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**HOUSE OF
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STANDING COMMITTEE ON FAMILY AND HUMAN SERVICES

Reference: Impact of illicit drug use on families

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HOUSE OF REPRESENTATIVES
STANDING COMMITTEE ON FAMILY AND HUMAN SERVICES

Wednesday, 21 March 2007

Members: Mrs Bronwyn Bishop (*Chair*), Mrs Irwin (*Deputy Chair*), Mr Cadman, Ms Kate Ellis, Mrs Elson, Mr Fawcett, Ms George, Mrs Markus, Mr Quick and Mr Ticehurst

Members in attendance: Mrs Bronwyn Bishop, Mr Cadman, Mrs Elson, Mr Fawcett and Mrs Markus

Terms of reference for the inquiry:

To inquire into and report on:

How the Australian Government can better address the impact of the importation, production, sale, use and prevention of illicit drugs on families. The Committee is particularly interested in:

1. the financial, social and personal cost to families who have a member(s) using illicit drugs, including the impact of drug induced psychoses or other mental disorders;
2. the impact of harm minimisation programs on families; and
3. ways to strengthen families who are coping with a member(s) using illicit drugs.

WITNESSES

HULSE, Prof. Gary Kenneth, Professor of Addiction Medicine, University of Western Australia 1

Committee met at 10.23 am**HULSE, Prof. Gary Kenneth, Professor of Addiction Medicine, University of Western Australia**

Witness was sworn—

CHAIR (Mrs Bronwyn Bishop)—I declare open the public meeting of the House of Representatives Standing Committee on Family and Human Services. Today the committee will take evidence from Professor Hulse, who is Professor of Addiction Medicine at the School of Psychiatry and Clinical Neurosciences at the University of Western Australia. I thank you for making your time available in your busy schedule to come to Canberra to give us the benefit of your expertise on the damage caused to people by using illicit drugs. We note with interest that your most recent work has been on evaluating the benefits of sustained release naltrexone. The transcript of what is said today will be posted on the committee's website. If you would like further details about the inquiry or the transcript, please ask any of the committee staff here at the hearing. This hearing is open to the public.

Prof. Hulse—I have two primary purposes here today. The first is to brief the committee on human trials to assess the safety and the efficacy of the Australian implant, particularly for management of heroin dependence, and the second is to talk about where to from here, what needs to be done and, perhaps importantly, why.

CHAIR—Would you like to make an opening statement to us?

Prof. Hulse—The opening statement that I am going to make is that, although I have primarily come to talk about the Australian sustained release naltrexone implant, I would like to deliver a little bit of background about where that fits into the whole structure. When I teach my medical students, I basically tell them that they need to understand about heroin dependence and that they have to recognise that heroin is a very charismatic drug. The best way of saying this that comes to mind is a young woman who I spoke to. She said: 'If you had told me a year ago that I would be lying and cheating to the very people that I care about—to my friends, to my family—that I would be ripping them off, that I would be dealing in drugs, and that I would be selling my body for \$30, I would have said that you were not talking about me—you were talking about someone else. I am a stronger character than that. Yet here we are a year later and that is me, and I don't like me. I don't like what I am doing. I don't like what I have become. I don't know what to do about it. Did I forget to tell you, I love to use heroin.'

People use heroin despite all of those negative things going on. This is a very powerful, charismatic drug. It is associated with a high level of mortality and morbidity. Mortality is 13 times higher than for other persons in the community for the same age group. The common treatments associated with heroin dependence—the gold standards at the moment—are methadone maintenance and, more recently, buprenorphine maintenance. Methadone is a drug which is an opiate. It binds to the opiate receptor and it causes an opiate-like effect. This is a drug that you become dependent on and, if you take it away, you have withdrawal. Buprenorphine is a partial agonist, so it partially acts similar to methadone. Clinical trials demonstrate that there is good efficacy associated with both treatments in terms of arresting heroin dependence. For example, that is for management of a respectable user using three times

a day. The difficulty is that it does not necessarily disengage people from the narcotic network. You can still use opiates. You can still use heroin while you are on methadone or while you are on buprenorphine. People continue to engage with the narcotic network and they do not shift away. Relapse is not uncommon. One of the criticisms that have been made of methadone and buprenorphine is that they may elongate the period of opiate dependency. Also, the restrictive nature of having to attend pharmacies for your daily pick-up tends to make these drugs incompatible with reintegration into the community.

The other alternative that we have in terms of pharmacotherapies is naltrexone. From a pharmacological point of view, naltrexone is unequivocally able to block high doses of heroin—that is heroin, morphine and methadone—but the difficulty with this is that it is currently available as an oral formulation—50 milligrams per day. It is a case of taking a tablet and swallowing it. I should say that methadone is also used orally. Buprenorphine is taken by putting it under the tongue, which is sublingual administration. So you take 50 milligrams of naltrexone a day, and, if you can take that 50 milligrams a day, then treatment is quite effective. The difficulty is that if you are a self-respecting user and you really like to use heroin, at any particular time, you are going to stop taking your oral medication and you will start to say, ‘I’ll just have that one little dabble; I’ll just go back and try it once,’ and people relapse. Relapse is quite common with oral naltrexone.

So we know we have a drug (naltrexone) which is very effective. The Americans have known this since 1970 and they have been endeavouring to develop sustained release formulations. The Americans currently have a number of sustained release formulations, one which has now been listed through FDA for alcohol dependence and will probably shift on to heroin dependence. It has clinical efficacy for about four weeks. The Australian sustained release formulation is in implantable form. The sustained release formulations are developed to overcome the problem of the oral formulation with compliance with the medication—of stopping the taking of medication—and it is a way of basically putting it in your system. The first objective that we have been looking at is about the safety—that is, if you are placing this into a body subcutaneously, you want to know that it is compatible with tissue, that it does not cause problems; that hopefully it is biodegradable; that it keeps the levels required in the blood for a sustained period of time; and that it has a clinical efficacy. The information about the profile of the Australian implant is in the briefing notes that I have provided.

I should also say that we need good information on mortality associated with naltrexone treatment. There has been some suggestion of increased depression and risk of suicide following entry on to naltrexone. There have been issues raised of significant withdrawal effects and perhaps death associated with naltrexone. I should stress that this is to do with the withdrawal treatment, not naltrexone per se. One of the things that I neglected to say is that, if you have a heroin dependent person, you can simply place them directly on to methadone or buprenorphine. You do not need to withdraw them.

Naltrexone is an opiate antagonist, that is, it antagonises the effects of heroin, morphine and methadone. You need to withdraw someone first of all opioids. You do not need to withdraw them by rapid opiate detox; you can go through a conventional detox. The GP can withdraw them or they can withdraw themselves. It does not matter about the mechanism, but they need to be withdrawn to start off with. A lot of the criticism that has been made about the implant and some of the adverse effects of entry are not to do with the implant per se but to do with

withdrawal and inappropriately managed withdrawal procedures. The other issue has been to do with whether people coming off naltrexone implants have a heightened or greater sensitivity to accidental overdose. Clearly, anyone who has not used for a period of time is going to be in that particular situation.

