

Health and Social Care Committee

Oral evidence: Drugs policy: medicinal cannabis, HC 1821

Tuesday 26 March 2019

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[Watch the meeting](#)

Members present: Dr Sarah Wollaston (Chair); Mr Ben Bradshaw; Rosie Cooper; Diana Johnson; Johnny Mercer; Andrew Selous; Derek Thomas; Martin Vickers; Dr Paul Williams.

Questions 134 - 255

Witnesses

[I](#): Professor Andrew Goddard, President, Royal College of Physicians; and Professor Finbar O'Callaghan, President, British Paediatric Neurology Association.

[II](#): Baroness Blackwood, Parliamentary Under-Secretary of State, Department of Health and Social Care; Professor Chris Whitty, Chief Scientific Adviser, Department of Health and Social Care; Nick Hurd MP, Minister of State for Policing and the Fire Service, Home Office; and Dr Keith Ridge, Chief Pharmaceutical Officer, NHS England.

Written evidence from witnesses:

- [Royal College of Physicians](#)
- [British Paediatric Neurology Association](#)
- [Department of Health and Social Care](#)



Examination of witnesses

Witnesses: Professor Goddard and Professor Callaghan.

Q134 **Chair:** Good afternoon. Welcome to the Health and Social Care Select Committee for our second session on medicinal cannabis. Welcome, Professor Goddard and Professor O'Callaghan. Could you introduce yourselves to those who are following this inquiry?

Professor O'Callaghan: My name is Professor Finbar O'Callaghan. I am here as president of the British Paediatric Neurology Association, which is the association that represents all paediatric neurologists in the UK. I am also a consultant paediatric neurologist at Great Ormond Street, an epileptologist and professor of paediatric neuroscience at UCL. I have a particular interest in epidemiology and clinical trials and in running clinical trials in childhood epilepsy.

Professor Goddard: I am Professor Andrew Goddard. I am president of the Royal College of Physicians. I am a gastroenterologist in Derby, which is my NHS job. I do not prescribe cannabis routinely myself. I have patients who ask for it and that is my clinical experience of it. However, I edited the RCP guidance, and I have edited and led many other national guidelines.

Q135 **Chair:** Thank you. Professor O'Callaghan, in your written submission you said that part of the chief medical officer's report was misleading. That is quite an accusation. Could you talk us through why you say that?

Professor O'Callaghan: Yes. I welcome the CMO's report and the rescheduling of cannabis-based medicinal products from schedule 1 to schedule 2; I should say that first. In the summary of the chief medical officer's report there is a quotation about there being conclusive evidence of benefit for cannabis-based medicinal products in some conditions. I was trying to point out that the evidence with respect to childhood epilepsy does not support that conclusion.

Q136 **Chair:** You are referring to it specifically in that context.

Professor O'Callaghan: Exactly.

Q137 **Chair:** Do you feel that there has been a certain amount of misinformation about the role of medicinal cannabis more widely?

Professor O'Callaghan: I do not think there has been misinformation as such. There is room for reasoned debate about the evidence, and I am not sure that that has really been in the public domain.

Q138 **Chair:** You welcome the wider debate.

Professor O'Callaghan: Yes.

Q139 **Chair:** Thank you. Professor Goddard, do you have any opening remarks about this to set the scene?



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Professor Goddard: I agree with Finbar that it is right to move cannabis out of the Misuse of Drugs Act. One of our challenges with cannabis-related medicinal products is that the evidence base is very diverse, and it has not been easily available in order to be able to do studies on it. Doing this now is, if you like, the first step. In meetings we have had with patient groups, we have talked about use of these agents as being very much in the foothills at the moment, and, having made that major step forward, we can now begin to do the work to see where their place is.

Chair: We will talk more about the evidence base shortly.

Q140 **Diana Johnson:** Focusing on what you have both just said, do you think that the Home Office and the Department of Health and Social Care have communicated well, effectively or appropriately to inform the public about medicinal cannabis?

Professor O'Callaghan: There has been a problem. When the Home Secretary announced the intention to reschedule the products, there was a lot of good publicity surrounding that statement. What was then needed was communication with the public about exactly what that meant; that it did not mean that these products were now going to be freely available to be prescribed on the NHS, because that is not the case, and it did not mean that clinicians in particular areas were necessarily going to think it appropriate to prescribe these products, given the evidence base. There could have been some management of how that was dealt with at the time.

It has been unfortunate that politicians, or the Government in general, have not communicated with the specialists in this area. I welcome the opportunity to speak here today. It is the first time that any politician or parliamentarian has spoken to us about the issue.

Professor Goddard: In retrospect, I agree that communication could have been done a bit differently. I am used to dealing with medicines that I want to prescribe to my patients in clinic that are either not licensed or are licensed for other uses. The mechanisms and steps that I have to go to in order to prescribe that medicine or any new medicine—leaving cannabis aside—are quite lengthy, require a lot of information, and often do not allow me to prescribe it in the long run because of funding issues and because the evidence is not there. While it is a good thing to move it into medicine scheduling, the prescription of unlicensed medicines is very difficult for good reasons, and the regulation is there for good reasons, and perhaps that needed to be communicated.

Q141 **Diana Johnson:** Is there something you think we could do to get the information to the public in a better way, to inform the public, and who is best to do that?

Professor Goddard: This Committee is ideally placed to do that. Clearly, you are reviewing the whole of it—the events that have gone on, the evidence and all the data that is out there—and, as part of your



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conclusions, that can be one of your recommendations. Then you can suggest how it might be done most effectively.

Professor O'Callaghan: Yes, I agree with that.

Q142 **Mr Bradshaw:** Professor O'Callaghan, you said a moment or two ago that this was the first time you had been asked to speak to any politicians about it, but it has been suggested to me by the all-party parliamentary group on medical cannabis that they have been seeking dialogue with the BPNA on this on an ongoing basis, and you have refused to see them or have that dialogue.

Professor O'Callaghan: No, that is not true. I have had no direct contact with any member of the all-party parliamentary group.

Q143 **Mr Bradshaw:** So it is not true that the all-party group has been trying to communicate and have dialogue with the BPNA, and that has been refused.

Professor O'Callaghan: No, it has not been refused. I do not know what efforts they have been making. I have met once with End Our Pain and Peter Carroll, but that is the sum total. He is not a parliamentarian or a politician.

Q144 **Mr Bradshaw:** Would you like to take up a dialogue with the all-party group?

Professor O'Callaghan: I would like to take up dialogue with any interested parliamentarian or politician.

Q145 **Dr Williams:** Can I check what you said right at the beginning of your statement about the evidence around medicinal cannabis products in epilepsy? Can you repeat what you said about the evidence?

Professor O'Callaghan: I said there wasn't conclusive evidence of benefit. That is essentially what I was saying.

Q146 **Dr Williams:** But your own guidance says that there is a median monthly reduction in seizure frequency that is greater in the patients who were randomised to CBD compared with patients who were on placebo, so your guidance says that there is a benefit.

Professor O'Callaghan: We have to be specific, don't we? Cannabis-based medicinal products cover hundreds of different products. The evidence is talking about pure cannabidiol. The one area where there is robust evidence of efficacy is in pure cannabidiol. There have been trials in two rare epilepsy syndromes—Dravet syndrome and Lennox-Gastaut syndrome—and those trials have shown that add-on therapy with cannabidiol has conferred moderate benefit compared with placebo. About 40%, or thereabouts, of patients who received add-on cannabidiol got a clinical response, versus somewhere between 25% and 27% who got a sugar pill or placebo.

Q147 **Chair:** We heard evidence from Professor Helen Cross about her clinical



experience in which she said, "Probably around 70% to 80%, if not more, of my clinics now are taken up with explaining the position." Is that your experience as well? Is that widely the experience of your members?

Professor O'Callaghan: I think it is a wide experience of paediatric neurologists. They will be discussing cannabis-based products now in a lot of consultations in their complex epilepsy clinics, yes.

Q148 **Chair:** Do you think it would be helpful for them if there was a much clearer explanation, because we have raised expectations that cannot be fulfilled?

Professor O'Callaghan: Yes. The professional community of paediatric neurologists understand the evidence well and understand what is happening. It is not so much the paediatric neurologists and the clinicians who do not understand what is going on. It is the public who do not really understand what is going on.

Chair: We are going to come on now to talk a bit more about the evidence base.

Q149 **Andrew Selous:** Can I ask you both what the current evidence base tells us about the efficacy and safety of medical cannabis? Perhaps you could say in your answer a little bit about the international comparisons as well, because, from what I have seen, it appears that Australia and Canada seem to be in one corner, and Germany, the Netherlands and Italy in another. If you would give us a bit of an international take on that as well as a UK-based one, that would be helpful.

Professor O'Callaghan: I will start with childhood epilepsies. Reiterating what I just said to Dr Williams, the evidence base for cannabis-based medicinal product use in childhood epilepsies is remarkably thin, with the exception of investigating the use of pure cannabidiol in the two rare epilepsy syndromes that I just mentioned. Other than that, there are no randomised controlled trials of cannabis-based medicinal products in childhood epilepsies, so you would have to say that the evidence base is thin.

There are a number of open-label, observational studies, including some from Canada, Israel and so on, which suggest evidence of efficacy for the cannabis-based medicinal products they were investigating. In Israel, they were looking at whole-plant extract, which was cultivated to have a certain proportion of cannabidiol versus THC. In Canada, they were using a pharmaceutical grade product, which was a cannabidiol THC product called Tilray. As I say, they suggest evidence of efficacy.

The problem with open-label, non-randomised, non-blinded studies is that they almost invariably overestimate efficacy. That is why, when we are licensing medicines, we demand randomised controlled trials as the level of evidence we need for efficacy. There are severe biases that could be at play in open-label studies that could distort the results.



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Safety is a big issue that needs to be talked about. In terms of cannabidiol, we have evidence of short-term safety data; adverse events were relatively common in people treated with cannabidiol. We do not have long-term safety data yet, but that is not unusual in a new medicine coming on to the market.

Q150 **Chair:** There will be a lot of people following this debate who do not know what open label is. Could you explain that for people who are following from outside?

