The New England Journal of Medicine: commercial conflict of interest and revisiting the Vioxx scandal

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At a recent cardiology conference in New Delhi, the cardiologist Deepak Natarajan raised the concern that commercial conflicts of interest (COIs) were corrupting medical journals (1). Natarajan cited "manipulated" publications in *The New England Journal of Medicine* (*NEJM*) as one example to support his view. His comments were met with silence and an air of indignation. Natarajan's medical colleagues were stunned, disbelieving, and then, angry.

Their response stemmed in part from the *NEJM*'s reputation as the premier medical journal in the world. The *NEJM* has the highest impact of any medical journal and physicians tend to see the *NEJM* – to use Natarajan's words – as "the holy grail of publishing" (1). Physicians wear their *NEJM* publications as a badge of prestige given the journal's reputation and influence. But as Natarajan noted, so do research sponsors who compete to have their research studies published in the *NEJM* to influence prescribing habits of physicians and increase drug market share. Journals can profit handsomely from research sponsors buying reprints of their studies to distribute to physicians. And the *NEJM* does not make public what it earns from reprints.

There was a curious omission in Natarajan's narrative. There was no reference to a notorious research scandal underpinned by commercial conflicts that involved the *NEJM* – the Vioxx scandal. Had Natarajan discussed the Vioxx scandal he might have overturned some of his colleagues' disbelief that the *NEJM* could publish tainted data and profit from it. The Vioxx scandal also raised concerns about commercial COI that went beyond the *NEJM*. It involved other gatekeepers that oversee the integrity of medical data and public interest. Vioxx symbolised what ailed a healthcare and regulatory system that had institutionalised and normalised commercial COIs and downplayed their potential negative impact on the public.

Natarajan's concerns about commercial COI and his colleagues' response afford an opportunity to review salient historical features of the issue of commercial COI and the Vioxx scandal. The *NEJM* had a legacy of leadership on COI. It brought the issue to critical attention in medicine and had a stringent commercial COI policy that other leading journals resisted. And yet the *NEJM* was involved in one of the most highly profiled research scandals underpinned by commercial COI in regulatory history. This paper addresses the Vioxx gap in Natarajan's narrative in order to better gauge his concerns for an Indian audience.

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Stepping into forbidden territory

The issue of commercial COI gained increasing attention in the early 1980s. This occurred alongside a shift in government policies towards a neo-liberal political economy which stressed de-regulation, privatisation of public institutions and relying on the marketplace to solve public policy issues. Through legislation, the government cultivated a greater entrepreneurial culture in medicine and forged commercial relations between the research community and industry (2). The result was a highly commercialised research and healthcare terrain where financial conflicts became tightly interwoven into the social and regulatory fabric of medicine. Against this backdrop, the *NEJM* required authors to disclose financial ties to industry in 1984 (3). It was the first premier journal to do so and other journals soon followed suit.

In 1990 the *NEJM* revised its COI policy in response to growing concerns over the commercialisation of medicine. The revised policy prohibited authors of editorials and review articles from having any financial interests with a company that could benefit from a drug or medical device discussed in the article (4). The zero-tolerance policy for editorials and review articles was intended to better ensure the independent interpretation of medical information that can influence prescribing practices of physicians and in turn affect patients' health and safety.

The policy was not received enthusiastically by the medical community. None of the other general American medical journals adopted it and it was suggested that the zero tolerance policy questioned the integrity of physicians (5). The *NEJM* had hit a nerve in the medical community. But its editors held their governance ground. In 1993 the journal published a paper by Thompson that examined the character of COI and clarified the rationale behind the policy to prohibit commercial conflicts (6).

Thompson defined COI as a set of conditions "in which professional judgements concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)" (6). He stressed that COI was a condition – not a behaviour or occurrence. It was a set of circumstances that increase the risk of a bias influencing a judgement. Determining whether factors such as ambition, the pursuit

of fame and financial gain had biased a judgement was challenging. Motives are not always clear to either the conflicted party or to an outside observer. Biases stemming from a COI can operate unconsciously. As a result, individuals in a conflicted circumstance were not in a position to know through self-assessment whether their judgement was biased or not.

Thompson's view of COI reinforced the view that transparency – the most prescribed remedy to COI in medicine – was a necessary but insufficient tool to combat bias. Disclosing a COI drew attention to a potential source of bias. But it did not indicate what to do or how to proceed once a COI was disclosed. Nor did it indicate that a bias was necessarily present. One simply did not know.

