

Women and Equalities Committee

Oral evidence: Health impacts of breast implants and other cosmetic procedures, HC 869

Wednesday 14 May 2025

Ordered by the House of Commons to be published on 14 May 2025.

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Members present: Sarah Owen (Chair); Alex Brewer; David Burton-Sampson; Rosie Duffield; Kirith Entwistle; Natalie Fleet; Catherine Fookes; Christine Jardine; Shivani Raja.

Questions 1 - 75

Witnesses

[I](#): Professor Michael Coleman, Professor of Toxicology, Aston University; Professor Prabath Nanayakkara, Professor in Acute Internal Medicine, Amsterdam University Medical Center; Professor Carl Heneghan, Director of the Centre for Evidence-Based Medicine, University of Oxford.

[II](#): Professor Vivien Lees, Consultant Plastic Surgeon and Vice President, Royal College of Surgeons of England; Ashton Collins, Director, Save Face; Sasha Dean, lived experience of severe complications following liquid BBL.

Examination of witnesses

Witnesses: Professor Michael Coleman, Professor Prabath Nanayakkara and Professor Carl Heneghan.

Chair: Good afternoon and welcome to the Women and Equalities Committee. Today we are holding an oral evidence session on the health impacts of breast implants and other cosmetic procedures. Our first panel are all online; we will hear from Professor Carl Heneghan, director of the Centre for Evidence-Based Medicine at the University of Oxford, Professor Michael Coleman, professor of Toxicology at Aston University—his camera is not working, but we will be able to hear him and he can hear us—and Professor Prabath Nanayakkara, professor in acute internal medicine at Amsterdam University Medical Center. Thank you very much, all three of you, for joining us today during this evidence session.

Q1 **David Burton-Sampson:** I am going to start with you, Professor Nanayakkara. I would like you to explain the difference between a typical breast implant and a PIP breast implant.

Professor Nanayakkara: The difference is that a PIP implant probably ruptures more often, at about three to five times the rupture rate. So patients with a PIP implant who we saw in the past had, in my opinion, a high rupture rate and spread of silicone all over the body. That is the first thing.

Secondly, industrial-grade implants were used, which are much cheaper than medical-grade implants. The medical-grade implants also cause problems in patients but PIP implants, in my opinion, cause more problems.

Q2 **David Burton-Sampson:** That is really interesting. Coming to you, Professor Coleman, do you agree with the Government's guidance that a ruptured PIP implant does not pose a serious health condition?

Professor Coleman: I absolutely do not agree. The issue with PIP implants is that they were so poorly manufactured, as Professor Nanayakkara says; they were made of very poor-quality silicone. If you make a polymer, you need to have a proper process and know how to use your monomers. Unfortunately, the monomers were cheap and of very poor quality, so the polymers did not hold together. The outer surface of the implants was uneven and prone to rupture. In one study, only about a third of the implants that were removed were complete. The rest of them were either ruptured or damaged in some way.

So the advice that this is not a problem is utterly ludicrous; there is a problem. These implants were not fit for purpose when they were implanted. The fact that they have been inside women's bodies for anything up to 10 or 15 years—sometimes many decades—means that the chance of rupture is extremely high. As Professor Nanayakkara says,



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rupture is up to six times more likely because they are simply not capable of withstanding the process of being in a woman's body.

They also release the monomer—D4, D5 and D6; the silicone building blocks of the polymer, if you like—because the implants are so permeable. Things go in and things go out. When the silicones go out, they go into the woman's body. Even if the implants are removed, silicones from the implants can be detected in women's blood for years afterwards. The silicones enter the body and leave very slowly indeed. So the idea that this is not a problem is simply wrong.

Q3 David Burton-Sampson: I really appreciate your answer, Professor Coleman, but I am going to press you a little more. We can appreciate that there is a problem through the design of these implants. Do you think it poses a serious health risk to women when these implants fail?

Professor Coleman: Yes. Once silicone is released into the body, we know that silicone or siloxanes—which are the components of the implants—appear to have an effect known as the adjuvant effect. They stimulate the immune system in many, though not all, women. Stimulating the immune system is an effect that is used in vaccinations to try to make vaccinations more effective. It seems that siloxanes have the ability to cause this stimulating effect, hence the overactivity of the immune system seen in breast implant illness. This is also partly linked to the cancer related to these implants, so there is no doubt at all that releasing silicone in those quantities into women's bodies is a very significant hazard.

Q4 David Burton-Sampson: Professor Nanayakkara, did you have something to add to that?

Professor Nanayakkara: What I do not understand is that we normally advise patients with silent ruptures to explant both implants. When PIP implants have a 3% to 6% chance of rupture, telling them, "There is no problem at all, you have no problem as long as you have no symptoms," is not logical to me.

Q5 David Burton-Sampson: Thank you, that is really helpful. Coming to you now Professor Heneghan, is it reasonable to assume that the majority of women with PIP implants will already have had them removed or replaced?

Professor Heneghan: This goes back to the previous question you asked. The Bruce Keogh review was in 2012, so we are talking about our view of the evidence some time ago. What has happened over time is the emergence of more and more evidence linked to breast associated illness and lymphomas.

What we find is that we are in a world now where the evidence we supply cannot inform a patient about the benefits and harms of this device. I set out in my report the problems with the registry; these affect our ability to inform women, and the first few suggestions we are seeing tell us we



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have an issue. There are lots of uncertainties because of our failures to collect and report an evidence base, as we do for many other implants; the national joint registry for hips and knees does a much better job monitoring the failings of metal hips.

My perspective is that because this is considered a cosmetic intervention, it is not an issue that the NHS takes seriously. However, we are in a world now where the complications are increasing, and we have a duty to do something about that in terms of collating the evidence and reporting it appropriately.

Q6 David Burton-Sampson: I just want to pull you back to the question about whether it is reasonable to assume that the majority of women have now had these PIP implants removed—or are there a large number of women still out there with these implants?

Professor Heneghan: The answer is yes. The exact number is not known because the registry—it was supposed to come into force in 1993 but was enacted in 2016—is failing, as far as I am concerned; but that registry should have a duty to report the number of women with PIP implants. We know that in 2012 there was an NHS call for women to be seen, but that was mandated only for those women who had operations within the NHS. We do not know exactly the number of women who have had private PIP implants, but it is likely to be substantial, and much more than in many other countries because our mantra—that they were safe and you could carry on with them—lasted much longer than in many other countries.

The particular reason why problems emerged in the first place was that these implants did not get into the United States of America, which has much tougher regulation, and that led to cost pressures, the use of industrial-grade silicone and the PIP implant scandal. So there is an issue about regulation, but another important issue to be aware of is that our post-market surveillance requirements come into force next month with the amendment. That means we should be collecting much more stringent data in the post-market surveillance world. We have the ability to do that, and your Committee has the ability to determine what that should be for implants.

Q7 David Burton-Sampson: Professor Coleman, do you think sufficient research has been undertaken in the UK on the risk of PIP implants to women, and if not, why do you think that is the case?

Professor Coleman: Absolutely not; there is nowhere near enough information. We do not know enough about the components that escape the implants—the siloxanes D4, D5 and D6, which are the small chemicals which circulate in the woman's body—and what they do to humans. We know that they have some negative effects on animals. We know that there are animal studies showing their impact on animal reproductive systems. They derange animal cellular systems; they also cause damage to animals when they are developing in utero—in the



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womb—and this moves forward to damaging the adult animals. We know that about animals and we know approximately the concentrations that cause that.

Now, we do not know whether this happens in human cells, other than some very limited studies that show that D4 does derange human cell control processes. Unfortunately, that has been done only in some very limited studies. We need a lot more research to understand exactly what D4, D5 and D6 are doing to the human body and to human reproductive systems, and to get some idea of how they are impacting or communicating with the immune system, which is probably linked to breast implant illness.

Q8 David Burton-Sampson: Finally, is there anything else any of you think the UK Government should be doing that they are not doing currently, regarding PIP implants?

Professor Nanayakkara: If I may say something; in the Netherlands, there were about 2,700 patients with PIP implants. Those implants were removed, paid for by the Government. But we started our clinic in 2012 for all the silicone implant patients with problems. They could come to us, and we could examine them. Up to today, we see patients who had their implants removed in 2012 coming to us with sometimes severe complaints.

I also have many patients whose implants leaked. They still have silicone deposits in their breasts and lymph nodes, and they are suffering from it. So after seeing more than 2,000 patients with implants, not only PIP implants but all the silicone implants, I am sure there are many patients walking around with complaints. The biggest problem with western doctors is that we think if we do not describe a disease, it does not exist. So this disease does not exist because we have not described it.

Two days ago, I saw a patient with PIP implants which were removed in 2012. She still has silicone deposits all over the body and she is still suffering. I am sure there are women walking around with lots of complaints, but we are not looking for them. It is the so-called streetlight effect: we look for things we know, and we do not look for things we do not know or do not believe exist.

Professor Heneghan: Just to clarify, Professor Coleman was talking about basic science research. You can split research into two areas. The basic science is what happens when you put this silicone into the body; you can do that in animal models and humans. Then you have the applied health sciences, epidemiology and evidence-based medicine. There are two substantial failures here. No. 1 is we do not know which implants are being used and what evidence their approval is based on. That is supposed to be enacted by EUDAMED within the new European directives; there should be a website that shows you which devices are approved and what evidence they are approved on. That has been stalled for quite some time, but we could enact such a database.



