The Scottish Parliament
Pàrlamaid na h-Alba

Official Report

PUBLIC PETITIONS COMMITTEE

Tuesday 24 February 2015

Session 4

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PUBLIC PETITIONS COMMITTEE
5th Meeting 2015, Session 4

CONVENER

*John Pentland (Motherwell and Wishaw) (Lab)

DEPUTY CONVENER

*David Torrance (Kirkcaldy) (SNP)

COMMITTEE MEMBERS

*Jackson Carlaw (West Scotland) (Con)
*Kenny MacAskill (Edinburgh Eastern) (SNP)
*Angus MacDonald (Falkirk East) (SNP)
*Hanzala Malik (Glasgow) (Lab)
*John Wilson (Central Scotland) (Ind)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Neil Findlay (Lothian) (Lab)
Dr Neil McGuire (Medicines and Healthcare Products Regulatory Agency)
Sally Mounter (Medicines and Healthcare Products Regulatory Agency)
Adam M Slater (Mazie Slater Katz & Freeman)

CLERK TO THE COMMITTEE

Anne Peat

LOCATION

The Robert Burns Room (CR1)

Scottish Parliament

Public Petitions Committee

Tuesday 24 February 2015

[The Convener opened the meeting at 10:05]

Current Petition

Polypropylene Mesh Medical Devices (PE1517)

The Convener (John Pentland): Good morning. I ask everyone to switch off their mobile phones and any other electronic devices, as they may interfere with the sound system. No apologies have been received.

I welcome everyone to the meeting, for which there is just one agenda item. We will take further evidence as part of our consideration of PE1517, by Elaine Holmes and Olive McIlroy on behalf of Scottish mesh survivors, on mesh medical devices. Members have a note by the clerk.

Neil Findlay, who has an interest in the petition, is with us. I welcome him to the meeting.

I also welcome Dr Neil McGuire and Sally Mounter from the Medicines and Healthcare Products Regulatory Agency. I invite Dr McGuire to make a brief statement for around five minutes before we move to questions.

Dr Neil McGuire (Medicines and Healthcare Products Regulatory Agency): I thank the committee very much for the opportunity to come and speak to it.

Everybody in the MHRA recognises the serious complications that women have had as a result of surgical procedures and greatly sympathises with them.

I will briefly outline the MHRA's role. Our remit is to ensure that the medical device directives are followed by manufacturers. That is done through notified bodies that look after the medical device directives in relation to manufacturers on our behalf. We ensure that goods that are manufactured and brought to market have a CE mark, which shows that they have complied with the relevant medical device directives that are in place at any given time.

The directives are enshrined in European and United Kingdom law, and we have certain responsibilities under those directives as the competent authority. Most of our work is to ensure that the directives are adhered to by the relevant parties. Once the device is on the market, we monitor it through adverse incident reporting; reports from notified bodies; manufacturers reporting; engaging with professional bodies; listening to what patients say; and engaging with regulators around the world and other competent authorities. Basically, I am saying that patient safety is a team sport. There is a mixture of regulation and all the people who are part of the process.

People do not always understand that we have no influence over clinical decisions that are made between individual practitioners—surgeons, in this case—and their patients. We work with organisations such as the National Institute for Health and Care Excellence, NHS England, NHS Scotland and other devolved Administrations to ensure that we all work together for the purpose of patient safety.

The Convener: Thank you, Dr McGuire. Do you have anything to say, Ms Mounter?

Sally Mounter (Medicines and Healthcare Products Regulatory Agency): No.

The Convener: Okay. We will move to questions.

As Dr McGuire said, manufacturers are required to undertake post-market surveillance to ensure that their products are safe and fit for their intended purpose. How does the MHRA ensure that manufacturers undertake effective post-market scrutiny?

Dr McGuire: That is done through the notified bodies, which audit manufacturers to ensure that they undertake those processes. To take one step back, before a manufacturer can get a CE mark, it must provide evidence of its post-market surveillance plan, as required by the medical device directives. At any time, either through the notified bodies or directly, we can make those inquiries of manufacturers. It is part of the process that we continue to look at those feedback mechanisms.

The Convener: In your introduction, you talked about a "team sport" in relation to the notified bodies. Although the MHRA has responsibility for the notified bodies in the UK, a manufacturer can go to a notified body somewhere else in Europe. What assurance can you give the committee and others that, whenever an incident is brought to the coal face, it is fully investigated?

Dr McGuire: We work with all the competent authorities across Europe and with regulators worldwide. If we are talking just about Europe, we have a monthly vigilance teleconference with all the competent authorities. Mesh and tapes are a standing item on the agenda for that. In relation to other devices, we work together as competent authorities and we undertake joint inspections of notified bodies across the European Union as part

of the European Commission's drive to harmonise standards. We take part in other competent authorities' audits of notified bodies in their countries and they take part in audits in the UK. We were aware of potential weaknesses in the system, and we have found that collaborative inspection and auditing have strengthened the process.

The Convener: Are you saying that a notified body in the UK works under the same strict criteria as its EU counterparts?

Dr McGuire: Yes.

The Convener: All adverse incidents should first be sent to Health Facilities Scotland. What relationship does the MHRA have with Health Facilities Scotland in investigating such reports?

Dr McGuire: We have a very good working relationship. We have regular contact so that any reports that come to us go into reporting systems and are investigated as necessary. As part of the process, we do not just investigate; we look at trends in reporting. For example, somebody might get a report in a particular location and to them, it is an individual report and is not a very strong signal. However, if 10 people in similar locations report the same kind of incident, we can see that there is a trend and that something is out of the ordinary, so we would investigate further.

We have daily or weekly meetings at which we look at individual reports and trending, and then we have higher-level supervision of the trending. I do not know whether members know about the type of people who work in the MHRA, but we have scientists, engineers, doctors, researchers and statisticians. Each of those groups brings something different to the equation. However, the common group in all the interactions is the clinical team. Certain aspects of devices are purely to do with engineering, biochemistry or whatever, but the key to all this is, as I said at the beginning, patient safety. We have to interpret the information from a clinical perspective. In the MHRA, we have some expertise, but we do not have all the expertise—that is not possible. However, we do have access to healthcare professionals who have expertise in all the clinical areas where we require extra advice. The clinical team takes in all that information, looks at it and then says, "This is the balance here." When we investigate and take action, we have to be proportionate and work on the best scientific evidence that is available.

10:15

If we applied the strictest criteria to regulation, there would be no innovation and no products would come on to the market. Patients would not get early benefit from new devices and new technology—and technology is turning over so fast. There are 500,000 medical devices out there that we regulate, and something like 90,000 plus of them are highest-risk devices. That is why the systems that we have in place are about surveillance and about working with all the different groups.

For example, we will watch the trend of how a product that has recently come on to the market is performing. We might suddenly get a whole flurry of reports in, which might be due to a manufacturing fault or a bad batch going through the system. We can pick up that there is an issue and then we can investigate it.

In the not-too-distant past, we had such an incident. Suddenly, a whole group of reports about the failure of devices came into the agency from different sources. When we investigated, we asked the manufacturer what had changed and learned that it had moved its manufacturing facility from one country to another: it had a workforce that was not as highly trained as the previous workforce and the manufacturing tolerances had changed. We picked up those changes and went back to the manufacturer and said, "This is not good enough." We said that the issue needed to be fixed within a specific period of time.

That was all about the manufacturing process and, between the manufacturer, the notified body and the MHRA, we agreed that the manufacturing would be brought back into proper tolerances. The number of incidents dropped as the old stock diminished. As it was not practical to remove all the old stock, we warned clinicians that there was a potential problem. If they experienced that problem, they needed to report to us and to stop using that batch.

We needed to make sure that there was constancy of supply and that the corrective actions were taken. It is always a balancing act—that is where proportionality comes in. We cannot suddenly pull a whole load of devices off the market if there is a small problem because if we do that, there may be nothing to use instead. It is a highly complex area—there are so many interacting factors that we have to make judgments on. That is why we engage with the widest possible community to make the balance a reality.

John Wilson (Central Scotland) (Ind): The MHRA's report relies heavily on the York Health Economics Consortium report from 2012. The consortium reported that there was significant variance in complications as a result of mesh implants and that the rates of adverse incidents in Scotland or in the rest of the UK were unclear. What is the basis for the MHRA continuing to promote the benefits of the device, rather than the risks?

Dr McGuire: Something that is not well understood is that regulation—in its present form and probably into the future—is about judging risk. Benefit is where the shift into the clinical community occurs. It is a question of balance. We need to ask whether the device, in itself, is inherently safe because it complies with all the regulations. Then, when it is used, we need to ask whether it is being used in accordance with the manufacturer's instructions and in the way that it was intended to be used. There is a spectrum, with the device at one end of that spectrum and, at the other end, clinical practice and the application of the device in a clinical scenario.

