Letter to the Editor

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Challenging Special Interest Groups: Whistleblowers May Help. Help Them!

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Prof. Fava's editorial not only offers a comprehensive analysis of the conflict of interest (CoI) issue but also dares to accept that it is now a crisis of credibility for the medical profession, regretting that the early warnings published in the journal were not taken into account [1]. Prof. Fava rightly: (a) summarized the criteria which indicate the presence of substantial CoI, without forgetting the issue of nonfinancial conflicts, (b) recognized the limitations of disclosure as the sole method, and (c) underlined the need of support for independent research [1]. The example of antidepressant drugs illustrated the complexity of the CoI issue and stressed the need for a comprehensive framework [1]. However, this example cannot be an excuse to mask our poor accountability regarding the CoI issue.

Too many conflicts are obvious and this does not even preclude them lasting for long. Indeed, the result is nothing else than a violation of evidence-based medicine, or even common sense, which leave no doubt about the CoI. Below are 2 recent examples from France.

Benfluorex (Biopharma-Servier, France) has been approved in 1976 as an adjuvant for diet in patients with either hyperlipidemia or diabetes. Benfluorex is a derivative of fenfluramine, which was withdrawn from the worldwide market in 1997 after reports of heart valve problems and pulmonary hypertension, as in the case of dexfenfluramine. Benfluorex sales in Europe were rapidly limited everywhere with the exception of France (e.g. in Spain the marketing authorization was revoked in 2003, in Italy no application was submitted for renewal, elsewhere the authorization was not used for commercialization). In contrast, France even renewed the reimbursement by the mandatory National Health Scheme (65%, the highest level, including hospital use) in 2006 after a formal evaluation by the 'Transparency Committee' (sic) of the 'High Authority for Health' (i.e. the Drug Assessment Committee of the French Healthcare Watchdog, http://www.has-sante.fr/portail/jcms/c_5443/english?cid=c_5443). Grossly 300,000 patients per year were exposed to benfluorex despite: (a) reports of adverse effects, (b) obvious illicit use of amphetaminergic properties (WHO's warning and posts from users on the Web), and (c) yearly claims from the French Drug Bulletin 'Prescrire'. Moreover, generics (Mylan and Qualimed) were authorized in 2009! The withdrawal of benfluorex was only implemented on 30th November 2009. Last but not least, the official pharmacovigilance warning advised doctors to switch to another treatment but eluded: (a) the issue of the early diagnosis of adverse effect and (b) the information of the patients.

Prostate cancer screening is another long-lasting French exception [2]. The French Association of Urologists (AFU) has developed a yearly public campaign since long [3]. The effect of these public campaigns may have been reinforced because the High Authority for Health, which is also in charge of quality of care and information to the public: (a) certified the AFU for the national quality improvement program in 2006, (b) accredited the AFU for the risk management and security program in 2007, and (c) certified the AFU's public Website. The Parliamentary Office for the Assessment of Health Policy evaluated this screening policy: it set up a working group which was chaired by a member of parliament, who is an urologist. The working group chose the French AFU for conducting the evaluation [3].

Accordingly, I propose to add whistleblowers as key participants in Prof. Fava's comprehensive framework. Whistleblowers need protection, but overall they need editors who: (a) accept to publish comments or promote controversies and (b) do not hide themselves behind the excuse of 'the lack of space' or a lawyer fearing libel action.

For Faunce and Jefferys [4], whistleblowing should have been expressly supported in the UNESCO Universal Declaration on Bioethics and Human Rights. Prosaically, in Europe, only the UK has developed a legislation (the Employment Rights Act, 1996) to support whistleblowers. This legislation is implemented as a critical item for quality and security in health care: (a) the Department of Health has had a guidance on whistleblowing since 1999; (b) the General Medical Council's Good Medical Practice (paragraph 6) expects doctors to promote patients' interests first: 'doctors must … raise concerns where they have a good reason to think that patient safety … may be seriously compromised by inadequate premises … policies, or systems'; and (c) the British Medical Association repeatedly makes statements underlining the right to report patient safety concerns and to advocate for a patient's well-being without the risk of disciplinary action [5]. Dr. Bolsin's achievements in establishing clinical governance across the UK must not be ignored (http://en.wikipedia.org/wiki/Stephen_Bolsin).

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Disclosure Statement

As a regional advisor for quality of care at the High Authority for Health in 2006, A. Braillon was not reappointed in 2007; as a senior consultant in public health (tenure position), he was sacked from the University Hospital of Amiens in 2009 (see Paul Benkimoun's article: 'Doctor's sacking is setback for French public health, supporters say', BMJ 2010;340:c711).

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