Professor O'Callaghan: Open label means that both the clinician and the patient taking the medicine, or the family, know what they are taking.

Q151 **Chair:** As opposed to the double-blind, where neither do.

Professor O'Callaghan: As opposed to a double-blind, randomised controlled trial where neither the clinician administering it nor the patient knows whether they are getting the active treatment or the placebo.

Q152 **Andrew Selous:** Professor Goddard, what is your take on the evidence?

Professor Goddard: I will talk about its use in chronic pain, because that seems to be the thing that is most contentious. When Dame Sally Davies produced her recommendation, she based it on the National Academies of Sciences, Engineering and Medicine from the States. They looked at evidence from 2015 to 2016, and from that evidence there was some weak suggestion of efficacy in pain.

There has been more recently a full analysis, by Stockings et al, of all the studies that have been done, which I think I have circulated to the Committee previously. That is from last autumn and is as up to date as we can get. That shows that it probably does help in chronic pain, but, if you were to put some figures on it, only 29% of people would experience a 30% improvement in pain, or, put another way, in a phrase that we often use, you would need to treat 24 people in order to see benefit in one person. When it comes to the harms of those drugs, you only need to treat six people to see significant harms.

From that data alone, yes, there is statistical evidence that it improves pain, but if you were to put that on a standard pain scale of 100 mm, it shifts pain by 3 mm. What none of the studies has done, of course, is look at quality of life. Pain is just one measure for somebody who is suffering with a long-term condition, of which pain is a significant part. How have those drugs influenced that person's quality of life? That data is not there.

If you look at all those studies, and there are all the types of study we have already mentioned within those studies, they all use very different agents. Some talked about smoking cannabis, and some talked about using cannabidiol and various other products; that is one of the challenges we have. We know a little bit about lots of things and it



probably makes a little bit of difference. Therefore, when I am faced in clinic with a patient asking if they can have a cannabis-related medicinal product, I say that, if I were to prescribe it, they would probably have a one-in-24 chance of its helping them and a one-in-six chance of its doing them harm.

Furthermore, I have to convince people that it is worth the money, and we do not have that evidence. Nobody has really talked about cost, but the biggest challenge I have if I want to use a new agent to treat my patients with inflammatory bowel disease, of whom there are lots, is the money. I have to go to a drugs or therapeutics committee, which may then go to the joint prescribing committee of the local CCG, and make those cost-effectiveness arguments.

I think both Finbar and I are looking forward to NICE's recommendations and seeing what they say. One of the challenges that NICE will have is that there is hardly any cost-effective data. We have heard various figures presented to this Committee about how much these drugs cost, ranging from £500 per month to £25,000 a year. The bottom line is that they are expensive. Yes, the prices will come down, but in the current NHS environment it is very challenging for me to convince my prescribing committee that I should use a drug that is very expensive when there is only a one-in-24 chance that it is going to work.

Q153 Andrew Selous: Can I move on to the research that we need in this area? I think, Professor O'Callaghan, you described it earlier as being thin. Perhaps you could say a little about the barriers and the challenges. Given the understandable public expectation in this area, is there anything that we can do to speed up the research and get a big enough sample size so that you can draw some valid conclusions perhaps slightly quicker than I was reading in the current schedules, which were talking about the middle of next year to get any indication? Is that possible or is that an unrealistic expectation from my point of view?

Professor O'Callaghan: One of the things I want to come back on is safety, and it comes into the question about where the research needs to be. One of the big questions is whether the addition of THC—or tetrahydrocannabinol—to cannabidiol provides any extra effectiveness? We simply do not know, so that is one of the big research questions that we need to look at: does adding THC into the mix improve the results that we see, and that I talked about, with cannabidiol?

There is a question about safety that needs to be bottomed out about THC. There is theoretical concern that THC may be harmful when administered chronically to children with a developing central nervous system. The reason that there is concern is both from animal data, that actually administering THC to animals can have a detrimental effect on their performance, and, obviously, the data that has had high publicity recently about the use of recreational cannabis, which is high in THC.



The counter-argument you will hear is that the amount of THC we are talking about in these medicines is so much less than in street cannabis that it cannot possibly be doing any harm. The problem is that we do not know what is a safe amount of THC to give to a child with a developing central nervous system, and we need to find that out. If we are postulating that adding THC has a pharmacological effect against the epilepsy, it is not inconceivable that it can be having a pharmacological effect in other areas. We need to get that safety data before clinicians are going to be confident about administering these products on a wide scale to infants and children. To finish, I do not think there are any shortcuts to doing randomised controlled trials, and they will take some time.

Q154 **Andrew Selous:** Is there anything you would like to add, Professor Goddard?

Professor Goddard: Another challenge is alluded to there. If you look at the studies in pain, the median—the middle length of those studies—was eight weeks, and none of the studies lasted more than six months. Most of my patients who have chronic pain have had pain for years, and pain is very common and multifactorial. We need to be looking at these agents over a long period of time and monitoring patients to see what the long-term harms are.

It seems likely that it is the THC bit that helps with pain, and we do not know, if you are taking a THC-containing cannabis product for six months or 12 months, what the likelihood of side-effects and harm is down the line. Sadly, that will delay things if we want to be truly safe. That does not mean that you cannot start and go ahead, but you have to be aware that we are not going to have a clear answer. You also have to be willing to pull the plug if you start to find that there are problems.

Q155 **Andrew Selous:** This is the final question from me in this area. In terms of industry participation, would it be helpful if suppliers were more co-operative with researchers? We have heard that some of the producers are not perhaps wanting to get involved and be as helpful as possible in this area. There is also the issue perhaps of commercial pressure, because I guess that possibly there is money to be made in this area as well. What is your take on the role of the producers and industry participating on the research side?

Professor Goddard: From my perspective, I suggest that we need to focus on a very small number of products. They can either be produced in this country or elsewhere, and then we would look to work with those producers to help fund the studies. We have talked about the OMC in this Committee before. The drugs that are available are three drugs that are created by one company. If you look at the evidence, they have done one study in 20 patients looking at chronic pain. If we were going to use, for example, that company, I would want to see engagement with a much larger number of patients over a much longer period of time.

Q156 **Andrew Selous:** Presumably that sample size is much smaller than you



would normally use.

Professor Goddard: Yes. It is very hard—and, oddly enough, they did not find any statistical difference for spontaneous pain in that study because it was not big enough.

Professor O'Callaghan: There has been reluctance previously by some of these producers to supply their product for clinical trials. There is some evidence now that they are engaging more, which is helpful. We have to ask the question, though, about why no randomised clinical trials have been done in this area in countries like Australia and America where it has been possible to do that kind of work in the past. It is certainly true that I have been at conferences and spoken to some of the producers and said, "Are you intending to do clinical trials in this area?" The response has been, that, no, they are not because they can see a way into the market without having to do clinical trials.

Q157 **Dr Williams:** That last comment was very interesting. I was going to ask about coming back to the evidence base here. Could I give you a hypothetical patient, maybe even your own child? That patient has multiple seizures and is not controlled on conventional anti-epilepsy therapy. You have done a trial of a pure CBD-based product and not found any significant change in the frequency of seizures. Would you, in that case, given that you might be concerned about the effect on the developing brain of multiple seizures, consider giving a CBD/THC combination product, like Tilray, on the current available evidence?

Professor O'Callaghan: There is a good reason why doctors are not supposed to treat their own children, because we are going to—

Dr Williams: A patient then.

Professor O'Callaghan: The answer is that I have no evidence, as a professional medical scientist, that the addition of THC is going to confer additional benefit over cannabidiol, and I have potential safety concerns that I think we need to bottom out. The evidence I have from the open-label study of Tilray in Canada does not suggest that it is any more effective than pure cannabidiol, so I would not be particularly inclined to use Tilray in that situation.

Q158 **Dr Williams:** Can you understand why, in those circumstances, some parents, given that nothing else is helping, think it is worth a trial?

Professor O'Callaghan: Of course I can.

Q159 **Dr Williams:** You would not be the doctor who would facilitate that.

Professor O'Callaghan: I think we should be practising evidence-based medicine. Of course, I understand the families; it is my bread and butter, and for the whole of my career I have been dealing with children with complex, difficult-to-treat epilepsy. No one—other than my colleagues—is more empathetic towards that situation than I am, but I am also



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passionate that the medical profession should be practising evidence-based medicine.

Q160 **Mr Bradshaw:** You seem to be relying on the absence of trials rather than the evidence and experience of these families, which is very real. We heard it last week in very graphic terms. Why deny their experience? Is it not valid?

Professor O'Callaghan: We have to approach this as medical scientists. We do not license drugs on the basis of anecdotes or open-label studies, precisely for the reasons that I outlined before, that actually the evidence you get from them is distorted and open to bias. To license medicines, we rely on randomised controlled trials because they are objective measures of efficacy and safety. If we were simply to start prescribing medicines on the basis of anecdotal report, we would very quickly get into trouble in the medical profession generally.

Q161 **Mr Bradshaw:** It is not just anecdotal reports. There is evidence from other countries. The families themselves were saying to us last week that their children are already given very potent drugs, which have very strong side-effects that are probably doing them damage, as well as the fitting itself. You are prepared to have those drugs that are unlicensed on children given to them but not a plant-based, cannabis product, which, in their experience and the experience of other countries, works.

Professor O'Callaghan: So many things that you said there are trailing at a problem. That it is plant based is irrelevant; there are lots of drugs we use that are plant based. It does not make it any more pleasant or healthy because it is plant based. There is not robust evidence, which is what I was trying to say before, in this country or in any other country that products with THC are effective and safe in childhood epilepsies. There are lots of anecdotes and small open-label studies, and what they tell us is that research in this area needs to be done, and that there is a legitimate question about whether these products are going to be helpful or not. Our responsibility is now to study them properly in rigorous randomised controlled trials.

Q162 **Johnny Mercer:** Forgive me, because this is well outside my comfort zone, but is someone actually doing these randomised controlled tests? Who is pushing at the wheel to get this done?

Professor O'Callaghan: We are.

Q163 **Johnny Mercer:** How long does it take?