The final issue about the implant is that you have to remember that oral naltrexone is not recommended for use during pregnancy. It is not a contra indication, but we simply do not know its safety in pregnancy. It is classified as a category B3 drug by the Therapeutic Goods Administration. That basically means that animal work has shown that there are some foetal issues to do with the naltrexone, but nothing has been shown in humans. This is as opposed to methadone and buprenorphine, which are classified as category C drugs. Category C means that detrimental effects have been shown in both animals and humans. Remember that methadone is still the recommended treatment of choice, with perhaps buprenorphine coming up to it, for the pregnant heroin user. Notwithstanding that, negative effects have been shown in both humans and animals with both these drugs.

CHAIR—I will just interrupt you there. When we were in Perth last week, we took evidence at the antenatal clinic of the King Edward Memorial Hospital that, of the 5,000 children born, 350 of them are born to drug dependent mothers. I think 102 of them were methadone dependent, and they fed the mothers methadone through the pregnancy.

Prof. Hulse—Correct. That is the standard, accepted treatment.

CHAIR—I said, ‘Why wouldn’t you take the mother off the drug and keep them drug free for that period?’ They said, ‘The withdrawal would damage the baby.’ That seemed to be very odd.

Prof. Hulse—I would say that there are two things. One is that keeping people on methadone is primarily for two reasons. One is that people are concerned about relapse back to dependent heroin use where the outcomes associated with neonatal and infant birth are worse than if they are on methadone. It is looking at the lesser of two evils at the moment. The second issue is that we have a situation where many persons believe we do not have an alternative and there is a common belief that it is impractical to withdraw women during pregnancy because of neonatal outcomes. There is not good data for this, and I suggest that women at the Perth naltrexone clinic have been withdrawn from methadone and have been withdrawn from heroin at different parts of gestational development without problems. This practice has gone on in the UK and it has also gone on in Portugal. Those are just three places that I am aware of and there has been published data to demonstrate that patients can be withdrawn during stages of pregnancy.

What we need to do is look at the best practice and identify where that might not be appropriate, where there might be other cofactors—cohealth issues. In the best interests of both mother and baby, we might determine not to withdraw during pregnancy. The other issue is if we do take people off heroin, we really need to provide them with a safe environment where they are likely not to relapse to heroin use. We need an environment that we can put them in where they can nurture the pregnancy and where we can nurture them until and after the birth.

CHAIR—But what happens to the babies? What is their future? All but 25 of those 350 babies went back to their biological, drug dependent mother? That is all but 25 of them. Three months later, another 25 were taken away. What is the future of those innocent kids? You have

got to look after the mother and have treatment programs for her, but you have got to have concern for that child.

Prof. Hulse—That is one of the reasons that we need to develop an abstinence based treatment which seems to have good efficacy and which does not seem to have detriment to the mother and the neonate. If we can develop that treatment and if we can look for information, then we have a step forward. If we can look at sustained release preparations, then we can have some level of guarantee that that heroin dependent mother will not relapse. Pregnancy is a great motivational force for women to change direction, to look at change and sustain change. They just need the window of opportunity to do so.

Mr CADMAN—Is it right that harm minimisation will only keep us on the track already laid down?

Prof. Hulse—Harm minimisation is one of those terms which tends to refer to what we do with people who relapse back to narcotic use—who are in the narcotic network and are still injecting—or we have them on a treatment where we accept that they will continue to use, whether this be injecting rooms, methadone or buprenorphine. Harm minimisation should never be the final objective. Harm minimisation should be, if anything, a stepping stone to stabilise someone to move them towards abstinence. Getting people out of the narcotic network should be the final objective. I am yet to meet a heroin dependent person who says, ‘I love being where I am. I love doing these things. I love ripping off people. I love having to do tricks for men down the road.’ They love heroin. It is an issue of breaking that nexus. Harm minimisation is very fine. Harm minimisation for those people who relapse is a necessary component, but it should be focused at then trying to shift them along that process back to where they are not using.

CHAIR—I have noticed that the language is changing again. Incidentally, I listened to Radio National this morning. I listened to the sports report and three times in four minutes I heard the sports reporter talk about footballers using recreational drugs. Now, something has to be done about the language, but harm minimisation to the people who are in the industry seems to be turning into harm reductionism. There is a new term. The message seems to be that the community—the rest of society—has got to get used to the fact that some people like drugs and that is okay. I think that is just pernicious. I think that is wicked.

Prof. Hulse—From someone who works in the area of drug dependence—and forget about the terminology—the objective is to stop people entering into drug use. I do not care about the terminology. It is to get those people who are currently using and, via whatever, mechanism look after them and then shift them in the right direction so they can get out of those networks.

CHAIR—That is why the language is important, because all the language says is that it is okay.

Prof. Hulse—The language is important, but more importantly the services need to be geared together so that if you enter someone on to what might be termed a harm minimisation strategy, you need an exit strategy from that. If you put someone on to buprenorphine or methadone, then you need an exit strategy. How do you get them off there and then move them to abstinence? Can we withdraw them and then put them on to, for example, sustained release preparations of naltrexone, which has thus far proved to be safe and effective? How do we shift them off harm

minimisation and get them on to those abstinence based treatments? What other services do we need to provide in order to be able to reintegrate them and let them shift back into the community?

The harm minimisation strategies are fine as a stepping stone, but you always need an exit. I would say the same thing for injecting rooms. I do not like the term 'injecting rooms'. We should have facilities where people who are currently dependent attend where they have options provided to them and they are told, 'These are the options that are available to you in terms of maintenance treatments. This would be the first one to go on to. This would be the next one.' That range of services gives them some alternative other than continuing to inject. If, while they are there, as a person who uses three or four times a day, they self-administer, that is just the nature of the beast. But to focus on simply having an environment where people come and inject is not the goal. The goal is to use that as an opportunity to then look at where you are going to shift those people.

Mr CADMAN—Let me just clarify what you have said. It seems to me that Mrs Bishop is saying that the language is important and you are saying that you must have the language and the program delivery in sync. That is not what we have now. We have got the language okay at the top, but the language and the delivery at the bottom is way out of whack.

Prof. Hulse—We have programs rather than linked programs which have a strategic plan that rationalises why you are placing someone on a particular program—harm minimisation—and justifies that. Is that the only possibility? If it is, fine; put them on. But where are you going with that? How are you then going to shift them off that particular program and get them towards an environment where they are more likely to reintegrate into the community? That is what we need to do. One of my concerns is that what we have is isolated programs. We talk about methadone programs and we talk about buprenorphine programs. What we should be talking about is the treatment profile for this particular dependent heroin user. That may incorporate a range of programs that need to dovetail together in order to be able to shift them from point A to point B—from being a dependent user back into the community.

CHAIR—But the aim is to get them off it.

Prof. Hulse—The aim is—

CHAIR—And the other aim has to be to prevent their getting into it.

