HOUSE OF COMMONS

Health and Social Care Committee

Oral evidence: IMMDS Review: follow up one-off session, HC 689

Tuesday 13 December 2022

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Watch the meeting

Members present: Steve Brine (Chair); Lucy Allan; Mrs Paulette Hamilton; Dr Caroline Johnson; Rachael Maskell; James Morris.

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Witnesses

I: Emma Murphy, founder, Independent Foetal Anti-Convulsant Trust (In-FACT); Janet Williams, founder, Independent Foetal Anti-Convulsant Trust (In-FACT); and Kath Sansom, head of campaign group, Sling the Mesh.

II: Baroness Julia Cumberlege, Chair, Independent Medicines and Medical Devices Safety Review; Professor Sir Cyril Chantler, Deputy Chair of the Review Panel, Independent Medicines and Medical Devices Safety Review; and Simon Whale, Review Member and Communications Lead, Independent Medicines and Medical Devices Safety Review.

III: Maria Caulfield MP, Minister for Mental Health and Women's Health Strategy, Department of Health and Social Care; Dame June Raine, Chief Executive, MHRA; Dr Aidan Fowler, National Director of Patient Safety in England and a Deputy Chief Medical Officer, Department of Health and Social Care; William Vineall, Director of NHS Quality, Safety and Investigations, Department of Health and Social Care; and Celia Ingham-Clark, Medical Director for Professional Leadership and Medical Workforce, NHS England.

Examination of witnesses

Witnesses: Emma Murphy, Janet Williams and Kath Sansom.

Chair: Good morning. This is the Health and Social Care Committee. This morning we are talking about the independent medicines and medical devices safety review. It was announced in February 2018 and asked to focus on how the health system responds when patients and their families raise concerns about the safety of treatments. In our second panel today, we will be hearing from Baroness Cumberlege, who was asked to chair the review. We will be talking about that and the Government's update on it, which was helpfully—he leaves a pause—published late last night.

We have three panels this morning. Before we begin today's session, I want to put on record that we were originally intending to hear evidence on Primodos hormone pregnancy tests. However, due to ongoing court proceedings on that matter we are not going to be able to discuss them today. It is known as sub judice here in the House. The Committee may return to that when matters relating to it are not covered by the House of Commons sub judice resolution. We are sorry if people were expecting to hear about that, but we are prevented by legal proceedings.

I am very happy to say that our first panel are in their seats. We have Emma Murphy, founder of the Independent Foetal Anti-Convulsant Trust—In-FACT—and from the same we have Janet Williams, a co-founder of In-FACT. We also have Kath Sansom, who is the head of the campaign group Sling the Mesh.

Thanks so much for coming; you are very welcome to the Select Committee. We have a few interests to declare. A couple of my colleagues wish to put some things on the record, starting with James Morris.

James Morris: For the record, I was recently a Minister in the Department of Health for a short period. Issues related to this matter were within my portfolio, including decisions about the publication of the interim report.

Dr Johnson: I was also briefly in the Department of Health with some aspects of this within my portfolio.

Q1 **Chair:** Thank you. Let's start with you, Emma and Janet. Would you tell us about your experiences of sodium valproate and how it has impacted on you, your family and your lives?

Emma Murphy: I was diagnosed with epilepsy aged 12. I was started on sodium valproate and pretty much just left on it, to be honest. When it came to starting a family, my husband and I questioned at every appointment whether valproate would harm during pregnancy. We were never warned at all. I was always told that it is the safest medicine to take during pregnancy to control the seizures.

I now obviously have five children affected, and they are all diagnosed with foetal valproate spectrum disorder, along with autism. Other diagnoses include cerebral palsy, hypermobility, scoliosis, deformed feet and valgus foot. My daughter, Lauren, was born with a hole in her heart, curved toes, speech and language delay, social interaction problems and sensory processing disorder. It is a long list of diagnoses. I am just one person affected; there are approximately 20,000 babies in the UK. It is a national disaster.

Q2 **Chair:** It has massively affected your life and those of your children. What has it done to your mental health, your physical health and of course the mental health of those around you?

Emma Murphy: It is devastating. To know that a medication that you are prescribed is deemed safe by health professionals and to later find out that it is the cause of your children's disabilities and to watch them struggle every day is devastating as a parent. It is not just on the mother; we speak on behalf of the fathers as well because it hugely impacts the family.

Q3 **Chair:** And the grandparents and the wider family.

Emma Murphy: Everybody involved. There is no support for these children. That is with us here, as parents. What will happen when we are not here?

Q4 **Chair:** Janet, tell us about your experience.

Janet Williams: I started with epilepsy when I was 17 and put straight on to valproate. The epilepsy was caused by scarring on the brain and hippocampal sclerosis which had been caused by febrile convulsions as a baby. I was on 1,200 mg of Epilim when I got pregnant with my first child. I have two sons, both affected and both diagnosed.

The seizures are ongoing. They have always been ongoing. We have tried different medications—about eight in total—and different add-on medications. I was taken off valproate round about 1995 and tried different things but the seizures are still ongoing.

As far as the children are concerned, my first son was born with withdrawal. Obviously, we had no idea what was going on at that time. Within 12 hours of him being born he was very sleepy, very floppy, very shaky and would not take his feed. He was taken down to the prem unit, where he was weaned off sodium valproate. Obviously, you panic—where is my child going and what's happening—and my husband was not there at the time. It was blind panic when he came back, so you can imagine the emotional rollercoaster.

Philip was born 16 months later and very much went through the same. They were both in the prem unit for a good seven days until they got everything sorted out and we were allowed to take them home. From that point onwards is when the problems started. We realised that neither

of them was doing the usual milestones. They were not reaching for toys. Smiling came very late. Walking was very late, and speech was the same. Sitting, anything with developmental milestones, was very late. They were very behind.

They are very different, so you cannot say that one is worse than the other. Lee has scoliosis. He was diagnosed with valproate syndrome at birth, but we were not informed about that. We were given a letter to take to the GP. The GP looked at it, put it in the notes and never said a word. Obviously, he'd had the diagnosis from birth. He was diagnosed with Asperger's and ADD at the age of 10. We had to fight for that diagnosis. He had always had educational problems. He had scoliosis, curved toes and problems with balance. He had problems understanding the circumstances and consequences of his actions. He had memory difficulties and difficulties with speech and language early on.

When Philip was born, it was totally different. He had withdrawal, but not as bad as Lee. Again, he was in there for seven days before they let him home. His milestones were not quite as bad as Lee's, but we have found that he has deteriorated and got worse as he has got older. They are both in their 30s now, but Philip is a lot worse than Lee in many respects.

He struggles with routine. He struggles with finding his way round if he goes out. Somebody always has to be with him. He panics at appointments at the dentist or doctor—blind panic. He finds it really hard to cope with any sort of change. As with Emma's children, the list goes on. Again, he has physical problems—feet problems—and problems with his balance. The list just goes on. You cannot really touch on everything; we do not have the time to talk about everything.

Q5 **Chair:** No; it is a perfect context. Obviously, your Philip and Lee know what you do, and I am sure that they know you are here today. What visibility do they have? What is their view on this whole situation? Are they the next generation of campaigners on this?

Janet Williams: I'd like to think so, but I do not think they would be able to do that. I really do not. This is terrible, because I know they are going to be watching this morning, but I do not think the mental capacity would be there to do that.

Q6 **Chair:** But they are obviously aware of the impact.

Janet Williams: They are aware.

Q7 **Chair:** Presumably they are aggrieved at that.

Janet Williams: We sit down and have family meetings. We talk them through everything, because if we did not talk them through everything panic would set in. They are aware that we are here today. They are aware of the campaign and what is going on.

Q8 **Chair:** I am sure they are very proud of your campaign.

Emma Murphy: With them watching this—we are aware that our children will see this—we want to state that, despite all the children and adults affected by this, they are amazing people.

Q9 **Chair:** Everyone is unique. Thank you.

Emma Murphy: Absolutely.

Q10 **Chair:** Kath, do you want to tell us about your experiences of surgical mesh?

Kath Sansom: I do, but first of all I would like to formally log that I understand Marie Lyon and Primodos cannot be here. I want to express my huge disappointment for her and on behalf of all the Primodos families that they cannot be represented today.

