

Product liability update

November 2018

Autonomous cars – the future

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Gosport hospital enquiry – faulty syringe drivers

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Any comments or queries?

Gavin Reese Partner +44 20 3060 6895

+44 20 3060 6895 gavin.reese@rpc.co.uk

Nick McMahon

Head of Health & Safety +44 20 3060 6896 nick.mcmahon@rpc.co.uk

Dorothy Flower

Partner

+44 20 3060 6481 dorothy.flower@rpc.co.uk

Robert John

Associate +44 20 3060 6944 robert.john@rpc.co.uk

Autonomous cars – the future

The Law Commission has launched its consultation into reforms which may be required to the law to keep pace with and support the development of autonomous or "self-driving" cars. It is not proposed that there will be dedicated road networks for autonomous cars and therefore the consultation concerns the introduction of greater automation to the existing network. It considers safety assurance prior to such vehicles being placed on the market, ongoing maintenance requirements, civil and criminal liability and adaptations to the rules of the road.

The automotive industry is a major commercial player and is the third highest investor in research and development, with only healthcare and software/electronics investing more. Increased automation of driving is a major focus of this. For example the European Commission has made it mandatory for all new cars sold in the EU since April 2018 to have eCall. This is software which automatically calls the emergency services and sends them GPS or Galileo information in the event of a serious collision. It can also send airbag deployment and sensor information wirelessly. The aim is to reduce emergency call response times. From June 2018, remote control parking and motorway assist has been permitted in the UK.

As with all additions of automatic transmission of information, there are privacy considerations to be addressed. Concerns about remote hacking, including ransom attacks and eavesdropping using such systems, are of particular note.

If cars become more autonomous, so that more decision making is made by software rather than the human driver, there could be significant difficulties in assigning legal responsibility in the event of an accident. For example, is the driver responsible, the software, the manufacturer or a combination of all three?

Currently, being in control of a vehicle is a matter of fact and degree. The Law Commission considers that there are six existing categories of driver obligations as follows:

- 1. qualifications a licence to drive. Will the existing driving test requirements need updating if automation becomes more prevalent?
- 2. fitness to drive that is, not to be impaired through drink, drugs or excessive tiredness.
- 3. managing distractions
- 4. civil liability causing injury or damage
- 5. criminal liability related to driving such as causing death by dangerous driving
- 6. criminal liability not related to driving such as ensuring children wear seatbelts and have appropriate child seats, the obligation to maintain adequate insurance and the car in good repair.

Automation is likely to change matters so that the driver is not always subject to all of the above. There are also concerns that existing offences may not cover novel situations, such as non-specialists knowledge of the roadworthiness of their vehicle where this is reliant on software.

Studies in aviation, in relation to the use of autopilot, have shown issues of overreliance, that is not taking over control when the software is incorrect and under-reliance where the software is insufficiently trusted. Additionally, warnings which are seen as legal disclaimers are often ignored.



Consultation proposals include limiting self-driving to certain scenarios, also known as the Operational Design Domain (ODD). An example of this is lane control being restricted to a motorway where all the traffic is travelling in the same direction at a similar speed. For proposals of this sort to be effective, drivers will need to be made aware of the scope of the ODD and the consequences including civil or criminal sanctions for using it inappropriately.

The preliminary consultation is now open and closes on the 8 February 2019.

Contaminated blood inquiry underway

The statutory inquiry regarding infected blood, headed by retired Judge Sir Brian Langstaff, has started. The inquiry relates to infection of people receiving blood transfusions, or plasma replacement for haemophiliacs, who were inadvertently infected with Hepatitis C and/or HIV due to contaminated combined blood products being purchased from the USA. It transpired that some of the blood products were being obtained from prisoners and intravenous drug users who were paid and not being adequately tested prior to mixing. It is estimated that 28,000 people who required blood transfusions and 4,700 people treated for bleeding disorders have been affected.

The inquiry was announced in 2017 by Theresa May. There was some delay prior to the appointment of Sir Brian Langstaff, during which time a Group Litigation Order was approved for some 500 plus claims to proceed against the Government.

In relation to the ongoing claims, any finding of blameworthiness in the inquiry would very likely lead to many claims for substantial compensation in the courts. Testimony was heard on the opening of the inquiry in September which highlighted the perceived inadequacies of the Government compensation scheme in place.

A significant number of claims were settled in the early 1990s. Some claimants may now be seeking to pursue matters further. How far this will proceed will depend on the circumstances of the cases, bearing in mind that some claims from 2002 have been stayed indefinitely due to the uncertainties of the impact on people who had not suffered significant symptoms by that point.

Public meetings are to be held in the first quarter of 2019, with the public hearings due to start at the end of April 2019. It has been confirmed that Sir Brian Langstaff will not conduct the inquiry with a panel of experts, but will establish advisory groups of experts with whom he will consult.



Pret sandwich allergy death

The inquest into the death of Natasha Ednan-Laperouse concluded that her death was caused by an allergic reaction to sesame, which was not listed on the ingredients of a sandwich she bought at Heathrow airport.

Whilst there was no suggestion that Pret a Manger did not comply with the law, calls have since been made to amend the relevant regulations, which currently does not require full ingredient information to be provided for non-pre-packaged food prepared on the premises. Pret has since confirmed that it is to roll-out full labelling of all its produce as soon as possible.

The Coroner also raised concerns about the length of the needle in the Epipen used by Ms Ednan-Laperouse's father. It is thought that at 16mm the needle may have been too short to properly reach the muscle and administer the required adrenaline.

Sean Cummings, the Assistant Coroner for West London who presided over the inquest, described Epipens as "inherently unsafe" for people with food allergies and called for manufacturers to take urgent action to prevent further deaths.

Gosport hospital enquiry – faulty syringe drivers

A whistleblower has come forward from the Government inquiry into the Gosport deaths, caused by potentially faulty syringe drivers, the suggestion being that the scale of the issue of the drivers which may have been used nationally has been covered up.

The drivers were used in the UK until 2015, despite some models being withdrawn from use in New Zealand as early as 2007. Medsafe, the New Zealand body responsible had the following concerns:

- the visually similar MS16A and MS26 models have a 24-fold difference in infusion rate. Confusing the two has resulted in multiple serious adverse events
- the device does not use standard measuring units requiring a calculation to set the flow rate, thus introducing the risk of error
- the pump lacks a stop button
- the rate can be changed while the pump is in operation
- there is no protection against misloading of the syringe, air entrainment, tampering or siphoning
- the occlusion response characteristics of this pump are very poor
- the pump does not retain a record of operation
- some models feature a "prime" button which provides maximum infusion rate when depressed. There is no limitation on the number of times this may be activated nor a record of activation. Serious adverse outcomes have resulted from inappropriate use.

The inquiry concluded in its report that Dr Jane Barton, a clinical assistant, was responsible for the policies which led to the deaths of 656 patients at the Gosport War Memorial Hospital. The GMC found her guilty of multiple instances of serious professional misconduct in 2010 but she has never been prosecuted. It is reported that suspicious deaths continued to occur after she left the hospital in 2010.

Around 40,000 of the pumps are estimated to have been in circulation in the NHS and at one stage were an essential element of palliative care. This was because they allowed a steady infusion of opioids with fewer requirements for clinical intervention. With the gravity of the issues being raised and the previous widespread use, there may be further claims or investigations to follow.



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