Prof. Hulse—That is correct. I do not think anyone in the industry would argue about that.

CHAIR—They do, and the 'industry' is a good term. There is a real industry out there.

Prof. Hulse—I would hope that no-one in the industry would argue about that, because it would just seem to be what we are all working on.

CHAIR—There are a lot of people making their reputations and writing papers.

Mrs MARKUS—What you are saying is that the outcome is the most important, which we would be in agreement with, and the outcome is abstinence. I have a social work background. In

relation to services, there might be a rehab over here, a methadone clinic here and a naltrexone trial, but none of them integrate. They are not linked and the focus is not on the outcome. The focus is: what are we doing now? We are maintaining these people. We are not looking at the next step. Often what I have observed is that there are very few services that provide all of the steps and there are very few individual services that may necessarily link effectively and focus on getting to the final outcome. I am not saying there are not services out there that do. Often one service that is focusing on just methadone maintenance may not necessarily have the time to do all of the other. Often all of those links to ensure the person's total wellbeing is looked after and that they are focused on the outcome is lost in the system and the industry as it appears now.

Prof. Hulse—If you enter people onto methadone or buprenorphine and your expectation is that a proportion of those people will dabble—they are not heroin dependent; you may have arrested the heroin dependence, but they may relapse back into heroin dependence—and if that is your objective, all you need to do is provide a bit of methadone and perhaps a bit of counselling and hope that they will shift along and not go back to use. The difference with providing a program such as naltrexone—a sustained release program—is clearly that the objective is that they are not going to use.

Mrs MARKUS—That is right.

Prof. Hulse—You have a different objective with that. The resources that you require are really going to be about giving people an idea that there is another life possible for them outside of that narcotic network, and it will likely involve housing, employment and social skills. People who are involved in the networks for a period—for several years—become deskilled. They do not feel comfortable talking to the general community. They can talk to other drug users, but they do not know how to talk to people. You need to reskill people. You need to make them feel comfortable about that and you need to provide a range of resources. That is why, when we talk about things such as naltrexone programs, it has to be a total program. It cannot just be, 'Give them naltrexone,' because, even if this is effective—a sustained release preparation for 4½ months; this is a window of opportunity for change—if you do not provide the vehicles for that change, you will get to the end of that time and people will go back, because that is where they still are and that is the only life they have.

CHAIR—Last week in Perth I visited a naltrexone clinic and spoke to a heroin addict as he was having the implant done. His wife was holding his hand. She is a non-user and they have a three-year-old child. That was his reason for wanting to come off it. He said that he had squandered a \$70,000 trust fund in four months. He said that he was coming back and that it was a family decision. I also met two women working there who were nurses, and I had quite a conversation with one of them who, as a heroin user, was working as a nurse. I said, 'You could have killed somebody.' She said, 'When I realised that, I knew I had to get off it.' It is all very well for us to talk about people who are users and often the different life and so on, but we have a lot of people who are using drugs, including recreational drugs, such as speed, crystal ice and so on, who are working in areas of responsibility where their negligence can kill someone, because they are on drugs. We cannot just be considering offering them a new life. We have to think of what the impact on them and the rest of them is.

Prof. Hulse—You have mentioned two different types of scenarios, which I will address in turn. The first one is your gentleman with a three-year-old child, married to a non-using partner and who has just squandered \$70,000. Did you ask him when he last used heroin?

CHAIR—Yes. It had been before he came in.

Prof. Hulse—To be able to opportunistically take someone off the street who is a dependent heroin user who has just had a hit before they come in—

CHAIR—Not immediately before, no.

Prof. Hulse—Within the last day?

CHAIR—Yes.

Prof. Hulse—To take that person, to withdraw them and have them on an antagonist program that will block the effects of heroin—did you see them afterwards? Were they ambulatory? Were they walking?

CHAIR—Yes, he was walking.

Prof. Hulse—To take this person who is heroin dependent and opportunistically withdraw them and then have them walking out of a clinic where, if they go and have a hit of heroin they are not going to have an effect, is a remarkable thing. This is something that we need to be aiming at. We cannot have this mentality where you have these huge waiting lists, you make people jump over hurdles, and where they have to ring up and make an appointment in a week's time to come down and have an assessment: 'Yes, now you have to be seen by a medical officer next week.' These are heroin users. People report and say, 'Of those people who enter our program, this is our success rate.' What about the people who have not entered that program because of the hurdles that you have made them jump? Set up services, which are opportunistic, which allow you to assess people and provide good medical assessment and psychosocial assessment at that time, withdraw them and get them onto a treatment. Don't lose that 30 per cent or 40 per cent who then do not come back for treatment.

CHAIR—That is interesting. On the Gold Coast we took evidence from a man who took the opportunity to give a community statement. He said that he had been a user for 7½ years. He said that there were times as he was using when there was a window of opportunity when he wanted to get off. He would pick up the phone to ask, 'Where can I go?' and there was nowhere. So he would just have another hit.

Mrs MARKUS—You are right on the money there. As somebody who has worked directly with these people, I can tell you how frustrating it is when a person is ready and you cannot get them a service because there are waiting lists. It is just ridiculous. I will also mention something that you highlighted, and that is the focus on the psycho-social, the importance of behavioural aspects, and the importance of the context that they are living in. They have lost skills and perhaps developed some behaviour that is not acceptable. The relationships they had with their family have broken down. Services that focus on the whole of the person are what will bring

results. I do not know about everything you have been doing. How do you focus on all of those aspects?

Prof. Hulse—I will answer the question, but let me back off a little bit and just say that in my previous life I ran and coordinated methadone services in Victoria. One of the biggest problems there was the one that I have pointed out to you—that is, the difficulty of getting people in when that window of opportunity arises, when they are ready to make that change, rather than putting them off until you only get the handful who come through. Perhaps 30 per cent or 40 per cent are lost during the process. Unfortunately, this tends to be more of a problem with large services. The larger the services the more procedures that are laid down as being, ‘This is the process we need to go through.’ You need procedures, but you need a level of flexibility and you need dedicated staff who are willing to say: ‘No, it might be my morning tea break, but there is a person out there. During my morning tea break I could actually do something for this person, and I would rather do that than have my cup of coffee.’ The staff member would rather get out there and do an assessment on someone and try to get them into treatment, rather than just saying, ‘No, they weren’t booked in two weeks ago, and I am not going to do that.’

That is a mentality about the treatment providers that needs to change. I have often said that if services for non-Indigenous persons, for Aboriginal persons and Torres Strait Islanders were run in the same way as we ran drug and alcohol services, there would be a public outcry. If we had Indigenous persons in Australia fronting up to services and being sent away and told that they had to wait for a number of weeks before they could be attended to, there would be an outcry, and yet we have drug and alcohol services that continually turn around and say: ‘No, you will need to go through this assessment. Yes, there is a waiting list. You will have to wait for 10 days. First of all, you are assessed by this person and then you need a medical officer.’ That is opportunistic. Get those people who are legitimately interested in helping.