Professor O'Callaghan: First, the National Institute for Health Research—the NIHR—has put out a call for research into cannabis-based medicines as a response to this whole question. There is a call-out in March and in July to apply for funding to do this kind of research. Groups like mine are actually developing—

Q164 **Johnny Mercer:** How long does that sort of thing take?



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Professor O'Callaghan: To complete and get a result for a randomised controlled trial will probably take in the region of three years.

Q165 **Johnny Mercer:** Is there a reason that we have not started this before if we have that evidence? All right, you say it is anecdotal, but if we have evidence coming in from around the world, why haven't we started it already?

Professor O'Callaghan: The major reason in the UK is that they were schedule 1 substances and we could not research them. We now can because of the rescheduling; they are now schedule 2. Yes, now we can do the research. It is a legitimate question to ask why in other countries, where they have been rescheduled or are able to be used, the randomised controlled trials have not been done, and it might be—

Q166 **Johnny Mercer:** You do not think the evidence is there.

Professor O'Callaghan: No. We need to get the evidence. There is a question about whether these medicines will help children, and we need to answer it. We need to do the research. It may be a problem that research is expensive, so pharmaceutical companies, perhaps if they can see another way of getting their product on to the market, will avoid the millions of pounds it costs to do the R&D, and to do the randomised controlled trials, to get the evidence.

Q167 **Johnny Mercer:** You made quite an important point at the beginning around the engagement of politicians and the public debate on this, and that nobody had reached out to you before. Are you saying that, on the balance of judgment, when the Home Secretary made that announcement, in your view, the balance was too far along political gain rather than engaging with professionals in the industry?

Professor O'Callaghan: I do not think that is for me to say. I welcome—

Q168 **Johnny Mercer:** It is kind of what you did say. You said that nobody had reached out to you and spoken to you. You said, "We try to practise evidence-based care," and that decision was not made with reference to the professionals in the sector.

Professor O'Callaghan: I welcome the rescheduling by the Home Secretary. It now allows us to do research into these products. I am completely behind the decision to reschedule the products.

The problem has arisen that that has been interpreted, for whatever reason, as the products now freely being available on the NHS for doctors to prescribe. Effectively, it is the doctors who then look at this and see that the evidence base in their particular area is not there and therefore are reluctant to prescribe them. They are then under pressure in the media and everywhere else as though it is the doctors' fault that they are not being freely prescribed. There has been a gap. After we rescheduled



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the products, there should have been some effective communication to the public around what that meant.

Q169 **Johnny Mercer:** Whose job is that, in your view?

Professor O'Callaghan: It is partly our job and we have tried—

Johnny Mercer: That is what I was thinking.

Professor O'Callaghan: We have tried to do that. We have produced guidelines and we have gone on the media when we have been invited and talked about it. We have tried to do that, but it is also a responsibility of Government, if they are making a legislative change, that they should communicate.

Q170 **Chair:** To clarify, some of the barriers that were there have been cleared away, so you welcome moving it from schedule 1 to schedule 2, and you welcome the fact that the NIHR is inviting applications and will be starting clinical trials. How much of a barrier at the moment is the lack of access to these products? If the manufacturers are withholding them from being used in clinical trials, is that going to be now the key barrier?

Professor O'Callaghan: As I said, there is some indication that some manufacturers are more willing to engage with clinicians and investigators in doing clinical trials. That is about as much as I can say at the moment. Hopefully, we will be able to do the research in this area that we need to do.

Q171 **Chair:** It is not a financial barrier, and it is not a barrier from the point of view of clinicians wanting to take part in the trials. Are there any other barriers that you have identified to trying to answer these questions?

Professor O'Callaghan: No. I think clinicians would be very keen to participate in well-organised, ethical trials in this area. I do not think clinicians are reluctant to do that. If we can get the product to study and we can get the money to do the trials, there is nothing stopping it happening.

Q172 **Chair:** Professor Goddard, can I bring you in on this? Where do you wish to see the focus of those trials?

Professor Goddard: As I said earlier, we need to focus on a very small number of products. If you are trying to choose from 50-odd different types of cannabis, it will get confusing and will take much longer to get some answers. You look at some pure CBD, CBD with a little bit of THC, and CBD with a bit more THC; then you focus on specific areas. That might be, for example, looking at pain in patients with fibromyalgia or patients with multiple sclerosis. If you try to do too many things, it is going to take much longer and we will not get a clear answer, so we have to be very focused.

The other issue that Dr Malik raised in giving evidence here is that we have to be very careful when talking about CDMPs, or however we choose



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to abbreviate them, that we do not normalise cannabis. These are new medicines and they have potential risk, and some of the conversation that goes around might make people think they are completely safe and that cannabis is completely safe. We have to be very clear on the dangers of cannabis to our society. CDMP should be considered separately and for specific patient indications.

Chair: Thank you. Do you have a supplementary point, Ben?

Mr Bradshaw: I will take it at the end.

Q173 **Martin Vickers:** Could we look at the procedures for prescribing medicinal cannabis? Do you think they are appropriate? Also, why might local prescribing committees in trusts not allow medicinal cannabis?

Professor O'Callaghan: With the rescheduling of cannabis-based medicinal products, it is now possible for clinicians on the specialist register to prescribe those products. The bar might be local. If I decided in an individual case that it was in the best interests of a patient to prescribe a cannabis-based medicinal product, I could write the prescription. The problem then is who is going to pay for that product, which we have already heard may cost in the region of £25,000 to £30,000 per patient per year.

If I put an individual funding request to my local trust to use the product, a drug and therapeutics committee would look at it and ask, "What is the evidence for efficacy, safety and benefit?" I have competing demands for my budget, and they are probably going to say that there is not enough evidence of efficacy and safety to pay out that amount of money.

Professor Goddard: I agree with that so far. Say I had a patient I wanted to give a new biologic to. I would go through exactly the same processes as I would with cannabis. I would fill out a concession request form, which then goes to my drugs and therapeutics committee. In that form, I have to provide the evidence for efficacy, I have to provide the costs and I have to provide the risks and harms.

I do not have to sign anything specifically to say that I will take all that liability; there has been some discussion of that in this Committee, but, certainly in England, I am not sure that that happens. However, I would expect to get my patient to sign a specific information sheet about it. The decision will rest with the drugs and therapeutics committee, or the joint prescribing committee in some places where it is joint between the CCG and the trust. They have very little money to play with and therefore they have to be pretty convinced that something is worth giving.

Q174 **Martin Vickers:** You mentioned liability. Do you think that doctors incur too great a liability?

Professor Goddard: Most doctors when faced with a patient will do their best for that patient, and the liability bit does not really come into play at



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all. The biggest concern is that we do not do them any harm; that is what keeps us awake at night, not worrying about being sued.

Professor O'Callaghan: I agree entirely with what Andrew said.

Q175 **Martin Vickers:** Do you feel that if there were less liability on doctors they might be more willing to prescribe, or will the lack of evidence weigh heavily with them?

Professor O'Callaghan: As Andrew said, I do not think it is worry about liability that determines what we are going to prescribe or not. If I thought something was in the best interests of my patient, I would prescribe it and I would not lose any sleep about that. The lack of evidence is an issue, because I do not think clinicians are going to want to prescribe something where there is not an evidence base, generally.

Q176 **Dr Williams:** I have a couple of questions about the guidance that your organisations have produced. First, have either of your organisations ever received any funding from GW Pharma, who produce Epidiolex?

Professor O'Callaghan: Not directly, but we run an annual conference and various companies put up stalls. As I understand it, GW Pharma were going to put up a stall at our last conference but withdrew because their product was going through the licensing procedure, so they did not do that. But I cannot say that they have never sponsored a stall in the past.

Q177 **Dr Williams:** Professor Goddard?

Professor Goddard: No.

Q178 **Dr Williams:** What feedback have you had on your guidance, and what can NICE, who I understand are producing guidance, learn from your experience and from that feedback?

Professor Goddard: The feedback from professionals has been very positive, and, indeed, from evidence this Committee has received, other groups have said that the evidence guidelines are well balanced and a fair representation of the evidence base at the moment.

There is no doubt that we have had some correspondence from patient groups that have been upset and feel that our guidance has been a barrier, but, as I said, the barriers that we have talked about are the real barriers, and the only way that we will move forward will be when we are able to convince clinicians that the drugs we should prescribe are effective and safe.

Professor O'Callaghan: I echo that completely. The professional feedback we have had on the BPNA guidance has been universally positive and appreciative. We have had some feedback from patient groups and lobby groups that has been negative for precisely those reasons, that they perceive the guidelines to be too restrictive. In effect, what is too restrictive is the fact that there is no evidence. We were



commissioned to produce evidence-based guidelines, so inevitably we are going to say where the evidence lies.

Q179 **Dr Williams:** Not many prescriptions have arisen since the production of the guidance. Is that what you expected?

Professor O'Callaghan: I am not sure what I expected in terms of prescription numbers. It is worth saying that our guidance, just as when NICE produces guidance, is guidance. We are not mandating or forbidding anything; it is just guidance. We were asked to look at the evidence. We did that, summarised it and gave guidance, but each individual clinician should do what they think is in the best interests of their patient.

Q180 **Dr Williams:** Could your guidance have been more permissive in enabling or encouraging clinicians to prescribe off licence on the basis of other available evidence?

Professor O'Callaghan: I do not think it is a question of being permissive or not. We were neither permitting nor not permitting anything. I think we fairly summarised the evidence. As I said, the evidence base is thin, and inevitably our conclusions reflected that. We are open as a professional grouping to any new treatments that are shown to be efficacious and safe. Manipulation of the endocannabinoid system as a treatment for epilepsy is an exciting area to look at. We just need to do the research.

Q181 **Dr Williams:** If it is not the guidance, are there any other barriers? Are there any improvements to educational materials that need to be made in order to help further clinicians' understanding?

Professor O'Callaghan: In terms of childhood epilepsy, the paediatric neurology group are pretty well educated about the evidence that is out there. They are very interested in the area and have read just about all the papers that are out there. It is not a question of their not knowing what the evidence is, or that they are unaware that cannabis-based medicinal products may potentially be helpful. I do not think there is a level of ignorance in our specialist grouping, no.