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The second aspect is that, like I have said, our registry has not published any annual reports yet and the data has been down since 30 June. So we cannot address what the devices are and the current UK complication rates, and answer that based on nearly 20,000 implants a year being put into women.

Q9 Chair: Just to be clear on this, Professor Heneghan, are you saying that because the register is stalled we currently do not know what implants are being used in the UK in people's bodies?

Professor Heneghan: Correct. We know the number of operations, but just to be clear, the national joint registry publishes interventions and outcomes annually. I have asked the implant registry why this is not happening, and it says it is, "Currently assessing whether this data can be published in the future as part of the outcomes and registries programme." Currently it is managed by NHS England, and the problem is that NHS England is about to be disbanded. So my perspective is that if we do not move it out of there and get some competent body to manage this registry, we may not know what is happening for the next two to three years.

Q10 Chair: If we cannot know what type of implants are being used, Professor Heneghan, how do we know that there is not something similar to PIP still being used, or whether industrial-grade silicone is being used instead of medical grade? How do we know that there is not another implant by another name that is substandard, causing illnesses and with a high failure rate?

Professor Heneghan: The new MDR is supposed to address this problem of equivalence, such as, "My breast implant is similar to previous ones, therefore we are going to let it on the market." The US FDA has a much more stringent process—requiring clinical trials—to prevent that happening. There is the new EU MDR, but the problem is that will not come into force until at least 2027, and it is not until 2030 that the UK certification process comes fully in process. That means up until that point you can still use a product based on the CE mark in EU regulation.

On top of this, you have the tourism problem; people are going abroad and we have no idea what they are bringing back into the country in terms of the implant. So this is a huge issue that needs to be addressed.

Q11 Chair: Thank you, Professor Heneghan. We are going to touch on the tourism aspect later but there is one other question I wanted to ask.

There will be women, predominantly, listening to this or reading it later on, who will be thinking, "I had a PIP implant," or, "I don't know if I had a PIP implant." How will they know what implant they have? What is the best advice to find that out? If they have a PIP implant, how can they be certain that it has not spread elsewhere and that silicone remains in their body?



Professor Heneghan: In all the scandals that emerge, you always get the same problem; women or individuals tell you that at the time they had the procedure, "Nobody consented me and told me about the true harms."

Secondly, how do you consent someone appropriately? What you want to do is to be able to say, "With this type of implant that you are about to have, here are the benefits in terms of cosmetic and procedural issues, but here is also the latest data on rupture rates, breast implant illness, replacement, and the cost to you." In the UK, as I have set out, we cannot do that comprehensively at this moment in time.

Professor Nanayakkara: In the Netherlands we have had a breast implant register since 2015, where they know exactly which implant has been put in. Before that, we had the same problem because even with PIP implants, when the patients got the call from the clinic that they had a PIP implant and it had to be removed, they were surprised not to know that. That is one thing.

Your other question is, how do you know the implants are still intact? An MRI has a sensitivity of about 85% to show that implants are intact, but we also see sweating. The implants leak from within, without a rupture, and I am sure that lots of these patients have silicone in their body or even in the lymph nodes. For that, you need a really thorough clinical examination by a physician who has experience with this problem.

So to your questions, first, we do not know what implants they have. Secondly, to demonstrate rupture or spread, you need a clinician and an MRI or ultrasound.

Q12 **Chair:** Professor Coleman, I just wanted to come to you quickly to answer the second part of my question which is, if a woman is concerned that she may have had a PIP implant, or any implant that has ruptured, or that they have been removed and silicone remains within her body, what signs should she be looking out for, and what action would you advise them to take?

Professor Coleman: I am not a clinician so this is outside my immediate expert opinion. However, I would say that if they think they have a PIP implant they should have it removed. It is as simple as that.

Breast implant illness is not that well characterised, and it is complex, but if they have any breast implant illness symptoms such as brain fog, immune issues or widespread muscle issues, they should talk to their GP. Ultimately, the PIP implant should be removed.

We should also be concentrating on warning women who are prospective implant recipients that there is enough evidence to suggest that women who have potential autoimmune issues, even something like asthma, are at greater risk of developing problems several years down the line. Women are not properly informed of the risks of implants in terms of



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triggering an almost unending engagement with their own immune systems. That is my opinion on the scientific basis of what seems to be happening.

Professor Nanayakkara: If I may follow up as a clinician, we have studied breast implant illness extensively and published more than 10 papers on it. Most of the ruptured breast implants cause local complaints such as pain, changes in feeling, not being able to wear tight clothes, and sometimes shortness of breath. Most patients take those symptoms for granted for a couple of years. They also have symptoms like morning stiffness, joint pain, muscular pain, changes in the skin, and losing hair.

The other thing is that 70% of patients with breast implant illness also have local complaints. What we see is that when they listen to us or see some TV programme talking about it, only then do they realise that their complaints, which are weak, can be due to the breast implants. So if a patient has these complaints, they have to see a doctor and maybe even get further diagnostics and explantation. Not everybody with implants gets sick, but some women get sick, and some women get very sick.

Q13 **Chair:** Professor Nanayakkara, that list you have just outlined could also be caused by many different illnesses, particularly if you are looking at perimenopause or menopause—all those things: sweating, shortness of breath, hair loss, and brain fog in particular. We just heard Professor Heneghan say that this issue is not being taken seriously in this country because it is seen as a cosmetic procedure rather than a medical procedure. Is it also the fact that women are not being listened to? We have produced a report on medical misogyny and we found that women are not listened to when they go to a doctor and say there is something wrong with their body. Is this also part of the problem?

Professor Nanayakkara: I certainly think so. Most of the patients who come to our clinic have been seen by three specialists, sometimes 10 to 15 doctors. The diagnosis of hysteria is made more often in women than in men, and there have been studies published in *The BMJ* and *JAMA* that women do not always get the benefit of the doubt. That is why we also started this. So what do we do? We talk to them and see whether we could exclude all the alternative explanations; if they have the classical symptoms, we come up with the diagnosis of breast implant illness. We have seen more than 2,000 patients. So to your question, yes, in my opinion the patient should get the benefit of the doubt, not the doctor; at the moment, we are giving the benefit of the doubt to the doctor and the industry.

Q14 **Rosie Duffield:** Professor Heneghan, you were talking about the different kinds of implant, and we have heard that there is a register in the Netherlands. So if there is no register for NHS England, presumably each hospital, or each CEO or whoever does procurement, can order its own type of implant from wherever you get these things. I am assuming that each private clinic also does its own thing and has its own supplier. Do we know where these implants are, who is getting them and what



kind? Is there any regulation of that at all?

Professor Heneghan: Just to correct the facts, we do have a register that is managed, I understand, by NHS England. In 2023, 18,367 patients underwent operations at 335 different organisations. The point is, there is no report on outcomes for that. What I am saying is that the other registries are mandated to produce an annual report updating us, so you would be sitting there with a report from the registry saying, "These are the implants that went in. Here is our 10-year follow-up," because it has been, nine years—it has been going since 2016. You and I would have an annual report, and we could use that information to help inform patients. Is that clear?

Rosie Duffield: Yes, thank you very much.

Professor Heneghan: We just do not have the outcome of the report. At the current moment it is unavailable; it says, "The dashboard's not working," and it has been like that for nine months.

Q15 **Alex Brewer:** Professor Nanayakkara, can you outline the symptoms referred to as breast implant illness—we have covered this a bit, so just succinctly?

Professor Nanayakkara: As I told you, people with breast implant illness are mostly really debilitated. They have severe tiredness—not just tiredness, but severe tiredness—morning stiffness and pain in the joints. They complain that they feel as if they have flu all the time. They cannot exercise because of muscular pain. Sometimes when they have had implants for a long time they also get allergies and skin allergies; we also find that allergies get worse after the implantation. About 70% to 80% of these patients also have local symptoms, which can be atypical chest pain or shortness of breath, up to a feeling of tightness. So there is a scale of symptoms that are called breast implant illness.

Scientifically, it has never been demonstrated that autoimmune diseases like lupus are caused by breast implant illness. But when patients have breast implant illness, they have a typical cluster of symptoms. What we see is that there are patients in hospital with all kinds of atypical diseases but nobody makes the link to breast implants. That is what we do.

So to answer your question, there is a scale of symptoms, which I have listed, but you have to think that they are linked to the breast implants, mainly because of local complaints also. It is a combination of systemic and local complaints.

Q16 **Alex Brewer:** Have you seen a rise in patients reporting these symptoms?

Professor Nanayakkara: Yes, and that is because awareness is small. In the Netherlands, there were lots of television programmes that spoke about this. That is why some people say it can also be a nocebo effect: that when people know that breast implants can cause symptoms in



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some patients, they get it also. Of course, diseases have many reasons so that could be one reason why this is increasing, but I am sure there are many other reasons for breast implant illness. So to your question, is it increasing? Certainly, yes; we have a waiting list of 13 months. Hundreds of patients are waiting to be seen by us, and we have started a consortium of clinics in the Netherlands to see these patients.

Q17 Alex Brewer: Thank you. Professor Heneghan, are you also seeing an increase in patients with these symptoms?

