Mediator°: all wrong from the very start

● In June 2020, at the end of France's Mediator° trial, the two prosecutors concluded that all the defendants were guilty of the offences with which they were charged. The judges' ruling is expected for 2021.

For the company, Servier, the charges were: obtaining marketing authorisation by improper means, deception with endangerment to life, involuntary bodily harm and manslaughter through deliberate violation of its obligations, and fraud (**a**)(1). For the French drug regulatory agency, the charges were: involuntary bodily harm and manslaughter through negligence, and for various experts and members of the health authorities: illegal acquisition of benefits and other offences (1).

The great illusion. In the opinion of the prosecution, numerous pieces of evidence proved that the company, Servier, knew, since the drug's market introduction in 1976, that *benfluorex* (Mediator°) was an appetite suppressant, like the fenfluramines, which it resembles in terms of *"chemical, pharmacological, clinical and toxicological"* characteristics. The company, and the French drug regulatory agency, should have withdrawn it from the market *"by analogy"*, at the same time as *fenfluramine* (formerly Pondéral°) and *dexfenfluramine* (formerly Isoméride°), as soon as the results of the IPPHS study showed in 1995 that the risk of pulmonary arterial hypertension was greatly increased by these two drugs (2).

However, *benfluorex* continued to be marketed in France for all of 33 years, positioned by the company not as an appetite suppressant, but for use in hyperlipidaemia and diabetes. In this context, one of the two prosecutors spoke of *"disinformation"*, *"cover-up"*, *"manipulation"*, *"manoeuvring"* and *"hoax"*. These words are very similar to those used by *Prescrire* in its *"Pub à la loupe"* ["Advertising under the magnifying glass"] articles on Mediator°: *"pseudo-scientific camouflage"*, *"the great illusionist"*, and *"the art of misleading"* (3-5). This illusion turned out to be a deadly one: it resulted in thousands of victims and hundreds of deaths. According to the prosecution, *"patient safety was not at the heart of the company's concerns"*.

The French drug regulatory agency: deaf and blind. One of the prosecutors noted that the regulatory agency was incapable of seeing through the fog which had been created, and she blamed it for not having withdrawn the drug back in the mid-1990s. She also blamed the agency for not having informed doctors and patients about the properties and effects of *benfluorex* throughout the 1990s and 2000s, despite numerous warnings, including those from *Prescrire*, which the prosecutor recited in her closing argument (6).

In the opinion of the prosecutor, the agency lacked the qualities displayed by Irene Frachon, thanks to whom the Mediator° disaster had been brought to light: *"curiosity, intuition, determination and courage"*.

For Servier's *"cynical decision to ignore the risks"* and its *"chilling gamble"*, together with the *"failure"* of the French drug regulatory agency, the prosecution called for the maximum sentences imposable (7). The judges' ruling regarding the defendants' guilt, as well as the demands for compensation by victims and social security agencies, is expected at the end of March 2021.

©Prescrire

▶ Translated from *Rev Prescrire* **October 2020**
Volume 40 N° 444 • Page 772

***a-** The information and quotes in this text come from notes taken by a member of Prescrire's editorial staff, who was present at the hearing on 23 June 2020, and have also been reported in other press publications and agency dispatches. We will return to this trial in more detail in a future issue.*

Selected references from Prescrire's literature search

1- Prescrire Editorial Staff "Servier and French drug regulatory agency on trial" *Prescrire Int* 2019; **28** (209): 278-279.
2- Prescrire Editorial Staff "Primary pulmonary hypertension on appetite suppressants" *Prescrire Int* 1995; **4** (20): 180-181.
3- Prescrire Rédaction "Publicité comparative. La banalisation maximale ? ou le camouflage pseudo scientifique ?" *Rev Prescrire* 1991; **11** (106): III.
4- Prescrire Rédaction "Le grand illusionniste. Quand l'art de l'illusion se mêle au génie des affaires" *Rev Prescrire* 1997; **17** (173): III.
5- Prescrire Rédaction "Mediator° - l'art d'égarer" *Rev Prescrire* 2009; **29** (309): III.
6- "Mediator°: Servier a manqué à son obligation de sécurité et de prudence, l'ANSM a fauté par négligence (procureure)" Dépêche APMnews 25 June 2020: 4 pages.
7- "Procès Mediator°: plus de 9 millions d'euros d'amende requis contre Servier et 3 ans de prison ferme contre l'ex-numéro 2 de Servier" Dépêche APMnews 23 June 2020: 2 pages.

COMING SOON...

NEW PRODUCTS
– Esketamine and depression: not acceptable
– Tafamidis and transthyretin amyloid cardiomyopathy: a real advance

ADVERSE EFFECTS
– SSRI antidepressants and pregnancy

REVIEWS
– Gout attack pain

OUTLOOK
– The invention of antidepressants

Downloaded from english.prescrire.org on 15/09/2026
Copyright(c)Prescrire. For personal use only.