Q182 **Dr Williams:** What about in terms of physicians?

Professor Goddard: More education has to be a good thing. It is clear that the endocannabinoid system is an important one that we need to understand better. A lot of patients use cannabis recreationally and as a medicinal product as well; therefore, understanding how that might help or harm our patients is an important part of being a doctor.

Q183 **Dr Williams:** You used the word "recreationally", but many people use it for what they consider to be medicinal purposes. Is this the most frequently used non-prescribed medication that people have?

Professor Goddard: Not at all. Over-the-counter medicine for pain relief by far outweighs it. Some stats are being put around that about 1 million people are taking cannabis. I do not quite know where that data comes



from, because, when you ask the public how many people have taken cannabis within the past 12 months, the figure for most people of our age, so to speak, would be less than 1%, so that is less than 1 million people.

There are lots of figures bandied around and we have to be very careful about that. The bottom line is that many patients take many things for their symptoms and often do not tell doctors about it. It is important that we understand cannabis and its potential benefits and harms, so yes to more education; we would support that.

The guidance that the MCCC has produced is a very readable, good summary as a primer about cannabis. It contains some inaccuracies that I would argue with, but, as something that talks about what cannabis is, it is quite readable, and I enjoyed reading it. I completely disagree that you could go into any hospital and write a prescription, for example, because that cannot happen.

Q184 Dr Williams: I would like to follow up on one other point that you made. We particularly heard from parents for whom there is urgency. They have a developing child in their family with an epilepsy for which they are desperate to find a treatment. They would perhaps listen to this and say that three years to conduct randomised controlled trials is certainly not what they want to hear in terms of the urgency of the problem they have in front of them. If there were any drug that was put into a randomised controlled trial that very quickly showed that it was considerably superior to the placebo, would the trial need to continue for the full three years?

Professor O'Callaghan: That is a very good point to raise. If you do a randomised controlled trial and you are comparing one treatment versus placebo or another treatment, and you show jaw-droppingly good superiority of one treatment, of course, it is ethically appropriate sometimes to stop that trial early. It is unethical to continue because you have seen such a dramatic benefit. Not to get too nerdy about clinical trials, you have to have very strict stopping rules before you start, because there is a temptation when you look at data early that you are exploiting the random variation of the data, so you need to have clear stopping rules, but it is certainly possible to do that.

I completely understand the desperation of families who have children with complex epilepsies, who are in real difficulty and are desperate for anything that might help, but it is fair to say that, in the countries where cannabis-based products have been used widely, they do not appear to be a magic bullet that has a dramatic effect. In Canada, Australia or whatever, there is some evidence of benefit sometimes, but they are not jaw-droppingly effective. There will be individual cases, and we have heard of one or two, where there appears to be a dramatic effect, but, for instance, with cannabidiol the number you need to treat to get one patient seizure-free is around 170 patients.

Q185 Dr Williams: That is if being seizure-free is the objective, but what is the



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number needed to treat in order to get a clinically—

Professor O'Callaghan: A clinical response?

Q186 **Dr Williams:** A clinically significant reduction in the seizures.

Professor O'Callaghan: We can only answer for cannabidiol because it is the only thing that has been done in clinical trials, but about eight patients is the number needed to be treated to get a clinical response.

Q187 **Mr Bradshaw:** When you published your updated guidance last July, had you actually completed your evidence review?

Professor O'Callaghan: We did not publish in July.

Q188 **Mr Bradshaw:** It says in the document you sent us that the BPNA—

Professor O'Callaghan: We were asked to look at the evidence in July and we published in September.

Q189 **Mr Bradshaw:** That is the statement I am referring to, in July. When you published in October, had you completed your evidence review?

Professor O'Callaghan: Yes.

Q190 **Mr Bradshaw:** Do you accept that, when you describe as “significant damage” the impact of cannabis on developing children’s brains, those trials were on street cannabis, not medical cannabis?

Professor O'Callaghan: Yes. We have a theoretical concern about exposure of young children chronically to THC. There is a legitimate question: is that going to damage their brains or not? We did not say that we had evidence that it did at that time. Our theoretical worries or concerns were, first, from animal studies, where there is evidence that administration of THC can cause damage; and, secondly, evidence from recreational drug users.

Q191 **Mr Bradshaw:** Yes, recreational—street drug users, not medical cannabis use.

Professor O'Callaghan: Yes.

Q192 **Mr Bradshaw:** Do you accept, whether or not it is the intention of your guidance, that the number of prescriptions has fallen, and that some people who were getting medical cannabis before are now no longer getting it?

Professor O'Callaghan: I do not know what the prescription numbers are. There are very few people who actually got prescribed cannabis before the rescheduling; I was on the Home Office expert panel, and I am not aware that any of the patients who were given a cannabis-based medicinal product as a result of the Home Office panel are no longer getting it. I think they all are actually.

Q193 **Mr Bradshaw:** That is what we were told by one or two patient groups in



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their evidence last week and in their written evidence. That is their experience of the impact of your guidance.

Professor O'Callaghan: Literally, you can count on the fingers of one hand the number of patients who got a prescription before rescheduling—I do not want to go to individuals—and I think all of them have access to a product at the moment.

Q194 **Mr Bradshaw:** That is not what we were told by patient groups last week. Do you accept, though, whether it is your intention or not, that the impact of your guidance is driving people to buy street cannabis?

Professor O'Callaghan: No.

Q195 **Mr Bradshaw:** You do not accept what we were told last week—

Professor O'Callaghan: I do not think it is our guidance that is driving people to buy street cannabis, no.

Q196 **Mr Bradshaw:** There is the fact that people cannot access medical cannabis legally; some are going abroad to buy it in other countries, which is illegal, and bringing it into the country. We heard from patients and parents of children last week who are doing that. In other cases, they are resorting to street cannabis, which you yourself have acknowledged is far more harmful.

Professor O'Callaghan: The point is that our guidance is just guidance. The individual clinician must do what they think is in the best interests of their patient. We produced evidence-based guidelines in the autumn, just as NICE will do about anything else. We are not driving patients to go abroad or do anything illegal. We just produced evidence-based guidance.

Q197 **Mr Bradshaw:** But that is the impact of your guidance, because they are not getting it—

Professor O'Callaghan: It is the impact of the evidence.

Q198 **Mr Bradshaw:** It is the impact of your guidance. Your guidance is voluntary.

Professor O'Callaghan: Yes.

Q199 **Mr Bradshaw:** Would you approve of medical practitioners prescribing medical cannabis if they thought it might be in the interests of their patients?

Professor O'Callaghan: Certainly, if an individual medical practitioner thought it was in the best interests of their patient to prescribe a cannabis-based medicinal product, they would have my full support and they are protected by the GMC. There is no doubt about that. But you have to be clear: our guidance is evidence-based guidance. The evidence says what it says. You cannot expect us to distort the evidence or come to a different conclusion. We have just given you the evidence.

Q200 **Mr Bradshaw:** The Secretary of State said a couple of hours ago in the



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Chamber that he wanted to do everything he could to unlock this problem for the families concerned. He met the families last week. What are your two organisations going to do to help the Secretary of State unlock this particular urgent, pressing problem for the small number of families concerned?

Professor O'Callaghan: The first thing, as I probably alluded to at the start, is that it would be nice to speak to the Secretary of State about it.

Professor Goddard: It sounds like a cop-out, but the families are concerned about their children with epilepsy, and our guidance is for adults, about pain, nausea and vomiting. The College supports evidence-based medicine. If you came to me as a patient with any condition and I was going to prescribe a medicine for you, I would only give you that medicine if I believed it was going to do you more good than harm, and I was able to back that up.

As to the argument that any guidance, whether it is ours or anybody's, is driving people to the black market, you would have to show that before the guidance came out there were a number of people going to the black market and after that guidance came out there were more people going. Given that the time from when the scheduling moved to when our guidance came out was very small, it is very hard to make that statement.

Q201 **Mr Bradshaw:** When you say that you would like to speak to the Secretary of State, have you asked to speak to the Secretary of State about this?

Professor O'Callaghan: No, but you can take this as a request. I am very happy to speak to the Secretary of State.

Q202 **Mr Bradshaw:** There seems to be a complete lack of communication between the policymakers and the clinicians who speak, or purport to speak, on behalf of the specialist clinical organisations. That is not helping anyone, is it?

Professor O'Callaghan: Not at all, and we have made requests through other channels. I have said to other people, civil servants and so on, exactly what I have said to you. I do not have a direct phone line to the Secretary of State, but I would welcome—

Q203 **Mr Bradshaw:** Come on, your organisation can make a formal request to a Minister to have a meeting. I am a former Health Minister and it used to happen all the time.

You said earlier that you would be happy to engage with the all-party group, who say they have been trying to engage with you and that you have refused to see them. I also understand that the families asked to address your annual conference last year and share some of their experience with your organisation. Might that have helped your members?



Professor O'Callaghan: We have to understand that the annual conference is a scientific conference, a presentation of science relating to paediatric neurology. It is not really a forum for members to meet families. Families are very welcome, and we meet families every day in clinic and talk to families about the issue on a regular basis.

Q204 **Mr Bradshaw:** That is a different relationship, isn't it? We are talking about a very controversial, hot medical and political topic where patients and families affected have asked to have access to your members to have a conversation and you have declined that.

Professor O'Callaghan: It is just that the conference is organised way in advance of any requests coming in. It is not the appropriate forum for us to be discussing this issue with parents. There may be other fora where it is appropriate, and I am very happy to do that. We also have to be careful that we talk to representative groups of all our patients and not just pressure groups that may or may not be funded by the cannabis industry.

Q205 **Chair:** I would reflect that most conferences are improved by having a user voice at some point. At any point in your conferences, do you try to involve the user voice?

Professor O'Callaghan: At the moment, we do not specifically have a user section in the conference, although that is a fair point and may be something that we might consider doing in the future.

Q206 **Chair:** Thank you. Are there any final points that either of you want to make today that you have not been asked about?