Professor Heneghan: I am a GP who works in urgent care, so I do not see patients within that context, but I did want to make some important points.

First, it is not classified as a disease. That has important issues for how it is reported and what is picked up. The problem is lack of evidence, but as more evidence accumulates, I am sure it will get a disease classification. Secondly, the latest systematic review data based on 31 studies shows that 84% of individuals' symptoms improve with removal of the implant, which is an important aspect in terms of diagnostics and causation.

Thirdly, to truly understand this—because of the vagueness of the issues—we need a prospective study, where at the time of implantation you consent people to be followed up and you start to understand and ask them about their symptoms. That is the type of story I think the professor is talking about; we need one of those in the UK to fully understand what is happening and the issues at hand.

Q18 Alex Brewer: Professor Nanayakkara, what percentage of women who get breast implants report negative side effects, and do you know why all women are not affected equally?

Professor Nanayakkara: The percentage of women reporting complaints can go up to 50% if you include local complaints. In the Netherlands, for example, there are about 13,000 breast operations. Up to 40% are re-operations, not first time operations, which means that almost one in two get a re-operation. Within 15 years, almost 40% of the patients get a re-operation, so that is the answer to your question. It varies according to every cohort, but most of these women get local complaints. They end up at the plastic surgeon and get an operation. The women who end up in our clinic are patients with some local complaints, but more systemic complaints. So local complaints are the biggest problem.

The second problem is breast implant illness. Why do they get it? It is probably genetically predetermined as not every woman who gets the implants gets the disease. In our cohort we showed that almost 70% had pre-existent allergies that got worse after implantation. So we think there is a genetic predisposition, just like some other diseases and if, let us say, a PIP implant leaks in these patients, they will get severe complaints. We are looking for a genetic predisposition just to see



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whether that could predict that they will get symptoms, but we are still not there.

Q19 **Alex Brewer:** You have touched on this a little, but to what extent does the removal of a breast implant completely alleviate the symptoms?

Professor Nanayakkara: In our cohort, just like Professor Heneghan said, two thirds get better. If the implant is older than 10 years, they are less likely to get better because the point of no return has probably been reached.

Q20 **Alex Brewer:** Professor Coleman, what research has been done on the causes of breast implant illness?

Professor Coleman: The problem is that research on the specific causes is very difficult to do. Animal studies have looked at the components of the implants—the small siloxane chemicals that leak out of them—and the industry has spent a lot of money on research and looking at these siloxane components in animals. They do cause problems in animals—they cause some issues in reproductive systems, as I mentioned earlier—but this has not been followed up at all in human levels. We know that these chemicals are found in the blood of women with implants. Also these chemicals were, until relatively recently, found in cosmetics; D4, D5 and D6 were in lots of different cosmetic preparations and were absorbed into people's bodies, but far greater concentrations are found in bodies of women with implants than in those who just use the cosmetics.

The problem is that we do not know what D4, D5 and D6 are doing to human systems. We do not know how these small football shaped chemicals cause all these different disseminated reactions. In toxicology, if you look at the effect of alcohol, you can say, "Oh, that has affected the liver." If you look at vaping, "Oh, that has affected the lungs." With these chemicals, however, there is no one organ that is impacted, so it is quite difficult for people to grasp how we can link these chemicals with all these complicated different effects in the brain—such as brain fog—in the endocrine system, in the muscles or in the joints. That is the real difficulty: trying to work out exactly how siloxanes cause these problems.

The EU has recognised that D4 is a problem and it is going to be pretty much banned from the middle of next year, except for its use in making implants; we may note the strangeness of that, but D4 is being phased out of cosmetics. It has been decided that it is too toxic to release into the environment as it is an aquatic toxin, but you can carry on making implants with it, which is rather strange. From a scientific perspective, that is not very consistent.

We need to find out much more about how D4, D5, and D6, the related siloxanes, are causing these problems because they are found in concentrations in women's bodies, and when the implants are removed, the siloxane polymers remain in the body, in particular if they were



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released through a rupture. We need to find out a great deal more about that.

- Q21 **Alex Brewer:** In the light of the picture across the EU and the irony of the situation, do you think it would be better if legislation prevented breast implants from containing silicones like D4?

Professor Coleman: The big problem is that if you do not make implants out of silicone, what do you make them out of? In the US they tend to use saline-filled implants, but those have a silicone envelope—a silicone barrier—so at some point, silicone is in the process. The industry, as far as I am aware, has behaved a little like the oil industry; “We are always going to be using oil. We do not need to research any alternatives.” It has been very narrow in terms of looking for materials that are not likely to impact the human system. For the last 50 or 60 years it has been assumed that silicones and siloxanes are inert, but they are not. The evidence now strongly points to the fact that they do impact the human body. The human body sees and recognises them, and those siloxane components are the root cause of problems with implants. Because the PIP implants were so leaky and so badly made, they were the most acute manifestation of the problem. In the future, I am sure that people will want implants—that need will never be satisfied—but they should not be made out of siloxane polymers.

- Q22 **Catherine Fookes:** Before I start, I just wanted to say a big thank you to Fleur Anderson MP, who has raised this issue consistently in Parliament and has really tried to raise awareness of it—perhaps it is thanks to her that we are doing this inquiry.

The French Government urged 30,000 women to seek removal of the implants and that was undertaken by the state. Do you think the UK Government should have done that?

Professor Coleman: Absolutely, yes. We would all probably agree on that one. Yes, they should put their hand in their pocket and pay for this.

Professor Heneghan: In 2012, there was an NHS offer for women with PIP implants, but that offer has disappeared off the horizon. I think that offer should be reiterated to women. The problem is that it applied only to those who had their implant within the NHS; there are women who had it done privately and were not aware of these issues at the time, who have had to go privately and fund them. That is what I understand.

- Q23 **Catherine Fookes:** We have compensation schemes for the infected blood scandal and for other scandals. I just feel that it is so important that, in my opinion, the Government should most definitely have a compensation scheme for women who have undergone these breast implants. It looks like everybody agrees.

Professor Heneghan: Can I come in on that point? What you really need is a mandatory insurance scheme that at the time of implant puts insurance in place that says, “If this is going to go wrong, we have to go



and pay for it in the future.” You could tie that to the quality of the evidence, so if the evidence is derisory, the cost of the insurance should be huge. As soon as you develop better evidence, your insurance should be less, but the NHS or whatever is putting these implants in needs an insurance system, because they do go wrong.

- Q24 **Catherine Fookes:** Can I ask a question for clarification? Apologies, Chair, I am going a bit off the question I was supposed to ask, but I do not understand; have PIP implants been banned here in the UK?

Professor Coleman: Yes, definitely.

- Q25 **Catherine Fookes:** I have a question about the rise of breast implant associated anaplastic large cell lymphoma, or BIA-ALCL. Has there been a rise in reports of that, and if so why?

Professor Nanayakkara: There has been a rise according to the FDA. The problem with BIA-ALCL is that you have to look for it to find it. When most private clinics remove the implant and remove the capsule, they do not check it under a microscope. So there is definitely an under-reporting of ALCL. Mostly the prognosis is good, but there are women who have died from it.

I have an international survey here that says that 31,000 British women received implants in 2023. That number will be more, because as Professor Heneghan also says, lots of women are getting implants in other countries like Turkey and Spain, and I do not think they check for ALCL.

- Q26 **Catherine Fookes:** Do certain types of breast implants, such as textured versus smooth, have higher rates of BIA-ALCL reported?

Professor Nanayakkara: It has been shown that the majority of women have macro-textured implants.

It is also worth saying that macro-textured implants were introduced because it was thought that they were better at preventing local symptoms. But we found out later that most patients with ALCL have had macro-textured implants, so it looks like there is a strong association or even causality with these symptoms. There are cases of ALCL with PIP and some smooth implants, but they are in the minority.

- Q27 **Catherine Fookes:** I have one final question: is there any risk of developing BIA-ALCL after having the implants removed?

Professor Nanayakkara: They have described one case in the capsule after removing the implants. Again, it is under-reported. So there is a risk, but the risk is not very high. ALCL risk is also not very high. The incidence can vary from 1 in 3,000 to 1 in 30,000, according to all kinds of things, but I think it is going to increase. So to your question, after removing the implants, the chance is low, but there have been instances.



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Professor Coleman: Can I just make one quick point? It is very important to point out that BIA-ALCL is not a breast cancer; it is a cancer of the immune system. That is a very important thing to see in the context of the impact of implants and siloxanes on the immune system.

Q28 **Kirith Entwistle:** My first question is for Professor Heneghan. To what extent are patients adequately warned of the health risks of breast implants prior to getting them?

Professor Heneghan: The answer is they are not, and that is a recurring problem that we have seen among a number of devices, including surgical mesh, the Primodos hormone pregnancy test and sodium valproate. I cannot understand how you can get informed consent at the current time. Importantly as well, given all the problems you have heard, FDA recommendations state that you should have an MRI scan at three years after the implant is first put in, and then every two years after that.

Kirith Entwistle: That is not going to happen.

Professor Heneghan: The problem is that the cost of the MRI scan and the monitoring far exceeds the cost of the implant. So there is a systematic problem in patient safety that we are not addressing, which does not allow us to inform patients with what I consider to be true informed consent.

