EDITORS' OPINION

# A trial to prevent a new disaster through understanding and dissuasion

The length of the Mediator° trial (seven months) makes it difficult to provide an exhaustive account of this trial. In its French edition, *Prescrire* chose to focus mainly on the part of the trial concerning the French drug regulatory agency and its experts, and less on the part about the company, Servier (1). The agency, as part of its public service mission, is supposed to defend the interests of patients. As France's "drug watchdog", it has a duty to monitor and control the actions of pharmaceutical companies, whatever their intentions, methods or business models might be. The agency should have withdrawn Mediator° (*benfluorex)* sooner.

**From the specific to the general.** Can one draw more general lessons about the functioning of the drug marketing system from the Mediator° case, as presented in the trial? *Prescrire* has chosen to anonymise those involved, in order to highlight established practices and views on drugs which were widespread at the time, rather than focusing attention on specific persons. The full article in our French edition only mentions two of the defendants by name: Jean-Michel Alexandre and Jean-Philippe Seta. Both had pivotal roles, one at the agency and the other in the company, both were convicted by the court.

During the trial, it also emerged that Servier was undoubtedly not like other companies, particularly in its relationship with the agency. It employed unorthodox methods, including exerting influence or even pressure, and going as far as intimidation and threats, according to some witnesses. The fact that it was a French company, with financial interests and a network of influence in France, also played an important role.

The company's conviction for *"deception"* and *"involuntary bodily harm and manslaughter"* did not surprise the Editors of *Prescrire*. We never believed that the company could have been unaware of the chemical similarity between *benfluorex* and the fenfluramines, the drug's metabolism, its appetite-suppressing properties, and its plausible (and later proven) role in causing pulmonary arterial hypertension and heart valve disease.

The Mediator° disaster is an extreme case. As is the opioid disaster in the United States and the many deaths linked to the excessive promotion of those drugs. But these extreme cases certainly provide examples which help raise awareness more generally of the risks incurred when there is a failure to separate the interests of stakeholders, such as experts, regulatory agencies, healthcare professionals and patient associations, from the very specific interests of pharmaceutical companies.

**Sentences and fines too light.** The judges, charged with deciding whether or not a given act amounted to an offense in the eyes of the law, acquitted several of the accused, either because of a statute of limitations, an absence of proof or because the accused had declared their personal financial interests at the time. However, such verdicts must not obscure the valuable contribution the trial has made by making certain things public. The statements made in court by defendants or witnesses revealed the context of industry-regulator relations in the Mediator° era, which led to patients being put in danger.

This verdict, which is subject to appeal, also raises questions as to the dissuasive nature of the penalties incurred. Will such penalties help prevent other disasters? At the end of the trial, Servier and its former second-in-command Jean-Philippe Seta, as well as the agency, were convicted of *"involuntary bodily harm and manslaughter"*. However, contrary to the prosecutors' request, no custodial sentence was imposed on the former second-in-command at Servier. This ruling was surprising, as was the acquittal of the company and its former second-in-command on the charge of *"fraud"* against the mandatory and complementary health insurance funders in France, which had reimbursed the prescriptions. The fines imposed on the company, its former second-in-command and the agency were the maximum allowed by the law in France at the time, but they are a pittance, when compared to the scale of the human disaster and to the profits Servier derived from the marketing of Mediator°.



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**1-** Prescrire Rédaction "Mediator°: procès d'un entre-soi entre des acteurs de l'Agence du médicament et une firme influente" *Rev Prescrire* 2021; **41** (454): 610-618.

## COMING SOON...

**MARKETING AUTHORISATIONS**

– Crizanlizumab to prevent vaso-occlusive crises in sickle-cell disease
– Fenfluramine and Dravet syndrome

**ADVERSE EFFECTS**

– Clopidogrel + a proton pump inhibitor: increased mortality

**OUTLOOK**

– DNDi: a collaborative research and development model focused on patients' needs