As I said, we do not have any influence over what the clinician does on a day-to-day basis. That is a judgment for the clinician in conjunction with informed consent from the patient. However, that does not mean—I am weasel wording—to say that we are not involved in the process, because we are. That is why we are so heavily involved in the Scottish independent review, which is moving forward as we speak, and with the NHS England working group, which is achieving the same things. We understand that there is the device perspective and the clinical perspective, but that question involves the information that has been reviewed by NICE, which has produced quite clear guidance about the use of the devices on a number of occasions, backed up by Sir Bruce Keogh's letters of 2012 and 2013, which reinforce the advice that clinicians should use the devices in the appropriate way with the appropriate training and should audit their practice under the particular measures that are in the guidance because complication rates have previously been difficult to interpret.

More than 3.5 million devices have been sold across the world, including 170,000 in the UK, and there have been something like 130,000 operations in England—I do not have the figure for operations that have been carried out in Scotland. However, we are not seeing the level of complications that we would expect from the information that we have been given by various patient groups who tell us that hundreds and thousands of women have serious complications. The evidence from the literature, from the studies that have been conducted by NICE completely independently of the MHRA and from the reporting that we get does not put those serious complications into the same ballpark—we do not have that evidence at all, and such evidence is not available across the whole world. No competent authorities or regulators anywhere in the world have taken steps to withdraw the products.

I am aware that two small Australian companies have been pulled from the Australian therapeutic goods administration's register. However, although we have not had the opportunity to speak to the TGA—this happened only a couple of weeks ago—it looks to us as though the reason for that was technical issues with the documentation. There is nothing to say that it was done on the ground of patient safety, so there is no new information there. In fact, we have just seen the TGA's report from 2013, which was delivered to the NHS England working group, in which it goes through the same things, although it is slightly behind the timescales for our own production of evidence, and it does not make any recommendation or come to any firm conclusions about further action or direction.

The independent review in Scotland and the NHS England working group are looking to the future. It does not matter how low the rate of serious complications is; when somebody has a complication, the working group—I am now talking as a member of that group—wants that complication to be recognised and a treatment pathway to be in place for it. We do not want to see the number of adverse incident reports increasing. When there is a complication following a surgical procedure, we want it to be taken seriously and we want something to be done about it.

I hope that that answers your question.

John Wilson: Thank you for your response. I am sure that other committee members will have questions arising out of it. You have certainly raised a number of issues in my mind.

Neil Findlay (Lothian) (Lab): Convener, I have some information that might be of assistance to Mr Wilson in relation to the point that has just been made.

The Convener: I will let John Wilson finish his questioning first.

John Wilson: A number of issues have been raised in that response. For a start, does MHRA have any views on the use of mesh implants in stress urinary incontinence and pelvic organ prolapse procedures? You seem to be referring to the clinical use of the device rather than the device itself.

Dr McGuire: The devices have been through the relevant procedures to satisfy the regulations in all countries; we, as a regulator, have overseen that process. Once the process is complete, the devices are given the CE mark or, in the United States, the appropriate approvals for use. Under the strictest interpretation, you could say that we could now step back and not be involved any further, but that is not how we see our place in the situation. When we see signals of complications and issues, we want to be part of the process and ensure that people feed back to us as best they can so that we get as much information as we can and can move forward and act together.

As I have said, the signals from all the different sources are giving us virtually the same complication rates. It is definitely the case that complication rates for stress urinary incontinence surgery are lower than those for pelvic organ prolapse, but something that must be added to the mix is that pelvic organ prolapse itself is a very complex illness and has a natural history of deterioration if not treated. This is my understanding from clinicians, because I am not an obstetrician or a gynaecologist; the reality is that this is a question for them. That said, for certain aspects of the procedure, we are seeing not particularly high complication rates, but for problems with sexual function, the rate is up into the 15 per cent range. To put that into context, however, I point out that up to 70 per cent of patients with pelvic organ prolapse and urinary incontinence have problems with sexual function before they have surgery. [*Interruption*.] That is in the published literature. Following surgery, that improves. [*Interruption*.]

The Convener: I am sure that everybody agrees that there is a great interest in this issue, but we need to follow parliamentary procedure. I say to the people in the public gallery that we really need to hear the answers to the questions. You might not agree with them, but we really need to hear them.

Mr McGuire, would you like to continue?

Dr McGuire: I was saying that if we had a level of reporting that showed more complications than we are seeing, we would always be prepared to change our view. If we had thousands upon thousands of reports to say that this was an issue and that complication rates were not within limits deemed acceptable by the clinical community, we would change our stance, but we cannot act without information, and that information does not appear to be out there.

The other thing to say in this situation is that thousands and thousands of women who have had these procedures have benefited greatly. Stress urinary incontinence and pelvic organ prolapse are distressing and unpleasant conditions for which women seek treatment. That is aside from the point that, according to NHS England figures, something like 6 million people in the UK have some form of urinary incontinence. Not all of those people seek help—that would completely overwhelm the health service—but I say that to put these things in context, so that we do not go down the line of disadvantaging people who are going to be helped by having these sorts of procedures. Large numbers have already been helped.

10:30

Again, that is where proportionality comes into our considerations and actions, and that is why we have engaged so heavily with the clinical community. The Royal College of Obstetricians and Gynaecologists, the British Association of Urological Surgeons and the British Society of Urogynaecology all agree, and all of you will have seen their letters, expressing surprise at the stance that was taken in Scotland on the request to suspend these surgical procedures. We are working with them, NICE and patient groups to find a way forward in addressing the serious concerns of those who have been affected by serious complications. However, we are not in a position, with the information that we have, to take any further action.

The other criticism that has been made of us is that we have not issued alerts. We have not put out a medical device alert or made the manufacturers put out a field safety notice. That was considered in 2012, and it was decided that, because the matter was so much in the clinical domain, it was better to come from Sir Bruce Keogh and Professor Keith Willett, and then be reinforced later, again by Sir Bruce Keogh. That is why we have not put out alerts.

People have asked why we have not put out alerts now, given what the Food and Drug Administration has done. We work a different regulatory system to the FDA, and it puts out different information. For example, one of its most recent statements was that complications are “not rare”. We do not know what “not rare” means, and we cannot base regulation on that kind of statement. At least we are working to the numbers that are coming in from different places, not just from one single source and not just from adverse incidents, but from the clinical community and from scientific papers, some of which are based on randomised control trials. If you want to see that information, you can. I do not have it at my fingertips, but NICE looks at all of it before it produces its guidelines.

John Wilson: At what point would the MHRA recommend that the devices be classified as high risk or removed from the market? You referred to studies, reports and clinical reports, but what decision or reporting mechanism would give the MHRA the confidence either to classify the devices as high risk or to recommend that they be removed from the market?

Dr McGuire: Given that these devices are already in the medium to high-risk category, there is no benefit in reclassifying them in the UK or Europe. We have discussed the matter with our European partners; the devices are already subject to the appropriate scrutiny for their type. In the United States, the situation is different; its

classification system is different from ours and cannot be matched up. The United States has said that it is considering reclassification, but at this point it has not done anything about the matter or changed its stance.

We have been working with the United States—for example, we have been to the public meetings where these sorts of things are discussed—and, as I have said, its website does not show any change in its stance at this time. It has made no moves to withdraw, ban or otherwise restrict the devices; if it does, it will talk to us first, as it would with regard to all other devices that cross over. After all, a lot of devices are made in the United States. Others are manufactured here, but given that some of the notified bodies for CE marking in Europe are in this country, we have regulatory powers in that respect.

When would we act? It sounds like a feeble answer, but the reality is that it depends on the device, the seriousness of the complications, the reporting rate and whether the complication rate is outside that which would be reasonably expected for the type of procedure, given current knowledge. If the manufacturer and the clinical community decided that the complication rate was—to choose an arbitrary number—5 per cent and all of a sudden the rate went from 4.5 to 5 and then to 5.1 per cent, we would start thinking, as we have done with other devices, that we had exceeded what was reasonably expected in the circumstance, given all the other information about the particular procedure, the risks associated with it and the complication rates of other procedures. Added to that mix is the question whether another device or product with a lower complication rate could reasonably be substituted for the one concerned. That, too, could be taken into account.

As I have said, if you consider suddenly withdrawing a particular procedure or device, you also have to think about the considerable number of people who are still benefiting from them. The balance will come down to the individual discussion between the clinician and patient, and it is up to them to make a judgment, provided—and I can say this as a clinician—that the process of informed consent has been undertaken in an appropriate and clear way. When the risks are explained to some people, they will still take the chance of having the procedure, because their life is being affected so badly by their current symptoms. They are in a situation analogous to that of the first people who had hip replacements. If we had analysed the results of those first replacements and concluded that the procedure was far too risky, given that the components wear out, nobody would be having hip replacements now. However, we know that the technology improves consistently over time and that, because of the natural history of all types of hip replacement, those who have such a procedure at a younger age might be looking at a revision anyway in 10 to 15 years.

We can test something to destruction in a laboratory or engineering plant, but when it comes to implanting it into a biological organism, some of the dynamics change in a way that cannot be predicted. Post-market surveillance and vigilance are important in identifying such things.

The natural history—

The Convener: Dr McGuire, I appreciate your explanation, but we have a number of questions that we want to ask.

