DRN-4029676

The complaint

Ms G says Tesco Personal Finance Plc has unfairly declined her claim under section 75 of the Consumer Credit Act 1974 ('CCA').

What happened

Below, I've summarised the material facts in this case:

- In July 2017, Ms G had an elective surgical procedure to replace breast implants – one of which had ruptured – with breast implants manufactured by Allergan. The procedure cost £6,140 – and Ms G used her Tesco credit card account to pay for it. In this decision, I'll call the consultant surgeon who performed the procedure 'Mr A'.
- Shortly after the procedure, Ms G started to experience some unexplained symptoms – including fatigue and nausea.
- In January 2020, Ms G saw Mr A in clinic. In a letter to Ms G's GP, Mr A explained that he'd examined Ms G and said he didn't think the implants were the cause of her symptoms. He recommended further tests. Mr A said that if those tests were inconclusive, a specific procedure might help 'but ultimately [Ms G] may benefit from removal of both implants'.
- In February 2020, Ms G had a mammogram, an MRI scan, and various tests.
- In July 2020, Ms G saw a consultant surgeon I'll call 'Mr B'. Mr B sent Ms G's GP a post-consultation letter, which said: the tests she had in February 2020 'ruled out any obvious cause for her symptoms'; her symptoms continued and she had chronic pain in her neck, back and legs; Mr B and Ms G had discussed her options and Ms G had asked Mr B to remove the implants; and, Mr B had explained to Ms G that removal of the implants may not resolve her symptoms.
- In October 2020, Ms G had the breast implants removed by Mr B. The procedure cost her £6,726.
- In or around November 2020, Ms G contacted Tesco to make a claim under section 75 of the CCA on the basis that the implants supplied were not of satisfactory quality. Specifically, she explained that Allergan had recalled its textured breast implants because of concerns they caused breast implant-associated anaplastic large cell lymphoma ('BIA-ALCL'). BIA-ALCL is a rare but serious form of cancer. She says she learned of the recall when she met with Mr A in January 2020 to discuss her symptoms.
- Tesco contacted the hospital, which instructed a law firm to respond to the claim on its behalf. The hospital denied that there had been a breach of contract. And Tesco declined her claim.
- Ms G then referred her complaint to our service.
- One of our investigators thought the possible link between Allergan's textured implants and BIA-ALCL, and the fact they were recalled by the manufacturer, was sufficient to conclude that Ms G's implants were not of satisfactory quality – and recommended that Tesco refund the full cost of the implant surgery (£6,140) with simple interest at 8% per year.
- Tesco disagreed with our investigator's conclusions and asked that an ombudsman make a final decision.

I issued my provisional decision on 1 March 2023, which explained why I was minded to uphold this complaint and tell Tesco to refund the cost of the implant surgery with simple interest. It included the following provisional findings:

Section 75 of the CCA protects consumers who buy goods and services on credit. It says, in certain circumstances, that the finance provider is legally answerable for any misrepresentation or breach of contract by the supplier.

Section 9 of the Consumer Rights Act 2015 ('CRA') is also relevant. This says that any goods supplied must be of satisfactory quality. And section 9(3) says:

> *'The quality of goods includes their state and condition; and the following aspects (among others) are in appropriate cases aspects of the quality of goods—*
>
> > *(a) fitness for all the purposes for which goods of that kind are usually supplied;*
> > *…*
> > *(d) safety;*
> > *…'*

In December 2018, Allergan announced that it had suspended sales of its textured breast implants and was withdrawing any remaining supply in Europe. It suspended sales because its Conformité Européenne ('CE') Mark for these products wasn't re-awarded. The withdrawal decision followed a compulsory recall request from the Agence Nationale de Sécurité du Médicament ('ANSM') – France's national agency for the safety of medicines and health products. At the same time, an update on the British Association of Aesthetic Plastic Surgeons ('BAAPS') website said:

> *'The BAAPS has advised its member surgeons not to insert Allergen textured implants from today.'*

In April 2019, the ANSM decided, as a precautionary measure, to restrict the use of certain types of textured breast implants (from six different manufacturers), to 'reduce the exposure of women to the risk of [BIA-ALCL] which remains a rare but serious risk'.

In May 2019, Health Canada, which regulates products and manages health risks in Canada, suspended the licenses for Allergan's textured breast implants 'because the potential risks associated with the implants outweigh their benefits, including the rare but serious risk of BIA-ALCL'.