Professor O'Callaghan: I want to clarify one thing that came up in the panel last week. There was quite a bit of talk about mortality from epilepsy.

Q207 **Chair:** I am very glad you brought that up because we were concerned that there was an impression left that somehow SUDEP was being contributed to by a lack of access to cannabis. It would be helpful to have your thoughts on that—sudden unexplained death in epilepsy, I should clarify.

Professor O'Callaghan: I think it was Mr Bradshaw who alluded to the fact that he thought epilepsy mortality in children was increasing.

Mr Bradshaw: No, I was quoting the evidence that was given to us by medical experts.

Professor O'Callaghan: Okay. Epilepsy mortality in children has been declining with each successive generation since the 1950s. Mortality from epilepsy in children is rare, and we have no evidence to date that any particular therapeutic intervention has been responsible for that reduction in mortality. It is probably more to do with factors around the time of birth that contribute to that reduction in mortality.



SUDEP occurs extremely rarely in children. It is fair to say that the factors associated with SUDEP are uncontrolled epilepsy and polypharmacy, and children with underlying symptomatic brain disease. Those are risk factors for SUDEP, but it is incredibly rare. It is misleading to suggest that access to a cannabis-based medicinal product is likely to have a dramatic effect on SUDEP rates.

Q208 **Chair:** Thank you. Is there anything you would like to add, Professor Goddard?

Professor Goddard: No, thank you.

Chair: Thank you both for coming this afternoon.

Examination of witnesses

Witnesses: Baroness Blackwood, Professor Whitty, Nick Hurd and Dr Ridge.

Q209 **Chair:** Welcome to our second panel. We particularly thank Minister Nick Hurd for appearing before the Health and Social Care Committee, because it is not always a requirement for Ministers to appear before Committees that do not cover their specific area. We really appreciate your being here. Welcome back, Baroness Blackwood, now that you have moved to the smart end of town, with all the red and gold. I know that you appeared before this Committee when you were a Minister. Thanks, too, of course, to our other two panellists. For those following from outside, could I ask you to introduce yourselves and who you are representing today?

Professor Whitty: I am Chris Whitty, the chief scientific adviser at the Department of Health and Social Care, which means that I am also head of the National Institute for Health Research. I am also deputy chief medical officer for England and a practising physician.

Baroness Blackwood: I am Nicola Blackwood, the Minister for Innovation in the Department of Health and Social Care.

Nick Hurd: Nick Hurd, a Minister at the Home Office.

Dr Ridge: Keith Ridge, chief pharmaceutical officer for England, representing NHS England.

Q210 **Chair:** As an opener, Nick Hurd, did the Home Office have a plan for the future of medicinal cannabis before it decided to reschedule it?

Nick Hurd: The honest answer is that we were waiting for the World Health Organisation review. That was our position. If I am candid, the trigger for change was an urgent question that I took in February 2018 on the Alfie Dingley case, which was the most prominent at the time. That was an opportunity for me to review the institutional position. I was, frankly, uncomfortable with it, and at the Dispatch Box made it clear that we would look at all our options within the existing rules to try to help



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Alfie, conscious that behind Alfie and such cases were lots of families and individuals who were deeply frustrated with the current process.

That was the start of a journey to explore how, within existing rules, we could provide the first individual licence for long-term care using cannabis-based medicine. That journey started to make it even clearer to me that the status quo was not viable and, therefore, we had to accelerate our processes to look at the evidence around a possible shift in regulation. The Home Secretary was very supportive of that process.

Chair: We have heard that there has been a welcome for the rescheduling part of it, but the rescheduling and the communication of it caused a number of difficulties.

Q211 **Diana Johnson:** Minister, did the Home Office raise expectations too high when you rescheduled medical cannabis?

Nick Hurd: I do not know what the protocol is of the Committee, but can I call you Diana?

Diana Johnson: You can call me whatever you like.

Nick Hurd: Okay. The short answer to that is that I am, first, painfully aware that there is still a great deal of frustration, anger and upset among communities of people who want access to cannabis-based medicine and feel that the system is still not working for them. I absolutely recognise that.

I would be very sensitive to any charge that we over-egged expectation as a Government. Obviously, we cannot control all communication around changes in policy or regulation. It is a collective process, for which everyone takes their responsibility. This all moved very fast, and once we had received the expert advice from the chief medical officer and the Advisory Council on the Misuse of Drugs, and once we had accepted their recommendations and explained our position in Parliament, I felt that we were clear that the guiding principle for us was that any change would be clinically led. We put that in practice through our interim process of setting up the expert panel, clinically led so it was not politicians taking decisions around licences. It was an interim process.

I felt that at the point when the regulations were changed there was clarity that what we were doing was about making it easier to access cannabis-based medicine, where there was a clear clinical need that was not being met by licensed products. If the Committee feels, as you go through your investigation, that the Government at that point were guilty or co-guilty of raising expectations, that is something we would take seriously, but it is not my memory. I felt that we were clear about what we were doing.

Q212 **Diana Johnson:** On reflection, months later, do you think that is still the case?



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Nick Hurd: I stand by what I said. Obviously, in that process, the Government cannot control all flows of information, and cannot control what people hear, or think they hear, or how they feel in response to news. We were very clear that we wanted to proceed on the basis of evidence from the chief medical officer and the advisory council. Their advice was clear about health benefits—qualified—and classification, and the need for checks and balances in that process.

I feel that is what we set up, and I think it was clear that access was going to be through specialist consultants, in recognition of the fact that we were talking about unlicensed medicines with a limited evidence base. I felt we were clear at that point, but it is possible that in that environment, when things were moving very fast and there was quite a lot of excitement around the whole agenda, expectations may have been different and people's understanding may have been different. The Committee will form its own judgment on that.

Q213 **Diana Johnson:** Dr Ridge, has there been appropriate communication from the Home Office and the Department of Health and Social Care with regard to the future plans for medicinal cannabis?

Dr Ridge: Perhaps I should outline what I did in response to the change in the law. I brought together a short-life working group, UK-wide, to consider this from a number of areas. It had representation from across the UK, typically through the chief pharmaceutical officers, but with policy colleagues as well, to begin to form how we would implement the change within the health service and across the UK. Throughout that process, communication with the Home Office and the Department was very strong.

At the beginning, I probably failed to declare that my function is system-wide and that I have a role that supports the health and care system more broadly. Therefore, it was fairly easy to bring together a group across the system to consider the implications. As for the future, that short-life working group still exists, and I expect therefore that communication and planning as a result of that to filter through to the NHS in implementation.

Q214 **Diana Johnson:** And you were feeding that up to the Minister.

Dr Ridge: We linked with civil service colleagues, who, I am sure, would have kept Ministers up to date, but you would want to ask them that.

Q215 **Diana Johnson:** And that is to the Health Minister, not to the Home Office Minister.

Dr Ridge: No. The link with the Home Office was through the Department of Health.

Q216 **Diana Johnson:** Do the Home Office and the Department of Health and Social Care have a plan now for informing the public about medicinal cannabis? That is a question for Baroness Blackwood and Professor



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Whitty.

Baroness Blackwood: Yes. But I would like to go back a little bit, if that is okay. Obviously, I was not in post from the beginning, which we have been discussing, so, to try to educate myself a little bit about the journey that has taken us here, I started with the CMO's review of reviews from 3 July last year, which I think you took evidence on last week. It was clear in that review that there were two purposes for the actions that the Government were taking. The first was, obviously, to reschedule, so that in the existing unlicensed regime medicinal cannabis could be prescribed by specialists, in line with guidance.

Chair: Could you speak up a bit?

Baroness Blackwood: Sorry. Diana is sitting quite close and I was answering her, but I recognise that I am answering to the room.

The second purpose was that we could begin to see the research and the randomised clinical trials to provide the necessary evidence for licensing and public funding, which we need to see, so that wider groups could receive medicinal cannabis, because both of those were obviously illegal before that happened. That is really important because, right at the beginning, it was clear from that action that that was the purpose of the Government policy.

I was not there at that point so it is not clear to me how effectively that was communicated; what is clear to me is that at the moment there is a gap between what people would like to see and what is happening in terms of the implementation of Government policy, and we need to close that gap. The Government have done some things to try to deliver that. The first is publishing the interim NICE guidance and the final NICE guidance, which will come out in October, which will cover not just epilepsy but pain, nausea and vomiting associated with chemo and MS-related spasticity. That will take into account all the latest evidence, which is obviously gathering pace all the time, so it should improve the picture.

The second thing is through professional bodies' published guidance, which was not the purpose of the review that the CMO put out; it was to assist clinicians in prescribing. That guidance has been found to be in line with guidance across the world. We are absolutely in line with world guidance. The NICE guidance, when it comes out, will be absolutely top-notch. NICE guidance is world-renowned for its rigour and high standards.

The third thing we have done is that Health Education England has been commissioned to produce an e-learning module to improve education among clinicians for prescribing.

Q217 **Diana Johnson:** Can I ask about the public? It is the public we are most concerned about.



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Baroness Blackwood: Absolutely. I am trying to help on communication. The last thing we have done is that the NIHR has put out calls for research.

On public communication, all the information about how medicinal cannabis can be prescribed and how you should access it has been on the NHS England website, and communication has been freely available through general practitioners and specialists, which is the route through which prescribing should occur.

Q218 **Diana Johnson:** There is nothing in particular being done to educate the public. They have to go to the website or go to a GP; there is no campaign and no materials being produced.

Baroness Blackwood: There is no specific campaign, but it is very well known that, if you want to get information about any specific indication, you can go to the NHS.UK website, which is a very accessible and well-known place to find information. If there are any concerns about the quality of that information, we would be very keen to hear from the Committee.

Q219 **Andrew Selous:** Welcome back, Nicola. To be clear, what is the Government policy on medical cannabis? You referred to it just now.