I would like to clarify my role. I work for the University of Western Australia and I am stationed at the Sir Charles Gairdner Hospital. My role in this has been to run some trials for both the NHMRC under NHMRC funding and direct funding from the Commonwealth to look at biocompatibility and biodegradability, or tissue reactivity, of the implant and to collect some data on how long it seems to last in the blood and, finally, to run a randomised blind clinical trial. That is where people are given both an oral medication and an implant—everybody, 70 patients. Half of those patients have the oral active and half have the implant. We do not know which ones. When we were entering those people in the study, we do not know and the patients do not know which formula they are receiving. When they are going in, the people following you up do not know. The first people to know if they have an actual implant are probably the users, because they will at some stage stop taking oral and try to have a heroin hit.

What I would say is that there is a difference if you have a look at the data. In Western Australia, there are services that provide halfway housing and counselling. I am talking primarily about places such as the Perth naltrexone clinic, which currently provides about 15 to 17 halfway houses. It has a large facility at Northam, which used to be the nursing home up there. Some of those halfway houses are for sex industry workers—often very young sex industry workers—to give them a place to go to after treatment, and for pregnant women to go and live.

Mr CADMAN—This should happen all over Australia. It is terrible that we are not doing this.

CHAIR—They do not need to have a Medicare number to give the treatment.

Prof. Hulse—The large facility at Northam is basically structured to allow families to live with the person who has just been treated. During the whole drug use, whether it be heroin or alcohol dependence, there is an enormous amount of destruction of family bonds.

Mrs MARKUS—Absolutely.

Prof. Hulse—Families often want a role to play. The objective is to have a facility where people can live for a short period to re-establish those bonds. It is terribly important for people to have a role and to get their connections back together. Those services are run, but not by me. We carry out the clinical trials. What I would say about the clinical trials is that the results we have so far demonstrate that the implant seems to be compatible with tissue and does not have major problems associated with it. This, of course, needs to be assessed by TGA. It is biodegradable. It does take a while to biodegrade, and you can have some residual material left up to 18 months to two years later. But you certainly cannot detect that palpation, by pressing down on the skin or subcutaneously. However, it does biodegrade. Tissue reactivity, which you would get with any type of foreign body, is not major to start off with and decreases over time. After six to 12 months it is negligible.

Mr CADMAN—You have some charts there at the end of your presentation. Do you want to talk about them?

Prof. Hulse—The charts are really just on the data at hand for the randomised clinical trial. This is the trial where people are given either an implant or an oral and people do not know. This is just on 51 of the 70 patients that were entered into the trial. This is at four months post treatment commencement. It is really saying that 56 per cent of the oral naltrexone group—that is, the TGA registered treatment group—were using heroin in excess of either one to three times a week or more, whereas 16 per cent of the implant group were using one to three times. I would say about the implant that you can shoot over the top of the implant. Drugs just compete for opiate receptors. If you want to use enough heroin at any particular stage—if you can afford it or if you happen to be a dealer—you could probably shove a couple of grams up your arm and get some effect. The effect will not be all that great, but you could get an effect as the amount goes down.

One of the things that goes on in terms of sustained release preparations is that you need to know what is the common availability of heroin on the street, what is the blood level of naltrexone, what is that likely to block, and that gives you some idea about retreatment. We talk about the psycho-social. The window of opportunity is only as good as the ability to effect change within that window. The earlier that you can get someone before their entrenchment in the narcotic network, before they say, ‘I haven’t had any contact with my family and friends for the last several years’—the earlier that you can do that, the better it will be and the less work you have to do. It is appalling to look at alternatives, such as buprenorphine and methadone, when naltrexone maintenance, if it is proven to be safe and efficacious, is an option that would be taken up by a person. You need to offer those things to people. You need to talk about it.

People often say to me, ‘Who will take up these options?’ If you find a dependent user, what they are concerned about is not being dependent: ‘I love to use, but I hate being dependent.’ What they often want to do is get back to the good old days when they just dabbled. Most of the people we see go through that circle a number of times. They start to dabble and they go back into it again. I think we need, firstly, to assess the issue to do with implant naltrexone. We need to get the TGA to look at the clinical data. If that seems to be an efficacious treatment, we need to look at how we roll that out, and then we need to look at the psycho-social services that need to be part of that. This is not just about giving this amount of drug. It needs to be funded as a package.

As I said, we also need to look at the pregnancy issue, because you are looking at a sustained release formulation. In Perth at the moment perhaps 60 women have been exposed to either oral or implant naltrexone during parts of gestation, and there is the capacity to follow up those people, look at their neonates, look at the developmental stages and ask, ‘Are there any issues with the developmental stages these neonates have gone through, or the infants?’ On the database we have all of the obstetrics and neonatal outcomes—birth weight, head circumference, length. All of that is sitting there. But no-one has gone through and looked at that.

I said to you that naltrexone is classified as a B3 drug—that is, it has been shown to have some negative effects in animals. But the studies that have been done on animals have been for huge doses. What we need are some animal studies that deliver naltrexone at a comparable level to what would be occurring with an implant, which is lower than would occur with an oral formulation. We need that data. We need some data using animals. We need some basic information. We need to get that before we launch into this too far. But we do have preliminary data sitting out there on women. Let’s go and collect it. Let’s get that information out there. Let’s look at a mechanism for doing that. Let’s look at a mechanism for setting up some simple studies with animals to try to get some information. This could be done very quickly.

CHAIR—What sort of funding would be required to do that?

Prof. Hulse—For the human data, you are talking about funding for perhaps a paediatrician to do some assessments of infants, in terms of development, and you are probably talking about a couple of sessions a week. You are talking about someone who can go through the linked database, perhaps a research officer. It would be perhaps \$100,000 as a ballpark figure.

CHAIR—Would there be people ready, willing and able to do that? Would you be such a person?

Prof. Hulse—Absolutely. We can step in and do that. You need the paediatrician to be able to assess whether they are at the appropriate developmental stage. It would be even nicer to compare them against some age matched controls and compare them against some methadone infants who have gone through so that we have some comparative data.

Mr CADMAN—Absolutely.

Prof. Hulse—You might be talking about that.

CHAIR—We know that is happening already in Perth because we took evidence about it.

Prof. Hulse—We already have the women sitting there. This data can be collected from these people. I think it would be silly of us to apply through NHMRC to run a clinical study on pregnant women. We are certainly not going to, without knowledge, go and implant a whole range of pregnant women. We have the data there, so let us go and do it. I have a PhD student at the moment who is trying to collect some information, co-supervised with Professor Dunlop in animal biology. They do not have a lot of resources. I would say that with \$50,000 this person could move really quickly and collect some animal data. That is another thing that needs to occur.

Mr CADMAN—How long has it taken you to get this current trial up and running? It could take 25 years to get a trial up and running.

Prof. Hulse—There were some delays in getting the trial up, but I would say that the delays in getting the trial up were primarily because the Commonwealth asked us to delay the implementation of the NHMRC trial until Go Medical, which is the manufacturer of the implant, was manufacturing under a TGA-approved GMP facility, so that what we are assessing is a product which could readily go onto the market. Once they gave us the go-ahead we started recruitment probably a year and a half ago and here we are. We are coming out at the end of the data collection.

