Product liability annotated problem question

After many years of research, Rack and Horse Pharmaceuticals (RHP) develop a drug to treat breast cancer. After only 18 months of clinical trials, it received a licence and went on the market in the UK in March 2016. Although the drug itself is completely pure, it is now known that in less than 0.5 per cent of patients (those who carry a particular gene) it can produce an undesirable side effect known as Tort Syndrome. This side effect is not widely publicised as both RHP and the government are keen to encourage widespread uptake of the drug in the relevant groups of women.

In 2021, 20 claimants who were given the drug between 2016 and 2018 and who contracted Tort Syndrome begin an action against RHP alleging both negligence and liability under the Consumer Protection Act 1987. RHP argues against liability because up until 2019, there was no genetic test that could determine which individuals carried the gene in question.

The claimants bring evidence to show there was an article in an Outer Mongolian scientific journal, published both in hard copy and on the Internet in 2017, which suggested a test to determine whether individual women carried the specific gene for the reaction to the drug that causes Tort Syndrome. Had RHP conducted clinical trials for longer, the company would have been able to identify the characteristics of the women likely to react badly to the drug and to issue appropriate warnings and advice.

Advise the parties.

In a claim under the Consumer Protection Act, Rack and Horse Pharmaceuticals would be the 'producer' and should be identified as such, using the relevant section of the statute.

Should this risk have been made public? Is it negligent not to have done so (this may be an alternative claim)?

Does this make the vaccine 'defective' for the purposes of the Consumer Protection Act (s 3)? Consider the cases **A v *National Blood Authority* [2001]** and *Gee and others* v *Depuy International Ltd* [2018].

The drug is clearly a 'product' for the purposes of the Consumer Protection Act and should be identified as such, using the relevant section of the statute.

The criterion is that such knowledge should be 'accessible'—is this? See ***EC v UK* [1997]**. Can RHP rely on the 'development risks' defence?

Under the Consumer Protection Act the test for liability is different and producers will be strictly liable for any harm caused by defects in their products.

But is the reaction to the vaccine the only potential cause, or might there be multiple potential causes? If so, cause in fact might be difficult to establish (see **Chapter 9**).

The claimants here have suffered physical harm (and there may be some consequential losses). Note that not all harms which may be caused by products are recoverable under the Act.

This suggests negligence and so the claimants may wish to claim in the tort of negligence as well. They would need to establish liability using the normal principles of duty, breach and causation—could they?

To succeed in a negligence claim the claimants must establish duty, breach and causation. There is no problem with duty (***Donoghue*) [1932]**, and possibly not breach—but causation is likely to prove tricky unless the drug is the only potential cause of Tort Syndrome.