacturer would respond rather than perhaps not taking it particularly seriously, that would give us a lot more confidence that we could move the manufacturer or the sponsor ahead to a satisfactory outcome.

Senator POLLEY—Would you take it on notice to get something back to us in terms of the types of breaches and the areas they are from just to give us some background, to try to justify the bill.

CHAIR—Presumably some of those might still be on foot, so there might be difficulty in how you describe them, but what you can supply to us by way of generalised information about the number and type of prosecutions, would, I assume, satisfy that question.

Dr Graham—Yes—the number identified and aggregated together, if that is okay.

Senator FIELDING—Is there any way of categorising those into small business versus the larger pharmaceutical groups?

Dr Graham—We would have to come up with a definition of what is small and what is large.

CHAIR—Are there any small manufacturers of therapeutic goods in this country? I suppose there must be.

Dr Graham—There is a whole spectrum, from the big multinationals right down to perhaps those that operate within a state—even a pharmacy, for instance. Some pharmacies manufacture therapeutic goods and put them into the marketplace.

CHAIR—Whatever you can provide to us on notice would be useful. Thank you very much for your evidence to the committee.

Committee adjourned at 5.51 pm