Mr CADMAN—You will not have to go through that process again?

Prof. Hulse—We will not need to go through that. This will tell us whether this particular Australian implant is as good as or better than the registered oral naltrexone formulation. What it will not tell us is how it stacks up against methadone or buprenorphine, and we need to be able to do a comparison of what people consider as being the goal standard for the treatment of heroin dependence. We need a study which basically says that these people have been randomised to methadone, buprenorphine or naltrexone implant and looks at how they fare over the next six months. This probably needs to be a multisite study. That would be something that I would hope to run in Perth and in somewhere like St Vincent's Hospital in Melbourne, because then, if you can produce data at two sites which says that this is the outcome, you have a much stronger case.

I believe it is difficult to run a blind study when you are delivering methadone, buprenorphine and implant naltrexone. In the current study everything was blind. People did not know what treatment they were getting. But, if you are going to attempt to do that with a comparison between methadone, buprenorphine and implant naltrexone, what you would have to do is withdraw everyone to start off with. But you do not do that with methadone and buprenorphine. Furthermore, you would have to implant everyone. If you tell me that a long-term or even short-term opiate/heroin user, when you stick methadone or buprenorphine in the system, will not be able to tell you that they are on an opiate rather than naltrexone, I will tell you that you have not been talking to heroin users. You can go through all of this elaborate hoax of trying to blind all of this and you are going to give someone an opiate and they are going to say, 'Well, I know what treatment I'm on.' This is just fanciful. That is what we need to be running there.

We also need some decent data collected on morbidity-mortality to do with heroin dependence. The Commonwealth Drugs of Dependence Branch funded the NDARC study—I do not know how much money—to review mortality to do with naltrexone implant treatment. They

did that over a two-year period and they published that in the *Medical Journal of Australia* recently. From memory, they came up with six cases. We do not know what sort of implant was studied. I should say that in Australia not only the Australian implant but also some of the overseas implants which have a shorter duration are used. So we do not know what sort of implant patients studied were on.

What we do know is that two of those people they assessed that had died were past a six-month period post-treatment. We know that an implant does not last that long. This is a bit like giving someone a contraceptive implant and then two years later, when they have not had it replenished, turning around and saying: 'They became pregnant. This must be a problem with the implant.'

In two of the cases, even if it was the longest acting implant, the implant was out of date. One case had had the implant removed. From memory, there were two cases where it was the non-opiate overdose. The title of the article was something like *Implant naltrexone and opiate overdose*. None of these cases should be in there, so that left one case. That is one case out of the Commonwealth funding which basically said that this person took a huge load of heroin and died.

CHAIR—To try to override it.

Prof. Hulse—Yes. Look in the *MIMS Annual*. The *MIMS Annual* will tell you that naltrexone, although it has an unequivocal efficacy to block heroin, can be overridden with huge doses of heroin. What we managed to do by funding this study was come up with one case. Yet in Western Australia we have what is called a linked database. Every hospital admission by ICD code goes onto the linked database. Everyone has a common name. Every mental health admission, whether they be inpatient or outpatient, every death and every cancer for that matter are all linked so we know which people have received implants. We can get a group on methadone. We could compare outcomes of morbidity and mortality for those populations.

As I said, I do not know anything about the Commonwealth funding, but I would say that it was one of the things that I suggested that the TGA should be looking at in their assessment of the product. The determination was made I think by Jenny Hefford when she was head of Drugs of Dependence that this should go to the national centre in New South Wales. Where they were going to get the data from at the time was never clear to me, but it was clear that they struggled to come up with that data and I think we need to review this area.

CHAIR—I would like to go back to the second part of that question that I asked you earlier about the two nurses who had been actively nursing while they were taking heroin.

Prof. Hulse—Please excuse me. This is not just something limited to the nursing profession.

CHAIR—It is doctors as well.

Prof. Hulse—As you know, it is doctors, anaesthetists and general practitioners. But anaesthetists who use opiates all the time are a big group who then start to use opiates. They believe that they can control it. What we need is a procedure to identify those people where they might be at risk. We need to set up a system where people with impunity can identify individuals

so they can be shifted out. Our first objective should be that there be no harm done to the community. That is the first objective.

CHAIR—Can we get rid of the term ‘harm’? Can we say ‘damage’? I hate to sound like a cracked record but ‘harm’ rhymes with ‘calm’ and it is like a passive word.

Prof. Hulse—You need to listen to the tone in the voice, but Hansard does not record that. You need to shift them out of that. If we are talking about opiates, as most anaesthetists and other people are, because this is a very compliant population, what you need to do is put them on the sustained-release treatment. If they do not comply with that treatment, they are removed from medical registration. You can have people deregistered. This is a very compliant population that will undergo urine drug analysis to demonstrate what drugs they are taking, and it does not matter whether you are talking about using one of the overseas implants—

CHAIR—We should be doing random testing?

Prof. Hulse—We should be. If those people are identified as problematic and if they are touching the public, we need to know and be assured that they are not using.

CHAIR—If I am a member of the public I want to be assured that nobody taking heroin or amphetamines is going to touch me at all.

Prof. Hulse—That is true.

CHAIR—I do not care how they are identified.

Prof. Hulse—I would say that it is probably impractical to test everyone.

CHAIR—What about random testing?

Prof. Hulse—It is very intrusive.

CHAIR—There is a study that says that medical people kill in hospital 15,000 people a year and probably maim another 12,000. What percentage of those deaths is as a result of people who are taking drugs?

Prof. Hulse—What I would say to you is that the first line of approach should be to manage adequately those people who we have had a history of opiate use or we know are currently using, then you can go onto your second line.

CHAIR—They should disclaim to people so people know that they are dealing with a defective person.

Prof. Hulse—You need to set up something through the medical board which basically treats this as an industrial issue and a medical issue where they are then provided—

CHAIR—It is also a criminal issue.

Prof. Hulse—If you do that, people will not come forward. But if you treat it as a medical issue people will come forward. The idea is to identify as many people as possible. We have people who come down to the clinic and say: ‘I just went to the toilet before. I cannot give you any urine.’ This can happen especially if doctors are more senior in the medical facility. Do not start to think that we are talking only about junior people. Some of the anaesthetists that front up are quite senior. In fact, it is difficult for the junior medical people to know who to identify them to.

CHAIR—People do not know who is a user and who is not.

Prof. Hulse—What I would say to you is to identify those people and set up a program so that oral naltrexone can be used with these people. Oral naltrexone is quite effective. Make sure they take them. Take a urinalysis or a blood sample and give them an implant.

CHAIR—Why do they start?