Q29 **Kirith Entwistle:** That is quite a stark picture. You mentioned earlier that you have some experience of being a GP, is that right?

Professor Heneghan: Correct.

Kirith Entwistle: So do you think GPs in the UK typically have sufficient awareness and understanding of BII and BIA-ALCL to believe women when they present with relevant symptoms? What do you think could be done to better educate medical practitioners on these health conditions?

Professor Heneghan: I am an academic GP who works in research and teaching, so as a professor of evidence-based medicine, I have an understanding of these issues and the device regulations at first hand. My colleagues are not aware of these issues at all. It is very difficult, though, to put more workload on GPs; you have to remember the range of problems that they see. The amount of advice and guidance coming in means they are overwhelmed.

The key issue here is for the regulator to improve the post-market surveillance and ensure that alerts are transmitted to all doctors and all trusts about what is going on. We have to do that well here, and the problem is that if we do not, as one of the other witnesses said, you will have a problem with more women going abroad to get their implants and you will increase the issues at hand.



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What we should be saying is that, "We are going to provide a safe system that is world leading in the evidence base. If doing so please come and do it here and don't go abroad, where the problems are bound to be much worse."

Q30 Kirith Entwistle: In addition to the regulators you have mentioned, do you think there needs to be updated and regular advice and guidance for medical practitioners?

Professor Heneghan: As I have said previously, we need an annual update from the registry. We need a report annually that goes to yourselves in Parliament, and to all the trusts, with everybody saying, "This is the latest state of what we know."

Secondly, we need to know what implants are available, what evidence has been used to approve those implants, and what follow-up evidence there is. In new regulations that came into force in 2010, the FDA requires 10-year follow-up studies in the post-market surveillance arena. So the manufacturer has to follow them up for 10 years and provide updates to the MHRA. That should be mandatory for all devices.

Q31 Kirith Entwistle: Thank you. Professor Coleman, you touched on this earlier; do you think there has been adequate research into the safety of breast implants? If not, in what areas is research needed?

Professor Coleman: The most direct way is through the advice process; when women are thinking of having the implant, you can advise them on the risk factors they might already have.

Professor Heneghan touched on the idea of insurance. Certainly, medical insurance is invalidated if you have a pre-existing condition. They will get out of paying if you have that. Now, the evidence so far seems to suggest that if you do have issues with your immune system and overactivity in the immune system, or a history of autoimmune disease, there is a much greater likelihood that you will have a problem with silicone implants because of this adjuvant accelerating effect on the immune system. So women need to be aware of that.

We need to do more research into strengthening, or having more understanding of, that link so that women in the future can be spared having years and years of suffering as a result of having an implant that is fundamentally likely to be incompatible. Many women can live with implants for many years without a problem, but scientific and medical literature suggests that a substantial number of women will have a problem, and those problems will not go away for quite a while. Even if the implant is removed, there are issues once you have triggered the immune system, as Professor Nanayakkara was saying; it can go past the point of no return, when the immune system is so over-triggered that it will essentially be very difficult to stop. You do not want that to happen—you need to prevent it from happening—so we need to understand much



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more about the link between implants, the immune system and other pre-existing conditions.

Professor Nanayakkara: We have a national protocol that we have been working on for more than 12 years. Still, doctors often do not believe in the diagnosis that breast implants cause symptoms. Most patients who come to us are frustrated and angry, and I understand that because they have been sick for, let us say, 10 years. These women lose their jobs, they lose their relationships, they are divorced, they are about 50 years old, and they have nothing. They have no money to pay for MRIs in the private sector, so they are really frustrated. They need recognition, and in spite of lots of work, sometimes they still do not get it. So there is lots of work to be done, including training doctors and creating awareness among doctors about the problem.

Q32 **Kirin Entwistle:** Professor Coleman, do you think patient safety is overlooked when it comes to women, and do you think there are signs that the cosmetic industry downplays or hides the risks of implants?

Professor Coleman: I would agree with that. I saw a study where surgeons were asked what coloured their decision as to which implants they used; only about 29% of them made a decision on the implant based on the risk of cancer. They made their decision on the implant based more or less on whether a capsule would be formed or the implant would move; therefore, they chose the textured implant, even though they know that the evidence links textured implants to BIA-ALCL. They were far more interested in whether the implant was going to move, and women coming back to them about that, than the women being at risk of cancer.

The risk of cancer is very much stronger with the textured implant. Almost all the cases—there are about 1,100 cases so far with BIA-ALCL—are related to textured implants. But the industry was more concerned with the take-up of textured implants and that manufacturing would be impacted by this. Their income stream seemed to be their primary concern.

There are issues with the smooth implants, obviously; they are more likely to move, there is more likely to be a capsule, as Professor Nanayakkara mentioned before, but their concerns seemed to be more about the practicality of the operation and not necessarily about the long-term health of women. That was my perspective from that study.

Q33 **Kirin Entwistle:** Professor Heneghan, do you think there is a case for better follow-up monitoring of women who have had implants? You did mention MRIs and the cost, but do you think there needs to be a better system for monitoring and follow-up?

Professor Heneghan: There needs to be a change in how we view patient safety when it comes to implants. That is what you are hearing, and this Committee meeting is recognising a signal that there is a



problem. That problem is multifactorial: lack of evidence, lack of ability to inform patients, and clearly a patient safety issue. What happens in every scandal is that there is a significant delay between noticing the signal of harm and taking concerted action to fix an issue. Somehow, your Committee has to escalate and bring action forward. There will probably be no new regulation enacted for the next 10 years, so one of the key issues is to work within the existing systems and make them function better. I am happy to write to the Committee about the five or six things I think could happen within the existing regulations that we could do much better to ensure patient safety.

Kirith Entwistle: Yes please; that would be great.

- Q34 **Chair:** Before we go back to Kirith, I want to ask a question. Many people might have Professor Coleman's words ringing in their ears about BIA-ALCL being a cancer of the immune system. That sounds incredibly worrying and incredibly serious. Could you talk about the prognosis and the treatment for this cancer of the immune system, Professor Nanayakkara?

Professor Nanayakkara: It is a form of non-Hodgkin lymphoma. So if you remove the implants and the capsule on time, the prognosis is quite good. But I also talked to my haematologist before talking to you about it; we have had patients who had to go through chemotherapy and who had complications from that. So the short answer is that prognosis is good, if it is detected in time, but there have been deaths and those are increasing.

Chair: Thank you very much.

- Q35 **Kirith Entwistle:** I will direct my final question to Professor Nanayakkara. What would be your advice to women considering getting breast implants?

Professor Nanayakkara: If it was a woman in my family, I would say no. If they are known to have a severe allergy, I would say no. If they have a family history of connective tissue diseases, I would say no. I am biased, so to any other women who asked me whether they needed breast implants, I would say no, but I do not know what I do not know. I do not see what I do not see. I do not know how many patients there are, or how many women without complaints. So it is a long answer, but for my family members, I would say definitely no.

Professor Heneghan: As an analogy, when you decide to have a hip implant you do it because you have a severe problem. You may not be able to walk 100 yards. I would not recommend you have an implant if you could walk to the shops and back and run down the street and operate normally. So the key issue here is, when you are having an implant, you have to recognise that you do not have a severe issue at hand. You may have legitimate reasons for doing it, but all the harms will be accentuated. Therefore, just like the professor, my advice in this



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situation is to be risk averse and try not to have the implant. I would try to explain the consequences in the long term when all the problems will emerge.

Based on that, right now, I would not be able to consent somebody, and I would not be able to provide the operation, because I say, "I cannot give you informed consent according to GMC guidance because of the problems we've outlined." That is the key issue. We should pause these operations until we can fix the issues.

Q36 Kirith Entwistle: Professor Coleman, did you want to add anything?

Professor Coleman: You have all seen the "Terminator" films when this thing comes after you and will not stop. You do not want to invite an immune system Terminator into your life; the problem with the PIP implants is that, unfortunately, thousands of women have done that. We must prevent this happening and find out more about it, find out what increases the risk, and do anything we can to stop it. You do not want your immune system pursuing you for the rest of your life and causing you to suffer to this degree just because of a cosmetic thing—something, as Professor Heneghan was saying, you do not need. You were fine before and now you are not because of a decision you made to enhance your body. It is too great a price to pay, in my opinion.

Kirin Entwistle: Thank you. There are some really powerful statements there.

Chair: I am obviously taking on board what you have said about informed consent, but in the interest of balance I should say that there will be some people, particularly breast cancer survivors, who have to think carefully about whether they have reconstruction. This is an issue for trans women as well, who would not classify themselves as fine before. So it is important to make sure that we have that in our minds.

I want to say thank you to all three of you for your expertise, your openness, your honesty and your determination to listen to and help women who have issues with their implants, whether they are PIP or not, and to try to help us make better decisions in this place and hopefully in healthcare settings across the country.

If any of you have anything that you want to add, please do feel free to send it to us in writing, particularly if you feel that something was not explored. On behalf of the whole Committee, thank you very much.

Examination of witnesses

Witnesses: Professor Vivien Lees, Ashton Collins and Sasha Dean.