Baroness Blackwood: The Government policy is that it has been rescheduled, from schedule 1 to schedule 2, so it can now be prescribed under the unlicensed regime by specialists who, in line with guidance, are able to prescribe for any condition according to their clinical judgment. Secondly, we would very much like to encourage research. We have asked the NIHR to put out calls for research and asked NHSE to conduct a process review so that we can see whether there are any blocks in the system. We have also put out a significant statement in which we encourage industry to conduct randomised control trials, because we think that cannabis should not be different from any other drug. This is a very lucrative market; there are some very successful companies in the sector, and there is no particular reason why they should not be conducting trials, just as any other pharmaceutical company would.

Q220 **Andrew Selous:** I shall come to the industry in a moment. We have just had representatives of the British Paediatric Neurology Association and the Royal College of Physicians in front of us, who described the evidence in this area as thin. What are you doing, given that the train has left the station? The reschedule was announced last November and it is now the end of March. What are the Government doing to improve the research and evidence base in this area? We have heard that some of the sample sizes in some of the trials were absolutely tiny, with some of 20. Thin is the right word, isn't it? What are the Government doing to get a proper evidence base, perhaps a little more quickly?

Baroness Blackwood: I shall ask Chris to come in on that in a second. First, obviously, guidance has come out. The professional bodies you have just spoken to have issued some guidance, which is available in the



interim. NICE has published interim guidance and will publish some final guidance in October, which will act as the standard, as it does for all other conditions. In addition, we have asked Health Education England to bring out an e-learning module, which should assist with circulating and socialising the prescribing of cannabis. NIHR has already put out one call for research and randomised control trials, and a second one will follow. That will be—

Q221 Andrew Selous: Sorry to stop you, but it is very slow, isn't it? The call for evidence was on 19 March, and we do not get anything out of it until summer 2020. That is after an announcement in November 2018, with, as Diana was saying, significant levels of public expectation in the area. I am just trying to press you a little bit on what we are doing to fill that gap.

Baroness Blackwood: That's okay. I shall ask Chris to come back on the pace of that in comparison with other controlled trials. If you want to develop clinical confidence in a randomised controlled trial, I suggest that it is important that cannabis trials meet the standard of other equivalent pharmaceutical trials, because that is of course what patients would want; they would want to know that the safety of the trial and the evidence of the trial—

Q222 Andrew Selous: I am not remotely asking you to cut corners; it is probably extremely important that you do not. I am talking about scale and speed.

Baroness Blackwood: Professor Whitty would be best placed to answer on the technical aspects of the trial.

Professor Whitty: Basically, there were four barriers to people getting cannabis products before the change in the law. The first and most important one at that stage was that all of those drugs were in schedule 1, which made it difficult to build an evidence base, because, although it is possible to do trials under those conditions, it is extremely difficult. Removing that barrier is the single most important thing that could be done by Government at this stage. That has now happened, and it is a lot easier to do stuff on a schedule 2 basis.

The next stage is to do the trials. The point the previous two witnesses made, which has been made by pretty well all your other medical witnesses, either in writing or in front of you, is that it is very dangerous to have a kind of cannabis exceptionalism. These are drugs; they have side-effects and positive effects. That is clear. What we have to do is to balance the two, but they are no different from any other drug in that sense. The history of medical development is littered with people rushing things through and ending up regretting it or, in a few cases—thalidomide is probably the best known—having an absolute disaster on their hands. It is really important that we balance throughout this a responsible look at the side-effects of the drugs and the positive effects of the drugs. We all completely accept that there are both.



I think we will get faster movement now, because quite a lot of people have been thinking about what they would do if the drugs were out of schedule 1, which is different from the situation with many other drugs. My expectation is that the field will actually move faster than many other fields when a new drug comes in. Nevertheless, to get a trial that is properly and ethically done involves patients in the design. That is a very important part of what NIHR does—really critical. It gets through scientific review and there is a proper study, properly powered, and it reports, and it has something that will actually change the minds of the medical profession, because they will believe that they have the evidence to balance risk against benefit.

That is not something you can just wave a magic wand and do. In reality, for the things we are talking about as indications for cannabis-based products, it will go faster in conditions where there are quite a lot of people—let us say spasticity in multiple sclerosis than other rarer diseases—because it is easier to do trials in that situation.

Q223 Andrew Selous: We talked a little bit about some of the manufacturers in this area, and what they could do to help, because I do not believe that all of them have stepped forward offering suitably large randomised controlled trials. You said “speed up” and “accelerate” twice in your answer. Does that mean that we will get some decent evidence and proper sample sizes before the summer of 2020?

Professor Whitty: It is unlikely that, in the UK, we will be able to stand up a trial that would be big enough to have convincing evidence in that time. But remember that this is a global market with a global research effort at the moment; it is something where evidence from South Africa, California and Paris is often just as useful as evidence here.

Q224 Andrew Selous: Who is co-ordinating that global research? Is there an alliance? Do you all talk? Are you pooling resources internationally in this area?

Professor Whitty: As with all other drugs, what is going to happen is that two different groups, at least, will put forward trials in the area. The responsible end of industry will. If a company is not prepared to have its drug trialled, you have to ask a very serious question why. The academic and charity groups will do so as well. NIHR will try to make sure that, first, we fund some of the publicly funded trials, but we also make available for industry the ability to do trials in the NHS as fast as possible. We hope they will rise to that challenge. We have put out one call already, which closed last week, and another opened immediately on its back, and we will continue doing that until enough evidence is assembled.

Q225 Andrew Selous: Just sticking with the companies for a minute, while being completely with you in wanting this done properly and not cutting corners, with sufficient sample sizes, is there anything the Government can do to make sure that these trials—notwithstanding what I said—are



not more expensive, bureaucratic or difficult than they need be?

Professor Whitty: We are clearly trying to do that across the board. The UK is one of the best countries in the world in which to do medical research. To have a thriving academic industry, and to have a thriving life sciences industry, which we are also very proud of, as it is one of the best in the world, we have to be able to do this very fast. We are trying to speed up the process through every stage. The time to get ethical approval and to get approval scientifically has come down substantially in the last four years. We can go further. That is not specifically for cannabis-based drugs, to be clear. It has to be across the board; the system has to be the same for everyone.

Q226 **Andrew Selous:** I think you said this already, but for the record you are saying that medicinal cannabis is part of a family of drugs and should be treated just the same as all other drug trials in terms of the evidence base that we need to prescribe it properly.

Professor Whitty: Exactly. It has side-effects and it has effects, and we need good evidence to make sure of the right balance for every individual patient group. It should be exactly the same as for every other drug.

Q227 **Derek Thomas:** Dr Ridge, you have heard that rescheduling allows the prescription of unlicensed CDMP, if the specialist clinician looking after the patient feels that it is in their best interests. Given that that is the case, why might local governance within trusts refuse an application? Why are CCGs reluctant to commission medicinal cannabis products?

Dr Ridge: On the current system, I would like to reflect on the Minister's statement about the process review. While the primary purpose of changing the law, as I see it, was to support the development of good evidence of benefits and risk, we also need to consider the needs of seriously ill patients. As the Minister clearly set out, there is a case to look carefully at the implementation of the changes, and I will place that in the context of how processes currently work.

In the circumstances that a specialist clinician has tried all other options and taken into account guidance from specialist societies, it is about how their patients, working with their carers and families, can access the medicines they need. In the current system—if you like, I can describe the rather bureaucratic process around individual funding requests and those sorts of things—at local or national level we are trying to get the balance right between good, evidence-based medicine and value for money for the taxpayer. At this point in time, it seems to us that it is important to try to work that out through the process review, to make sure that those processes are being used well in these particular circumstances.

Another thing I forgot to declare at the beginning is that I have been a proper chief pharmacist, in at least two organisations. I was five years as chief pharmacist in Glasgow hospitals and in Birmingham. It was my



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responsibility, in many ways, to oversee the medicine system locally, so I have dealt with these things at local level too.

The systems for trying to promote evidence-based safe practice in the context of a cash-limited budget are important. It is also about being able to ensure that, when a patient needs a medicine urgently, there are systems in place to go through to get to that point. But those systems are based on evidence, and, as we heard from the previous witnesses and from this panel—particularly from Chris and the Minister—at the moment we find ourselves in a situation where evidence is lacking. Therefore, despite what I have said, the importance of robust randomised clinical trials is still at the top of the list.

Q228 Derek Thomas: In the vacuum of evidence, if you have a specialist clinician who is saying, “This is the best we can do for this individual,” surely the commissioners would follow their lead. Would you not hope that they would?

Dr Ridge: I would hope that they would take into account that process. Again, I can describe the process for individual funding requests; it draws on, as Andrew Goddard said, the need to supply evidence in that process, considering the needs of the health community as a whole as to where the product or medicine fits in terms of local priorities. In the particular circumstances we are dealing with, there is a need to examine carefully the process in relation to cannabis-based medicinal products, as to whether, having come this far, the process is working well in this context.

Q229 Derek Thomas: Baroness Blackwood, is it right that practitioners take full liability for prescribing unlicensed medicinal cannabis?

Baroness Blackwood: Keith will answer some of that in a second. Can I go back to the funding question? We are taking some actions to try to assist with that, which I think will be helpful. First, it is a problem that most countries are struggling with. In most countries, cannabis prescribing is on private prescription at the moment. We are trying to understand through the process review where the blockages are happening, so that we can understand that in a lot more detail. I know that sounds frustrating, but we need to understand what is going on on the ground. That is why we have done that. In addition, we believe that, when the NICE guidelines come out, they will be of great assistance to CCGs and funding bodies. That is a really important step and will happen in October.

One of the problems with cost is, obviously, that there is no UK supply. That is something we are working with industry to try to address, because the import cost is significant. That is another issue that we would like to encourage industry to help us to address. The supply chain is a barrier in that context.

It is not the case that individual practitioners bear the entire liability, as there have been changes to clinical negligence. That was an issue Keith



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particularly wanted to respond to, because he knows that it came up in one of your previous sessions. I hope that is okay.

Dr Ridge: In terms of clinical liability—notwithstanding the professional regulation element of that, if you see what I mean—two schemes are very relevant. One is the clinical negligence scheme for trusts whereby, if a medical practitioner is practising in compliance with local policy as part of their terms and conditions, the clinical negligence scheme for trusts covers them for what they do. Very recently, a similar scheme has been set up for general practice; a general practice clinical negligence scheme is part of the new GP contract. I do not want to underestimate the concern that professionals generally, not just doctors, have about professional regulators, but from a medical liability point of view, providing that people are operating within local policy, they will be covered.