Dr McGuire: I am sorry.

The Convener: Angus MacDonald has a supplementary question.

Angus MacDonald (Falkirk East) (SNP): I want to clarify Dr McGuire's point about the level of complications. Are you saying that no mesh device out there has a complication rate of over 4.5 or 5 per cent?

Dr McGuire: No, that is not what I am saying.

Angus MacDonald: Okay. Can you clarify the point?

Dr McGuire: The published scientific and research papers show a range of figures for complications. There are different complication rates, because of the mixture of the time when the device is introduced, the experience of the surgeon and the surgical team and the device's development. It is well recognised across all medical practice that when any surgical procedure is introduced—it does not have to involve a device—there is a higher rate of complications. Over time, however, the learning curve flattens out, training programmes are put fully in place and guidance is issued.

I should go back a step and note that when we introduce a procedure, we have to bear in mind the potential complications, based on what has been seen before with the same type of surgery, procedure or device. Indeed, the manufacturers have the same thing in mind when a device is involved. The issue forms part of the complications list that goes into the instructions for using a device, and it is well known to the medical profession for training et cetera. However, there could be completely unforeseen complications, and they have to be picked up to ensure that adjustments can be made. For example, when meshes were first used, it was not known that the number of anchorage points was significant and that when you went over a certain number, the complication rate associated with that particular design of mesh also went up. There was no way that anybody could have predicted that, but now

that that is known, the anchorage points are considered in the design of the latest devices.

When the first pacemakers were introduced—I have no other way of describing things other than to use analogies—they were huge clunky things; the batteries needed changing frequently and the leads that went into the heart used to break. That was the risk that went with that new technology. Over time, things have improved, and we are thankful for the experience of the surgeons who were doing those procedures and for the fact that the manufacturers put money, effort and time into the matter. All medical devices have a similar track record.

The first of these devices came about when surgeons looked at the mesh that was being used for hernias and thought, "Let's try it in a different place." Bespoke meshes and bespoke tapes for urinary incontinence were produced, and there have been increasing improvements in those technologies. There is a balance to be struck in offering people surgery and medical technology that will improve their lives. People seek treatment, because their lives are upset by pain, urine incontinence, parts of their body coming out where they are not supposed to come out and, in this instance, sexual dysfunction. It is highly distressing and very unpleasant.

Hanzala Malik (Glasgow) (Lab): The MHRA report notes that there are

"a number of ongoing research projects that are likely to provide useful information about the long-term safety and effectiveness of vaginal mesh implants."

What is the scale of those projects and when are they likely to report?

The Convener: I ask you to answer briefly because we have a lot of questions.

Dr McGuire: The PROSPECT trials—the prolapse surgery: pragmatic evaluation and randomised controlled trials—are sponsored by the Department of Health and are due to report in 2016. A NICE report is being produced to look into hospital episode statistics. Some preliminary work has been done on that, but I do not know when it is due for completion. We can find out for the committee and let you know.

The scientific committee on emerging and newly identified health risks is looking at meshes generally and is supposed to report in quarter 1 this year. There is also the Scottish independent review, which is due to report in early summer, and the NHS England-led report, which is due some time in the next 12 months—

Sally Mounter: In spring.

Dr McGuire: Yes, but it has been moved a little bit, for the same reason that the Scottish independent review has been moved, which is that they realised that the amount and complexity of the information is so great that if they are going to do it properly, they might as well take the time to do so. We will be completely receptive to the findings of all those reports and take them on board.

The Convener: It would be extremely helpful if you would pass some of that information back to the committee.

Dr McGuire: Yes, of course.

Kenny MacAskill (Edinburgh Eastern) (SNP): You have given us an anecdotal description of issues relating to the manufacturing process. You referred to the TDA report, which says:

"the complication rate did not appear to differ between products, but factors such as the skill and training of the surgeon, selection of the patient and procedure were important."

To what extent are adverse incidents due to clinicians' actions and how does that influence your assessment of the device?

Dr McGuire: As an agency, we want every adverse incident to be reported to us because, to the person doing the reporting, it is not always apparent which end of the spectrum that incident is at. Our judgments are around whether the device has failed or has a problem that we were not aware of. We would then go to the experts who advise us and ask, "Is this a recognised complication of this type of procedure? What was the level of training?" We would pull all those things together. We would act as the honest broker in that situation to try to determine whether the device, in itself, was the problem, whether there was an interaction between the device and the surgical procedure in that particular circumstance, or whether it was a purely clinical issue. Until we view that spectrum, we cannot make a judgment.

10:45

We are happy to get all the reports and we are now working even more closely with the NHS and the national reporting and learning system so that all reports that go to NHS England from Scotland eventually—I understand that Scotland is looking at being part of that—will give us a much broader base of reporting of incidents. This number might be completely wrong, but I think that something like 1 million reports of adverse incidents come into the national reporting and learning system every year. Those data can be searched and we are now being given access to search it and make it into one database, with a single portal for reporting to make it easier for clinicians and other folks to use.

We have also streamlined reporting to the MHRA directly. The yellow card now covers drugs and devices. That is all moving forward.

There is also an initiative to produce a European database that will cover all Europe. That depends on the European Parliament and its decisions.

David Torrance (Kirkcaldy) (SNP): Evidence suggests that adverse incidents might be underreported. Why has there been underreporting and what is the MHRA's view of the petitioner's call for mandatory reporting by all clinicians?

Dr McGuire: We know that there is underreporting. We know that healthcare professionals have not been as good as they could be and, in our view, should be. That is why we have had to consider evidence from all different areas.

We discussed that at the Scottish independent review meeting yesterday and I had a think about it. We were talking slightly at cross-purposes. To me as a regulator, mandatory reporting is something that carries a regulatory sanction if you do not do it. That is not the same as the profession saying to the members of its organisation that they should report it as part of good medical practice and, if they do not, the organisation will ask questions about how fit the member is to practise and do these procedures and so on. That is a different thing altogether.

From experience, we know that, in a system with mandatory reporting, if there are sanctions for those who do it wrong and if there are sanctions that result from the report, reporting goes right down. People do not report to put their neck in a noose. Some of the most tightly regulated systems for reporting are in eastern Europe, where the level of reporting is among the lowest that there is anywhere.

We are working together towards a collaborative system, and part of the working group in England and the Scottish independent review is about engaging with all parties to improve reporting. It is about making sure that the positive incentive is that the culture is to report, that the discussion of the problem that has been exposed by the reporting is open and free and not subject to sanction and that, in doing that, we are all serving patient safety much more strongly.

The last bit of that is that people who report have to have feedback. If they do not get feedback, there is no incentive to report again. That is a loophole that we have never properly closed because it is such a big issue and it covers so many different devices. That is not just a problem for the MHRA; it is a problem for all regulators and we are looking hard at it. It will be solved only by everybody working together. As I said right at the start of today, this is a team sport. If we are not all working for the same thing and people do not understand why it is important to do these things, they are just not going to do them.

From a regulatory perspective, we do not think that mandatory reporting would work. This is going to sound a bit foolish, but we believe that mandatory voluntary reporting within a professional set of circumstances and with incentives to do that would produce results. It has certainly worked for orthopaedic surgeons, to the point where the national joint registry and the MHRA are working so closely that they are working beyond compliance and the level of reporting is above what is required for any regulations. The manufacturers have signed up to that and are part of the process. We sit around a table together with the clinicians and manufacturers and we now have results on joint replacements that have been done over the past 10 or 20 years. Manufacturers can then go out and say, "Look, we've got a 10-year tick. Our devices have a survival rate of up to 10 years." The incentive for them to be part of the process is that they can be shown to be responsible in what they are doing.

Angus MacDonald: The MHRA's October report concludes by proposing the following actions: improved reporting of incidents, which you just mentioned; structured post-market clinical follow-up; registries on the use of unique device identifiers; and patient-reported outcome measures. What progress has been made on taking those suggestions forward? What role does the MHRA envisage for the Scottish Government in that process?

Dr McGuire: All those things are really important, which is why we put them in the report. We are keen on the idea of registries; the difficulty for us is that we cannot have registries for all the medical devices that we look after because that would be completely impractical. We would require 10 times the number of people that we have.

Whoever set up a registry would need to engage with the people who wanted the information out of the registry. In the past, registries have been set up that have not provided the information that was required, and the process has become useless. If the right things are put in at the beginning, you will get the right information out at the end. As a regulator, we want the adverse incident reporting whereas the clinicians want the patient-recorded outcome measures, and that is also what the patients need. We need to have all those things together. From the Scottish Government perspective, any acknowledgement of the resources that would be required to produce those things would be good. Registries are expensive—they require staff and data input

individuals—and that is one of the impediments to good reporting.

Reporting in the clinical setting relies on the ability to have things such as multidisciplinary meetings and morbidity and mortality meetings, and those things need to be resourced in terms of time and people being able to attend them. I am not saying that as a regulator; those issues were brought up at the meeting in Glasgow yesterday by the clinicians. They want to increase their reporting and be more compliant, but they need more time—it needs to be in their job plan—and the resources to do those things. In my clinical practice, the average morbidity and mortality meeting takes up an hour a week.