Chair: Thank you for your patience. I am sorry we have slightly overrun, but you can understand why that evidence was incredibly powerful and informative for the Committee. Welcome to everybody on panel two, and a massive welcome to Ashton Collins, director of Save Face; Professor



Vivien Lees, consultant plastic surgeon and vice president of the Royal College of Surgeons; and Sasha Dean, who has lived experience of severe complications following a liquid Brazilian butt lift—we will use the term BBL. Thank you all for being here, and welcome.

- Q37 **Christine Jardine:** Thank you all for joining us. Professor Lees, I wonder if we could start with you. We are particularly interested in whether the Royal College of Surgeons has any view on the safety of breast implants, particularly in the light of the emerging evidence of the potential effects on women's health and what we have all heard today?

Professor Lees: As practising clinical scientists, we are obviously open to new evidence that emerges. The position we take depends on the evidence available at the time. It is obviously concerning to hear some things that have been presented in the last session. There are very important benefits of breast implants, though. You yourself have mentioned breast reconstruction, and the psychological benefits for women who are particularly self-conscious about their shape are undoubted. We do not want to deprive people unnecessarily of their implant, but we have to make sure that they are safe, first of all. We do not have a formal position on that, but we will be very mindful of evidence that comes forward.

- Q38 **Christine Jardine:** Are there any plans to examine whether you need to make a formal decision, or any inquiry under way?

Professor Lees: We have the national breast and cosmetic implant registry database, which started in 2016. All implants are logged on that by responsible practitioners. That includes the type of implant, so we understand which manufacturer it is, they have serial and lot numbers, and the reason for putting them in has to be recorded. Obviously, the PIP implants were not put on to that database, but they are being captured as they come out again. If an implant is removed, that is also recorded, and new implants may or may not be put in. There is some narrative around why that implant was used and why a subsequent set has had to come out. We are gaining that information. It is absolutely right to flag the fact that we must not lose this database with what is happening to changes in NHS England; it must be migrated.

- Q39 **Christine Jardine:** I am sorry to press you on that, but will this database be used to come to a view or a recommendation of any sort on the safety of breast implants?

Professor Lees: The point of the database is to flag concerns, but I would probably agree that we are not capturing enough data about possible symptoms on it at the time of removal. At the moment, it is not set up to do a biannual review and record that, and equally, symptoms are not captured at the time of removal. It would capture, however, things like capsule contracture, whether the implant has ruptured or not, and any other concerning features at the operation itself.

- Q40 **Christine Jardine:** Ashton, the number of cosmetic procedures has been



steadily rising in recent years. What do you think is driving this?

Ashton Collins: There are two primary factors. Without doubt, the biggest proponent has been social media. If you look at non-surgical treatments, in particular, when they first came to the UK circa 20 years ago, they were very much the reserve of the rich and famous. Nobody wanted to discuss having them done, whereas with the advent of social media and reality TV, more and more people are happy to discuss the work that they have had, and in turn, promote that work on social media. Especially for younger people, that is where they look both to get information and to find practitioners. It is a constant source of misinformation about how safe these treatments are, and end users are not informed about the risks. It is also a hotbed for unscrupulous practitioners to prey on and target women into believing that they need these types of procedures.

Q41 **Christine Jardine:** Is the rise uniform across the board, or is it most notable in certain demographics? If it is, why do you think that is?

Ashton Collins: The surge has definitely been geared more towards younger people. We have been established for 10 years, and in that time, we have gathered patient-reported data on complaints and concerns, and we have helped over 15,000 members of the public either with unwanted outcomes or adverse reactions and complications. Over 50% of those have been from women aged 18 to 30.

Christine Jardine: Sasha, I wonder if I could ask you those two questions as well. First, what do you think is driving this increase? Would you agree with Ashton?

Sasha Dean: Yes, I agree. It is definitely social media. For me, for my liquid BBL, it was something that I had hated on my body for a long, long time. So, yes, when it started coming through, I thought that that was definitely going to be the easy option for me. Seeing so many women have it done and it being deemed safe, that is what spurred me on to do it rather than the surgical route. But yes, it was anything but safe.

Q42 **Christine Jardine:** It is interesting you say that. You obviously believed it was safe.

Sasha Dean: I was told it was safe, and I believed it was safe.

Q43 **Christine Jardine:** You were told it was safe. Would you say that perhaps that lack of awareness that we have heard about earlier needs to be addressed, and addressed quickly?

Sasha Dean: Yes, because the people who are carrying it out all know that it is not safe. The clinic and the practitioner who did me know it is not safe, and their social media is still saying it is safe. They know that they nearly killed me.

Q44 **Shivani Raja:** I would like to discuss specifically the liquid BBLs and liquid boob jobs. Professor Lees, if I can come to you first. As we know,



liquid BBLs and liquid boob jobs have gained popularity in recent years. What specific risks are associated with these procedures?

Professor Lees: I perhaps had better explain that there are two versions of enhancement of large-volume areas like the buttocks. It is typically the buttocks, because implants are used for the breast area, but it can be both. Surgically, we tend to use a fat graft, which is from that person's own body, taken from one place and then re-injected into the target area. Then what is called liquid BBL is an off-the-shelf filler—for example, Restylane, but it can include free silicone, and from what you have just heard you will understand the implications of that.

There are a number of filler materials typically being injected under a local anaesthetic, rather than under a general anaesthetic in a hospital. One of the big issues is the environment that this is being done in, which may not be a sterile environment, may not be clinical, and may just be on the high street, which is very concerning. The other issue is clearly informed consent about the risks that somebody is running. If you inject any of these materials, be it fat or filler injection, and you hit one of the large veins in the gluteal muscle, that can result in the material travelling around into the lung and causing a pulmonary embolus, which can be fatal.

Q45 **Shivani Raja:** Just so I am clear, the non-sterile environments could lead to infections, is that correct?

Professor Lees: Yes. It is a very serious matter for any of these procedures, or indeed other surgical procedures, to be performed in a non-clinical environment. The confusion of the term "beauty clinic" makes it sound like a clinic, but it is not. What we are talking about is a medical clinic, which comes under the regulation of the CQC, and the medical practitioner under the GMC, versus the high street clinic, which is under the environmental health authority, who are not clinical specialists.

Q46 **Shivani Raja:** Ashton, I know you just discussed this, but were you aware of specific risks associated with these kinds of procedures?

Ashton Collins: For us as an organisation, we became aware of how severe the risks with these liquid BBLs were in 2023. We launched a campaign at the end of 2023 calling for the Government to restrict the administration to plastic surgeons only in CQC-regulated settings. We have helped over 700 women who have fallen foul of these types of practices and have ended up in hospital with sepsis and needed corrective surgery. I cannot stress strongly enough the impact that these procedures have on both their physical and their emotional wellbeing.

Q47 **Shivani Raja:** Sasha, were you not informed of any of the risks before you went for yours?

Sasha Dean: No, none whatsoever.

Q48 **Shivani Raja:** If I can just come back to you, Professor Lees, can liquid



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breast augmentations make it more difficult to accurately screen for breast cancer?

Professor Lees: It is not commonly done. Generally, our surgical community would offer breast implants, but we also use autologous fat, or maybe a combination of the two techniques together. When that was first described there were concerns that the fat graft might cause some confusion because it got a little lumpy, and it might be mistaken for a breast cancer lump. Those concerns, if you will, have not borne out in practice, so people are more comfortable with doing that surgically now. If we are talking about filler materials, those could certainly confuse a diagnosis. That is a safety issue, clearly.

Q49 **Shivani Raja:** How do those risks compare with a surgical BBL or breast augmentation?

Professor Lees: There is not really good data on the comparison of surgical with liquid butt lift. It is one of the problems we have in the whole area, that we do not have really good data, because non-surgical practitioners are not recording outcomes. We are calling for Government to make an amendment to the Health and Care Act 2022 to restrict the practice of cosmetic surgery to surgeons who are board certified in cosmetic surgery. The board certification is something that has been supported by the four Royal Colleges, including that of Ireland and of the relevant surgical specialty associations.

A lot of time and effort has gone into building this programme, which demonstrates for those who hold the boards that they have a real commitment to safety; they have reached the training requirements; they have experience in dealing with this; they have undertaken a professional masterclass in communication skills with patients; they reflect on their activity; they audit their activity; and they do an annual appraisal, including a whole practice element, so if they practise cosmetics, that is included and is part of revalidation. That is really to say, there are people there the public could access and hopefully have a good experience with.

Q50 **Chair:** Sasha, thank you so much again for being here. Could you tell us a bit about your experience of getting a liquid Brazilian butt lift, please?

Sasha Dean: Yes. My journey started many years ago with an asymmetry on my body. It was never to do with wanting a big Kim Kardashian bum or anything; I have a very, very flat glute muscle on one side compared with the other side. I started off on my exercise journey, and it did not work.

I then looked into the surgery journey, but that did not work for me. I had to gain some weight, then I went to have the fat taken out of my body, and when it went to be transferred into me, I was not well. The surgeon said it was not safe to continue. I had the fat taken out, but I could not have it transferred. I went back to my exercise journey to try to correct this asymmetry. It was a big deal for me. I am tall; I find it hard



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to get clothes. After I had my children, I gained a bit more weight around the middle, and so I was very narrow on my hips and very flat on one side, and it became even more challenging to get clothes for me.