And in July 2019, the US Food and Drug Administration ('FDA') asked Allergan to recall specific types of its textured breast implants from the US market 'due to the risk of BIA-ALCL'. In a statement issued on 24 July 2019, the FDA Principal Deputy Commissioner said:

> *'Although the overall incidence of BIA-ALCL appears to be relatively low, once the evidence indicated that a specific manufacturer's product appears to be directly linked to significant patient harm, including death, the FDA took action to alert the firm to new evidence indicating a recall is warranted to protect women's health.'*

Following the FDA request, Allergan announced a worldwide recall of its textured breast implants.

As I've explained above, the hospital denied that there had been a breach of contract. First, it said it wasn't liable for any acts or omissions of Mr A. Second, regarding the risk of BIA-ALCL and the recall of the implants, it said:

- *The decision of the GMED and ANSM (4 April 2019) to permanently withdraw macro-textured implants was a precautionary decision based on limited evidence. The decisions in themselves do not support the assertion that textured implants in general, and Allergan implants in particular, are not of satisfactory quality. (I understand the reference to GMED here to be a reference to the expiration of Allergan's CE Mark for these products in December 2018 as GMED was working with Allergan on the CE Mark renewal process.)*
- *While it admitted that Allergan recalled its textured breast implants globally in July 2019, the 'voluntary recall does not amount to an acceptance that the textured breast implants were not satisfactory quality'.*
- *The research into a potential link between BIA-ALCL and textured implants is limited because the number of instances are so small; BIA-ALCL remains an 'extremely rare disease' and the number of known cases is 'extremely small' compared to the number of textured implants sold worldwide; there are different types of textured implants, of which Allergan's are just one; some patients may have had a variety of different implants over the years and their medical histories may not always be accurate, which 'further confuses the epidemiological picture'; and, the results of individual studies should be treated with extreme caution.*
- *The hospital doesn't think there is sufficient evidence to prove that textured implants in general, or Allergan textured implants in particular, are associated with a risk or increased risk of the development of BIA-ALCL.*
- *The implants supplied to Ms G complied with all relevant standards and regulations in place at the time.*

When Tesco declined Ms G's claim, it said:

- *There was no evidence to show that her implants caused the symptoms she was experiencing and Mr B would not confirm they were the cause. (Here, it would be more accurate to say Tesco was not willing to pay Mr B the amount he wanted to produce a report.)*
- *As the recall of the implants was voluntary, and there was no evidence to show that Ms G's implants were removed for health reasons, it didn't think there was a breach of contract.*

In reply to our investigator's recommendation, Tesco said:

- *The December 2018 update on the BAAPS website specifically says: 'There is no need to remove or exchange any current implants based on the most up-to-date scientific data available'.*
- *The CE Mark was 'temporarily removed purely as a precautionary measure'.*
- *In July 2019, the FDA did not recommend removal for patients without symptoms due to potential risks.*

I'll quote it's last point in full:

> *'Given that there's no evidence that [Ms G] was in any danger as confirmed by BAAPS, and the best medical advice at the time was (and still is) not to remove [the implants], it is very much an important point that the ongoing symptoms which led her to the explant surgery were not due to the implants being of unsatisfactory quality.*

> *Ultimately, [Ms G] would have them removed no matter what, due to developing unrelated symptoms.'*

Both Tesco and the hospital say the recall of the type of implant used in this case was 'voluntary' – and at the very least imply that this is significant in some way. However, the recall in Europe was not voluntary – it was compulsory. Allergan made this clear in the press release it issued on the 19 December 2018: 'The withdrawal decision follows a compulsory recall request from Agence Nationale de Sécurité du Médicament (ANSM), the French regulatory authority.' (Emphasis added.) In any event, when, as here, a product is recalled by the manufacturer at the request of a regulator, I'm not persuaded that it can accurately be described as 'voluntary' – or that there's a difference between a recall in these circumstances and a compulsory recall. Similarly, I don't think it's accurate to say, as Tesco does, that the CE Mark was 'temporarily removed as a precautionary measure'. The CE Mark for Allergan's textured implants expired in December 2018 – and it wasn't renewed before Allergan announced a worldwide recall in July 2019.