This is my story. I am a mum of two. They are now 20 and 25. When I was in my mid-40s, I started suffering mild stress incontinence; as a result of childbirth, one in three women suffers incontinence. A lot may get it instantly, but it may get worse as you approach menopause.

I went to my GP, and he directed me to the hospital consultant. Hindsight is a wonderful thing. What should have happened was that I should have been sent to physiotherapy. It has been proved that 80% of women can have things eased or fixed through good-quality physiotherapy. I am delighted that NHS England will be improving their pelvic health physiotherapy service for women from March 2024 because I, like many women in my campaign group, had a mesh implant when I did not even need one. It is outrageous that thousands of women have had their lives irreversibly harmed and damaged by a treatment that was aggressively marketed but which they did not even need in the first place.

My story was that I went for surgery. I was never warned of any of the risks. Nine out of 10 in our group were not warned of any risks with mesh. I had no idea it was polypropylene plastic. I had no idea it was permanent. I assumed it was a bit like a contraceptive coil, so that if I did not get on with it I could have it removed, as had happened with Mirena. I did not get on with Mirena and I had that removed. I had no worries about the simple day-case, gold-standard, minimally invasive surgery that I went for.

I went in super fit. I used to high-board dive—yes really—off the top boards. I used to box and mountain bike. I was super fit, and that was half the reason why I suffered from stress incontinence. I was so active. I went in super fit and came out in enormous amounts of pain. At first, I just assumed it was the surgery, but as the days went on the pain got worse in my back, hips and groin. It was like a scraping and scratching pain internally. It felt like I had been battered with a baseball bat down my legs. It was horrific.

I was a single parent and self-employed at that time as a journalist in our local newspaper. I just had to keep going to work. After a couple of

weeks things were getting worse. At that stage I decided to google my mesh, which was called a TVT. It is the type of incontinence mesh that Baroness Cumberlege suspended four and a half years ago. I googled that, and I was horrified to find that it had been suspended in Scotland a year earlier. I had not been told about any of that. I did a little bit more googling and found a blog from another woman, whose story was exactly the same as mine. Literally, within two weeks, I decided to set up Sling the Mesh with 20 women. Nearly eight years later, I have 10,000 members and it is the largest global mesh support group.

There are key things that come up time and time again. We were not warned of the risks. When we go back to our implanting surgeon, we are belittled and gaslighted. We have our symptoms downplayed. In my situation, he tried to blame it on a bad back, which was not the case at all. The second thing is that there is no long-term logging. In fact, there was no logging at all. When I went back to my surgeon he said to me, "So you are here today with problems, but did it work?" I said, "Well, yes, it did work. It fixed the incontinence." He went, "Oh, tick, yes, that is a success."

All that we had was from BSUG—British Society of Urogynaecology—which was something called the pad test. That is as simple as it sounds. If you do not need a Tena pad any more, you are considered a success. I have women in my group in wheelchairs with a disabled Blue Badge. One in four needs a stick to walk. Seven in 10 have lost their sex lives. I have people who are getting antibiotic resistant, but on the databases they are listed as a success because their operation worked.

So many things continue to shock me as I run this campaign. There is the lack of evidence, the no long-term logging or follow-up as well as the initial approval of medical devices. Mesh is approved on something called equivalence, which meant it was approved on the basis that it was similar to hernia mesh. It is absolutely completely different from hernia mesh when you are implanting in a woman's vagina or pelvic cavity. There is no follow-up and no market surveillance.

It is the same, I am sure, with your community, Emma and Janet. When you are advocating on behalf of people who are so harmed and damaged, it is completely heartbreaking to feel that our voices have not been properly listened to and to see shattered lives. Today it is really important to know that we make change. I do not want my children or grandchildren to go through what I have been through.

Chair: That is useful, Kath. Thank you, all three, for setting out the context for those watching.

Q11 **Mrs Hamilton:** Good morning and thank you. Listening to what you have been saying has been really moving. I would like to ask a question directed to Janet and Emma. How would you describe what the Government are currently doing in terms of support and follow-up with mothers like yourselves and with the children? What have you

experienced re the adverse effects of sodium valproate, including monitoring of its transgenerational effects and how it is being passed on? Emma, would you like to start, and then Janet can follow up with anything that you have missed? Would that be okay?

Emma Murphy: To be honest, the response from the Government, even though in the last few years they have been sympathetic, was to have a review. It found such failings that have been caused by the regulators and the Government, when they knew at licensing in 1973 that this medication would harm babies, and they purposely concealed that risk. To have a review that should be centred around the harmed people—children, babies and now adults—publish the response and give no support for these children is truly horrific. It is just continuing the disaster. The regulators were aware of the risk, and they did nothing to prevent it.

In the archive evidence, we found documents showing that they knew in 2001 and watched it. How can you watch children being born with autism? That is horrific. That is where this disaster is continuing. They are not getting a grip on it.

Janet Williams: We are fully aware from archive documents from 1973 and 1974 that they were aware this was likely to happen, through the datasheets that were produced. One of the archive documents that we have from 1973 states that they were to tell doctors but not put it on packaging inserts, so that the patients themselves would not see it.

It is terrible the way this whole topic has been dealt with over the years. Like Emma said, there are documents from 2001 where they just watched it. It was not until our campaign came along in 2013 that we were able to get things in motion. Even then, and we have been doing this for 10 years now, I am sure that things could have been done much quicker than they have been. During our time on the campaign, going from the figures released through the review, there could be as many as 2,000 children who have been harmed over the past 10 years. Knowing what they knew, that could surely have been avoided.

Q12 **Mrs Hamilton:** You made an excellent point when you said you were taken off sodium valproate in 1995. Were you taken off because they recognised the risk?

Janet Williams: No. I was taken off because it was not working for me, with the actual adverse effects that I was suffering. The dosage kept going up but the seizures kept happening. I eventually got to 2,000 mg and I was still having seizures. I was losing my hair. I was very tired.

Q13 **Mrs Hamilton:** It had nothing to do with the fact that you were of child-bearing age—

Janet Williams: Nothing to do with that at all, no.

Q14 **Mrs Hamilton:** —and they saw the adverse effects.

Janet Williams: No, nothing to do with that at all.

Q15 **Rachael Maskell:** Thank you so much for your powerful testimonies today. I am going to ask you all what question you would like us to put to the Minister, but first I want to drill down on the issue of data. One of the things I have picked up from what you have been saying today is that we do not know exactly how records are kept. What is your experience of the way records have been used, and the way data has been used, to monitor what is happening around either the prescription of surgical techniques or medication?

Janet Williams: As far as prescriptions are concerned, that is something that has only come about obviously since the campaign, working with the MHRA. When we started this in 2013, like I said, after finding the archive documents, we had meetings with the Minister for Life Sciences and the Health Secretary at the time. Round about that point there were about 37,000 women who were on a prescription for valproate. As figures stand now, we believe there are still 20,000 women on the drug.

The pregnancy prevention programme really has not got going. It has been there since 2018, and there are still women coming to us saying that they have not been called in, or that they have had an appointment but the doctor has not brought up the topic. There are ladies out there who do not have an epilepsy review or a bipolar review, so the information is not getting through.

Q16 **Rachael Maskell:** That is a very powerful image. Do you have anything to add?

Emma Murphy: No.

Q17 **Rachael Maskell:** Kath?

Kath Sansom: Oh gosh, where do I start? I will start with a recommendation in the "First Do No Harm" report, which calls for a retrospective audit of mesh from 2010. That still has not happened. It is an ask. We desperately need that, because at the moment we have no idea how many women are suffering from mesh complications. We literally have no clue. That is how poor the data is. At least with that retrospective order we will gain an idea of how women are faring 12 years on.

The key thing with mesh is that it is a bit of a ticking time bomb. In many ways I feel lucky that my complications were instant, because it was very clear to see that they were caused by mesh surgery. We have some women coming to the page and they might be fine for two years, five years or eight years. We even have someone 15 years after her mesh sling for incontinence was implanted. It sliced through her urethra. That is after 15 years. That woman has since had an organ removed. She has a stoma bag. She has been in hospital six times in the last 18 months for sepsis because she has had so many infections that she is becoming resistant to antibiotics. The kicker to that story is that she has just had

her PIP turned down. She had PIP, but she has had it taken away from her because she is not ill enough. We need that retrospective audit.