Angus MacDonald: My question is how much time they need to get their act together on reporting.

Dr McGuire: You would have to ask the clinicians that.

Jackson Carlaw (West Scotland) (Con): Let me take you back to the University of York report of November 2012. We have quoted quite extensively from it this morning, and you quoted from it and relied on it in your November 2014 submission. When in 2012 was the report commissioned?

Dr McGuire: I cannot answer that question, but Sally Mounter can.

Sally Mounter: It was around January or February of 2012.

Jackson Carlaw: What budget did it have? What was the report's cost?

Sally Mounter: I have not got that information to hand. It was something like £40,000, I think.

Jackson Carlaw: How many people at the University of York were involved in its production?

Sally Mounter: I am not quite sure. We liaised with around three people, but they may well have had their own teams of people.

Jackson Carlaw: What call for evidence did the University of York issue in advance of its consideration of the issue?

Sally Mounter: The university put together a protocol—it was a literature review.

Jackson Carlaw: A literature review.

Dr McGuire: It was similar to the literature searches that NICE does. Evidence is taken in a particular way. If you look at the procedures that NICE goes through to get information, you will see that it starts with the highest evidence levels and then works down to case reports.

Jackson Carlaw: A report that was commissioned from three people, without any call for public evidence, and then seen by you in October 2012 and published in November 2012 at a cost of £40,000 is regarded as being—in the light of everything that has happened in the two years since, including the petition being lodged in May 2014 and there appearing to be sufficient grounds for the Cabinet Secretary for Health and Wellbeing to issue a call for a moratorium on the meshes being installed—sufficiently robust to allow you to continue to make the recommendation that you are making.

Dr McGuire: If you review the report that we have just produced, you will see that it draws on more information—

Jackson Carlaw: Such as?

Dr McGuire: —and does not just rely on the York report.

Jackson Carlaw: I have the report here. It says that the MHRA used data from adverse incident reporting, manufacturers' sales figures, patients—although I understood you to say that you thought that they were unreliable as an evidence base—representatives of clinicians, manufacturers and other regulators around the world. Are all those literature-based surveys? What further evidence was taken by the MHRA in its consideration of its recommendation? Was it just a bigger literature review?

Dr McGuire: No, it was not just a bigger literary review. We looked at manufacturers' reporting. Bear in mind that the manufacturers under the device regulations have to report only certain incidents that come under the heading of vigilance. We went back to the manufacturers to look at all the reports that they have received in those circumstances. That included matters that did not even get to the level of vigilance.

That is something that we do with clinical investigations, for example. We take all the signals that we see and put them into the equation, to see whether they have an additive value or benefit. We also engaged directly with the clinical community that was doing surgery for problems with meshes. We also discussed it with the senior people in those professional areas.

We also have soft signals, which we get from engaging people who are speaking at conferences and who are looking at things that do not get to be published, such as posters and presentations, and different people reviewing aspects of their research and the literature. It is about accumulated experience with the devices. Therefore, we also engaged authorities across the globe to see whether they had received any other information that would lead them to act in any different way. They did not. We realised that the

York report had limitations. Therefore, we went to those extensive efforts for the report that we produced for the chief medical officer for England.

Jackson Carlaw: This is where I am at a loss. You said that various organisations and parties expressed surprise when the previous health secretary, with all-party support in this Parliament, called for a moratorium in June last year. Do you believe that he was acting irresponsibly in making that call?

Dr McGuire: I think that that would probably be a question that I would not answer, because—

Jackson Carlaw: I take that to mean yes. [*Laughter*.]

Dr McGuire: No, no. I mean—

Jackson Carlaw: Some health boards have ignored the cabinet secretary's call for a moratorium and have used the MHRA report as the basis for ignoring that call. Are you comfortable with that?

11:00

Dr McGuire: I am comfortable with the fact that we have taken all the robust evidence that is available to us into account in coming to our judgment.

Jackson Carlaw: Where is caution in all this? One of the reports to which you have referred as being near to reporting back to us is not a £40,000 report but a £2 million report. On that basis, is there not a need for a degree of caution to suggest that the cabinet secretary's call for a moratorium was a perfectly sensible call to make until that much wider, more contemporary and seemingly better-researched and founded evidence is made available to us?

Dr McGuire: In our discussions with the former cabinet secretary and the subsequent inquiries that we made as to why he took the actions that he took, we asked whether there was any further evidence that we had not been made aware of that led to that decision, and we were told that there was none. On the basis of there being no further information, and given the information available to us and across the world, we were not in a position as a regulator to take action to do anything different from what we were already doing.

Jackson Carlaw: All right. I understand that. You have made analogies at various points today. I suppose that I could make the analogy of a contaminated food substance in a store being withdrawn across every store in the United Kingdom because the manufacturer does not think that the fact that only a handful of people might suffer because of it is an acceptable basis for its being available for sale elsewhere. I offer that analogy to you in contrast to your own.

I respect and appreciate the dispassionate way in which you have given evidence this morning, and I understand that that has to be the case, but my final question is this. In the light of everything that is happening just now, I would not recommend to a family member of my own that they have a mesh device implanted until further evidence is available. Would you recommend to a family member of yours that they have a mesh device implanted at this time? [*Interruption*.]

The Convener: Let us remember parliamentary protocol.

Jackson Carlaw: It is a serious question, because these are human beings.

Dr McGuire: I am sorry, but I was not answering—

Jackson Carlaw: I appreciate that you cannot answer questions from the gallery.

The Convener: Mr Jackson and Dr McGuire, please listen for a minute.

Dr McGuire: I am quite prepared to answer that question.

The Convener: Let me finish and then you can answer. Members of the public need to be aware of conduct in the Parliament. We may hear things that we like or things that we do not like, but please, let us listen to what is being said.

Jackson Carlaw: Dispassionate evidence has been given, but these are emotional issues. I simply want to ask Dr McGuire what he would recommend to his own family members at the present time.

Dr McGuire: I completely understand and I can answer as a husband and as a clinician. As a practising clinician, what I would say to my wife if she had incapacitating problems with incontinence or pelvic organ prolapse is, "You need to sit with the clinician who is going to do this procedure and decide what is best for you. I'll come and sit with you. I'm not going to say anything, but I will listen to what is being said on both sides. If I want to ask a question of the clinician, I will do that, but at the end of the day the judgment is about whether your quality of life is affected to the point at which you would be prepared to accept the risks of this particular procedure, which are known. If you accepted those risks, I would want to be 100 per cent assured that, if you had a complication, even if it was something that is not regularly reported, like pain, it would be treated seriously by the whole of the multidisciplinary team from the general practitioner through to the incontinence nurse, the physiotherapist and the surgeon, and that there would be mechanisms in place within

that health service to deal with those complications effectively."

On top of that, I would want to know that we had been offered all the alternatives, that the non-surgical alternatives had been properly funded and had been gone through, and that there had been a point at which the situation without surgery was intolerable. Those judgments should be made.

Jackson Carlaw: I will conclude with an observation. Your experience and background have qualified you to understand everything that you have just said would need to be asked of the clinicians and others who would perform this surgery. I can assure you that I have heard from many constituents who had none of the benefit of that advice or experience and who found themselves with a mesh implant that had consequences that were not drawn to their attention at any point in the process whatsoever.

Neil Findlay: Mr Carlaw makes some pertinent points.

I apologise for interrupting Mr Wilson earlier. The point that I was trying to make related to the Australian situation. A number of mesh items have been removed from the register of therapeutic goods because they do not adhere to the medical devices essential principles checklist. That is the fact of the matter, as you will see if you look at the website.

Dr McGuire: That is in effect administrative and is not about patient safety.

Neil Findlay: The essential principles are about issues such as the use of medical devices not compromising health and safety and about conforming with safety principles. I could go on and on, as there are umpteen principles. It is not a minor administrative error.

Dr McGuire: I did not say that it was a minor administrative error. I said that an administrative process can be about major or minor conformities with regulation.

Neil Findlay: You say that it "can" be about that.

Dr McGuire: It can, but the TGA says on its website that, if there is a question of patient safety, that comes under a separate heading, and that separate heading does not apply to any one of the products that have been removed from the register there. Without going into the issue further and questioning the TGA personally, that suggests to me that there is not an issue of patient safety with the devices, and that the removal is due to failure to comply with regulation.

Neil Findlay: You used the words "can" and "suggests". I think that we might need to get to the bottom of that.

Dr McGuire: We will speak to the TGA soon, and we would be happy to come back to the committee on that.

Neil Findlay: I was going to ask what discussions you have had with the TGA about the withdrawal of the products. Are any of those products being used in the UK?

Sally Mounter: As far as we know, they are not.

Dr McGuire: As far as we are aware, they are not. The seven major manufacturers of the products are well known to us. Before yesterday, I personally had never heard of the two manufacturers that are involved, which are based in Australia. Because we found out only yesterday from one of our researchers and subsequently at the meeting in Glasgow that the items have been removed, we are not even sure that those companies are the manufacturers. Under the regulations, a company becomes a manufacturer when it imports from somewhere else. Therefore, we do not even know where the products are being made, and that will be part of the inquiries that we make.