When the gym was not working and then this liquid BBL was coming through, the clinic that I was going to for my anti-aging bits and bobs said, "There's this new filler coming out. It's really safe, it's hyaluronic. It's what you have in your lips, and you've had your lips done before, so you know you're going to have no reaction." I thought, "Wow, this is fantastic." I entered on my journey with the clinic, and it asked me if I could be its model, which I did. I had it done, and it was actually okay the first time; excruciating pain, but I was okay. I was just pleased that there was something that could be done. The clinic said, "You probably only need 200 ml. You need to do the other side as well as that side to get it looking the same, so 200 ml and you'll be good." No: it was very apparent that it was then going to have to be an ongoing situation, because you could see where the filler was sitting.

I had it done a second time, and we thought that was going to be good. Again, the pain was excruciating. I did not actually know if I could then embark on it a third time. I did, and the third time there were problems. I do not know whether it was just the volume of filler; there was 200 ml in that side now. I started to get an infection. I rang the clinic. It said, "Just take some antibiotics." As blasé as that, "Just take some antibiotics." I actually had some antibiotics at home, but by this time I was oozing all down the leg, and I thought, "This isn't good." Anyway, the antibiotics cleared it all up and it was okay.

A few months on it started going a bit of a weird shape, so I actually spoke to the person who was its nurse, effectively. It transpired she was not a nurse at all; she was just anybody who could carry this out. She said to me, "Look, I reckon we just need to do another 200 ml. You're going to be done. You're going to be fine." I said, "I can't afford this any more." It is so expensive, but I had been their model and stuff before, so I did not have to pay the full amount. She said, "Come to my house. I have a clinic at my house, and we'll do it there," which I did.

In itself, at first glance it looked okay. It was sterile enough, until I was lying down and halfway through, my partner, who was in the room, noticed the state of my feet. He said, "I used to really like your feet until I saw the state of them," and I looked back at my feet, and they were black. To which she turned round—her mum had come in and was sitting at the end of the room—and had a go at her mum for not sweeping the floor when she had done her client's hair. So, that was that.

I remember thinking, "Okay, this isn't good, but it's too late now. Let's finish." I would say immediately when we finished, we were just getting out of there—it was cold anyway; it was 30 December—my temperature just dropped out. I remember getting home and it was 35-something°. I could not warm myself up. I could not have a bath because you cannot



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get it wet, and I said to my partner, "I'm going to go to bed." Unbeknown to me, the sepsis was creeping in. I lost all sense of reality for the next couple of days, until the ambulance was called on 2 January, and I was in full-blown septic shock. Yes, that is where my journey began.

Q51 Chair: Thank you for sharing that, Sasha. I am sorry you have had that ordeal. Obviously, there was the immediate sepsis. Were there any long-term health complications following this?

Sasha Dean: Yes. Obviously, I was admitted to the hospital. I was transferred immediately into ITU. My family were told there was no chance—5%. I was then in ITU. A few days later, it was apparent I was struggling to breathe, so I was put into a coma for five days. Whatever they were doing, it was not working. I had a heart attack, my kidneys failed, and my lungs collapsed. Yes, it was pretty much just hopeless. I do not actually remember anything pre-coma—from being in A&E to ITU to the coma—but I remember being in the coma. I remember my partner trying to do a rose in what was then my long hair, my daughter obviously telling me to fight, my dad telling me to fight. I remember trying to signal to say, "I'm fighting. I can hear you." And I did, obviously; I made it.

Five days later they woke me up out of the coma, and it was the most traumatic time. The terrors I had: Ian Huntley standing in my wardrobe trying to get me to go in there, and just all these nightmare things happening to me. I was in hospital for the next five weeks just getting better. They could not really get the infection under control—they were trying everything—but eventually after about four weeks they said, "You can go home." I went home with my lines in, to recover. I had to learn to walk again, because obviously I had been lying flat for five weeks.

I have had an MRI of my brain because walking and talking at the same time is challenging. I have weakness on my right-hand side; I drop things with my right hand. While I have no brain damage, they felt that I have small vessel damage, which will just be enough to keep me displaying weird symptoms. I have ongoing kidney issues, which I have to have checked out, my lungs keep having to be checked, and I have been left with a leaking heart valve.

I have struggled with my partner's and my business. All last year I could not really work, so the business was in real jeopardy. It was only okay because my partner and family stepped up to try to help. I have a mortgage, I have my children I have to look after, and the last year I have been completely unable really to do anything. Then I lost all my hair.

Yes, the impact is profound. What has made it even worse is there is a grey area with all my issues. Although I had a heart attack, because they treated me so quickly, I thankfully do not have any muscle damage. My critical illness will not pay out for my leaking heart valve, because it does not cover it. There is no recourse for everything I have been through, and even if I am not able to pay my mortgage and stuff, it will not pay out.



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There is nowhere to go with the clinic. I cannot sue it, because even though my solicitor got a court order sorted, which was handed to the clinic and to the girl who did me, it will not pass its insurance to it. Even though there is a court order, it is just saying, "No." It does not have to provide that, so there is absolutely nowhere for me to go with this. There is no recompense. That is just it.

Q52 **Chair:** Is this clinic still up and functioning?

Sasha Dean: Yes. The clinic is saying that it is not its fault because I chose to leave that setting and go to the girl's house. But we know—Ashton knows—that yes, while my setting was not sterile and not ideal, there are many clinics that are sterile and are ideal. I saw the Olivia Attwood case and the gentleman was going on about how sterile it was, and how he was using state-of-the-art lasers, and the girls still get sepsis.

What concerns me is poor Alice, who died last year. I do not know the circumstances around her—whether she had a blockage or whether the other girls had blockages. I did not have a blockage; I just got sepsis. Some girls got blockages; some girls got sepsis. Is it the filler? Is it the area? Is it the lidocaine? We do not know what is causing all these issues, and it is crazy.

Q53 **Chair:** You said, "Just sepsis." Sepsis kills. What you have described is horrific, but clearly you are not the only person who has experienced this. Sasha, what would you say to somebody who was considering cosmetic surgery now of any kind?

Sasha Dean: It is hard for me, because I understand why women do it. I worry about the young girls. As I was saying to Ashton just before, I am so thankful now. Obviously, I never wanted my daughter to witness what she witnessed, but I am so thankful that she is not going to go on that journey. I understand why women do. I cannot sit here and say, "Oh, don't do it," because so many women are doing it, but at least do your research. These BBLs are being carried out by anybody. They do not need any qualifications. The irony is that my daughter, the day that I was taken into hospital, went to the very clinic whose girl did this to me and was training to carry out Botox and lips. Obviously, she paid a lot of money for that course, and now she will not go near it.

Q54 **Chair:** There is a real imbalance here. If somebody had beaten you up and caused the amount of damage that this woman did to you, in any other setting, they would be behind bars. Ashton, what measures are in place to track and report adverse events related to non-surgical cosmetic procedures?

Ashton Collins: None. The MHRA operates a Yellow Card reporting system for dermal fillers, but again, it is at the discretion of the practitioners. Many of the people who are carrying out these liquid BBLs are unscrupulous. They are advertising them as being risk-free, pain-free, with no downtime, and those are all complete lies.



Sasha's story is not isolated. We have dealt with over 700 women, many of whom have been in very similar situations to Sasha: they have nearly lost their lives, their loved ones have been called in to say goodbye, they have been told they might not make it through the night. Some have been told they might wake up without their legs, because the abscesses and the sepsis have grown so severe. We have had one death related to these procedures.

These are surgical procedures that should not be carried out on the high street. They are being carried out in people's living rooms, in Airbnbs, and in hotel rooms, by people who are using products they are buying unlicensed from places like China and Korea. They are decanting them from huge vats into individual syringes, and injecting thousands of millilitres into people's breasts and buttocks.

Then when things go wrong, they are misdiagnosing these problems and telling them there is nothing to worry about. Luckily, all these women have taken themselves off to hospital, because if they had not, there would have been countless deaths in the UK because of this. It should not be allowed to happen.

Q55 Chair: One of the other inquiries that we have at the moment is on female entrepreneurs. We know that the beauty industry is one where female entrepreneurs are growing, and it is fantastic to see. What is the sense in the cosmetic industry about your campaigns to see tighter regulations on this issue?

Ashton Collins: The vast majority of practitioners are 100% behind the fact that these procedures should be limited, because they are surgical, so they should be carried out only by surgeons. Anybody who does not agree with that is not a scrupulous practitioner who has their patients' best interests in mind. These treatments, even in the safer surgical hands, still pose significant risk. If you are a layperson with no medical background offering these incredibly dangerous procedures, you should not be operating.

Q56 Rosie Duffield: Gosh, that was pretty shocking. Thanks so much for being so honest with us. People at home watching will be really moved by your story. Professor Lees, we are going back to talking about education and informed consent, if that is okay. Are patients adequately informed about the risks of implants or wider cosmetic surgery, in your opinion? Are cases like Sasha's common enough for that to be factored in, do you think?

Professor Lees: Well, Sasha was not treated by a surgeon, I would like to just say that. From the point of view of the surgical community, what we would recognise as best practice consent would be a clinical assessment of the need for a procedure, be that physical or with a psychological element; providing information through staged discussions, through written generic information, and then a personalised letter to the



patient as to the facts, the pros and cons; and trying to work with the patient as a partner to reach the right decision for them.