We need a registry for high-risk medical devices. We need a registry that tracks a patient for their lifetime, with maybe a barcode tracker—just something, so that we can log that patient and their device for their lifetime. I believe there is a hip registry. We need something similar, certainly for mesh but for all class III medical devices.

While I am on class III, mesh was class IIa, but I believe that under the European regulations it is going to become class III. Since we have left Europe, I am not sure if it is now class III. That is something that needs checking. It absolutely needs to be. If you have something permanently implanted in your body, that is high risk, and it needs tracking for life.

Q18 **Chair:** We will pick that up with the MHRA in the next panel.

Kath Sansom: Please do. Another thing to pick up with the MHRA is that there is no mandatory logging of adverse events of anything by doctors. That is not just mesh—it is anything, be it medication, a medical device or a vaccine. It is not mandatory for a healthcare professional to log it. We know from checking data that two thirds of mesh complications were not logged for that reason. The MHRA was able to keep saying that mesh was a low-risk, satisfactory treatment option simply because the adverse events were not logged.

The irony is that it is mandatory for industry to log complications of mesh, but how is Johnson & Johnson going to know about my friend Mrs Smith down the road, who is in a hideous amount of pain from her mesh implant, be it prolapse or incontinence mesh? They are not going to know. There needs to be mandatory logging. There is probably a mesh going on now, but we do not know because those adverse events are not being logged.

Finally, the other issue is that primary care data obviously does not feed into HES data. If a woman goes to the doctor, the doctor may never have heard of mesh. This is so standard in the campaign; they do not know what on earth it is, so they are not then feeding into any data at all that it is a mesh-related complication. Again, we have a whole load of women floating around in the primary care setting with no one quite understanding what their problems are. In the case of data, it is not being reflected in the data in any way at all.

Q19 **Rachael Maskell:** Thank you. That was really powerful. What question would each of you like us to put to the Minister, when we meet her later?

Janet Williams: There are quite a few, actually. If we are talking about the Health Minister or the Health Secretary, we have already had meetings with Maria Caulfield. We would like to know, even with what came out yesterday, how women are going to be warned about the dangers of valproate. We understand the changes that are going to be made. However, it is making sure that those women actually receive

those instructions and are taken off the medication. Should that be the choice? At the moment that is not happening. We need a system to make sure that that is definitely going to happen and that no one is going to fall through that net.

Q20 **Chair:** That would be your top question.

Emma Murphy: I would like to bring in the topic of redress or compensation. They are talking about NHS Resolution and that valproate should go down that avenue. However, this is not an NHS trust problem. It was caused by poor regulation, and it has continued for 50 years. We have tried the route of clinical negligence against the NHS, and that has failed. Even to suggest that to parents is an insult, and it continues the insult to our families to keep suggesting that and to keep knocking our families back. This is 50 years of harm.

Janet Williams: In the 1990s, there were about 90 families who went through clinical negligence against the NHS, which failed. That took 10 years. In 2005 those families were put through product liability against the drug company because they were led to believe that it was the drug company's fault. That took five years, and the funding was withdrawn because they said they had less than a 50% chance of winning. That was 15 years of their lives and their children's lives wasted, fighting for the cause and fighting for the things that they should have been getting, and there was the pain and anxiety those families went through. We have been through a review, and now they want to push families back down to NHS Resolution, which we know is not going to work because it is not an NHS problem.

Janet Williams: And the Government know that as well. That is very important.

Q21 **Chair:** Finally, Kath, what is at the top of your Santa list for the Minister? What is your question?

Kath Sansom: There are so many, but I think it is important that I add something about financial redress. You heard me talk earlier about the PIP fails, and women not being able to get PIP or losing their PIP because they are told they are not ill enough. The medical negligence is an absolute nightmare. Some women fall out of the three-year timeframe. We have medical experts who are cherry-picking evidence to say that their problems are nothing to do with mesh. In Northern Ireland there isn't even no win, no fee, so women cannot take their cases to court.

Again, as with your families, how outrageous that these women—innocent victims who have been harmed—are being told to go through the stress of a court case. It is too much. We are people who innocently trusted our doctor. Women have lost their jobs, relationships and pensions. They have travel costs, healthcare costs and they need automatic cars because they are in so much pain that they cannot use gears and things. They need physio. They need practical things like

stairlifts and mobility scooters. It is unfair to expect these women to get no financial redress, and it is certainly unfair to expect them to go through the court system.

Chair: It is on our list. We will add the PIP thing. Lucy wants to ask something finally.

Q22 **Lucy Allan:** You have all been incredibly brave and I am in awe of what you have been doing. We have heard how women's voices have been ignored and that you have been belittled and minimised. Why do you think it is that women's voices have been treated in this way?

Kath Sansom: Because of misogyny in medicine. Can I add at this point the specialist mesh removal centres? They engaged with three women, and two of those did not have mesh implants. That is absolutely outrageous. Why do they not want to listen to the patient voice? Baroness Cumberlege made it very clear that women and their experiences should be put at the heart of this report. All we have seen is tokenistic patient engagement. It just continues the hurt and the pain that women have gone through. It is the misogyny in healthcare. We are not taken seriously.

Q23 **Lucy Allan:** Do you agree?

Janet Williams: I would probably agree with Kath. As an epilepsy patient—my two children are in their 30s, so we are going back quite a long while now—I found they thought, "Oh, she's got epilepsy. She's not going to understand. There's no point in trying to explain because she will not be able to take it all in." Even when I got the diagnosis of epilepsy, I was not told face to face. My parents were called in and they were told. I was sat outside waiting. That is how things have been.

In certain circumstances, I do not think that has changed very much over the years with some doctors, obviously not with all of them. You still tend to get a little bit of that.

Emma Murphy: The issue with valproate is that it is too big a scandal. It is too big. There are too many affected children and adults. To be told by parliamentarians that we are bored, hysterical housewives when all we have wanted to do is warn women of the risk—something the regulator has never done—is scandalous.

Q24 **Chair:** Emma Murphy, Janet Williams and Kath Sansom, thank you very much for making the effort to come down to see us.

Janet Williams: Before we go, Chair, if you don't mind, we had something sent to us by a parent two days ago. They gave a small statement. Would you mind if I read it out for her?

Q25 **Chair:** Yes, but we are slightly tight for time.

Janet Williams: She said: "My son was stillborn at 22 weeks due to spina bifida. My 32-year-old daughter has had open-heart surgery, cleft

palate surgery, et cetera, plus has developmental delay. I was taking Epilim (valproate) and despite asking on several occasions, I was never told of the damage it could cause. After requesting my medical records, I found that they stated foetal valproate to be the likely cause.

"You did know. Despite consultants many, many times, and attempting to get my daughter the support and the help that she needed, you all continued to lie and hide the truth. Unforgiveable treatment and hidden lies, which in turn never prevented the harm and the damage to thousands of other children. Just tell me why you never told me, and what gave you the right to prevent me from keeping my baby safe? No more excuses or blaming others. Please do the right thing now."

Chair: You have put it on the record beautifully. Kath, Janet and Emma, thank you for making the time to talk to us. That concludes panel one.

Examination of witnesses

Witnesses: Baroness Cumberlege, Professor Sir Cyril Chantler and Simon Whale.

Q26 **Chair:** With seamless efficiency we move to the next panel. In panel two we have Baroness Julia Cumberlege, chair of the independent medicines and medical devices safety review and a former Health Minister, a much respected peer. Professor Sir Cyril Chantler is the deputy chair of the review panel led by Baroness Cumberlege. Simon Whale is a review member and communications lead of the independent medicines and medical devices safety review. Thank you very much for joining us. I hope that Simon can hear us okay.

Simon Whale: I can, Chair, yes.

Q27 **Chair:** Excellent news. I hope you are not too snowed in where you are. You look warm and cosy. Thank you for joining us.

Baroness Cumberlege, it is nice to see you again. Thank you for your work. First up, I want to ask you, after five months, when the update from the Government, which was due in July, landed at 6 pm last night before a 10 am sitting this morning of a Committee of the House of Commons, what was your view?

Baroness Cumberlege: My view was that this is a disgrace. One of the things I want to say, certainly about the Department, is that I think they can be very diligent and very, very thorough, but they are very, very slow. All this lastminute.com is just not good enough in running our country and running our health service.

Q28 **Chair:** You have made that point very clearly.

