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.

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