Prof. Hulse—That is the million dollar question. It has probably got to do with availability and accessibility. I know that part of the recommendations of the committee and part of what has been implemented around the place is to look at the more careful management of schedule 8 drugs within hospital environments. There needs to be good management of schedule 8 drugs so people cannot just walk up to a cupboard and take those drugs. These are schedule 8 drugs, drugs of dependence. This is both the TGA and international classification for drugs of dependence. These drugs of dependence need to be managed in a highly responsible way. That is the first line. Then you need to identify people who appear intoxicated and have a mechanism for checking those out. There are many services set up where general practitioners and other people can ring for assistance. We have dealt with a number of practitioners, and an anaesthetist from South Australia has been dealt with in Western Australia by a naltrexone implant. The medical board, in putting those people back into work, did not put a requirement down that they continue to attend treatment. The medical board did not put down a requirement that they undergo urinalysis or urine testing on a regular basis and that that be provided to the management of those hospitals or those services employing those people.

CHAIR—There has to be a duty of care between the employer of a doctor and patients. There has got to be a duty of care to know that the person who is being offered as a treating person is fit and able to treat. Someone is going to bring a suit against someone fairly soon and say, ‘You breached that duty of care.’

Prof. Hulse—I would think that if you talked to any management facility they would look you in the eye and say, ‘Yes, there needs to be.’ Good. Let’s tell them what the profile of that duty of care should be: urinalysis, in-treatment and collection of information so that we can be assured that person is not using.

CHAIR—If I come in as a patient and the hospital is knowingly allowing drug addicts to treat people and placing those people’s lives at risk, that is a breach of duty of care.

Mr CADMAN—That is one instance where you have a compliant population. I agree that strong measures need to be taken. What about a prison population?

Prof. Hulse—As you know, you can dabble in just about anything you want while you are in prison. You may not be able to become a dependent user but you can certainly get access to drugs in there. The real problem is when you leave that prison environment. We know that, in accidental overdose and deaths, women are the major concern to do with opiates. The majority of fatal opiate overdoses occur with women. Notwithstanding that, men obviously do, too. People return to heroin use. What a great idea if we could give someone a treatment at two-thirds of their term, when they are coming up for release. We could give them a treatment, perhaps even an injectable naltrexone, which will cover them for the first 30 days after they were released. This is the most destabilising period. They are thinking, ‘Where am I going to live, how am I going to be accepted back by my family or my friends and what work am I going to do?’ This is a daunting experience. People often go back to what they know well, the networks that they know well. We need to provide a prophylaxis against return to opiate use at that time while we stabilise people newly released from prison. At the end of that time they could determine what sort of treatment they would like to go on to and where would they like to go from there. It would give breathing space for people in that critical period of return to community, and it is something that I would love to see investigated and implemented.

Mr CADMAN—How does New South Wales continue methadone treatment even while people are in prison?

Prof. Hulse—And other states.

Mr CADMAN—Isn’t that an opportunity for a choice to be made if a person is already on methadone at that point? Shouldn’t another option be offered? Don’t you want to get away from these blokes that are around you and preying on you because you are dependent? Aren’t you being encouraged to save some of the methadone to pass it on to others?

Prof. Hulse—Of course. That is part of the problem. If you are on methadone you want continuity of program when you come out. Notwithstanding that, you can go back and use heroin and you may return to heroin use. Methadone is the conventional treatment used. We need a comparison with sustained release preparations as opposed to methadone.

Mr CADMAN—Absolutely right.

Prof. Hulse—On the current clinical trial that we are running we have three or four people who have entered prison. We have collected data from them when they have been in there and they have been clean. They basically say to us: ‘Is there some way I can get another implant while I’m in prison? Can I get this? I do not want to even go back to dabble at the moment, and everything is available around me.’ You have to remember that naltrexone basically has two effects in terms of heroin dependence. One is that it blocks the effects of what would be considered to be a normative dose of heroin, morphine or methadone. Secondly, it is an anti-craving drug. People are not hanging out to use. It is one of the reasons why it is efficacious and it is PBS listed for alcohol dependence. I need to correct myself because I think I did refer to oral naltrexone as being PBS listed, but of course it is not. It is registered for heroin dependence but it is not PBS listed.

Mr CADMAN—So it is not readily available?

Prof. Hulse—It is PBS listed for alcohol and this is probably the reason why it is efficacious with alcohol. It is an anti-craving or anti-impulse drug, so the patients do not think about alcohol or, if they think about it, they can think about it and not go and drink. Naltrexone does have an efficacy with other drug forms and certainly we have seen a reduction in amphetamine use and cannabinoid use in people who have gone onto the clinical trial.

Mr CADMAN—Were you able to administer the implant in jail or not?

Prof. Hulse—No. The problem is that it is probably easier to escort someone out and have it administered outside in a facility which is used to putting the implant in rather than doing it in the prison environment, where you have to train people up, notwithstanding that this is just a relatively small surgical procedure. But to do that you would probably need two prison guards to accompany you. So this is resource intensive. When the company gets this information to TGA and TGA makes an informed assessment as to the safety and efficacy, that is the time to say that this should be considered within the prison. But before that we can still set up some clinical trials.

CHAIR—Why is the TGA not making this assessment?

Prof. Hulse—The TGA will make an assessment as to whether the product is then registered within Australia when information is provided. The studies that were funded by the Commonwealth to do with compatibility with tissue, biodegradability and blood levels, were raised by the TGA as being information which was necessary for them to make an assessment of the product.

CHAIR—We were handed a volume of evidence as to efficacy and so on. Do you detect a bias against naltrexone?

Prof. Hulse—Within the TGA, no.

CHAIR—What about in the industry? That is what I am observing in the industry.

Prof. Hulse—Sustained release naltrexone suddenly shot onto the Australian stage in about 2000. At that stage, people were being treated in different states. In Western Australia people are currently treated under TGA SAS, likewise in Victoria, Queensland and New South Wales. They are treated in different environments—not only with the Australian but by other implants—and at this time people in administrative jobs, medical practitioners and other health persons were asked by their governments and their ministers what they thought of this product and what the response should be. They were being asked to make a premature assessment of sustained release naltrexone in the absence of clinical data, and people were forced into a position. They took a conservative approach and basically said, ‘We have concerns about this.’ Taking that stance has made it very difficult for people to back-pedal.

What I have noticed is that people who very strongly came out against sustained release preparations of naltrexone are now starting to lessen their statements about the product itself as more information is coming out, and certainly since one product has recently been registered for alcohol treatment through FDA. They are starting to lessen these comments and they are starting more to play the man. They are starting to say: ‘No, I was never against sustained release

products. I was against the way it was used perhaps by Dr O'Neil and within the SAS system.' They are starting to change it around. Unfortunately, it has created an environment where misinformation has been rife. One of the reasons we set up this clinical trial in such a careful manner so that it was completely blind is that this data needs to be as clean as possible. It is the reason why I suggest that, when we move towards a methadone/buprenorphine implant comparison, it should be done at two separate sites. This needs to be clean so that it is accepted and cannot be questioned. Problems might have arisen, but more and more people are coming around; people are looking at rewriting history and how they extricate themselves from the negative positions they were placed in.

Mrs ELSON—Are you conducting clinical trials or have you conducted clinical trials?