Baroness Cumberlege: Thank you.

Q29 **Chair:** You can probably guess our view, and we shall be picking it up with the Minister in the next panel. Looking back, as you now can, where are you most happy and where are you most disappointed in the work

that you did, Baroness Cumberlege?

Baroness Cumberlege: It is very interesting that, when we look back to our key recommendations, there were only nine. There were 50 other items for improvement, but that is really up to the health system to put into operation. We were very anxious that our nine strategic recommendations should be implemented.

Q30 **Chair:** You deliberately kept it at nine because you wanted to stay focused and keep it strategic. Correct?

Baroness Cumberlege: Absolutely, and when you have Sir Cyril Chantler with you there is no chance at all to veer away from what is important. He will be saying something about that, possibly, a bit later.

What we have done is to look very carefully at the recommendations that we put. I am talking about the nine. Three have been agreed to, and we are pleased with that. Four are still under review and two have been rejected. When we look at that, it shows that actually some progress has been made, but it has been very slow and not nearly enough has been done because there are still four recommendations to be looked at and they are under review. Two have been rejected.

Q31 **Chair:** What do you put that down to? Is it the slowness again? Is it the change of Administrations? Is it cock-up or conspiracy? Is there a lack of will?

Baroness Cumberlege: Sometimes we see that there is a lack of will. I pay tribute to Maria Caulfield, who I have to say is also my MP so I know her very well indeed. She really does care about all this. I think the problem is that the Department is completely bound by process. They think process is critical, and in some cases of course it is and you have to get it right. People have to understand what you, as part of the Government, are doing and why you are doing it, but it can slow things down.

I will take just one example, which is the patient safety commissioner. We called for that. It has taken so long for Henrietta Hughes, the new commissioner, to be appointed and to get under way. From our review in 2020, she took up her post this year in September. It is a very good appointment. I have no criticism of the process because the Department made sure it was done properly, but I think that lives could have been saved and we could have made huge progress if it had been done in, say, a year as opposed to at least two years.

Chair: We are going to come to the patient safety commissioner in a bit more detail with my colleague Lucy Allan in a short while. Thank you for those opening remarks. I will pass over to my colleague Paulette Hamilton.

Q32 **Mrs Hamilton:** We are going to come to that question now. I believe the creation of the patient safety commissioner was absolutely vital. The

recommendation was to bring together a disjointed system, as you have just highlighted. You have highlighted that it took too long, but do you believe that the role has been successful? Do you think that the remit of the role is correct? Do you think it is being resourced correctly? The patient safety commissioner and having the name there is not enough without the proper resourcing. I will ask that question of Mr Whale and Baroness Cumberlege.

Baroness Cumberlege: Simon, I will come in and then you can come in after me. It is very hard to see whether it has been successful. It is interesting though that we, in England, are the first in the country and possibly the first in the world to make such an appointment because we are so anxious to ensure that safety is put at the heart of everything that the NHS, and indeed Parliament, does.

It is hard to tell whether it is successful because Henrietta has only been in post since September, but she is already recruiting her team. What I have said to Henrietta is that I want her to be independent. I do not want her to be the creature of any part of the healthcare system. The Department are supporting her, which is good, but I am very anxious that they do not put their arms totally around her and that she becomes a creature of the Department.

She is there for patients, to listen to patients and be a voice for them. That must be her key role. Already I am really impressed with what she is doing, going around the country and telling people on platforms, but also individually, and answering letters; 25% of her workload is answering letters at the moment. It is quite hard to assess whether it is successful, but I honestly think it is a very good appointment. I have been impressed by her work so far and the way that she is keeping in touch with as many people as she can.

Q33 **Mrs Hamilton:** Do you agree that the remit she has been given is appropriate?

Baroness Cumberlege: I do. On resource, it is quite hard when you set up a whole new system or organisation to decide what the budget should be. She was given a minimal budget to start with. It is a set-up budget, ensuring that she has an organisation that is fit for purpose. For the future, I know that the Department are looking at her resources because at the moment it is too tight. She needs to employ researchers. She needs to study the data and should be working not only with the healthcare system but with patients and all the rest of it. She needs a really good budget that is sustainable and that will be, as I say, fit for purpose. Simon, you know more about this.

Simon Whale: I would not go that far, Julia. Mrs Hamilton, you asked about the remit. We recommended that the remit should cover medicines and medical devices, at least initially. That is a significant area of healthcare. As Baroness Cumberlege said, this is a role that is starting from scratch, from a blank sheet of paper. It would have been too much

for the patient safety commissioner to take on all other aspects of healthcare. However, in due course when the patient safety commissioner is properly established and is running with good momentum, it is for the Department, for Government and perhaps for Parliament to consider whether to broaden the remit to include other aspects of healthcare. Our focus, of course, was medicines and medical devices. That is why we recommended that the patient safety commissioner focus on that.

On the question of resources, I agree with Baroness Cumberlege. It is not possible for the patient safety commissioner to do the most effective job—she needs to do the most effective job—if she is not given adequate resources with which to do it. It is not just about the amount of money. It is about the type of people she can employ, and the speed with which she can access resources. That is absolutely crucial. She needs quick access to resources to make a difference quickly.

Q34 **Mrs Hamilton:** I will push you slightly. Do you believe that side of things—the people resource—is in place? Do you think it is coming into place, or do you think that is questionable at the moment?

Baroness Cumberlege: At the moment, she is recruiting. She has only four members of staff, and that is to cover everything. That is not sustainable. She has to recruit more people with expertise, and they are quite hard to find. I mentioned data, which Cyril knows a lot more about than I do. We need somebody who can analyse things that are happening. She also needs to take a much broader view and see what is happening in the totality of the healthcare system. I am talking not just about the Department; I am talking about all of healthcare.

Q35 **Mrs Hamilton:** The only reason I ask—then I will hand straight back to the Chair—is that four people in this area does not seem to be enough. If she has the resources to recruit more, all well and good, but if she is going to be limited to three or four people, it is giving lip service to what you recommended and what needs to be achieved. If she will be given the resources to have more people and to do this role, all well and good. I just want to make it clear. Are the resources enough that she can do the best job she can?

Baroness Cumberlege: No, not now. It obviously has to grow. It has to be a sustainable, expert organisation that is working with patients, working with the healthcare system and working with the regulators. You know the system. It is huge. It is also the private sector and so on. It is an enormous task.

It is very interesting that Scotland has just invited me to look at what they are going to do with a patient safety commissioner. I think we are on a roll. I honestly think that in the future other countries will say, "This is a very good idea and it is something we ought to follow," as Scotland is doing.

Q36 **Lucy Allan:** Minister Caulfield recently said in the House that the redress

scheme would fall under the remit of Henrietta. Could you comment on whether that is capable of being done within that Department, given what you have just said about resources. I will start with you, Baroness. I add that I have tremendous respect for Minister Caulfield as well. I am glad that you put that on the record.

Baroness Cumberlege: Maria is doing a very good job, and I am very pleased.

Redress is absolutely critical. We must acknowledge the harm that has been done and help people—as you heard in your first session—whose lives have been turned upside down, with decisions being made by patients not knowing any of the information that it was necessary for them to know. We have a duty as a nation to recognise that and to help those people with minimal resources that would make all the difference to the quality of their lives.

Q37 **Lucy Allan:** Will the patient safety commissioner be able to review the redress system, in your view?

Baroness Cumberlege: Of course. I hope she will review everything because she is full of ideas, energy and enthusiasm. I think that will be really important and will come through: "I'm sorry, Julia, you've got that bit wrong." Fair enough.

Q38 **Lucy Allan:** Would anyone else like to comment on the review that Minister Caulfield announced, that the safety commissioner would look at a review of redress?

Simon Whale: It is encouraging that the Minister has asked Henrietta Hughes to look at redress. As Baroness Cumberlege has just said, as a society we owe those who have suffered through no fault of their own support and help. As you heard in the previous witness session, people have been fighting for that and struggling without that help and support for years and years. The damage that has happened is lifelong. It is not going to get any better.

Henrietta Hughes has an opportunity. I am sure that all of us would be willing to help her to come up with a redress scheme arrangement that would deliver help and support, and deliver it quickly, to the people who really deserve it.

Q39 **James Morris:** I have a quick question on redress. One of the things that the Government have announced as an update was something on NHS Resolution, which was meant to give a pathway for people to put in claims, and so on. What do you think of that, Simon?