We recommend two consultations with a cooling-off period—two weeks apart minimum—so people do not consult with a non-doctor, meet the doctor five minutes before the operation, and then go straight into surgery and then regret it. We want people to be suitably supported and happy with the procedure and have successful outcomes. That is what we want. Clearly, informed consent is key. Is it what always takes place? We have no idea. But as the responsible end of the practice, we will be auditing our results, and we can look at outcomes and satisfaction surveys. These things are all doable, of course.

Q57 Rosie Duffield: Is there a problem with regulation? Because obviously you are one end of the scale, and then we have these people doing it in their houses. It seems like anyone can do anything. In a way your reputation might be damaged by this, and the other way round—people are going to assume the same standards are going to be carried out at that end of the market.

Professor Lees: Yes, that is absolutely right. One of the problems is because we have such a degree of regulation in this society around all sorts of things, the public think that all this is regulated, when it is not actually. If we may, Chair, through you, we would like to ask the Secretary of State when the consultation that took place in 2023 around the regulation of non-surgical procedures might be published, and when we will learn of his determinations around that. That would be really helpful, because clearly there is no regulation around who can do what. We have non-doctors doing operations, as you have just attested to, and misrepresenting themselves to the public, which is a really difficult dynamic and something that we would like to see ended.

Q58 Rosie Duffield: Ashton, do you think there is adequate informed consent given before procedures like Botox and everyday procedures?

Ashton Collins: No. Just drawing on the data that we have gathered over the last 10 years, over 90% of the people we engage with, who have had procedures gone wrong or have had unwanted outcomes, have not been appropriately consented or consulted before having the treatment. They are not explained to what the risks are, or how that practitioner would mitigate those risks, should they occur. What we see is that when these unexpected things happen, the lines of communication are closed down completely, so they are often blocked and ignored and left to fend for themselves. The consultation and consent process is something that is incredibly important, but is incredibly lacking.

Especially among the younger age group, as I mentioned before, these procedures are incredibly trivialised. They see them as an extension of their beauty regime, like getting your hair or your nails done. They do not have any medical association at all, and so that group are vulnerable to being exploited into thinking that this is a transactional-type treatment.



We see scenarios where they are just sitting in a waiting room with numbing cream on, they are brought in one by one, they have the treatment, they pay their money, and off they go. It is a very real problem, and even more so when you consider higher-risk treatments that are really surgical, like the liquid BBLs and breast augmentations, because they are being mis-sold on an enormous scale.

Q59 Rosie Duffield: How can we better educate people? Obviously, you are doing your bit, and people who have survived are doing their bit, but what role might Parliament play?

Ashton Collins: Education would be key, even where legislation exists. For example, Botox is a prescription-only product, but in 96% of the Botox complaints that we deal with, people do not realise it is a prescription-only product and therefore have no expectation that they ought to be seen by a medical prescriber before having the treatment. Even where rules and regulations exist, without that public education to empower them to make safer choices, no rules are going to be robustly enforced, because the public need to be aware that they exist in the first place.

Q60 Rosie Duffield: So when people go and get a bit of Botox with, let us say a dental practitioner or something, that is not actually supposed to happen because it is supposed to be prescribed? I know people here who have that done.

Ashton Collins: Yes, exactly that. Anybody can inject Botox—your beauty therapist or any layperson; there are no rules around who can and cannot inject it—but because it is a prescription-only product, every patient should be seen in person by either a doctor, a dentist, a nurse prescriber or a prescribing pharmacist. That is something that is grossly under-enforced at the minute and under-policed. We are also seeing a huge increase in people now circumventing that prescription element altogether, and buying unlicensed products and illegally importing them from places like China and Korea, with devastating consequences.

If the Government were to tighten up on those two pieces of legislation—both of which are in place at the minute—and they were properly policed and properly enforced, it is estimated, based on our data, that around 80% of the complaints that we have dealt with would not have happened in the first place. They would have been appropriately dealt with and managed if that system were more robust.

Q61 Rosie Duffield: Finally, Sasha, thank you for being so brave again. Do you feel that you had enough informed consent from the beginning of your two or three procedures? Would it have changed your mind if you had had more information, do you think?

Sasha Dean: It absolutely would have changed my mind if I had more information. As Ashton was saying, it is so played down. They say, “Oh, well you’ve had it in your lips. It’s no different; it’s not painful,” and you are sitting in the same waiting room, with the women in and out, just



going and having it done. You are in the same room, the same environment. That is what lulled me into the sense of security that it was not going to hurt as well. I just thought because it is just in that room where I have had my lips done, it is just going to be a little bit—but it really is a surgical procedure.

I was misinformed to start with, and obviously I took the decision to do it again because I was on that journey and it was too late, so I had to keep going. Interestingly, I signed a consent form—you were saying about the consent—and the consent form was actually the same as the one for having my lips done. When I went to the other girl's house, she did not get me to sign at all. There was no consent at all for it.

Chair: There is consent and then there is informed consent. They are two different things.

Q62 **Kirith Entwistle:** Ashton, you and I met last year, and you told me about a constituent. For the purpose of the Committee, I will just tell the story a little. Louise Moller experienced significant trauma following a botched liquid BBL procedure at a non-surgical clinic. She travelled from Bolton to Chelmsford in Essex for the procedure. She had been assured that the procedure would be carried out by a qualified professional with whom she had previously communicated. However, on arrival, the treatment was instead administered by a man she had never met, who was later revealed not to have completed medical training. She had already paid a non-refundable deposit of £435, so she felt pressured into proceeding.

The procedure itself was rushed and deeply unprofessional. The practitioner walked in on her while she was undressing, he took photos of her buttocks without consent, acted aggressively during the treatment, and used the same needle on both sides, posing a serious infection risk. Within days, Louise developed sepsis and was rushed to hospital for emergency surgery to remove a life-threatening abscess. She sought this treatment in good faith, believing it to be safe and professionally conducted. Almost a year later, she has still not fully recovered, has lost her previous job, and is experiencing significant mental health challenges. Ashton, if Louise had been properly informed about the risks, how the procedure was going to be carried out, and where it was going to be carried out, do you think she still would have gone ahead with the procedure?

Ashton Collins: No, definitely not. None of the women I have spoken to would have gone ahead if they had known the risks. It never occurred to me in my wildest dreams when I started Save Face 10 years ago that I would be one day sitting in front of a family who have lost a loved one because of one of these procedures. Nobody, if they were told that they could potentially lose their life, or they could end up in hospital with sepsis through one of these treatments, would go ahead. They absolutely would not. These women have all been misled into thinking that these are risk-free beauty treatments, when the exact opposite is true.



Q63 Catherine Fookes: My question is around the public education side of things. We are talking a lot about informed consent and consent. If the Government were to do a national communications campaign saying to women, "These procedures aren't safe. Don't have breast implants and don't have liquid fillers," how might that impact those people who have already had it done? I am just thinking about the psychological impacts, or whether you think we should really take the bull by the horns and do a big campaign, so women know the dangers?

Ashton Collins: Telling people they should not have any sort of cosmetic procedure is not the right way to go. That might drive people underground to rogue practitioners. The vast majority of treatments, depending on patient selection and informed consent, can be safe in safe hands, where the benefits outweigh the risks. It is about educating people on how to make informed decisions and avoid rogue practitioners, and really helping them to understand what their treatment options are and how to go about finding a safe practitioner.

Q64 Catherine Fookes: This is for you, Vivien, please. Are the current regulations regarding cosmetic surgery sufficient? If not, what changes would you like to see?

Professor Lees: The current regulations are not sufficient, in a brief answer. Sir Bruce Keogh's review from 2012 was quite clear in seeking to address what regulation we need, both in non-surgical and surgical interventions. Quite a part of that has not been enacted or finally adopted by Government, and we would like to see it. There is value in thinking of both happening together. It would be really helpful if the surgical side could be regulated along with the non-surgical, because out there we have practitioners who think they are surgeons, who are doing procedures, and perhaps the very high-risk interventions are falling in the middle. It would be helpful to regulate all at once.

From the surgery side, we have the board certification ready to go. We have a lot of people signed up to that, and a lot of people are busy getting signed up to it. It is a solution if it is wanted. The Keogh review wanted the right practitioner and proper providers—by which I mean the hospitals and the actual clinics—working together. He asked for high-quality care with prostheses and other injectables. Injectables are classified as devices, to make sure that they are properly sourced and safe to use. That was partly addressed through the national breast and cosmetic implant registry database, but clearly from what you have heard earlier, some issues are outstanding there.

We need an informed and empowered public. One of the difficulties we have is that however many communications we put out from a place like the college, it is not necessarily what people are listening to. We tend to all be in our own echo chambers on social media, and it is quite difficult to get past that.



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We need accessible redress and resolution when things go wrong. At the English college we are supporting the *Daily Mirror* campaign, which wants cosmetic operations to be done by trained surgeons who are on the relevant specialist register. Currently in law there is nothing to stop a GP undertaking procedures, if the patient consents to it. That is a gap. All operations and high-risk procedures must be in safe environments inspected by the CQC. That is the *Daily Mirror's* other ask, and for it to be a legal requirement for beauty clinics to have some malpractice insurance for the non-surgical interventions, to help support patients if things go wrong.