Q230 **Derek Thomas:** We talked earlier about education and how well medical professionals are informed. The evidence we heard last week, and even this afternoon, suggested that medical professionals felt they had liability and that they were expected to take liability.

Dr Ridge: Perhaps I might suggest that it is about the definition. The GMC guidance on prescribing, for example, is probably helpful; it categorises the use of medicines, from a licensed medicine being first choice, an off-label licensed medicine being second choice and an unlicensed medicine being third choice. That is set out in the GMC's prescribing guidance. No doubt, if medical practitioners complied with that, in terms of professional regulation, I am sure the GMC would take a particular view.

I am sure that employees of trusts are reasonably aware of the clinical negligence scheme for trusts. Indeed the BMA and others, in terms of general practice, have worked quite hard with NHS England as part of the new contract associated with GPs. Part of that is liability. As to whether there is more to do around liability, potentially there is.

Q231 **Derek Thomas:** One of the barriers that families and patients might face is that, while liability might be covered, the risks are potentially far greater for the clinician. Is that what you are saying?

Dr Ridge: As I set out in a letter I sent to the system—it was the second letter I sent—alongside my fellow chief medical officers and chief pharmaceutical officers across the UK, ultimately, this is about individual clinical decision making, and working very carefully with individual clinicians, patients and, no doubt, their carers and parents. Again, as was said in the previous session, guidance is guidance. That is all it is. At the end of the day, it comes down to individual clinical decision making, and then the interface with the systems I described earlier, which I think, and clearly the Minister thinks too, need a bit of a look at in relation to cannabis-based medicinal products.



Q232 **Dr Williams:** Following on from that, Dr Ridge, do you now feel that practitioners have the right knowledge and guidance to prescribe medicinal cannabis?

Dr Ridge: I think there is more to do. My short-life working group commissioned the BPNA, the RCP and the ABN to produce interim clinical guidance, which is out there and, I think, well known. On the general education and training associated with what is a new practice in many ways, as the Minister has already mentioned, we have commissioned HEE, which is working with the University of Birmingham to produce an e-learning package, to start the process of education and training across not just medics but the full gamut of healthcare professionals involved. Of course, there is more to do, because this is new, but there are some steps that are taking us in the right direction. How we then think about the distribution of that guidance is something I shall no doubt take to my short-life working group.

Q233 **Dr Williams:** Nicola Blackwood, you said that NICE would be producing guidance by October. How are NICE going to involve patients in that work?

Baroness Blackwood: They do consultative processes with patient groups and stakeholder groups, as well as with professional groups, in the normal process. They will follow their normal consultative process, which must involve patient groups as well as the general public.

I want to follow up on your question to Keith, if that is okay. It is important to remember that medicinal cannabis is unlike other medicines, because it was illegal to prescribe or research it until we changed the law. Obviously, experience of the drug in the healthcare system was not there, so we come from a low base in the medical profession. Now that has to be addressed, so we are trying to address it and to bring in informal experience from those who were using it outside the system, which means that you can move at a faster pace than you otherwise would, as Professor Whitty said. Obviously, that needs to percolate through the system, which is why we brought in the HEE e-learning module and why we are bringing forward guidance as quickly as possible, with the specialists who are best placed to know how to prescribe for the specific conditions they would be prescribing for. They naturally network and share best practice.

We hope that the upskilling will happen quite quickly, but what we have seen from other countries is that there was a slow uptake initially and then it sped up. I understand that it is heartbreakingly frustrating for those who are waiting, but there is an initial slow pace while clinical confidence in the evidence has to be established, and the evidence has to be developed. That is where we are right now. If the Committee can propose any additional measures that it thinks we should be taking, which are in line with clinical evidence standards, and that it thinks clinicians would accept, we would listen. This is about making sure that



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medicinal cannabis meets the gold standard of other medicines, because that will be the most likely way to raise confidence in prescribing.

Q234 **Chair:** On that point, we heard from the British Paediatric Neurology Association that there has been pretty much no contact with them about establishing what should happen next. Does it strike you as strange that there has not been significant contact?

Baroness Blackwood: I shall follow that up. It is not what I have understood, but I shall follow it up.

Q235 **Chair:** We were told that there had not been meetings with MPs, which seemed rather strange.

Baroness Blackwood: I am surprised to hear that.

Q236 **Chair:** Have you met the British Paediatric Neurology Association yourself?

Baroness Blackwood: I have not, but I shall follow that up.

Q237 **Chair:** Thank you. That is very helpful.

Nick Hurd, could I ask you about ensuring that there is a sufficient supply of these drugs for the research that we hope will now be taking place? As you know, moving cannabis from schedule 1 to schedule 2 means that it is still very tightly regulated and licences are required. We heard from GW Pharma about some of the challenges they face in making sure that there is sufficient product available, including the fact that under international conventions there are cannabis quotas, and so forth. Could you set out to the Committee what the existing barriers are, and how you intend to make sure that it is not the Home Office that is acting as a barrier?

Nick Hurd: My understanding is that the Department of Health is doing a lot of the market engagement work; our role is around any licensing that is required. At the moment, the current systems for licensing have been around for quite a while. We are extremely open to any suggestions as to how we can make this market work more effectively. I have not heard specific criticism of Home Office processes in that respect, but we are extremely open to any criticism or constructive suggestions about what we can do. What we are discussing, which Baroness Blackwood put very clearly, are the immediate issues around clinical confidence. As that builds, we need to be sure that there is supply. I am not aware of any specific problems or criticisms of Home Office processes that have been raised with me.

Q238 **Chair:** You are not aware of any delays in approving licences.

Nick Hurd: I am sure that lots of people out there are expressing frustration at some of the questions that are being asked, or the answers they are being given. There has certainly been an increased volume of interest and applications to us, but I have not heard any serious systemic criticism of Home Office processes in that way. If there are, I am



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extremely interested in and open to knocking down barriers, as we have done before.

Q239 **Chair:** Perhaps I could bring you in, Dr Ridge. Are you aware of any barriers in getting the required licences?

Dr Ridge: I am not, in that importation of medicines is not an unusual thing.

Q240 **Chair:** I am talking about the requisite Home Office licences to bring in a controlled substance.

Dr Ridge: There are two sides, not just the Home Office but the MHRA as well, for the licences required to import a medicine. From the MHRA side, I am aware of a number of applications that have been put forward; there is a 28-day turnaround for that type of thing, which can be expedited if it becomes necessary. I think there is strong contact with manufacturers abroad. We have been keeping the NHS up to speed on that, in terms of the pharmacy world, in particular the hospital pharmacy world.

I heard a Committee member in a previous session say that they were surprised that their local hospital pharmacist was unable to tell them how to go about importation. I am a bit disappointed about that, because it is a routine thing, and hospital pharmacies have specialists in each department who deal with it. I hope that was a bit of a blip.

The only thing I would add is that these are unlicensed medicines and MHRA regulation means that they cannot be advertised. Therefore, the way they are brought into the country tends to be through specialist routes, and with specialist pharmacist involvement. I am not aware of delays, as such, in the licensing process.

Q241 **Chair:** To go back to a slightly different issue, is consistency of availability between different trusts something you will be looking at, Baroness Blackwood?

Baroness Blackwood: That will be part of the process review, which will look at the consistency of decision making. Obviously, these are specialist cases, so they are quite individual. It is not a generalised policy in the same way, because these are individual cases made by specialist doctors, but the policy has to be consistently applied, and that will be part of the process review.

Q242 **Chair:** One of the concerns has been around access to Sativex. Depending on where you live in the United Kingdom, you might be spending thousands of pounds trying to access a product that you would not have to pay for if you lived elsewhere. Do you want to comment on that?

Baroness Blackwood: I think Professor Whitty would like to talk about that. He might like to pick up on the work that the MHRA has been doing to expedite import licences, as well. Quite a lot of work has been done to



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try to speed up access to medicinal cannabis where it has been prescribed, in an attempt to improve the situation. That is not always visible.

Professor Whitty: On the specifics of the Sativex question, of the four barriers, schedule 1 is gone, and we need to do a lot more on research. The third thing is that, once you have demonstrated benefit over risk, there is the question of cost-effectiveness, which is where NICE comes in. The reason why Sativex is not available is that it was the judgment of NICE, on the basis of the clinical data at the time they made the judgment and the price at the time they made the judgment, that it was not cost-effective compared with other things in the area. They are reviewing that, but that is the next barrier down. Then there is the mechanistic one of whether you can actually get hold of a drug. But that was the reason why that decision was taken by NICE.

Q243 **Mr Bradshaw:** Listening to this afternoon's evidence, you can sympathise with the families who were here last week about the confusion around a lot of this stuff. On the one hand, in the session this afternoon, we have been told that cannabis has to be treated the same as any other drug; on the other hand, we have been told that it is completely different, because it was proscribed until you de-proscribed it last year, and it has been around for thousands of years. Which is it?

We heard from the BPNA representative an hour or so ago that the guidance, which last week we were told was the single biggest obstacle to patients who want this stuff now getting it, is just guidance and that he would support any clinician who decided to prescribe medical cannabis to one of their patients. Can you understand why families are feeling so frustrated about this Alice in Wonderland world? They had been given the impression that this should all be happening now, but in fact it has got harder.

Baroness Blackwood: Are you asking me?

Mr Bradshaw: Yes. I think it is a question for politicians.

Baroness Blackwood: Okay. I am sorry if they have received that confused impression. There is a clinical standard that clinicians need to be reassured of, if they are going to prescribe. As we have heard today, and as I think you have heard from a series of different witnesses, that evidence is not there, and it will take some time to assemble. There is no real shortcut to that. However, the Government have tried, in creating the simultaneous unlicensed route, to provide a way for certain patients whose clinicians believe they should have medicinal cannabis now to get it now.

Q244 **Mr Bradshaw:** How is that going to work, Minister?