Simon Whale: We saw that announcement. The problem, as mentioned by Janet, Emma and Kath, is that that is all predicated on a clinical negligence approach. What we are talking about is something different; it is an approach based on redress rather than fighting for compensation. It is based on a no-blame approach rather than a blame approach. Clinical

negligence, effectively, requires someone to be blamed and the system closes ranks when that happens, perhaps understandably so. A redress scheme is not about assigning blame. It is about saying, "There has been avoidable harm. People deserve help and they should be given help irrespective of the assignment of blame."

A redress scheme does not mean that individuals who wish to cannot litigate. It would not prevent them from doing so, but it would ensure that they get help and support for their unmet needs. It is quite a different thing from the gateway that has been announced through NHS Resolution. That is still based on a clinical negligence approach.

Q40 **Rachael Maskell:** Thank you for all your work on the report. Earlier, we were hearing about the inadequacies of data. We have heard about the lack of counsel that is given at the start of a treatment pathway. Are you confident that the existing protections that are in place could prevent similar harms starting again, particularly as you are looking at strategic objectives from your report? Perhaps I could come to you, Sir Cyril.

Professor Sir Cyril Chantler: Thank you; that is very kind. Being able to measure the outcomes of a treatment, both in the short and the long term, is important when you are going to judge both the quality and the safety of it. As Kath said earlier, we could not do this with plastic mesh used to treat stress urinary incontinence because there is no outcomes register. This is in spite of its being recommended by the National Institute for Clinical Excellence in 2002, when the treatment was first introduced. NHS England reinforced that recommendation in 2012 and in 2017, and it did not happen. Almost three years to the day, we went to see the Secretary of State for Health and said, "Would you please mandate such a register?", and he did. It still has not happened. That is the present position.

There is a register in place for a completely different purpose, so it can be done. The National Joint Registry works, and achieves 100% compliance, which is essential for a decent register. Patients give their consent for it at the time of surgery. Something could be done along those lines. NHS England is using that model to create a devices register. It has achieved 15% compliance now and reckons that it will get to 80% three years from now. We do not think that is anywhere near ambitious enough. We would like to see success achieved in months—actually, by next April, I think.

There is an irony. The NHS in the United Kingdom is the healthcare system in the world that can do this stuff because of the way it is organised and the fact that we have an NHS number. The potential is huge, not just for safety and to benefit patients—the primary aim; it would also be beneficial to the pharmaceutical and the device industry. My urging to them is just get on with it, please.

Our next recommendation, if you want me to go on to it, is about interest, but I will leave that for the moment.

Chair: Rachael, do you want to explore further on data with Professor Chantler?

Q41 **Rachael Maskell:** The key thing is how data is maintained, not just for the immediate review of a patient's pathway but in the medium and long term as well. We certainly heard evidence this morning of why that is so crucial. What steps need to be put in place to achieve that?

Professor Sir Cyril Chantler: I think all interventions need to be registered in this way. We are particularly concerned about devices. That was our remit. There need to be registers for other outcomes. I used to be a children's kidney doctor. We established such a register for children with transplants 50 years ago, and it is still in existence today. It really works to find out what has happened.

There are other systems we could go into, from the hospital episode statistics and the OPCS data, which we could do much better with, with support from the profession. It is coming but that is another question. It comes up in the Paterson review.

Baroness Cumberlege: I clearly am not a medic, but I grew up in a medical family. It seems to me that when an operation is booked there needs to be an immediate follow-up, if possible by the surgeon who is doing it. We need to know who the patient is and, as Sir Cyril said, we have the number. We need to know who the surgeon is. We need to know the hospital and we need to know the device that is being used. We have known none of that in the past. If you have a trail like that, it could be very simply introduced and scanned for safety. Some of you may know the system that is happening in some hospitals; they are working to that and they are not bowled over by the administration. They can actually implement it. That would do a lot for safety.

Q42 **Chair:** It could be introduced, but, in my experience of NHS IT and data, I am not sure that it could be very simply introduced. Baroness or Professor, we are looking at digital transformation as one of our threads of work at the moment. We will be talking early in January about the NHS app, which has great potential and has some road map as to where it wants to get on the different channels of its journey. Professor Chantler, should that be a part of the journey that the Baroness was just talking about?

Professor Sir Cyril Chantler: It is perfectly possible to do, because we know the National Joint Registry does it and patients give consent to the operation. I have a device in me, and I readily consented for it to be followed up. I do not think it is difficult to do. There is the breast implant registry as well. We can do all of this stuff. We just need to get on and do it.

There is a bigger question, though, about the hospital episode statistic data, which is anonymous. If we had that, Kath would not have to ask for a retrospective audit. It does not need to be anonymous if the patient consents. That is a bigger question and is more difficult, but it is actually

a crucial recommendation of the Paterson review. I am sure you will be dealing with that too.

Chair: I am sure we will. Thank you for your succinct answers. Baroness Cumberlege, Professor Chantler and Simon Whale, thank you for your time and happy Christmas.

Baroness Cumberlege: Can I thank you? Parliamentarians have made such a difference to the implementation of our report. When I see all the debates, the questions you are asking and all the rest of it, it is brilliant. We had a very good one on sodium valproate last week on Tuesday. I want to thank the parliamentarians. I include Members of the House of Lords as well as the Commons because my colleagues have been fantastic.

Chair: I agree completely. There is a lot of expertise in the House of Lords. Let's hope everyone remembers that in the future. Thank you very much for your time this morning.

Examination of witnesses

Witnesses: Maria Caulfield MP, Dame June Raine, Dr Fowler, William Vineall and Celia Ingham-Clark.

Q43 **Chair:** This is our third and final panel. We have half an hour left of the session. We have in front of us Maria Caulfield MP, the Minister for Health and Women's Health Strategy at the Department. Welcome, Maria. It is your first time before the new Committee, so thank you very much for coming. We have Dame June Raine, the chief executive of the MHRA. It is very nice to see you again. We have Dr Aidan Fowler, national director of patient safety in England and a deputy chief medical officer. William Vineall is director of NHS quality, safety and investigations at the Department of Health and Social Care. It is very nice to see you again, William. Virtually is Celia Ingham-Clark, who is the medical director for professional leadership and medical workforce at NHS England. Thank you all very much for being here. Some of you have heard all of the evidence that we have had so far. Minister, you have heard some of the last evidence with Baroness Cumberlege and colleagues.

Minister, it is five months late now that the update was due. It was published at 6 pm last night before a 10 am Committee sitting. I asked Baroness Cumberlege about it and her exact words were that she thought this was a disgrace. She went on to say what a good job she thinks you are doing and how proud she is of the work you are doing as her constituency MP, as well as being the Health Minister.

There is much good, but I want to ask you how we are in the position where, at 6 pm the night before a 10 am sitting, something that important lands with us. We have not had a chance to consume it as well as we would like, and our advisers have not had a chance to consume it as much as we would like. How does that happen?

Maria Caulfield: The bulk of the work was ready a few weeks ago, but there is ongoing work on sodium valproate. We wanted to give the Committee an up-to-date position. Work on that will be changing over the next few weeks as well. The Committee may come back and say, "How come some of this was not in the report?"

This is not just an annual report and job done. It is a live piece of work, whether we are looking at mesh, sodium valproate or some of the other recommendations in the report. We wanted to make sure that it was as up to date as possible. Even in the last few days you will have seen the "Dear Colleague" letter that was issued last night. There is a lot of work happening in this space. Apologies if it has come as late as that, because it was signed off last week. We will continue to update the Committee on it, because there will be further updates in the next few weeks and months that I am sure you will want to hear about as well.

Q44 **Chair:** Could you take back from us that if something is signed off last week, knowing that you are coming before us today, we would not be having this exchange if it was sent to us last week? I understand the challenges of sign-off from the Department of Health and through No. 10, and so on.

Maria Caulfield: There were last-minute changes as well because there is work happening in this space. Obviously, I have been a member of a number of Select Committees and it is very frustrating if you get things very late.

Q45 **Chair:** It is not about us trying to catch you out. It is just about us trying to do our job and ask you questions that are the most up to date and informed as possible. When it lands so late, it is very hard to do that.