If the TGA was going to do a product withdrawal for patient safety reasons, it would have come to us directly before it took that action to let us know what it was going to do. We have no reason to believe that it would not have done that, because it has with all other things. The FDA and regulators across Europe also do that. Therefore, from our observations so far, we are pretty confident that the issue is not patient safety related, but we will definitely check, now that we have that information.

Neil Findlay: Given the problems that we have in Scotland and the UK with underreporting, can you take a guess, or has anybody taken a guess, as to how many problems there have been worldwide with these products?

Dr McGuire: We know from the literature and from our discussions with other competent authorities and regulators that the complication rates that we are seeing here are mirrored across the world.

Neil Findlay: How does that reflect the number of people who have submitted claims to courts? In Scotland, you suggest that we have had a small number of adverse incidents or problems. What is the number that you suggest?

Dr McGuire: From 2005 to February 2015, there have been 88 reports for stress urinary incontinence and 37 for prolapsed organs.

Neil Findlay: So we could almost suggest that that entire number of people are sitting behind you.

Dr McGuire: One of the things—

Neil Findlay: Wait while I make my point.

That seems inconceivable. We know that tens of thousands—indeed, probably hundreds of thousands—of litigation cases are sitting in courts in the US and Australia. Are those people making it up? Are they chancing their arm to try to get a few quid out of something, or is any assessment being made of whether those are legitimate cases of people having the same problems as the people who are in this room today?

Dr McGuire: What has given us the confidence to carry on with the same stance that we have taken is that, despite all those cases—I understand that only four or five in the States have actually happened—there have been different judgments. Again, that is not my area of expertise in any way, shape or form, but the judgments have been made not on the materials or the design; rather, they have been about how the products have been used and the instructions that the surgeon has had or has conveyed to the patients.

We need to understand more about that, but those individual cases have not led to any regulatory action in the United States. If the FDA were being inundated with reports of adverse incidents, all those things would appear on its manufacturer and user device experience—MAUDE—database, but there are just not the numbers. All the evidential information that we have from literature and from the reports that we have, even with underreporting, does not reflect hundreds of thousands of patients with problems. We find that difficult to reconcile.

Neil Findlay: Given that assumption that you are making and your earlier comments about pacemakers and the technology being crude at the beginning and advancing with time, you are saying that it is not the product that is the problem, in your opinion. That can only lead me to assume that you think that it is the clinical practice that is the problem. Is it your opinion that the product is not a problem, as you are continuing to allow it to be used, and that the only thing that can be causing the problem is poor clinical practice?

Dr McGuire: We have to be careful when we talk about ascribing the problem to any particular group or area. We have to bear in mind that we are dealing with people who have a serious and complex problem in the first place and on-going other illnesses that have an influence. We all get older. If a person smokes and is overweight, that adds to the surgeon's problems and the procedural likelihood of complications. We have to put all that into the mix; we cannot just make a blanket statement. Therefore, we would not have an opinion that the problem is any one part of the entire process, from the selection to the device being used to the procedure. Any part of the whole process has potential.

Neil Findlay: Okay. So it is not the product that is the problem and you are not prepared to say that clinical practice is the problem.

Let me tell you about my experience over the past two years. I have met hundreds of women from across Scotland and beyond who have come from different towns, cities and geographical locations. They have had different socioeconomic backgrounds and cultures and have come from all over. Some of them have lost their organs and some of them have to walk using crutches. Some of them use wheelchairs. Some of them have lost their jobs, marriages and all the rest of it. They are very different women of all ages and from all backgrounds. The only thing that they have in common is that they have been fitted with polypropylene mesh and have injuries. Is that just a coincidence? They are not all overweight and they do not all smoke. They do not all have the characteristics that you have described, although some of them may have them. I find it inconceivable that all of them from all those backgrounds have one thing in common, but the MHRA is not prepared to turn around, look at them and say, "They are the evidence that there's a problem here."

11:15

Dr McGuire: We are aware that many patients have had serious untoward complications following their surgery and their procedures. The relative contribution of each of the elements related to those procedures has to be taken into account against a background of the complexity of the underlying condition. We cannot make judgments on those small number of individuals who have had problems compared with the thousands of patients who have benefited from the procedures and who have had an improvement in their quality of life as a result.

A balance has to be struck. In all medicine, as I said earlier, there is a balance between the risk of doing something and the risk of doing nothing versus the benefit of doing something and the benefit of doing nothing. The final decision on the best thing to do in a particular circumstance rests with the individual patient and the individual clinician. That involves informed consent, patient selection, picking the appropriate device and following the guidelines. If people want to minimise risk, we all have to work together to make that the case. However, we cannot get rid of risk. There is no medical procedure and no drug that we take that is without risk.

Neil Findlay: But you can minimise risk.

We have been full of analogies today. The analogy that I use here is that, even if just a small number of drivers of a car produced by a certain

manufacturer reported their concerns that there might be a problem with the brakes, there would be a recall or a halt in production until the problem was resolved. Why do we appear to treat an inanimate piece of metal more compassionately and systematically than something that affects the lives of so many people so badly?

Dr McGuire: To be fair, that is not what we are doing. In the case of a motor vehicle, we are not saying to the owner that, when they get into their car and drive it, there is a risk involved because the brakes might not work or whatever it is. Drivers know when they get in their car that there will be a risk, because of the way they drive—

Neil Findlay: You are missing the point. I am talking about what happens when a problem has been identified by a number of people.

Dr McGuire: What we do not have with cars—inanimate objects, as you say—is the issue of a complication rate for driving a car. We have to accept that, with any medical procedure, there is a complication rate. We have to ensure that, if complications happen, which they invariably do, there are things in place in the health service that are supported by the various agencies, practitioners and so on to deal with them. Complications are inevitable; they will happen. There is not one thing in medicine that does not have a complication attached to it. It is not a risk-free environment.

John Wilson: I will follow up on Mr Findlay's questioning. I will not use the analogy of a car, but I wish to raise the issue of reporting and the underreporting of the number of cases.

Mr Findlay has spoken to hundreds of women. We know from the campaign that has been established that there are hundreds of women in Scotland who have been affected by the mesh implant operation. How does the MHRA justify the failure to take action, based on the number of cases that we are hearing about? You admitted in response to an earlier question that there is underreporting, because clinicians are not reporting. You have said that the question whether reporting is voluntary or mandatory is an issue that must be addressed.

What are the criteria for taking action to stop the use of mesh implant operations and of the device? The Parliament and the committee are getting responses from women throughout Scotland and elsewhere who have suffered severe effects from use of the device and from the operations that have been carried out for a number of years and are still being carried out.

Dr McGuire: I return to some of the points that I made earlier. If you are aware of hundreds of cases, and we are not seeing the reports, you need to use your influence. With our help, those numbers can be subsumed into the reporting. That is part of one of the reasons for having the Scottish independent review, and it is why we have been so keen to be part of it.

It is absolutely vital that the difference in the numbers that are bandied about by various groups is reconciled. I do not mean that flippantly; I mean that we get lots of numbers thrown at us, but we cannot work without evidence, and there is no evidence about it from anywhere else in the world.

We have talked to other competent authorities, including the UK Bladder and Bowel Foundation. We have asked whether they are seeing and hearing of reports of lots of women—or men—with incontinence who have had procedures and who are having problems. They have said that they are not.

I cannot understand why we are not able to reconcile those differences. We have asked the groups to get everybody to report to us. It does not matter if they do not have the details. If we verify that they are all different people—we do not want vote rigging, if you see what I mean—and that the reports are all from individuals, they go into the system and we then have that information. For years, we have requested that information and we have not received it. That has been the case in Scotland and in England, too. We are at a loss to explain those differences.

Mr Findlay said that there were thousands and thousands of women in the United States who are awaiting litigation. We heard recently that a report was obtained from a patient, and attempts were made to investigate it, but the patient said that they could not provide any more details, because their lawyer had told them not to say anything. If the legal system is standing in the way of reporting, that is a real problem to us. That occurred within the past few weeks.

The Convener: Thank you, Dr McGuire and Ms Mounter, for giving evidence on the petition today.

I suspend the meeting while the videolink is set up.

11:22

Meeting suspended.

11:28

On resuming—

The Convener: Our second evidence-taking session today is with Mr Adam M Slater from Mazie Slater Katz & Freeman LLC.

We are taking Mr Slater's evidence this morning from the United States via videoconference, and I

remind members that a delay will occur between members finishing their questions and the witness hearing and responding. Equally, there will be a delay the other way. For these reasons, it is important that no one tries to speak over anyone else. Members should speak only when called to do so and should not try to interrupt their colleagues or the witness, as that will affect our ability to hear the answers.

I welcome Mr Slater and thank him for making himself available at such an early hour to speak to us here in Edinburgh. I will start by introducing myself. My name is John Pentland, and I am the convener of the Public Petitions Committee. Each of the members of the committee will now introduce themselves.

