Mediator° trial appeal: a judgement that better reflects the harm done

● French appeal court finds Servier guilty of four charges, handing down sentences more respectful of the victims of decades of constant, organised deception.

In March 2021, following the initial criminal trial over the Mediator° (*benfluorex*) disaster in France, the pharmaceutical company Servier and its former chief executive, Jean-Philippe Seta, were convicted of "*aggravated deception*" and "*involuntary bodily harm and manslaughter*". But they were not found guilty of "*fraud*" against the mandatory and supplementary health insurance providers that reimbursed prescriptions of Mediator°, nor of "*improperly obtaining marketing authorisation*", and no custodial sentences were handed down (1,2). The judgement on an appeal pursued to challenge these acquittals was delivered on 20 December 2023 (2-4).

The appeal court judge set out in extensive legal and scientific detail how the court had reached its judgement on the four charges: aggravated deception; involuntary bodily harm and manslaughter; improperly obtaining marketing authorisation (MA) and fraudulently obtaining MA renewals; and defrauding health insurance providers (1,2,4).

It has been proven that in order to obtain marketing authorisation for Mediator° in 1974, Servier took the risk of developing and promoting a new amphetamine drug, concealing its appetite-suppressing effect and misleading people about its metabolisation to norfenfluramine, the cause of the drug's adverse effects on heart valves in particular. Over the decades that followed, Servier not only denied that the drug had serious adverse effects, but sought to expand its indications, even though it would have been withdrawn from the market had the pharmaceutical company not hidden what it knew from patients, health professionals and the regulatory authorities (2-4).

The appeal court found that Servier's actions illustrated a peculiar concept of the harm-benefit balance: "*financial benefit for the company, deadly harm to patients*" (our translation) (2,4). It went further than the original court in its judgement, finding Servier guilty on all counts (2-5). Jean-Philippe Seta was given a 4-year suspended prison sentence (with 1 year of house arrest under electronic monitoring), and Servier was ordered to pay a fine of over €9 million. It also ordered the pharmaceutical company to pay €420 million in reimbursement to health insurance providers (2,3).

This judgement, which Servier and its former chief executive are once again contesting by appealing the decision to the supreme court, better reflects the harm caused.

The appeal court was highly critical of Jacques Servier, who died in 2014, finding that he acted in a deliberately deceitful manner over a period of several decades. Let us hope that this judgement sends a message not only to other pharmaceutical companies, but also to the many health professionals and policy makers who put too much trust in Servier and the "big man" at the top.

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Selected references from Prescrire's literature search

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.

2- "Notes d'audience prises par deux rédacteurs de Prescrire" 21 December 2023: 2 pages.

3- APM "Mediator°: condamnation aggravée en appel de Servier et son ancien numéro 2 Jean-Philippe Seta" 20 December 2023: 3 pages.

4- APM "Mediator°: l'escroquerie de Servier à l'assurance maladie et aux mutuelles était "parfaitement caractérisée" (cour d'appel)" 20 December 2023: 3 pages.

5- APM "Mediator°: une sanction "exemplaire" pour restituer les "fonds escroqués" par Servier au système de santé" 20 December 2023: 3 pages.

New data after marketing authorisation: European Commission consultation

● Prescrire has contributed to a public consultation on the proposed revision of the rules governing variations to marketing authorisations, submitted to take into account new data, for example on efficacy or a new adverse effect.

In September 2023, Prescrire responded to a consultation organised by the European Commission prior to revising the "variation framework", which sets out the required procedures for updating marketing authorisations when new data become available, for example on adverse effects, efficacy or use in children (1).

The Commission's initial call for evidence stated that it wants to increase the efficiency of the current regulatory framework for post-authorisation changes. It is aiming to reduce the administrative burden for marketing authorisation holders and authorities, and to free up some of the resources currently needed to process the large number of post-authorisation changes. Its proposals

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