Before I hand over to my colleague James Morris, could I ask you this, Maria? My son's school report will come out later this week. I am sure he is looking forward to it. It will have a green, an amber and a red for how he is doing in each subject. Where on the traffic light are you right now on these recommendations?

Maria Caulfield: We accepted most of the recommendations. We have made progress on all of those that we accepted. I would say that we are on amber. We had an Adjournment debate last week on sodium valproate. There is clearly work to do there. We have made great progress on mesh centres, setting up nine centres that are in place that are seeing and helping women right now. I hear from women myself that they are not as accessible as they want them to be and that the experience is not as good as they would like it. Clearly, there is work to do there.

We have appointed the patient safety commissioner. Henrietta Hughes has been doing amazing work from day one. When I talk to patient groups, they are very happy with her as well. We have made some really good progress on some of the key recommendations. This first anniversary report is not saying that it is job done and we have solved all

the issues. I would say that we are at amber: good progress but still work to do.

Q46 **Chair:** There were nine recommendations. In Baroness Cumberlege's words, three were accepted, four partially and two not. It is a generous amber, I would suggest.

Maria Caulfield: In 12 months, we have appointed the patient safety commissioner, got nine mesh centres up and running, and made progress on sodium valproate in terms of reducing the number of pregnancies. There are still too many, in my view, and that is why we are working with the MHRA to make that as low as possible, but in a short space of time that is a significant amount of progress to have made.

Q47 **Chair:** I met the patient safety commissioner last week and I know you also met her last week. She is enjoying that relationship with you. She said she wanted to meet regularly. We actually hold her to account, but you want to work with her.

Finally, on the yearly update—I know it was due in summer—will the next one be in July 2023 or in December 2023?

Maria Caulfield: What we want to do is make regular updates. Rather than waiting 12 months to look at problems that are still outstanding or that need improving, some of the work we are doing is looking at the mesh centres and auditing the experience of women going through that system. Part of the women's health strategy told us that women are often not heard when they raise complaints and issues. Rather than waiting 12 months and women saying that either they are still waiting for surgery, or they are not happy with the experience, we want to be on top of that. There is some real proactive work and we will be able to report back on that on a regular basis before July next year.

Chair: Great. That is really encouraging.

Q48 **James Morris:** Recommendation 8 of the review was about improving transparency of the register of interests, effectively, and pharmaceutical companies' payments to the healthcare system generally. How are we getting on with that?

Maria Caulfield: We are setting up the registry. William will probably be able to give the up-to-date scale of that. That is something we want to introduce and I think that is right and proper. Patients will have more confidence if they know—the same as with MPs—the interests and background that you have had. I was listening to Baroness Cumberlege as I came in. I think the pace is not where we want it to be, but it is absolutely something that we want to deliver on. William will be able to give you the latest on that.

William Vineall: We have had a working group this year, which has included patient groups and professional regulators. It has been decided to do the pilots locally, rather than hold them centrally, because that is

more accessible for patients. We are due to announce where the pilots will be.

Q49 **James Morris:** When you say that pilots will be held locally, what do you mean?

William Vineall: That we will pilot them in some trusts. We are going to hold the registers locally via trusts, rather than centrally via the GMC. That was one of the upshots of the working group.

Q50 **James Morris:** Why do we have to have a pilot? Why can't we just get on with it?

William Vineall: Because we need to make sure that it works effectively before we take it out across the country. I think that piloting is reasonable, accepting the fact that we need to move quickly.

Q51 **James Morris:** What is the programme for pilot evaluation?

William Vineall: We expect the pilots to run during 2023 and then to bring forward results after that.

Q52 **James Morris:** In 2024?

William Vineall: Or possibly at the end of 2023.

Q53 **James Morris:** The second thing was about pharmaceutical companies. There are provisions and powers in the Health and Social Care Act that would enable that. What is the latest on that?

William Vineall: The latest on that is that we have not yet decided what to do, but we are prepared to regulate in this space. We want to make sure that any action that may be taken is proportionate in the impact on life sciences and the production of drugs and drug products. June, do you want to add anything to that?

Dame June Raine: I have nothing to add at this moment, although we have clear policies—

Q54 **James Morris:** When are you going to decide what we want to do?

William Vineall: We have not put a timescale on that decision yet.

Q55 **James Morris:** Why not?

William Vineall: Because we have not yet decided. I assume that it will be some time next year as well.

Q56 **Chair:** Could we get on and decide? Baroness Cumberlege was very complimentary about you in many ways. She said that there are many good things in the Department—many of us in this room know that—but it is incredibly slow. There are a lot of you in there. What is the problem? "We have not decided yet." Are these decisions that you are getting from the Secretary of State's office or from No. 10? How can we help?

William Vineall: No. It is that there is work still to do to decide the way forward and we have not made any decisions yet. I cannot say anything other than that, but I take your point about moving on at pace.

Q57 **Lucy Allan:** Minister Caulfield, I would like to say at the outset that I am absolutely delighted that it is you sitting in that chair. I am very grateful to you for the work that you are doing. This morning we have heard some devastating testimony from victims. Where exactly are we on redress for those victims?

Maria Caulfield: Are you talking specifically about sodium valproate?

Q58 **Lucy Allan:** I am talking about the victims we heard from this morning—about sodium valproate redress, but anything else that is covered by the patient safety commissioner and the work that will be done with you by Henrietta. Can we have an update on redress, please?

Maria Caulfield: I met the In-FACT campaigners when I was a Minister previously and when I was not a Minister. I have heard their powerful case. There is no doubt that the children born to parents who were taking sodium valproate often have lifelong changes that need support.

When I was a Minister previously, the issues around redress and the decisions around the report had been made before I was a Minister. The feeling at that time was that the money that would be spent on that would be better spent on improving patient safety. I have now heard the testimony and the stories, and I am very sympathetic to them. That is why earlier in the year we set up a gateway scheme with NHS Resolution.

When I talk to the campaigners, they do not feel that that is enough, although we are yet to see the data about women who have gone down that route. It is not necessarily a compensation route, and it is not a blame system. In a number of areas, including maternity, NHS Resolution often sees patients and relatives where an instance occurred. It does not necessarily apportion blame, but it will help them through the compensation system and give them advice and guidance. They do not often go to court, as NHS Resolution can get them funding without doing that.

Whether it is for mesh or for sodium valproate, the gateway system is a way of enabling people to access NHS Resolution to help them through that process. Even so, I am sympathetic to the position those women are in. Obviously, it is mainly women. That is why I met Henrietta Hughes fairly soon after she was appointed. It is one of her priority areas. She feels that a redress scheme would be appropriate. Bearing in mind that that is her view, I have asked her to work out what a redress scheme would look like. I cannot give any commitments about whether we will be able to roll out what she proposes, but I am willing to look at it because I hear loudly from both mesh and sodium valproate—

Q59 **Lucy Allan:** To clarify, you have turned down the recommendation for an independent redress agency. Is that correct?

Maria Caulfield: That was the position of the Government when they responded to the report. What I am saying is that I am willing to look at the idea. That is why only last week I asked the patient safety commissioner to look at it. It may take her a bit of time to work that up, but she is very sympathetic.

Q60 **Lucy Allan:** What are the options? During the Adjournment debate in the House last week, you responded positively to this question and said that you would be exploring the options for redress. Apart from NHS Resolution, what redress is there for the people we have heard from this morning and the people they represent?

Maria Caulfield: The patient safety commissioner will set out what the options are. I have also asked her to cost those options. She has met the campaigners herself, so she will be live to the sort of redress scheme they are looking for. She will present the options to me, and I will be happy to discuss them with her to see where we get, but it is important to look at it properly before we make any decisions.

Q61 **Lucy Allan:** Does she have adequate resource to do that, given that she has a four-man team?

Maria Caulfield: Yes. We talked about resources across patient safety. At the moment, she feels that she does, but she has chosen a couple of areas to look at in detail over her first few months. Valproate is one of those.

William Vineall: You do not need a redress agency to introduce redress. We run some redress schemes through NHS Resolution. Just the other week, we announced a redress scheme for the victims of David Fuller. There are options within the existing structures to introduce redress, if we wish.

Q62 **Lucy Allan:** And the Department is mindful of the fact that it must be prompt and timely, rather than a long drawn-out process.

William Vineall: The David Fuller one was done in 10 months.

Q63 **Lucy Allan:** That is quick.