David Torrance: I am David Torrance, the deputy convener.

Hanzala Malik: I am Hanzala Malik, a committee member.

John Wilson: I am John Wilson, a committee member.

Angus MacDonald: I am Angus MacDonald, a committee member.

Kenny MacAskill: I am Kenny MacAskill.

Jackson Carlaw: I am Jackson Carlaw.

Neil Findlay: I am Neil Findlay. I am not a committee member, but I am an interested party.

The Convener: I invite Mr Slater to make an opening statement of around two or three minutes, after which we will move to questions.

Adam M Slater (Mazie Slater Katz & Freeman): I thank the committee for inviting me to provide information to you regarding the pelvic mesh devices.

I met my first client who had been injured by these polypropylene mesh devices in 2007. Since then, I have been working almost exclusively on the mesh cases and meeting with many of the leading consultants and physicians in the United States regarding injuries that women have been suffering and the serious complications that are caused by the products.

I have been spending a great deal of time studying the literature. In my state, New Jersey, we now have more than 7,000 cases for which I am lead counsel. I have tried several of these cases and spent a great deal of time on them, so I hope that the information that I can provide to you today will be helpful as you consider the way forward with regard to these dangerous devices, the closest analogy to which that I can find is asbestos—something that, for a long time, was thought to be a wonderful invention but which is now something that everybody in the world knows is something that you would not want to go anywhere near. That is the closest analogy that I can find to these horrible devices that are now in many women's bodies.

I am ready to answer any questions that you may have.

The Convener: You mentioned that more than 7,000 devices have been implanted in the USA. What recent data is available on the number of those that have resulted in medical device reports?

Adam Slater: What I can tell you is this: one of the benefits of litigation is that we get to see the internal documents of the companies—documents that they have not shared publicly. For example, Johnson & Johnson—the largest manufacturer—states in its internal documents that its devices are in more than 2 million women.

The 7,000 number is the number of women who have filed cases in the state of New Jersey. There are about 70,000 or more cases filed in the federal courts that are placed in front of one judge in the state of West Virginia, and there are many more cases that are filed in various other state courts that nobody has been able to count. There are probably tens of thousands of other women who have been harmed who either do not know that they can bring a case or who found out too late that they had a case and therefore cannot bring it, and there are others whose complications have not yet manifested. We are talking about millions of women, according to the data from the manufacturers themselves.

The Convener: On what grounds have the patients sued?

Adam Slater: There are two basic claims that will be seen in any lawsuit. One is that the devices are defective. That generally means that they are unreasonably dangerous. Doctors balance the risks against benefits. However, in essence, the companies created a market for the products by having doctors who were being consulted and paid by them speak at national conferences and publish articles saying that suture repairs—which have always been the tried and true way of treating these conditions—were not effective and that the mesh materials were therefore needed, and people began to use them.

The studies that I think that you can rely on, which do not have industry funding behind them, show that there really was not a need for the mesh, and that, in fact, it does not work any better than the suture repairs. That deals with the benefits side. When you look at the risks side, you will see that the risks are catastrophic complications that, for many women, cannot be treated. When you put those two together, and you

see that the risks outweigh the benefits, you can see that you have a defective product.

The other claim is failure to warn. Doctors and patients have never been publicly given the full story of the complications and the dangers that the companies know of. How do I know that? Because I have read the internal documents of the manufacturers and I have seen the unbelievable internal conversations.

By the way, everything that I am telling you is now public. I have tried these cases and the documents that I am referring to are not confidential any longer. This is public information, although it has not been widely disseminated.

For example, internally, Johnson & Johnson talked about running a registry that would count every woman who got a Prolift, which is one of its products, and would follow their progress. The medical people in the company said, "No, we can't do that, because that would make our risk and complication data more accurate, which would be bad for sales and bad for competition." Unfortunately, that is the thought process in the companies.

Those are the two main claims. First, the women are not warned and their doctors, especially, are not told the truth about how serious the complications are and how untreatable they are for so many women. Secondly, the products are defective and it is unsafe to put polypropylene mesh in so many women.

The Convener: Mr Slater, in the court actions that are pending, is it the manufacturer or the clinician who is being sued, or is it both? What has been the outcome?

Adam Slater: That is a great question. It is both, although it depends on the court, the client and the law firm that files the case. Last month, I tried a case in which both the doctor and the manufacturer were sued. Many doctors are caught up in this because they did not have the full information and they believed what they were told by the manufacturers about which women were appropriate to have the devices put in their bodies. They basically said that any woman is a good candidate, and doctors believed that. Now, when you look at the internal documents, you see that that is not borne out.

Some doctors are now having lawsuits brought against them, but that is not as pervasive. There is a thought process in United States litigation that you do not want to get the doctors angry by suing them. That was the thought process early on, but more people are now suing their doctors because the doctors turned a blind eye to good data and instead believed propaganda, and that is a problem for a doctor.

Angus MacDonald: We are aware that the Food and Drug Administration regulates the use of medical devices in the US. On 29 April last year, the FDA issued proposals to reclassify surgical mesh for transvaginal pelvic organ prolapse from a moderate risk device, class 2, to a high-risk device and to require all manufacturers to submit a pre-market approval application for the agency to evaluate safety and effectiveness. Has the FDA proposal to reclassify the products come into effect? What has been the effect of any regulatory changes on the medical profession, the regulators and the manufacturers?

Adam Slater: That is a good question. I will give you a three-part answer.

First, the FDA has not issued those orders yet, which is disappointing but is, unfortunately, typical of the regulatory authorities in the United States, which do not move quickly. Unfortunately, there is a collaboration between the FDA and the medical device manufacturers—I have seen it in the internal documents. For example, before the FDA issues pronouncements about mesh it consults the medical device manufacturers, and it is being lobbied. There is a close relationship there, which is unfortunate and takes the FDA away from the neutral, objective position that it should hold. The answer is that the proposal is just sitting in limbo and nobody knows why.

Secondly, what has the FDA done that has been positive? When it issued what are called 522 orders in early 2012, it was saying to the manufacturers that they had to study the products more and that it wanted to see real, robust studies. That was a good thing, but many of the manufacturers pulled their products off the market instead of having them studied by those robust randomised controlled trials. That is a very damaging fact against the manufacturers.

For example, I have seen the internal emails, which are now public, from Johnson & Johnson. When the orders were issued by the FDA—the very day that they were issued—the regulatory affairs professionals at Ethicon and Johnson & Johnson were already asking, "If we pull the product off the market, can we avoid having to do these studies?" and products were pulled off the market. For example, Johnson & Johnson pulled four products off the market—both incontinence and prolapse devices—rather than do those studies. The conclusion from that is that there has never been a high-level study, such as the ones that the FDA mandated, to prove the mesh to be safe and effective. That has never happened.

My third point harks back to my first point. Maybe I am cynical because I have been doing this for a long time. There is an expert for Johnson & Johnson in the mesh litigation who used to be a head of enforcement in the FDA, and we learned

in his deposition that he side-switched when it was investigating a Johnson & Johnson company over a product. He switched and became a private consultant on the same matter for the Johnson & Johnson company. You can draw your own conclusions, but we who are a bit cynical do not really look to the FDA as an entity that has the resources or the structure to be able to protect women in this area or, for that matter, patients in other areas.

Angus MacDonald: Thank you. You mentioned that the reclassification has not happened yet. Has the FDA said publicly or indicated to you when the reclassification will happen or come into effect?

Adam Slater: I have seen no indication of when the FDA will do that. Given the documents, with which you are familiar, and the awareness of the issue, everybody expected that the reclassification would happen quickly because it involves the health and safety of women, and we would have thought that the FDA would therefore move quickly. However, we have no indication of when the FDA is going to act.

In practice, because of the information that has started to come out, many doctors are treating the products like high-risk devices even though they do not have that classification, and many doctors now refuse to use the devices when they learn about the issues. Unfortunately, we have found that many women who have a complication because of the device leave their doctors, so the doctors think that they are having wonderful results because the women do not return to them. However, to remove the mesh, women go to the most high-level pelvic reconstructive surgeons, who are usually doctors who do not put mesh into women's bodies.

Among studies that have been published by doctors from the Mayo Clinic in Minnesota, a recent study—the name of the first listed author is Abed—recognised that across the board women typically do not return to their doctors but go elsewhere when they have very serious complications from meshes, and doctors do not really know that. Fortunately, information about the mesh products is getting out now and many doctors are avoiding them, which is a good development.

Angus MacDonald: Thank you, Mr Slater. It is good to have on our record that at least some clinicians in the States are now refusing to use the implants.

John Wilson: Good morning, Mr Slater. The Medicines and Healthcare Products Regulatory Agency in the UK has continued to argue in a recent report that the benefits of mesh implants outweigh the risks. What would be your advice for that regulatory body?

Adam Slater: I would tell it to look at the studies that the mesh manufacturers rely on because it would find out a few things. First, most of the studies that they rely on were investigated or written by paid consultants. I would throw those studies in the garbage immediately, because if somebody is being paid by the manufacturer, there is financial bias and it is recognised in the scientific literature that financial bias affects conclusions.