Prof. Hulse—We have conducted clinical trials and we are finishing off data analysis and other things with the current trial. The information that I have given you is over four months on 51 patients, but we will be crunching the data on the 70 patients.

Mrs ELSON—I have no doubt that naltrexone works. I remember when it first came on the market—in my area there are a lot of drug rehabilitation centres—they were in uproar about it, saying, 'We don't want to use it here.' One of the staff told me that the reason is that it might fix up some of their patients and they might be out of a job. That is the biggest concern that I have about the negative side of it. If the implant were approved, I can see that a lot more people would want to have it administered. I would like to move off this for a minute. The other day I read about a trial of fat-reducing tablets that they put into chemist shops. People take these tablets to reduce the fat content in their system, and then they will eat something that has a lot of fat in it because they have taken a tablet. With naltrexone, once they get this little disk in their arm, they will think, 'I can take some now' or 'I'll have to take a double amount because I've got this in my arm' if they do not have the support systems. When you are taking something like this, in order to make sure that they do not take big doses and die, there has to be a lot of support ongoing systems underneath them to say, 'If you do feel like this, we are here to look after that side of it.' I would hate to see them just put it in, and you walk off down the street with no-one knowing what happens to them over the next six months.

Prof. Hulse—The issues you raise are valid. We know that people have gone out and tested these. Any self-respecting heroin user will want to test the implant. That is what you do. They want to make sure that their treatment is effective. That is what people routinely do. They come back and say, 'I used. I didn't get an effect.' Some of them have used quite large doses.

Mrs ELSON—Can that put them into a deadly situation?

Prof. Hulse—No. The opiate naltrexone will basically give you primarily a prophylaxis against opiate overdose. When we talk about the preliminary data that we have on the blood levels, we talk about 5.5 months in a 70 kilogram person. It probably translates to about 4.5 in a male and about 5.5 in a female. When we talk about those levels, that is above two nanograms per mil. We know from clinical studies where they have actually put naltrexone into people and injected diacetylmorphine—injected heroin—what amount of opiate naltrexone will block. We know that achieved levels are enough to block what would normally be considered to be a decent level of heroin. The implant then delivers a lower level for up to nine or 10 months—one nanogram per mil—which is enough to give a prophylaxis against accidental overdose.

In our work, the first 360 patients were given implant naltrexone. A linked database in Western Australia records any accidental overdoses where there is a hospital admission. We found—and this is from memory, so this might be imprecise—there were something like 21 opiate overdoses in that cohort of 361 patients that we looked at in the six months prior to coming on to naltrexone implant. We had 20 people within that six months prior to treatment who had 21 opiate overdoses of those 361 people. This is a sequential cohort of people. They were then given a treatment. There was not one opiate overdose admission to hospital out of that whole group during the next six months.

In the following six months after that—so in six to 12 months—there was a reduced number of about seven, compared with the 21 opiate overdoses before. It still does give a level of prophylaxis; there were no deaths. It is quite effective. That is one of the good things about the Western Australian implant. Our professor of public health, D’Arcy Holman, set up this linked database when he was deputy health commissioner. He is a doctor and an epidemiologist. He set up a linked database that collates all hospital, mental health, cancer—anything from the state—incidences for a person under one category. We go through and ask, ‘Are people on methadone more subject to cancers?’

What I have not said to you is that there is a big issue to do with methadone and buprenorphine. With both of these drugs, there is a growing level of evidence to suggest that they are immunosuppressant. They reduce your immune response. There is a level of evidence to suggest that naltrexone may enhance your immune response. A lot of heroin users and injecting drug users—amphetamines and whatever else—have hepatitis C. They are perhaps 60 per cent to 80 per cent of people coming through treatment services. We put them on methadone. How does that alter the course of disease? Does it make it better? Does it make it worse? Sure, we might be arresting their sharing of needles and their use. We might be able to educate them. But what about them as an individual? What is that doing to that individual? What about providing them with treatment for the hepatitis C? Do we manage to be able to do that and how effective is it?

In Western Australia, at the Sir Charles Gairdner Hospital where I am based, referrals from the Perth naltrexone clinic used to be made up to the hospital for treatment of hepatitis C. Very few patients—perhaps two out of every 10 referrals—used to come up, which is what you can imagine. Heroin users have better things to do than simply make another trip to another place, especially to a hospital; it is very daunting. It is a bit like coming to parliament. You do not understand it; there are people running around corridors doing who knows what.

We looked at the situation. Professor Gary Jeffries, who heads the hospital’s hep C treatment, set up a room at the Perth naltrexone clinic. Every Tuesday, that becomes a hospital room. A general practitioner room is next door. It is a basic one-stop shop. They go and see the GP and get a referral to the hospital. They walk from one door to the next door, see the hospital and then enter into ribavirin and pegylated interferon treatment. This is how services should run. This is about integrating different services so you provide the easiest convenience to the maximum number of people. We have just published a paper on this. The results from this service are good in terms of resolution of hepatitis C. Patients were not lost from treatment. Patients remained in contact with the hospital, and there was good resolution of HCV for those patients. When it was published in *Hepatology*, an editorial was written saying that this should be a model for the way that services should cooperate and work together.

One of the other things I would suggest is that we need to look at and support that model. At the moment, the hospital does not get any funding for this program. The hospitals get a lot of funding, but I am just saying that there are extra nurse needs down there to make appointments for people. They do not pay for the rent of the room. This is something that the Perth naltrexone clinic, again, like the halfway houses, simply provides as an additional service, because it is one of those services. We also need to be mindful that we might be doing a disservice to people who are hepatitis C or HIV infected in terms of placing them on methadone or buprenorphine, as opposed to placing them on implant naltrexone. It has been suggested by the gastroenterologist, Professor Jeffries, that even where people have not entered into the ribavirin treatment—the antiviral treatment—but have been on naltrexone, their condition starts to improve. They just start to improve, apparently, by being on naltrexone. Again, that is something that we need to look at.

Mrs ELSON—Once they get this implant, which you have said lasts up to 10 months, are they obligated to come back on a monthly visit? I am concerned that they will get this implant, go off and you have lost really what was intended, that is, to keep an eye on them to see if it was really working. Is there is a support system that says, ‘You must come back’, and if they do not, someone will go and check to see if they are okay?

Prof. Hulse—We are talking about two situations. We are talking about the clinical trial and then we are talking about how things are run in Western Australia, in Perth. In the clinical trial people are followed up every two weeks. We basically check on them every two weeks. The committee has visited the Perth naltrexone clinic twice and probably has an idea of how it is run, but my understanding is that it is very labour intensive. They have people who make phone calls and encourage patients to come along. They find out the contacts of parents, partners and other people so that they do not lose contact with patients. They put an enormous amount of effort into following up—similar to the clinical trial that we had.