William Vineall: I do not know whether this would be as quick, but you can do things relatively quickly.

Q64 **Chair:** Isn't it the case that NHS Resolution can provide compensation only where it has apportioned blame?

William Vineall: Yes, but if it is redress and you do not apportion blame, you can run a redress scheme. NHS Resolution has done that in a number of instances over the years, not very many, but a few.

Q65 **Chair:** If you have a redress scheme.

William Vineall: Yes, exactly. You can nestle that within NHS Resolution, if you wish to. That is the point I was trying to make.

Therefore, you would not need a new agency to make a redress scheme. It comes back slightly to your point about speed.

Q66 **Rachael Maskell:** We heard quite powerfully from our witnesses earlier today about clinical pathways and a way forward. I want to home in particularly on the Sling the Mesh campaign and the work that it has been doing. When it has been highlighted that 80% of successful treatment for stress incontinence can be achieved through non-invasive physiotherapy, why are we going for surgical procedures, which are clearly invasive and have carried such risk? If it is an issue of workforce, why isn't that workforce issue being addressed? Can I turn to Dr Fowler first?

Dr Fowler: I would probably refer to Celia Ingham-Clark on the mesh issue, because she is more of an expert on it.

Q67 **Rachael Maskell:** I am happy to reverse that.

Celia Ingham-Clark: I am happy to take that. It is important that women who have had problems in relation to things like stress urinary incontinence have the opportunity to talk to an expert about the pros and cons of treatment. Exactly the same situation obtains for women who had complications of mesh and need expert advice so that they can make a shared decision on what treatment they would like to have.

For some women, surgical treatment is appropriate, but for many women it is not. The option of physiotherapy is quite important. Indeed, a lesson is going to be introduced in the curriculum at key stages 4 and 5 in schools so that young women learn about the importance of physiotherapy when they have babies in order to reduce the risks of later urinary incontinence.

One of the particular strengths of the specialist mesh centres that have been set up is that they have a multidisciplinary team. Every woman who is referred there is discussed by a team that includes a physiotherapist, a nurse specialist, a psychologist, a pain management specialist and so on, so the opportunities to give women good choices that are effective for them are there. I regret that they were not always there in the past.

Q68 **Rachael Maskell:** I hope that there will also be a focus on ensuring that postpartum women have physiotherapy at that point, which always used to be the case—a very important juncture.

Dr Fowler: It may be helpful for me to add that in separate work, through the maternity workstream, there is a focus on pelvic floor physiotherapy. As a former pelvic floor surgeon, I am very keen on that.

Rachael Maskell: I am glad to hear that. I am a former physiotherapist, so I think that is really important.

Chair: A meeting of minds.

Q69 **Rachael Maskell:** I want to turn to the issue of women who have been

prescribed sodium valproate and the warnings that they have had, either at the time or subsequently. When we asked the witnesses today about the question they would put to the panel, they wanted to know how women are warned of the dangers of sodium valproate, as clearly that did not happen in the past, and how that will be taken forward in the future, if indeed it is on prescription.

Dr Fowler: There are a number of ways of doing that. We accept that in the past they were not given the warnings they should have been given. One of our responses to Baroness Cumberlege's report was to write to all women of childbearing age who have been prescribed valproate to reiterate those warnings.

We have been working on ways of sharing that information both with professionals, so that they make sure that they are clear about the risks, and in the world of prescription, which is quite difficult sometimes. Dame June Raine may wish to add to this. If you issue a prescription with a certain number of tablets on it, that is what has to be prescribed, understandably. If it is not the number of tablets in the box with the warnings on it, sometimes in the past they have been issued in plain packaging. We are working to address that, working around the fact that we need to make sure that prescriptions are issued as prescribed.

Dame June Raine: The regulatory requirements have resulted in a range of materials, from a patient card to an image on a pack, brochures and other materials, but it is absolutely true to say that those do not uniformly reach a woman with every dispensed prescription of valproate, which is what is intended. Her situation may change, so she needs those warnings every time. Therefore, as Aidan said, the idea is that at least one original pack should be provided so that the signs are there, the leaflet is there and the conversation should happen. That is currently on the way to becoming a statute.

Dr Fowler: We have also developed support tools for patients around prescription for epilepsy and bipolar. We are cognisant of your concern about delays. The issuing of those has been delayed because we knew that CHM advice was coming and we wanted to make sure that we did not issue something and then reissue it with the new advice from CHM. That is now being adapted in light of CHM's announcement and will be issued as soon as we have done the adaptation. We work with a specialist unit in Cambridge, the Winton Centre, which looks at the best way to put out information to make it accessible.

Q70 **Rachael Maskell:** That will be received by every single woman.

Dr Fowler: Yes.

Q71 **Chair:** I want to ask a couple of questions on mesh before I hand over to Dr Johnson. This is probably for you, Dame June. In the recent medical devices consultation, it was proposed that mesh be put into the highest risk class, class III. This is something that Kath Sansom raised with us

earlier. Can you confirm that this reclassification will happen?

Dame June Raine: Yes, I can.

Q72 **Chair:** That's very helpful. Thank you. I like those answers.

Celia Ingham-Clark, can I ask you about the specialist mesh centres you were talking to my colleague about? How many women were consulted when they were set up, and how many of them actually have mesh?

Celia Ingham-Clark: They were set up as part of the specialised commissioning by NHS England. It followed its normal procedure, which was to involve both patients and public representatives. I do not have a figure for how many of the women involved had mesh themselves.

Q73 **Chair:** Could you find that and write to us, please, via the Minister? That would be really helpful.

Celia Ingham-Clark: Yes.

Q74 **Dr Johnson:** I have a couple of questions, first about anticonvulsant usage. Some women who have epilepsy need anticonvulsants in pregnancy or while trying to conceive. What guarantees can you give women today who may be looking to conceive or be pregnant that they are being given the latest information about the anticonvulsants that they are using during pregnancy and their relative safety? What are you doing to monitor women who are receiving anticonvulsants during pregnancy so that you can identify potential problems earlier and that it does not take many years, as it has in this case?

Dame June Raine: After we issued the pregnancy prevention programme in 2018, we set up the valproate registry, which has been extended to all anti-epileptics precisely for the reason you are asking about—so that we can monitor switching and change.

The data that we have give some reassurance, as the Minister said, but we have much further to go. In a nutshell, the alternatives—levetiracetam and lamotrigine—are increasing in use in women of childbearing potential, to the extent that there has been an increase of about 30%. We are seeing switching, and there is some evidence from our registry that women come off before they are pregnant. These are good signs, but that does not take us away from the fact that, as the Commission on Human Medicines announced, much more needs to be done to ensure that no one is on valproate if there is an effective alternative for them.

Q75 **Dr Johnson:** If, as we heard from the first panel, someone is diagnosed with epilepsy when they are 12, they may well be given advice about pregnancy but it may not feel very relevant, particularly if they have not even started their periods yet, so that advice needs to be given repeatedly. We give other drugs that are pretty teratogenic, such as Roaccutane, to teenage women, in particular. Women receiving Roaccutane must have a pregnancy test each time they are prescribed it.

In some cases, they may not be sexually active, but they still have the test. It is a continual reminder to them that this drug is potentially dangerous, were they to get pregnant. How are you making sure that women who may become pregnant when taking valproate, or indeed any drug, are reminded of the dangers of that on a regular basis?

Dame June Raine: It is done by recognising exactly what you have just said. An annual review is required, with a specialist, and there is an annual risk acknowledgment form, which is really a framework for a discussion so that the woman or girl has a chance to talk about her situation and a judgment can be made jointly about whether valproate is still the right medicine. The CHM advice will be that there need to be two independent prescribers at least once in that journey for someone on valproate, to judge that there is no alternative. The annual review is really important.

The registry will be developed so that the ARAF, as it is called, is digitally enabled and enables the kind of communication that is lacking at the moment. You saw the pharmacy audit. We are very concerned that not every woman is getting an annual review and we will be reminding people of that repeatedly.

You are absolutely correct about other anti-epileptic drugs. We need to ensure that the pregnancy prevention proposals and advice are there. For example, we know that topiramate is under review. We are looking across the piece at all medicines, not just anti-epileptics, but any others that have a teratogenic or birth defect risk, so that we can have the best possible systems for today. Regulation over the years has made individual drug-based judgments. We now have a chance to look at what is the best way of doing this. In our delivery plan, we committed to undertaking this review. It is under way. It is a complex and quite challenging review, but it is very much under way now.