Secondly, the grandfather product in this area is considered to be Johnson & Johnson's TVT—transvaginal tape. The studies of the TVT in the late 1990s are the bedrock studies supporting the use of all mid-urethral slings. Unfortunately, what people did not know about the studies is that the lead investigator was the inventor of the TVT—a European doctor called Dr Olmstead—and that it is acknowledged that his contract with Johnson & Johnson had a clause that said that, if he reported certain complications, he would lose a $400,000 payment. In addition, we found out through discovery investigation that the studies by Nilsson, which are long-term studies over 17 years, used the same patients as Dr Olmstead.

The data on TVT was paid for. Our discovery investigation has shown that, and I could send you reams of testimony on it. The bedrock studies are therefore not reliable, and safety is never their primary end-point. They did not study safety in a robust and objective way, as they should have; rather, they looked at whether there would be less leakage and whether the organs would stay in the right place better. Modern concepts about such types of surgery recognise that the most important thing is how the woman feels, because it is elective surgery that nobody needs.

Study after study bears out that reoperation rates for surgeries that make suture repairs to the native tissue are far lower than for surgeries that use mesh, and that the functional, day-to-day life outcomes for women who have suture repairs are the same as, or better than, outcomes for women who have mesh surgeries.

The only thing that the manufacturers can say is that some studies show that women will remain dry for a longer time with some mid-urethral slings—but at what cost? The studies do not study safety in a robust and thorough way. I can tell you what was in internal documents: Ethicon, for example, admitted in depositions that the risks include—I am quoting what Ethicon said—"life-changing complications", "recurrent, complex erosions", and "contraction of the mesh, causing pain syndromes."

Those things are not in the warnings from most of the manufacturers, and their sales representatives will tell doctors that they are not serious risks. When somebody tells you that the

benefits outweigh the risks, you have to look at the women who are suffering catastrophic complications. It is easy to say that that does not bear out in reality.

11:45

John Wilson: Are you aware of the exchange of information between the US regulatory authorities and others throughout the world, including those in the UK?

Adam Slater: I am not aware of the FDA sharing information with the UK or European regulatory authorities. I have not seen any documentation that shows that that has happened. If it has, I am not aware of it.

We have a saying in the United States, and you probably have it over there—"it is like fighting with one hand tied behind your back." Ultimately, that is what the regulatory authorities are doing. They are not funded in the way that they need to be and there are only so many resources to go round, so they can only do so much. The key information has not been shared, so the regulatory authorities do not have the full information.

Again, you should look at the influence of the mesh manufacturers on the authorities. They meet and speak regularly, and I have seen many documents that show that, when something alarming is brought to the FDA's attention, people there immediately pick up the phone and call the people at the manufacturer and say, "Hey, what's this?" It is not an objective, arm's-length process, unfortunately.

John Wilson: Thank you.

Hanzala Malik: Good morning, Mr Slater. Under the current European Union regulations, the manufacturers' role and responsibilities within the framework are clear. Within the US regulatory framework, what role do manufacturers have in both pre-market and post-market scrutiny of their products?

Adam Slater: That is a great question. In the United States, the mesh products were able to get on to the market through what is called the 510(k) procedure, which is essentially an exception to the rule that people have to get robust pre-market approval. The products got on to the market with a simple application that said, in regulatory buzz words, "This is substantially equivalent to something else on the market."

The manufacturers said that the products were similar to hernia mesh, or to another mesh. Many of them used as what they call the predicate—the earlier product—which is a product by Boston Scientific. It was a mid-urethral sling that was recalled from the market, but companies were able to rely on that to get their products on to the market, and their approvals were not touched. It took very little for the mesh products to get on to the market.

As I said, the robust protections that are used for drugs have never been instituted for the meshes. When the manufacturers were threatened with having to do the types of studies that people should have to do to get them on to the market, many of the products were pulled off the market instead of the manufacturers doing the studies, as I mentioned earlier.

It is a very easy process compared with getting a drug on to the market, for example. The products have never been scrutinised in the way they need to be.

Hanzala Malik: How might that affect clinicians' or healthcare providers' views of the information that manufacturers provide on their products?

Adam Slater: Unfortunately, what happened is that many physicians in hospitals said, "This sounds great. Let's stock it and allow it to be used." Obviously, that has not worked out well.

I have not seen an analysis of the cost to healthcare authorities and insurance companies, but I would venture to guess that the numbers will be staggering. To use a suture to repair these conditions is not that inexpensive a procedure. The mesh is very expensive so, for example, in your country, your Government is paying for that. Then, when a woman has complications, she has to go and have more examinations because the mesh is eroding or contracting, and every time the woman sees the doctor, that is another exam. Then the doctor will do an ultrasound and try to image the problem, and then they will do surgery to try to find it. The data shows that, once a woman has surgery, the odds are that she will start to have more. That relates to the Abed article that I cited—women end up with multiple operations and the complications are bad.

Now there are multiple hospitalisations, so there are staggering, compounding, increasing costs to your Government for this healthcare, and the clinics do not have the wherewithal, so there are only a few places in the country where you can find doctors who are equipped to remove the mesh.

I talk to the doctors who remove the mesh all the time. They have still not established a safe and effective way to remove mesh from these women. The other day, a doctor told me that even some of the hardest surgical scissors that they use are not effective at removing mesh, so they have to use tools that they never imagined using in a woman's body to remove the mesh because it is so tough and so difficult to remove. You will not find that information being given to doctors or to clinics, even today.

Hanzala Malik: What effect has the litigation had on the role of manufacturers in the US regulatory framework? You touched on it briefly, but can you expand on that point a little?

Adam Slater: Sure. What the manufacturers have done is damage control from the very start. I have seen the internal documents. The same day that the FDA came out with its first public health notification in October 2008, the manufacturers put out talking points, saying, "Well, this is nothing different." The next public health notification came out in July 2011 and then there were meetings in September with the FDA. The companies got very polished members of their industry to speak, to try to convince the regulatory authorities that everything was fine. Their testimony was contrary to what their internal documents showed, which is frustrating. It is frustrating for any one of us who looks at the situation.

The manufacturers have continually met with the regulatory authorities. They have delayed action and they have continued to peddle bought-and-paid-for studies—studies that were run by their own funded consultants. The FDA, because of how things are structured, works in tandem with those manufacturers. The FDA feels that it needs to work with them on a daily basis. We would prefer the FDA to be at arm's length from the manufacturers and to carry out much more scrutiny of them. However, the manufacturers continue to play their game. I can tell you what I have been told by the manufacturers, many of whom do not want to settle these cases. They have said, "Hey, there is no court that can handle all these cases, so let these women wait." That is what I have heard. That is their attitude.

I implore you to beef up the justice system. You are going to see a lot of women in your country with similar cases and special courts will be needed to give those women justice quickly and efficiently. In the United States, we have 70,000 women or more in this situation and most have no hope of ever getting a court date or getting their case heard. It is really tragic. There are women who are bankrupt, who are losing their marriages, who are suffering and who cannot afford their medical expenses and they do not have any light at the end of the tunnel, unfortunately.

Hanzala Malik: Thank you very much indeed.

Neil Findlay: We have just heard from the UK regulator, which is looking into the issue. The regulator would not say that any of the problems were associated with the product; the regulator spoke about the product being fit for purpose and said that the benefits outweighed the risks. I have looked at the list of some of the cases that have been settled in the US, most of which appear to have been settled because of defectively designed products. Is that true overall or is that just true in the cases that I have looked at?

Adam Slater: You are correct. When the cases have gone to trial and a jury has decided on them, the plaintiff has won almost every single case. Most of those cases have been won because the jury has found that the product is defective. In US law, if the warnings are inadequate, that is considered a product defect as well because it means that the doctor and the patient were not able to balance the risks and benefits.

Our hands are tied, to a large extent, by the evidence rules. I try these cases, and I have not yet been able to tell a jury that products I am trying cases against have been withdrawn from the market by the manufacturer. I have not yet been able to tell a jury—again, this is information that has been filed publicly—that Johnson & Johnson and Ethicon destroyed tens of thousands of pages of documents regarding their mesh products. I have not been able to tell a jury that. The judges are doing the best job that they can under the evidence rules. We have an intellectual disagreement. I think that a jury needs to know that, in the case of certain medical directors at Ethicon who allowed those products to go on the market, entire hard drives were wiped clean and we never saw any of their internal documents. That raises questions and I think that a jury should be able to hear about it.

When a case gets to the courtroom and a jury hears the evidence, what does it do? It finds against the manufacturers. The verdicts have uniformly awarded compensation in seven figures, and in several cases punitive damages have been awarded, which in the United States is done to punish and send a message to those companies.

I would tell the regulators that, if they want to know what is really going on, they need to take the time to look at the evidence. I tried to send documents to the Parliament—I understand that you have certain rules that mean that you are not allowed to keep those documents on file, but if you want documents I would be happy to send you reams of sworn deposition video transcripts from medical directors as well as internal documents.