More substantively, the hospital says it doesn't think there is sufficient evidence to prove that textured implants in general, or Allergan's textured implants in particular, are associated with a risk or increased risk of the development of BIA-ALCL. Regulators around the world, however, clearly think there is – and they are, in my opinion, best placed to assess the available evidence (whatever its limitations) and to understand the epidemiological picture. The FDA's Principal Deputy Commissioner's comments are particularly stark in this regard: Allergan's textured implants '[appear] to be directly linked to significant patient harm, including death'. It's also worth noting that Health Canada updated its 2019 safety review on BIA-ALCL in April 2022. The update on its website says:

> *'Updated data from 2019 indicates that the estimated risk of developing BIA-ALCL with Allergan [ ] macro-textured implants has roughly doubled since Health Canada's 2019 review.*
> *…*
> *An increase in reported cases in Canada is consistent with trends seen in other countries, including the United States.'*

It says the updated risk estimate for Allergan's textured implants is 1 in 1,636 compared to 1 in 3,565 in 2019. For a different manufacturer's micro-textured implants, the risk estimate is 1 in 17,627 and the risk estimate for a smooth surface implant is zero.

In the circumstances, I think Tesco is wrong to say, 'there's no evidence [Ms G] was in any danger'. And in light of the regulators' actions and comments, I am, on balance, satisfied that the breast implants used were not of satisfactory quality. This was a breach of contract for which Tesco is legally answerable.

I've carefully considered Tesco's point that there's no evidence that Ms G's unexplained symptoms were caused by her implants. Later, its position seems to harden in response to our investigator's recommendation, when it says the 'symptoms which led to the explant surgery were not due to the implants being of unsatisfactory quality'. Given the available evidence, it simply isn't possible to say what caused Ms G's symptoms – and there certainly isn't sufficient evidence to say unequivocally, as Tesco does, that the symptoms were not due to the implants. In any event, I don't think Ms G's implants were of satisfactory quality for the reasons I've explained above – irrespective of whether or not they caused her symptoms.

Similarly, while I appreciate the FDA, Health Canada and the UK regulator – the Medicines and Healthcare products Regulatory Agency ('MHRA') – don't generally recommend preventive removal for patients without symptoms because of the risks

associated with surgery, having provisionally concluded that the implants used were not of satisfactory quality, I think it was for Ms G to weigh up the risks involved and decide what was right for her.

As I'm considering Tesco's liability for a 'like claim', it's important I consider what remedies or relief a court may order against the supplier in similar circumstances. That said, unlike a court, I can't make an award for 'loss of amenity', which refers to the impact an injury has had or will have on someone's quality of life. I appreciate that Ms G hasn't asked me to make an award of this sort, but it's important she knows that this is something a court can consider that I cannot.

I can, however, make a money award to compensate Ms G for any financial loss – which is something a court would also consider in a case like this.

Here, I think Tesco should refund the cost of the implant surgery (£6,140).

I've carefully considered whether I think it should also refund the cost of the explant surgery. However, as I've explained above, the Allergan implants replaced other implants – one of which had ruptured. Ms G told us that if she'd known about the risk of BIA-ALCL and the symptoms she'd experience, she would have simply had an explant surgery in 2017. So it's likely she would have incurred the cost of an explant surgery in any event. Consequently, I'm not currently minded to tell Tesco to refund the cost of the explant surgery.

Finally, if Ms G accepts my final decision – which I will issue when I've had the chance to consider any additional comments or evidence I get – it may prevent her from subsequently suing either the supplier or Tesco in court for any complications caused by these implants. Ms G may therefore wish to seek some independent legal advice.

I asked Ms G and Tesco to send me any additional comments or evidence they'd like me to consider by 15 March 2023.

Ms G has confirmed that she's received my provisional decision and says she has nothing to add.

Tesco has also confirmed that it's received my provisional decision. It hasn't sent me any further comments or evidence to consider, or asked for an extension to do so.

What I've decided – and why

I've considered all the available evidence and arguments to decide what's fair and reasonable in the circumstances of this complaint.

As I haven't been asked to consider any additional comments or evidence, I confirm my provisional findings. My reasons remain the same.

My final decision

For the reasons I've given, I uphold this complaint and direct Tesco Personal Finance Plc to refund the cost of the implant surgery (£6,140) with simple interest at 8% per year from the date it declined Ms G's claim until the date she receives the refund.

If Tesco think it's required by HM Revenue & Customs ('HMRC') to deduct tax from the simple interest it pays, it should tell Ms G how much it's deducted and give her a certificate if she asks for one.

Under the rules of the Financial Ombudsman Service, I'm required to ask Ms G to accept or reject my decision before 14 April 2023.

Christopher Reeves
Ombudsman