

Vaccine ruling from Europe's highest court isn't as crazy as scientists think

Media and scientific uproar over admissible evidence 'exaggerated', say legal scholars.

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Going by news reports, Europe's highest court threw science out the window last week.

The Court of Justice of the European Union (ECJ) in Luxembourg handed down a judgment on 21 June in a compensation case involving a French man who claimed that a vaccination for hepatitis B caused his multiple sclerosis. The ruling specifies what type of evidence is allowed in EU member states in such cases, but it prompted a flurry of negative press coverage: "Vaccines can be blamed for illness without scientific evidence," warned CNN, while *The Telegraph*, a UK newspaper, claimed that the ruling "could open floodgates for spurious vaccination claims".

But legal experts contacted by *Nature* say that the judgment says nothing of the sort, describing it instead as balanced and in line with long-standing legal traditions. *Nature* examines what the judgment means — and what it doesn't — for future vaccine-compensation claims in Europe.

What's the background?

Mr W, a French national, was vaccinated against hepatitis B in December 1998 and January 1999 and received a booster shot that July. The following month, he began to experience symptoms that led to a diagnosis of multiple sclerosis (MS), a debilitating disease caused

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by nerve damage, in November 2000, and he was considered unfit to work in 2001. The man died in 2011.

In 2006, Mr W and his family members sought compensation against Sanofi-Pasteur, the manufacturer of the vaccine. They claimed that the vaccine had a “defect” under the EU law concerning liability for defective products and argued that the immunization had caused Mr W to develop MS. Establishing such a defect is crucial to win compensation under EU law, but is extremely difficult to prove. The man and his family argued that a body of circumstantial, or indirect, evidence, including the timing of the onset of disease, supported the link between the vaccine and the man's illness.

Mr W and his family won in a 2009 ruling in a lower French court. This was overturned in later appeals, which ruled that there was no scientific consensus supporting a causal link between the vaccine and MS. Because much of the case turned on what forms of evidence were admissible, it eventually came before the Court of Cassation in Paris, France’s highest civil and criminal court. The court deals only with questions of law, not the facts of a case.

The Court of Cassation sought guidance from the ECJ as to whether taking into account circumstantial evidence conformed with EU product liability laws. The ECJ also does not rule on the facts of individual cases, only on questions of law.

What does the ECJ judgment mean, and is it fair?

The ECJ's judgment said that EU laws do not stop courts from considering "serious, specific and consistent" circumstantial evidence in such cases, alongside scientific evidence.

The court emphasized that liability claims for vaccine harm must be considered on a case-by-case basis. It also ruled that the burden of proof remained on plaintiffs (the man's family, in this case) and that courts must consider relevant evidence from medical research. These caveats are important, says Alex Stein, an expert in civil liability law and medical evidence at Brooklyn Law School in New York. "Under this framework, credible medical evidence showing that the vaccine is safe will win the case," he says. "Those who say that the ECJ decision has opened a floodgate for multiple vaccine liability suits are therefore mistaken."

The judgment does not mean that vaccines can be blamed for illness without scientific evidence, or that spurious cases can win when the scientific evidence is against them, says Stein. Vaccine makers, as defendants, will ensure that courts hear the most compelling medical evidence in their favour, he adds.

"The judgment is measured," says Joasia Luzak, an expert in consumer law at the University of Exeter, UK. Where the science is sparse or contradictory, the ECJ's decision may make it easier for people to win cases against vaccine makers, she says. But the ruling makes it clear that courts should reject spurious and weak evidence, she adds.

What do scientists think?

Many scientists have expressed consternation in the media as to the judgment. Some have interpreted it as perhaps lowering the bar for claims of compensation for alleged vaccine harm in cases where scientific evidence has either not found, or not ruled out, a causal link.

But Stein says that these concerns often ignore the wider legal context. "Scientists' concerns are exaggerated and do not show full awareness of how courts and the legal system as a whole operate," he adds. "If courts were to use scientific methods of proof in all cases in which they must determine disputed facts, they would hardly be able to make decisions and to deliver timely justice to people."

"Justice is generally best served when courts are free to admit whatever relevant evidence they wish and judge it on its own merits along with the rest," says Stein.

Does this mean that all EU countries must now implement this ruling?

Not necessarily. EU product liability law largely leaves it up to member states' courts as to how they implement ECJ rulings, says Luzak. The judgment also gives courts leeway in the evidence they admit. It has ruled that incorporating circumstantial evidence of vaccine harms is not out of line with EU law, but it does not mean that other EU countries need to follow suit.

Different countries might read the ruling differently, says Jean-Sébastien Borghetti, an expert in private law at the University Paris 2 Panthéon-Assas in Paris. In countries where liability claims are difficult to win in courts, such as the United Kingdom or Germany, this ruling may have no effect, he says, whereas it may carry more weight in plaintiff-friendly countries such as France, Spain and Italy.

What impact will the judgment have on the French case?

It's difficult to predict, says Borghetti. The Paris Court of Appeal, where Mr W's case is currently being heard, affirmed that there is no causal link between hepatitis B vaccination and MS. It will have to rule again, taking into account the ECJ judgment, and it may be several months before the court takes up the case, he says. Stein reckons that, given the evidence in this case and the high burden of proof, "the manufacturer will win the case and the plaintiffs will lose", even with the latest ECJ ruling.

Ultimately, the most worrisome outcome of the ruling might be that it increases public suspicion of vaccines, which is already substantial in France, says Borghetti.

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