Q65 Catherine Fookes: Why do you think regulations regarding who can perform cosmetic surgery are not as stringent as other types of medical intervention?

Professor Lees: Largely because it is practised in the private sector. There are a lot of guardrails within the NHS to make sure that high-quality standards are applied and maintained, but that has never happened within the private sector. It is clearly one area that is desperately needing some regulation.

Q66 Natalie Fleet: Thank you for everything that you have told us today and all the things that we have learned. It was really harrowing. Thank you for the work you are doing around raising awareness. Ashton, what steps are being taken to ensure that cosmetic treatments, like Botox and dermal fillers, are administered by adequately trained and qualified professionals?

Ashton Collins: From our perspective, we run a PSA-accredited register, which permits only registered healthcare professionals on to it who are competent to prescribe within aesthetic medicine. We take all those individuals through a robust 116-point check. We inspect every clinic listed on our register to make sure that not only is the person holding the needle trained, qualified and insured, but the environments in which they work are safe and hygienic, and the products that they use are licensed and fit for purpose.

Picking up on the informed consent angle, we also take them through a role-play scenario where they have to take our assessor through an informed consent, either for dermal fillers or for Botox treatments. That way we can be assured that when a patient visits that clinic, they fully understand exactly what they are embarking upon, so that they can make an informed decision as to whether to go ahead.

Q67 Natalie Fleet: You have some clinics near me that I will absolutely take a look at. What qualifications should practitioners possess to perform non-surgical procedures, and how can we ensure that these qualifications are consistently adhered to across the industry?

Ashton Collins: It is a very difficult question, because the level of training varies greatly because of the lack of regulation. There are recognised qualifications that are available through Ofqual and university



outlets. From our perspective, because we register only healthcare professionals who, by virtue of their initial backgrounds, have an understanding of anatomy, physiology and pharmacology, they can select appropriate training courses based on how they feel those things meet their competencies in these areas. For the other general spectrum of practitioners who offer these treatments—that is, the non-regulated healthcare professionals—more needs to be done to ensure a standardised approach in terms of qualifications, because at the moment it varies so significantly.

Q68 Natalie Fleet: You have already covered this, but it is definitely worth asking because it is so important. Is there adequate oversight and enforcement of regulations for those administering cosmetic treatments?

Ashton Collins: No, in short. The thing that we have observed over the last 10 years is that people complain that this sector is unregulated, which is true today, in terms of who can and cannot do these procedures. But there are pieces of legislation and regulations that exist that should be safeguarding patients having these treatments today, but that are being grossly under-policed and under-enforced—for example, advertising rules, remote prescribing and illegal imports of unlicensed medicines. Like I said, if those things were adequately policed, we would see a huge transformation of the safety of people having these types of treatments.

Q69 Natalie Fleet: That brings me on perfectly to the next question. What are the consequences for practitioners who operate outside the regulatory framework and administer these unsafe procedures?

Ashton Collins: At the moment, very little. Like Sarah mentioned earlier, if what happened to Sasha and all these other women happened in any other context, these perpetrators would be behind bars—they would be charged with assault and GBH. Actually, what these women have been through is technically assault. But out of all the women we are supporting—we urge them all to go to the police and make formal reports—not one of these cases, outside Alice Webb, who lost her life, has been taken seriously by police departments. Women are constantly being perceived as silly individuals who are making decisions through vanity, and therefore their complaints are not being taken seriously enough by regulators, and they are being failed.

Q70 Natalie Fleet: What changes would you like to see to current regulations and practices in the UK?

Ashton Collins: I have long called for a taskforce that would span all the regulators that currently have a responsibility within this sector: the MHRA, trading standards, and the statutory bodies. They would meet regularly to make sure that there is accountability within those departments—that complaints are being investigated and followed up, and action is being taken—and to pre-empt emerging trends. Like Vivien mentioned, we would like to see mandatory insurance for practitioners,



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because around 80% of the people we help cannot seek any financial compensation, because the practitioners are not insured.

We would also like to see—this is something that we are hugely concerned about at the minute—the reclassification of certain fat-dissolving injections that are being used for cosmetic indications. They are currently only regulated through the General Product Safety Regulations, which means that the manufacturers are not duty-bound to prove that their products are effective. They do not have to go through any safety or efficacy trials. It is a crisis waiting to happen, and we will have an untold number of people coming through with various health issues that are not being captured, because of the grey area in these regulations.

For us, the most important thing is for Alice's law to be enacted, to make it illegal for anybody to do BBLs other than surgeons in CQC-regulated hospitals. We cannot be in a situation where somebody else loses their life because of one of these procedures.

Q71 Chair: On this, is there a risk that we are going to have to constantly keep ahead with the law? Law is slow to change—we have seen that—so how do we keep it current? How do we ensure that we are one step ahead of bogus practitioners, who will use emerging technologies and tools as part of their arsenal to, say, trick people like Sasha, for example, or anybody, into having a procedure that is not safe?

Ashton Collins: Yes, that is a very, very difficult issue that needs to be addressed, because if you look at the most dangerous of practitioners, they operate like ghosts. What tends to happen is they entice people through social media. They have spurious names, like Amy's Aesthetics, for example. Amy comes to your house, or you go to a pop-up location. She does the treatment. You may have a mobile phone number, if you are lucky; if not, you just have social media contact details. When things go wrong, Amy blocks you. You have no fixed address, and you do not know her full name, so how do you go about contacting her? Then when the complaints mount up, she closes that page down and pops up somewhere else.

We have seen this time and again, with perpetrators of these liquid BBLs. We have had individuals who have caused over 39 people to end up in hospital, yet they are free to carry on with impunity.

Q72 Chair: Professor Lees, what are the primary risks associated with travelling abroad for cosmetic procedures? Is cosmetic tourism having an impact on the NHS, do you think?

Professor Lees: Yes. I was going to say that we regularly, in the emergency and on-call have, people in both from this country and from overseas, who have acute problems that cannot be sorted out by the people who originally did the treatments. In the case of practitioners here, it is because they do not have the skillset to sort them. In the case



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of overseas tourism, it is because the patient is too poorly or has otherwise lost confidence in the facility that treated them. They are not going to go back again, and it will probably be unsafe for them to travel in any case.

I have seen things like a young woman with infected filler injections in the lips having to have chunks of her lip cut out. You can imagine what that will be like for her over a lifetime. I have seen infected buttock implants coming out, abscesses, collections, and bleeding problems in the middle of the night—all from medical clinics here that do not have the ability to treat their own complications. That lands up with the NHS. It is turning into a significant burden of work, particularly for the plastic surgeons and for the breast surgeons, on the service. Clearly, that is something that needs to be thought about.

- Q73 Catherine Fookes:** I have a question for Professor Lees about the NHS list we talked about earlier; I cannot remember exactly what the register is called, but you said some improvements are needed on that. I wonder if you could outline what those are. Then the wider question, if we have time, is whether we have enough data on this problem across the whole of the UK, and on all the different procedures. Are we gathering the data around Sasha's procedure and other procedures? Is there a central register, so we can keep an eye on these things?

Professor Lees: There is no register for non-surgical procedures. We have PHIN data and the NHS HES data, which capture the private hospital and NHS work. We are looking at coding for work that has been done overseas that has generated a complication. This will take some time to come in.

In terms of the implant registry database, I thought the suggestions made earlier were helpful, in terms of using that database to perhaps gather more information and provide practitioners with an annual summary of emerging trends, so that they can better counsel and inform the next set of patients who are presenting. That seems sensible.

- Q74 Chair:** Can I just ask a question? You said it will take some time for this coding to include overseas cosmetic procedures. What is the timeframe for "some time"? Because my definition of that is very different from, say, my little girl's.

Professor Lees: I would like it to be done immediately, of course, but my understanding is that the HRG codes are varied only twice a year. We would hope it to come into the next batch.

- Q75 Kirith Entwistle:** I have one final question. Ashton, you used the word, "perpetrators" earlier. I wanted to ask you all, do you see this as another form of exploitation of women?

Ashton Collins: Absolutely. Not only are they being exploited and let down by the people who are doing these procedures, but actually they are being let down by the system that is designed to protect them at the



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minute. Like I said, the police are not taking this seriously and very few regulators currently take these issues seriously. That is because of the perception that they are related to cosmetic treatments, and therefore it is the women's own fault. That needs to change from the top down.

Professor Lees: Also, when something has gone wrong for you, and you have approached a practitioner to have something done in good faith, you feel really shy about coming forward. It is not easy to do that. Your account has been very, very moving. It is not easy to complain about some things. We need to understand that as well. Also, 94% of cosmetic operations are received by women and only 6% by men. It is estimated that the global market for cosmetic surgery is going to grow threefold within the decade. We are going to see a lot more problems, in terms of absolute numbers. We need to set up a structure that will adequately support legitimate work.

Kirith Entwistle: Thank you so much for sharing your story earlier.

Sasha Dean: I would like to see it banned, basically. I really, really would.

Chair: Thank you very much. We have had an incredibly powerful and informative session. I am so grateful to all our panellists and to you three for how fantastically you have been able to articulate the issues, the problems and the solutions. Quite often we get panels with witnesses and experts who might give us ambiguous answers. You have been clear about what needs to change. I am so grateful for that, and I know the rest of the Committee is. Thank you very much.