

France's Mediator° disaster: creating awareness around conflicts of interest

● **In France, media coverage of the Mediator° disaster in 2010-2011 opened the public's eyes to the conflicts of interest of many experts working for the French drug regulatory agency. The Minister for Health subsequently proposed a reform of the agency as well as new legislation regarding transparency about conflicts of interest among its experts.**

● **In practice, as of 2020, some healthcare professionals still either do not perceive, or deny, that the influence of product companies is an obstacle to the quality of expert opinion and patient care. One hopeful sign is that students seem to be much more perceptive.**

Two researchers have analysed the concept of conflicts of interest from a sociohistorical viewpoint and its central role in the Mediator° (*benfluorex)* disaster, which followed other health-related crises in France (1).

A problem which has taken time to be recognised. Healthcare crises such as the growth hormone, contaminated blood, and mad cow disease scandals occurred, one after another, in the 1980s and 1990s. They contributed to the creation of a drug regulatory agency in France (French Law of 4 January 1993 pertaining to blood transfusion and drug safety) (**a**). As part of that initiative, as of 1994, permanent members of the agency, as well as members of the committees and working groups, have been required to submit a signed conflict of interest disclosure form. Following a ministerial decision to make them publicly available, these declarations were published as an annex to the statutory annual report of the agency. They showed that most of the experts sitting on the various committees had numerous conflicts of interest. The agency justified the presence of these experts at meetings *"because it could not deprive itself of input from leading experts as a result of their relationships with the pharmaceutical industry"* (2).

The French Law of 4 March 2002 pertaining to patient rights and healthcare quality (otherwise known as the Kouchner Law), reinforced the principle of declaring, publishing and updating direct and indirect personal financial interests, and introduced measures to exclude experts with conflicts of interest. However, these measures were very poorly implemented by the drug regulatory agency (1). And the European Directive 2004/27/CE, which also insisted on transparency and the *"impartiality"* of experts and others, was only very slowly adopted in France (3).

Growing media coverage. It is this dangerous compromise which the public in France gradually became aware of following the publication in June 2010 of the book by Irene Frachon: "Mediator° 150 mg, combien de morts?" (**b**). This book cites a report from the former pharmacovigilance committee of the French drug regulatory agency, which mentions the presence of experts who had conflicts of interest with the company Servier (1).

The concept of conflicts of interest reached unprecedented notoriety with the Mediator° disaster. Media interest was sparked by an opinion piece written by a member of parliament, Gérard Bapt, in *Le Monde* in August 2010, entitled "Mediator: how many deaths?", in which he condemned the dysfunctionality of the drug regulatory agency, its treatment of conflicts of interest and the influence of pharmaceutical companies (1).

Media attention increased in January 2011 with the publication of a report by the French government audit office for health and social security (IGAS) explaining the malfunctioning of the agency by a *"structural and cultural"* environment of conflicts of interest (**c**). The public thus became aware of the influence of pharmaceutical companies on decision making by the agency, to the detriment of patients and public health (1).

Transparency regarding conflicts of interest as a solution to the crisis. During 2011, two parliamentary commissions led by the Senate and the National Assembly concluded that legislation

a- *Since its creation in 1993, the French drug regulatory agency has changed names twice: Agence Nationale du Médicament (ANM) from 1993 to 1999, Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps) from 1999 to 2012, and Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) since 2012.*
b- *"Mediator 150mg, how many deaths?".*
c- *According to the authors of the sociohistorical analysis, the number of articles dedicated to Mediator° in the French press was: 1 in September 2010; 17 in October 2010; 64 in November 2010; 56 in December 2010; and 203 in January 2011 (ref 1).*

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on personal financial interests was not being applied nor was it effective (1). The members of parliament proposed the prevention and management of conflicts of interest as a solution to the public's crisis of confidence in drugs and healthcare stakeholders. The Minister for Health convened a national medicines consultation, and then put forward a bill to reform the drug regulatory agency, and requiring transparency about the conflicts of interest of experts and committee members, and of their working sessions (**d**)(4).

Conflicts of interest continue to exist in 2020. For all that, have health care professionals realised that personal financial interests and relationships with companies influence expert appraisal and healthcare decisions, and damage their credibility, patient confidence and quality of care? Many professionals seem to feel that measures involving transparency and management of conflicts of interest do not concern them (1,5). Many of them have not changed their working practices and accept, or even expect, personal financial interests (**e**)(6,7).

Some cause for hope. Nevertheless, there is some tangible progress. The French "Transparency in Public Health" database, despite its limitations, provides information on the monetary value of benefits that companies have provided to healthcare professionals and on any agreements signed with them (8,9).

In 2014, a medical student association published a booklet aimed at making students aware of company influence and the concept of conflicts of interest (8). A joint national medical student trade union organisation, *"Intersyndicale nationale autonome représentative des internes de médecine générale (Isnar-IMG)"*, has freed itself from funding by pharmaceutical firms for its annual conference (10). There are no pharmaceutical companies among the partners of the French National Association of Medical Students (ANEMF) (11). ANEMF contributed to the adoption of an ethics and professional conduct charter by the French Council of Deans of Medicine and Dentistry. Together with Isnar-IMG, ANEMF is monitoring implementation of this charter, as part of the ranking of medical schools according to their independence from industry. This ranking is being compiled by Formindep (a French nonprofit organisation dedicated to independence in medical training) (12,13).

These future healthcare professionals, committed to fighting for independence from external influences in training and clinical care, are showing that it is possible to change practices and to put an end to conflicts of interests.

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***d-** The national consultation on medicines, which was opened on 17 February 2011 by the Minister for Health at the time, Xavier Bertrand, mainly brought together representatives from companies and a range of other institutions (ref 14). Their objective was to "map out a reform which would restore public confidence in medicines, medical devices and the institutions responsible for their safety" (ref 15).*

***e-** A study in France has shown a link between the monetary value of the benefits that companies give to general practitioners and the quality and cost of their prescriptions. We will return to this study in a future issue (ref 16).*

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