

Sanofi says charged in birth defects case

February 4 2020

Pharmaceutical firm Sanofi has been charged in France with failure to adequately warn patients and causing injury over an anti-epilepsy drug linked to birth defects following a three-year probe.

The French group said in a statement late Monday that prosecutors had decided to move forward on charges of aggravated fraud and unintentionally causing injury.

Under the French legal system, the charges do not automatically mean the case will reach a courtroom as prosecutors could decide not to move to trial.

The investigation, launched in September 2016 following [legal action](#) by victims and their families, sought to determine whether Sanofi misled doctors and patients about the dangers of the drug valproate—marketed around the world as Depakine, Depakote, Stavzor and other trade names—and thus caused injuries to patients.

Two French government agencies had earlier concluded that Sanofi had not sufficiently warned about known [risks](#) to having [pregnant women](#) take the drug.

Studies found that babies of women who took the medicine while pregnant had an elevated risk—around 10 percent—for congenital malformations. The risk for autism and learning difficulties reached as high as 40 percent.

Sanofi in its statement welcomed the advancement of the case as "it will be the occasion to demonstrate that it respected its obligation to inform" [patients](#) and was transparent about the drug.

The firm said it would defend itself vigorously and said valproate remains the primary drug for many forms of epilepsy.

Sanofi shares rose in early trading on Tuesday, climbing 0.6 percent to 88.12 euros, but trailed the blue chip CAC 40 index which was up 1.1 percent overall.

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Citation: Sanofi says charged in birth defects case (2020, February 4) retrieved 3 May 2024 from <https://medicalxpress.com/news/2020-02-sanofi-birth-defects-case.html>

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