With respect to oral naltrexone, the issue is to do with compliance. Oral naltrexone can be made to be more effective if you simply do not hand someone a 50 milligram bottle—30 tablets—and say, ‘Take this once a day.’ What you need to do is set up a system. Partners or parents are often interested in having a role. ‘What can I do?’ You can negotiate a role for them so that, during Weeties in the morning, they administer a tablet to a person; they will know that they have taken it. They could get a urine sample from them so that we can check to make sure there is naltrexone. There are ways of improving compliance with oral naltrexone. With the sustained release preparation the efficacy is not 10 months. It is the 4.5 or 5.5 with the Australian. Some people come back for a retreatment and some people do not.

With the clinical trial, we have had a number of people who have relapsed and have been taken off the trial, and we offer them what they would like. Some people have said, ‘No, I would like to go on buprenorphine or methadone.’ That is their choice. A lot of people have said, ‘I would like an implant’ and they have had another implant. We will need to crunch that data later on, because I suspect that those people who have been more likely to go on to methadone have been the ones on oral naltrexone; the ones on implant probably opted to remain on implant.

There are ways of improving compliance with the oral product. This has been known for years and years, and yet, when the oral formulation was launched on to the market in Australia, there was nothing that said, ‘Set up mechanisms to improve compliance with this product.’ It is the

same with alcohol. You do not just hand a bottle. These are PBS-listed drugs. These are expensive drugs. Oral naltrexone probably costs about \$120 to \$130 a bottle. What do you do? Do you hand this to someone and say, 'This is up to you. Take it'? Disulfiram as a treatment for alcohol dependence has probably fallen into disrepute, but there were some studies a number of years ago, that I have been told about, where they got two groups of alcohol dependent persons in; with one group they said, 'This is your problem. This is your responsibility. You need to take this drug. It is no-one else's problem. No-one else can do this but you.' That sounds a reasonable sort of clinical approach. With the other group they said, 'This doesn't just affect you. This affects you, this affects your family, this affects other people. This is not just your problem.' This is the approach that I would go for, and involve that person in assisting that person to be compliant with the medication. What did they find at the end of the trial? The group that had been left up to themselves returned to heavy drinking and the ones that had been given some support framework did not.

What does that tell us about sensible management strategies that we need to implement? This is not just about handing over drugs. This is about looking at how we put them in a framework that is likely to maximise output. I am not saying that everyone will have access to a whole range of services, but look at what services you do have and utilise them. Our funding model often does not allow for services to dovetail. We talk about that. We say, 'We will talk to Housing about this. We have X, Y, Z and we will talk about the employment service.' The funding model does not allow that. You need it to be there at the time. Fund for resources as a package, get rid of part of the bureaucracy and be able to respond to people as they walk through the door.

Mrs MARKUS—I would like some feedback about the impact of incorporating that package into any trial. I do not want us to find that, having done a trial on the efficacy of naltrexone, we did not incorporate at that first point the broader package to look after the psycho-social, the re-establishment or development of new skills, the re-establishment of relationships or the skills so that they can establish new ones. If we do not incorporate that from the start of anything that we as the Commonwealth initiate, then we are further down the track where maybe funding is given only to the medical aspect of it without incorporating all of the other support structures, services, education, skills and so on. Can you respond to that in terms of the trial and funding of the package and when you incorporate that and when you do not?

Prof. Hulse—You incorporate those issues right from the beginning. People have fronted up during the trial and not had somewhere to live; they had been on the street. Part of our job has been to look at where we house them to start off with.

Mrs MARKUS—Who would do that?

Prof. Hulse—Within Perth there is a good network of people who work together.

Mrs MARKUS—A multidisciplinary type of team?

Prof. Hulse—It should be the primary case provider who manages those types of resources. Interestingly, we talk about oral naltrexone and people will often talk about the compliance and relapse back to heroin. Often studies will say, 'We only had 15 per cent of people left at three months, or 30 per cent.' What I would point out is that in the randomised trial we have been

doing we actually have 44 per cent at four months, and we are in contact with more. These are very good outcomes for oral naltrexone. Oral naltrexone works with some people, but it has to be put into a framework.

In one respect we have probably done a disservice to the assessment of sustained release preparations by setting up a good framework for oral naltrexone delivery; when people have gone on to an oral formulation, we have made sure that we identified someone who will encourage the utilisation. If we cannot find a family member we will appoint someone who can keep in contact with that person, talk about their using, and get them back in. That is part of the job. Every two weeks when they come back, people are encouraged to take their oral formulation. Even with the oral formulation we have got good results. Notwithstanding that, we have 85 per cent of implant treated patients who still have not returned to what I would consider to be dependent heroin use, once to three times a week, on the implant, and 44 per cent on the oral. If you do not provide those at the start of the program, what is the use of providing them later on?

It is also about early identification and intervention. To come along and find that people have been to treatment services previously but have walked out the door one, two or three years ago because they have not been able to get in quickly is not early identification-intervention. There is an enormous difference between dealing with someone who has been dabbling for six months and has then become involved for the last three months, when it has gotten out of control, and dealing with someone who has been out in the networks and that is all they know; they have become deskilled from the general community and separated after three years.

Early identification and intervention is what this is about. Identify them early, be pragmatic, and get them into treatment. Let us look at rapid opiate detox. Let us look at the type of people who should not go through rapid opiate detox. Let us look at best practice. Best practice is not taking a 50 milligram tablet of oral naltrexone, popping it in someone's mouth and saying that they had a bad withdrawal experience. Of course they are going to have a bad withdrawal experience. This is not a sensible clinical practice. I hear people saying that they have had a bad experience with ROD. We need to establish what is best practice with ROD.

Sometimes it is difficult to establish best practice. What you can establish is what should not be done. You can say: 'Do not do this. Do not pop 50 milligrams in someone's mouth. Do not do these sorts of things.' Have access and backup to medical services if you do this as an outpatient service. Give them a phone number. Talk to your emergency department in case people need to be rehydrated because they have uncontrolled vomiting and diarrhoea. This is where the problems occurred in the US. This is where the deaths occurred from rapid opiate detox in the US; they did not have the backup services. This is why in Perth those problems do not tend to occur. There is a very good relationship with the hospital where I work in the ED. If people are treated and they have a problem, we have a standing relationship. They front up there. We have talked to people. They are trained and they know how to deal with those situations 24 hours a day.

CHAIR—We are very grateful for your travelling here and for giving us tremendous evidence today. I have more questions and I know others will have more questions, but as usual the clock starts to beat us. If we need to contact you through the secretariat to get additional information,

we hope that you might be happy to give us information that way as well. As I said, we are very grateful for the depth of understanding that you have given us today.

Prof. Hulse—I am grateful for the opportunity to come along. I will be in Canberra for the next couple of days. As you know, I have a meeting with the Tony Abbott tomorrow afternoon. If anyone wants to talk to me in the interim, I am quite happy to do that.

Resolved (on motion by **Mrs Elson**):

That this committee authorises publication, including publication on the parliamentary database, of the transcript of the evidence given before it at public hearing this day.

CHAIR—I now declare this meeting closed. Thank you for your attendance, and thank you also to Hansard.

Committee adjourned at 11.46 am