Baroness Blackwood: Some can get it on private prescription now, where trusts cannot prove the case for funding. What we are trying to do by bringing forward the NICE guidance, the process review and the HEE



training, and by all the other measures we are taking, is to take us further forward in making the unlicensed route work.

As a politician, I am not going to instruct clinicians or the system on how they should treat patients. That is not my job. It is not the job of Government; it is the job of clinicians and the system to make that decision. But it is my job to do my best to make sure that the policy is clear. I hope that I have done that today, or that I have at least done my best to do that today. It is our job to test whether the system is working, so that is what the NICE guidelines are about and what the education programme is about. That is what the process review is about: to test whether it is working.

Most importantly, the only thing that is going to fix this in the long term is getting the randomised controlled trials right. I think pressure should be put on the industry, because these are multibillion-dollar companies and it is a billion-pound market. There is no reason that I can see why they should not be funding clinical trials like any other drug company.

Q245 Mr Bradshaw: We understand that. You have just said something very helpful: you want to get a move on through the unlicensed route. But that is not happening on the ground, as we heard in the evidence last week, because clinicians are interpreting the guidance as not permitting them to prescribe medicinal cannabis. If not you as a Minister, could the chief pharmacist in your Department, or somebody, make it clear to clinicians, as the BPNA did here earlier today, that that is not what the guidance says? It is up to an individual clinician to make that decision; if they think that it is in the interests of their patient, they should be able to do it, and you will defend their right to do that.

Baroness Blackwood: I will come back on two things. First, I was very clear that it is not for me to instruct, or for the Government to instruct. We have created a permissive regime, and it is for clinicians to make that judgment, based on evidence. Secondly, what we are experiencing is similar to what other countries experienced when they first created a permissive regime; it took some time for confidence to emerge, which is deeply frustrating and difficult for patients at the beginning. Designing trials, which patients can participate in, gives them access to the medication and the ability to help other patients who come after them, to create more certainty in the system. That is what clinical trials are all about.

Q246 Mr Bradshaw: But what can we do to help the small number of families now?

Baroness Blackwood: That does help them now.

Q247 Mr Bradshaw: Your Secretary of State said in the House a couple of hours ago that he met the families last week and he wants this unlocked now. What can you do to get medicinal cannabis to that small number of children now?



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Baroness Blackwood: All of this does that. This package will help to do that, but I am not going to sit here and raise false hope. That is not the right thing to do. I am going to be honest and say that we have created as permissive a regime as we can. It is in the hands of clinicians. We are putting in place every measure we can, but it has to be up to clinician judgment, and I will let the clinicians speak now, because that is the right thing to do.

Q248 **Mr Bradshaw:** Well perhaps the clinicians could speak briefly, if the politicians are not prepared to—

Baroness Blackwood: I don't think that is fair.

Q249 **Mr Bradshaw:** I can understand why you do not want to say. You are absolutely right that it is much better for an independent or departmental clinician to issue guidance or make it clear that it is perfectly possible for this medicinal cannabis to be prescribed now, because it is not happening on the ground.

Professor Whitty: I am somebody who has to prescribe drugs. In my clinical role, and I am sure this is true for the clinicians around this table, I know that, if Government people started instructing doctors how to prescribe, they would go berserk—and rightly. They would see it as complete interference with clinical judgment in individual cases.

I fully accept that there are some families who have desperate medical problems—either themselves or their children—and are therefore desperate for something to happen. They have been told that cannabis is a solution, and in some cases it is entirely possible that it is. But that has to be between them and the clinicians who are dealing with them. What is clear is that all clinicians dealing with rare conditions—all the situations you are talking about are rare—accept that they try as far as possible to conform to guidelines when it is appropriate, but, when you come across a situation where the guideline does not fit, you have to use clinical judgment. That is what clinicians are trained and paid to do.

To go back to what Baroness Blackwood has just said, I would expect that this would be completely in the lap of the clinician advising the family or individual to say whether it was the right thing or not. What the Government are trying to do is to make it possible to happen if the clinical judgment is that that is what should be occurring.

Nick Hurd: Can I make a sub-point, strictly as a politician involved at the start of this? The honest truth is that, in five months, we changed regulations that had been in place for 40 years. Prior to that, the only access to medicinal cannabis was effectively for research, so we drove this very fast. We might be criticised for driving it too fast, but it felt very urgent at the time, because as Ministers we were being asked to uphold regulations that felt very out of date, and felt as if they were causing unnecessary suffering. We drove it very hard. The changes to the legislation were widely approved in the medical community. We are now



dealing with a ground truth that Baroness Blackwood put very well, about a lack of clinical confidence in the process. To my ears, the system has a plan for that, but surely the fundamental point must be that, for this to build in the way we want it to, it has to be clinically led. We cannot go back to where we were, with politicians taking decisions or intervening in individual cases. Forget it. This has to be clinically led.

The reality is, Ben, that we ended up with a more cautious approach than many people wanted, which I think is highly defensible, given the point around evidence. We certainly ended up with a more cautious approach than many people wanted, so there is a process of expectation adjustment, and a challenge around building clinical confidence, which we cannot deny, but we have a responsibility to articulate an action plan to address it, as I think my colleagues have done.

Q250 Mr Bradshaw: You said your decision was widely welcomed by the clinicians, but the guy from the BPNA in the earlier session was clearly furious. He thought the Home Secretary had made the announcement for political reasons, and that it was not thought through or properly co-ordinated with the Department of Health. He also seemed pretty furious that he had had no contact with a Health Minister over this, still, until today.

Nick Hurd: He is entitled to that view, Ben, but the Royal College of Physicians supported the changes to legislation, and the British Paediatric Neurology Association supported those changes, as did the Association of British Neurologists. The BMA welcomed the change in law, and the Royal Pharmaceutical Society was supportive of the changes. I could go on, but there were not that many people in October saying that it was a bad idea.

Chair: There is no doubt that there has been widespread support for the change and moving it to a different schedule. The point is about whether expectations were raised that have now been dashed, and whether we have got it right. The focus of this inquiry is whether we have got it right. I am going to bring Andrew in.

Q251 Andrew Selous: A couple of weeks ago, we took evidence on Orkambi, which is a different issue. This is probably a question for you, Professor Whitty, if I may. There were some clinical trials, one in Canada and one in New York state, which were actually not very positive on Orkambi. But we heard evidence from families about significant additional effects, and it seems that the clinical overview here was on the side of the families. That may not be quite the right way to put it, but it recognised clinically the benefits to the families we were talking about.

I would never want decisions made on the basis of anecdote; they absolutely should be done on proven evidence, but I am wondering whether there is an issue between families and a small group of children with a severe, intractable epilepsy experience, and where some of the clinical trials are. I speak as a non-clinician, asking you as a clinician to advise me as a politician on that. These are two different areas, but I see



shades of the same argument on both issues.

Professor Whitty: Thank you. That is a very helpful comparison, because Orkambi is, in a sense, the exact opposite problem. With Orkambi, the situation is that there is good clinical evidence, although these are not perfect drugs.

Andrew Selous: I am sorry to interrupt you, but some trials—the Canadian and the New York ones—said that it had terribly low efficacy on increased lung function, and were quite down on it.

Professor Whitty: For people new to this debate, Orkambi is a drug used in cystic fibrosis, which is clearly a terrible disease and where, again, people are desperate about their children's health, or their own health, and reasonably so.

The drug is not perfect, and I think that some of the clinical evidence was, in a sense, trying to temper some of the overstatement that had reached into the system that the drug was completely transformational; but it is a good drug. That was a situation where for the clinicians, to go back to my stages of barriers, there was clear evidence that for a number of people with cystic fibrosis, although not for everybody, Orkambi would be a very useful drug.

The problem in that case is that the drug company has pitched the price at such an extraordinary level that, for the next level down, we have to ask whether it is cost-effective compared with other uses for the money in the NHS. The view of NICE has been really clear that, on that pricing, it was not. If the price were to come down in that situation, the clinical judgment would be that it is not for everybody, but it would be an important drug to add to the drugs we currently have available for people who have very serious medical problems. It is a very good example of the opposite situation: the clinicians are worried in that situation not on clinical grounds but, overall, for the health service on financial grounds.

In these situations, it is primarily in the first instance that we do not have the clinical data on safety against benefit. Once we have that, we will need to take a judgment on cost-effectiveness in the same way, against all the other drugs. That is what NICE is set up to do.

Q252 **Chair:** To follow up on that point, you made a very clear case for not having exceptionalism for cannabis, and that it has to follow the same processes if we are to make sure that we do not end up with a disaster down the line, because we have not researched it properly. But what are we going to do, Minister, if we see a situation where, having had agreement for trials to go ahead, manufacturers simply refuse to supply the product? For example, we have heard from the British Paediatric Neurology Association that it has not been able to secure agreement from Tilray to provide a product for a trial that it proposes to conduct. Is there anything you are able to do in that situation? If we cannot build the evidence base, we are in difficulties.



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Baroness Blackwood: That is a completely unacceptable response from a cannabis company. We obviously need to develop the clinical evidence, and I cannot for the life of me understand why a cannabis company would not want to develop the evidence base in order for its drug to be more prescribed and for there to be more confidence in it. That seems completely perverse, and I do not understand it at all.

Q253 **Chair:** Is there anything you are able to do to step in?

Baroness Blackwood: I will take that away and talk to the Department to see what action could be taken.

Q254 **Chair:** It is extraordinary that it would not co-operate with making its product available so that we can actually answer the questions. That has become one of the very significant barriers, just as we sweep some out of the way. It seems extraordinary, and I wondered whether there was anything you were going to do to take that forward.

Baroness Blackwood: I will take that specific point away. In the course of the inquiry, I wonder whether looking at the amounts that individual cannabis companies have spent on R&D in this year would be a worthwhile line of inquiry, because in comparison with market cap it is distressingly low.

Q255 **Chair:** Thank you very much. Are there any points that any of you want to make?

Professor Whitty: If this Committee can make it clear to the industry that in the UK we take evidence very seriously, and if you cannot provide the evidence you are very unlikely to have your drug prescribed, it would be a very powerful signal.

Chair: Thank you. Thank you all for coming this afternoon.