The regulators can look at those documents, and they can look at the inside truth in the emails. When the manufacturers wrote those emails eight years ago, they did not know that the matter would end up in court and they were telling one another things candidly. You should tell the regulators to talk to the doctors who are removing the mesh and who do not use it, rather than to the doctors who have a financial stake in seeing those products used. The doctors who remove the mesh—such as the doctors at the Mayo Clinic, who wrote about the catastrophic complications—will give the regulators the most honest, objective information. I

would be happy to get the studies emailed to you today so that you can see all that information.

Neil Findlay: I would definitely welcome that. Just to be clear, are you saying that your clients have received a compensation payment even though the product has not been withdrawn from use?

Adam Slater: There are women who have—well, it's funny: there are some women who have settled their cases on a confidential basis, so I am not allowed to say much more about them. The public jury verdicts have gone against both the withdrawn products and the products that remain on the market; they have not been limited to the withdrawn products. In fact, the mid-urethral slings sold by both Boston Scientific and Johnson & Johnson and Ethicon have been the products in relation to which plaintiffs have won trials in various states, including Texas, and they have been the subject of federal litigation in West Virginia and a federal case in Florida.

I will tell you one other thing, because you asked me about what the regulators should look at. They should be shown studies. We learned from our discoveries that a study of one of Johnson & Johnson's mesh devices that was published in *The New England Journal of Medicine*—which is considered to be perhaps the most prominent medical journal in the world, or at least it bills itself that way—featured significant involvement from Ethicon in the design of the study, the analysis of the data and the writing of the manuscript, and yet the author had said that there had been no such involvement in any of those things.

When I took the deposition from the editors of *The New England Journal of Medicine*—I got a court order from the state court judge in Massachusetts, because the editors fought me like crazy—we found out not only more about the fact that there was no disclosure of involvement by industry, but that certain bits of the data were unreliable because the measurements of women's re-prolapse had not been done in a valid way. In the opinion of our experts, that entire study was invalid, but it still sits on the books. Again, I would tell any regulator that they should read published studies with great scrutiny.

Neil Findlay: I have two final points. First, we have a national health service, which is different from your health service. As an outsider looking in, what do you think are the financial implications of the mesh implant situation for our NHS?

Adam Slater: I can answer that in very basic terms. Surgery with mesh is more expensive, and the consequences are incredibly expensive, because women need intensive medical care when the complications happen. Manufacturers will tell you, "Oh well, if a woman has some erosion of the mesh, it's not that big a deal—it can be easily fixed," but that is not what the data shows. It shows that more than 50 per cent of women need surgery, and that—as the studies that I mentioned show—women end up having multiple operations.

By the way, there is a lifelong risk: as a woman gets older and the tissue of her body ages, there is a higher risk of the mesh contracting and eroding, so the risk goes on. I had deposition testimony from a doctor in California who has removed more mesh than perhaps any doctor in the United States or the world. His name is Shlomo Raz, and he is a widely published and highly respected urologist and pelvic reconstructive surgeon. He referred to the mesh as a "social cancer" in sworn testimony.

Shlomo Raz used to use the mesh. When women started showing up seven or eight years later with complications, he looked at that and said, "You know what—I can't do this any more." He has ceased putting the mesh into any women's bodies—and all that he would do was use small pieces of it. He did not use the large kits, such as the kits for the urethral slings; he used smaller amounts that were carefully placed. What is the implication? That it will be costly. Every time a woman gets the operation, there is a 50:50 chance that she will need a lot of care. That is what the data shows.

Neil Findlay: I have one final point. I am glad that you mentioned the conflict of interest, which was an issue that I wanted to raise with the regulator, but I did not have time to do so. It would appear that the whole situation is riddled with conflicts of interest among the manufacturers, the doctors, various clinicians and the regulators, whether in the US, the UK, Europe or, indeed, throughout the world. Do you agree?

12:00

Adam Slater: I agree 100 per cent. I will tell you something that is very shocking. I will refer to the manufacturer's internal documents. I am a lawyer, so when we get those documents, that means a lot to us. Perhaps I am a little biased on the issue, but I will give you a great example of what the company said internally when it did not think that anyone would see those documents.

The medical director at Ethicon is Piet Hinoul, a Belgian urogynaecologist. He was hired by Ethicon and Johnson & Johnson. He talked in an email about one of their highest paid consultants, Dr Vince Lucente, who was paid $1.7 million by the company. He said that when his group publishes that they have no erosions, no one believes that. He is essentially saying that they are

publishing false data. The day before, the company authorised $400,000 in payments to that same doctor, because he was so good at marketing the product to other doctors. He is someone who has published studies saying that he had no erosions on multiple occasions. The doctors in Ethicon know that that is not true, yet they were used to promote the product, to speak at national professional societies and to publish literature. Similar doctors were then used to lobby organisations.

I will give you another example. The American College of Obstetricians and Gynecologists published what is called a practice bulletin in February 2007 calling the procedures experimental. The internal documents show that the same Dr Lucente and other doctors who were paid consultants lobbied behind the scenes because they were worried that the insurance companies and Medicare and Medicaid—our Government's providers—would not pay for experimental procedures. They got ACOG to change that and to remove the word "experimental" in 2007. Emails showed Dr Lucente writing to the marketing people at the company saying that that was a great victory. The email response from Ethicon's marketer says, "I love you, man. I'm doing the happy dance." Every one of the emails talks about the doctors being able to get paid for the surgeries. There is not one word about women's safety or health, or whether it was right to call the procedures experimental. It was absolutely the right thing to do.

By the way, one of the other Ethicon lobbyists at the time now works for regulatory affairs at ACOG, where she lobbies the Food and Drug Administration. I have all those documents. None of them is confidential any more. If you want them, I have them here for you.

Neil Findlay: I look forward to receiving them from you.

The Convener: You have been heavily involved in the issue over the past couple of years. Have you at any time been approached by our regulator to provide any evidence or information? Have you ever offered any evidence or information to our regulator?

Adam Slater: The regulatory authorities in the United States have never picked up the phone and called me; they have never asked for information from me. To my knowledge, I am not aware that they have asked any of the attorneys who are involved in the litigation for such assistance.

The regulators have stayed far away from people like me who would be more than happy to give them all the internal documents that we have obtained, to show them the true story. They have not asked for that, which is a shame.

The Convener: Would that same offer be made to the UK regulator?

Adam Slater: I would be happy to provide anything that is requested. I have here everything that is no longer confidential. I have dutifully battled to de-designate documents so that they are no longer confidential. I would be happy to provide those to anyone who asks for them.

The Convener: Have you ever approached the regulator to offer that evidence?

Adam Slater: I have written to the regulators and provided information, but I have never been approached.

The Convener: Have you approached our regulator?

Adam Slater: I have offered to provide information, but I have never been approached and nobody has asked me to provide anything.

The Convener: There are no further questions, so I thank you for giving evidence on the petition, in which, as you are probably aware, there is a great deal of public interest. I apologise for keeping you late, but you can go and have a hearty breakfast now. Your evidence was very much appreciated.

Adam Slater: I appreciate the opportunity, because there are a lot of women who really need people to stand up for them. Ultimately, it is the politicians and the members of Parliament in your country who need to stand up for them, because they do not have anybody to battle for them. I feel honoured to be able to do this, because I know how hard the women in Scotland are working. Thank you very much.

The Convener: Thank you.

I now ask the committee to decide on what action it wishes to take on the petition. Members have a note by the clerk that sets out the possible courses of action. Does the committee agree to draw to the Scottish Government's attention the evidence heard with the request that it is taken into account by the review?

Members *indicated agreement.*

The Convener: The committee has already agreed that it wishes to hear from the cabinet secretary, the chair of the independent review of transvaginal mesh implants and the European Commission. Does the committee agree that that should happen after publication of the independent review's findings?

Members *indicated agreement.*

Neil Findlay: Can I ask the committee to do one other thing—to ensure that the documentation that Mr Slater offered is sent to both the Scottish

Government and the MHRA? I do not know whether, on looking at that, the Government will have to make a reassessment of where it is, or whether it will have to pass it on to individual health boards. It might be that, when the cabinet secretary comes, we can hear her views on the evidence that Mr Slater produces.

We must take into account the very substantial information that Mr Slater will provide and it must form part of the committee's deliberations. Given that he is saying that internal documents from the manufacturers show what are in his view some very serious things, I think that the committee would want to know about them.

The Convener: I think that that is right. We will pass on today's evidence to the Scottish Government for information. We will have the cabinet secretary and others in for further evidence, and I am quite sure that everything that was said here today will be part of that evidence session.

Neil Findlay: As well as being provided to committee members, could Mr Slater's evidence be provided to me and to the mesh group?

The Convener: I have been advised by the clerk that, when the evidence comes in, we will review it, then we will come back and let people know.

I thank committee members and people in the public gallery for being here. There is certainly public interest in the petition. Although what you have heard today might not be the solution, it is probably more evidence that we can take into account for future evidence sessions.

Meeting closed at 12:08.

Members who would like a printed copy of the *Official Report* to be forwarded to them should give notice to SPICe.

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