Q76 **Dr Johnson:** What about other medicines? I appreciate that epileptic women may need to take medicines, but there are other people, for example with Crohn's disease or forms of rheumatoid arthritis, who may need to take medication during pregnancy whose long-term effects on the baby may not be completely clear. What work are you doing to ensure that there is proper oversight of that, so that we do not end up here in 10 or 15 years' time looking at a different type of medication that is having similar effects?

Dame June Raine: The whole issue of understanding the benefits and risks of medicines in pregnancy is something the agency is very committed to, and it has a number of activities under way. This is because, since thalidomide, medicines have not been studied in pregnancy. There is often a gap—quite an important gap—in our knowledge, not just around safety but around dose and so forth. We have a number of activities under way to ensure that trials that appropriately gather that kind of information are done, so that evidence-based judgments can be made. We are looking to the revision of our clinical

trials legislation to start to push at that barrier to change, much as we did with the legislation for children's medicines.

Q77 **Dr Johnson:** Another question is about the transgenerational effects. Some research suggests that valproate taken during pregnancy may affect not just the child born of that pregnancy, but the grandchildren—the children of those who were born initially. What work is being done to support people who received valproate as a foetus but now want to conceive their own children?

Dame June Raine: At the moment, we are looking to strengthen and to find out more about the evidence. There are animal studies, and there are small, and potentially biased, studies that are done in clinical use, but we need a much better clinical evidence base to be able to give good advice. I come back to the Commission on Human Medicines advice, which is that no one should be receiving valproate unless there is no safe effective alternative.

Q78 **Dr Johnson:** We know that a population of people out there received valproate through their mother as a foetus. Do you know who those people are in sufficient detail to be able to review what is happening to their children and to offer them support, or do we just not have that information?

Dame June Raine: We do not have it at present, but we are encouraging and looking into further ways of doing research in this area. It should be possible to get some results and data in a reasonable timeframe. I believe that there are results coming through from European-commissioned studies. If it would be helpful to the Committee, we can write to you about that.

Q79 **Dr Johnson:** It would be helpful. My final two questions are about the register. We have talked about the register. When is it going to happen? The last panel said that it is happening too slowly. When do you expect it to be up and running?

William Vineall: Do you mean for valproate?

Dame June Raine: For valproate, it is up and running.

Q80 **Dr Johnson:** No. Let me change the question slightly. You are going to have a register of doctors' interests. William, you talked about that earlier. When will that register be up and running?

William Vineall: We will finish the pilots I was talking about by the end of 2023. We will have to make decisions about the overall register after that. I would hope to do it in the light of the pilots.

Q81 **Dr Johnson:** You talked about the GMC, which registers doctors but does not register other health professionals. Can you confirm that the register will not just have doctors on it but will also have nurse prescribers, nurse consultants and other managerial people who may have a significant influence on those staff?

William Vineall: I will have to take that away because it is probably a component of the pilots. Can I write to you on that?

Dr Johnson: Don't you think it is important? I am a doctor, as you are aware. I remember a battle going on between somebody who was not a doctor and a group of us, as doctors, about which particular medical device we should start using. Unfortunately, the doctors lost the battle on that.

Q82 **Chair:** You will be aware that Sharon Hodgson, who chairs the First Do No Harm all-party group, has called us—in fact, she wrote to us ahead of this session—on the subject that Dr Johnson was just raising, around a sunshine payments Act such as they have in the USA. In her report, Baroness Cumberlege presented evidence that medical professionals receiving payments from the medical industry was a factor in mesh and sodium valproate. The report recommended a statutory requirement, a sunshine Act, as Sharon Hodgson calls it. What do you think about that, Minister?

Maria Caulfield: I am not sure that we need legislation. There has been a look at whether the regulators for health professionals, the GMC or the NMC, should hold a register. That was felt not to be the best way to do it. It was felt that the register should be held at the individual trust where the person is practising.

I take Dr Johnson's point around whether we need to look at other healthcare professionals, because we are expanding prescribing. Pharmacists are looking at prescribing during their training now. Paramedics can prescribe. Nurses can prescribe. That may be something we need to look at, and not just from a medical point of view.

I take James Morris's point around the speed of this. We need to look at whether we can do it more quickly, but I do not think we need legislation to do it. If we have the sign-up from trusts, we should be able to hold registers that are publicly accessible and that we can make work effectively, but legislation is there if that is not happening in practice.

Q83 **Chair:** People do not work at one trust throughout their career. The point about a regulator-held register is that it sits as an umbrella, doesn't it? The point of a sunshine Act is that sunshine is the best disinfectant, as somebody used to say. We in this place are subject to huge amounts of sunshine and scrutiny, on every level. We had a debate on it in the House last night. From a patient confidence point of view, I think that this is something we should look at some more. I see nods from the Public Gallery.

Maria Caulfield: Yes. We absolutely want it to happen, but we want a system that will work and provide that sunshine and transparency with regard to interests. We need to bring the professions with us as well. That is why we are looking at trusts, so that patients can look on the trust website and find out about those interests.

Q84 **Chair:** I don't want to bore on about this for too long. I will bring in Paulette Hamilton to close. You talk about bringing the profession with us. At the end of the day, Baroness Cumberlege's report was very clear. The profession is the one that is receiving payments for these devices, so good luck bringing them with you. Sometimes this place has to assert itself, doesn't it? They are not going to want to come with you, are they?

Maria Caulfield: That is why we are bringing in the register, so that information will be clearly accessible for the public. It is about making sure that it is done in the way that is the easiest to access for patients. If you are going to a hospital trust for an operation, you are much more likely to go on to that website to find that information than to go through a regulator's information.

Q85 **Chair:** You take my earlier point about the NHS app. That really should be the front door for patients, shouldn't it? It is not accessible for patients at the moment, is it?

Maria Caulfield: The Secretary of State is doing a lot of work on the NHS app at the moment. If registers are established, they may be accessible on the NHS app in the future. We want to make it as easy as possible for patients to be able to find this information.

Q86 **Chair:** It is this simple. When your appointment appears on the app, surely there should be information related to that appointment—patient information and the registered interests of the surgeon who may be working with you. We will leave that with you. I ask Paulette Hamilton to close.

Q87 **Mrs Hamilton:** Why are the Government not looking at banning the use of sodium valproate and the mesh procedure when the Government know that they are causing harm and we have made clear that we should first do no harm? Can I ask Dame June Raine?

Dame June Raine: This is a question in relation to sodium valproate that we—

Q88 **Mrs Hamilton:** And the mesh. The mesh system has been causing problems since I was a nurse.

Dame June Raine: I will start with the valproate. With sodium valproate, we are assured by clinicians that there are some patients whose epilepsy is so serious that it cannot be managed by any other medicine. That is the reason that we are pursuing the present strategy of driving down prescribing and having much more rigorous scrutiny to ensure that valproate is used only in people who cannot be treated safely with any other medicine, but—

Q89 **Mrs Hamilton:** I am sorry to butt in, but time has gone. If women of pregnancy age are using valproate and are about to get pregnant, or are saying that they will get pregnant, is there no way that something can be done so that during that time—until, say, a year after they have had the baby—they do not have valproate, because it is so dangerous? The

effects have been talked about this morning.

Dame June Raine: Absolutely. Any woman who is thinking about becoming pregnant should not stop but should have the appropriate advice. We will revisit this as we gather more data on the effectiveness of the current measures. As the Minister said, no doubt there will be updates on how effective our new measures are, once the health service has established them in practice. Dr Fowler might like to come in on mesh.

Dr Fowler: I think Celia is about to cover that.

Celia Ingham-Clark: Steve Powis, the national medical director, put a national pause on the use of mesh for stress urinary incontinence and pelvic organ prolapse back in 2018. That pause is still in place at the moment. We did a thorough audit early last year and found that there was just one insertion of mesh for stress urinary incontinence during the year to April 2022, so it is being used in this context virtually not at all at the moment.

Chair: Minister Caulfield, it was nice to see you. Thank you very much for coming before us. Dame June Raine, Dr Aidan Fowler, William Vineall and Celia Ingham-Clark, thank you very much. That concludes our session today. Happy Christmas to all of our guests.