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A growing crisis in confidence

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Revelations made by the US Congress in October this year regarding the apparent failures of individual clinical investigators to accurately disclose their consulting arrangements with the pharmaceutical industry have raised additional questions about the integrity of clinical research, and the medical profession as a whole (Harris G [online 3 October 2008] Top Psychiatrist Didn't Report Drug Makers' Pay [http://www.nytimes.com/2008/10/04/health/policy/04drug.html?hp] [accessed 20 October 2008]). These revelations build upon other reports of possible financial conflicts of interest in Contract Research Organizations, especially those with academic affiliations (Lenzer J [2008] *BMJ* 337: 602), and claims of the use of ghost writers and guest authors in clinical trial reports sponsored by pharmaceutical companies (Ross JR [2008] *JAMA* 299:1800–1812). Furthermore, there are concerns regarding the influence of pharmaceutical companies on continuing medical education and clinical practice (Steinbrook R [2008] *JAMA* 299: 1060).

This crisis in confidence in the objectivity of the clinical research enterprise might be one of the greatest threats the medical profession has ever encountered, as its ongoing success depends, largely, on the positive regard of the wider community, not only for research funding but also for public support for medical education, as well as the very nature of the doctor–patient relationship. Furthermore, unresolved questions regarding the integrity of clinical research or medical practice run the risk of undermining public confidence in medicine. At a time of serious financial concern and growing governmental regulation of health care, a loss of public confidence in the objectivity and commitment of the medical profession to patient well-being could have dire consequences.

Unfortunately, the medical profession's response to this evolving problem has so far resembled the classic stages of grief, with little progress past denial, anger and bargaining. In the absence of a comprehensive approach to deal with the problem, sweeping recommendations that would fundamentally change the current process of clinical investigation and reporting of clinical trials have been made (DeAngelis CD and Fontanarosa PB [2008] *JAMA* 299: 1833–1835). In addition, members of the pharmaceutical industry, as well the US Congress, are suggesting the imposition of new rules of disclosure that would have a major impact on clinical research and practice (Harris G [online 3 October 2008] Top Psychiatrist Didn't Report Drug Makers' Pay [http://www.nytimes.com/2008/10/04/health/policy/04drug.html?hp] [accessed 20 October 2008]).

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A consortium of medical societies, funding agencies and editors/publishers of medical journals must come together to identify the real problems with researcher conflicts of interest, and develop meaningful solutions that will address them appropriately. Critically, these solutions must not merely seek to scapegoat or punish individuals or companies. Rather, a set of guidelines needs to be established that not only prevent any further abuse of the system, but also permit efficient functioning in order to identify effective and safe new therapies rapidly and provide the opportunity for them to find their rightful place in appropriate therapeutic strategies. Overly draconian approaches might prevent abuse of the system, but will also stultify clinical development, whereas ineffective 'Band-Aids®' might make us feel better but will not solve the root causes that underlie the current crisis in confidence.

I am optimistic that the medical profession can deal with this problem appropriately, but I also have no doubt that if we fail to do so comprehensively and promptly, regulations will be imposed from outside the profession that will interfere with our ability to continue to develop better treatment options for our patients. The goal should be to restore confidence in the integrity of the medical profession without unnecessarily damaging its creativity and initiative.

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