

## France's Mediator<sup>o</sup> trial: Servier and the French drug regulatory agency convicted and sentenced

### ● There will be appeal proceedings.

At the end of March 2021, a Paris court ruled that the company Servier and its former second-in-command, Jean-Philippe Seta, were guilty of “*aggravated deception with endangerment to life*” and “*involuntary bodily harm and manslaughter*” for having concealed, over many years, the true properties of Mediator<sup>o</sup> (*benfluorex*), which include the risks of heart valve disease and pulmonary arterial hypertension arising from its use. Servier was fined 2.7 million euros, and Jean-Philippe Seta was given a four-year suspended prison sentence. More than 200 million euros will also have to be paid to the thousands of victims, according to the initial calculation by a lawyer familiar with the proceedings (1).

On the other hand, Servier and Jean-Philippe Seta were acquitted of “*improperly obtaining marketing authorisation*” and “*fraud*” against the mandatory and complementary health insurance funders in France in relation to reimbursement of Mediator<sup>o</sup> (1).

The French drug regulatory agency was convicted of “*involuntary bodily harm and manslaughter through negligence*”, because it only withdrew Mediator<sup>o</sup> from the market in 2009, whereas, according to the court, it already had the necessary information to do so as far back as September 1998. The agency was fined 303 000 euros (1).

Nine individuals were charged with “*breaches of probity*”, five of whom were acquitted and four convicted (1,2). Jean-Michel Alexandre, former director of drug evaluation at the regulatory agency, and Jacques Massol, former member of the French National Health Authority, were given 18-month suspended prison sentences and fined 30 000 euros for having provided advice to Servier less than three years after carrying out public service missions involving pharmaceutical company inspections.

Christian Bazantay, a former Servier official, was convicted of “*complicity*” in the offence committed by Jean-Michel Alexandre. Bernard Rouveix, a former agency expert, was given a one-year suspended prison sentence and fined 30 000 euros, for “*illegal acquisition of benefits*” (1).

Claude Griscelli, a former director general of the French National Institute for Health and Medical Research (Inserm), who was accused of “*influence peddling*”, and a former senator, Marie-Thérèse Hermange, accused of “*complicity in influence peddling*”, were both acquitted (1).

The French drug regulatory agency has indicated that it will not appeal the convictions (1). The public prosecutor's office has, in turn, lodged an appeal against the acquittal rulings involving Servier and Jean-Philippe Seta, while Servier and Jean-Philippe Seta have appealed their convictions. The mandatory and complementary health insurance funders, as well as the victims, have also appealed the ruling. According to one of their lawyers, the victims are hoping to obtain “*harsher criminal sentences and civil compensation at a level commensurate with the harm suffered*” (3).

The appeal proceedings will probably start in eighteen months to two years, at the earliest, again according to a lawyer familiar with the case (3).

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**References** 1- Notes from a *Prescrire* editor at the Paris court, 29 March 2021. 2- “Servier and French drug regulatory agency on trial” *Prescrire Int* 2019; 28 (209): 278-279. 3- “Mediator<sup>o</sup>: les caisses d'assurance maladie font également appel de la relaxe de Servier pour escroquerie” *APMNews* 8 April 2021: 2 pages.



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