While factors that can bias a judgement could be hard to manage, commercial COIs were more identifiable than other secondary interests and, as a result, could be better controlled through prohibition. Resistance to prohibiting commercial conflicts often involved appealing to the observation that other secondary interests exist which are as powerful as money, but more difficult to control. Thompson affirmed the observation, but noted that it did not follow that nothing could be done. "Just because we cannot do much about other secondary interests it does not follow we should do little about financial gain." (6). Prohibiting commercial COIs was a choice, and, as editors of the *NEJM* pointed out, a policy option that other professions had chosen (5). Judges are expected to recuse themselves from cases where they have a financial conflict. Editors and journalists in the lay press cannot write on topics where they have a financial COI. Prohibiting commercial COIs was an established governance practice in various professional contexts and aligned with public expectations. According to Thompson, the policy served two purposes: to ensure professional integrity, and to foster public trust and confidence in professional judgements.

Thompson's discussion, however, did not alter the medical community's view of the *NEJM*'s zero-tolerance policy for editorials and review articles. Research sponsors and physicians with commercial ties to industry thought that they were being unfairly singled out by the policy (7). Further, critics of the policy received some additional support from across the Atlantic. The editors of the *BMJ* (Richard Smith) and the *Lancet* (Richard Horton) asserted that seeking prestige, a scientific reputation, a pressure to publish, career advancement, and even religion can be as influential as money (8,9). Horton claimed that to "put financial conflicts to the fore is to provide a smokescreen for more cover and possibly more influential commitments." (9). In the USA it was charged that the *NEJM* policy compromised objectivity and stifled open debate. It was a form of McCarthyism – shorthand for a witch hunt and censorship (10). Horton echoed this view noting "the *Lancet* prefers a pluralistic solution to one based on censorship" (9). Horton stressed that it was important to engage in open dialogue with all the parties or interests around the publishing table to minimise bias.

Smith acknowledged Thompson's view that COI was a condition and not behaviour and that physicians who thought that they were impervious to commercial influence failed to appreciate that biases stemming from a COI can operate unconsciously (8). Still, in Smith's view the *NEJM*'s zero-tolerance policy for editorials and review articles was not a good policy fit for the *BMJ*. Smith felt the policy was unenforceable and commercial conflicts did not warrant being singled out for prohibition given other sources of bias. Smith was seeking a policy for the *BMJ* that "covers all conflicts of interest" (8). For Smith and the medical community at large transparency was the key to COI (11).

Transparency framed ongoing discussion and debate on commercial COI. Questions typically included how much and what kind of information about commercial COI should be made public; if disclosure should be mandatory; and whether disclosure of a commercial COI was too intrusive (12).

The *NEJM* had stepped into forbidden governance territory on both sides of the Atlantic with its zero-tolerance policy for editorial and review articles. To step beyond disclosure – as the *NEJM* had done – and prohibit commercial conflicts was off limits for most of the medical community. Among the leading general journals, the *NEJM* stood alone stressing disclosure was not enough to tackle commercial COI.

In 2000, there was a change in the editorial guard at the *NEJM*. The new editor-in-chief, Jeffery Drazen, was seen as having strong industry ties and more aligned with the business aspirations of the Massachusetts Medical Society's (MMS) vision of the *NEJM* – the MMS's flagship journal (13). In 2002, Drazen weakened the *NEJM*'s zero-tolerance policy for editorials and review articles. It now only applied to authors with "any significant financial interest in a company [or its competitor] that makes a product discussed in the article" (14). A significant conflict was defined as anything beyond $10,000. But there was no restriction on how many other companies a physician could consult for at one time, nor on the financial amounts. The reason offered for weakening the policy was that it was difficult to find expert reviews from a "small and shrinking pool of authors eligible to evaluate drugs" (14). The implication was that the best experts consulted with industry. Previous editors of the *NEJM* noted that they might have to go down a long list of names to find independent experts, but they existed (15). One had to look a little harder.

The weakening of the *NEJM* policy occurred against a rising tide of concerns over the commercialisation of medicine. Previous editors of the *NEJM* had expressed concerns over the industrial-medical complex (16); whether financial interests, influences, and conflicts were affecting physicians' commitment to patients (17), and whether academic medicine was for sale (18). Their concerns were reinforced by high profile research scandals underpinned by commercial COI (19, 20). Against this backdrop, the *Lancet* ran an editorial that posed the question: "Just how tainted by commercial conflicts has medicine become?" "Heavily, and damagingly so," was the answer (21). And in another public forum, its editor

Horton noted "that medical journals had devolved into an information-laundering operation for the pharmaceutical industry" (22). It was a provocative remark coming from someone who had earlier downplayed concerns over financial conflicts compared to other potential sources of bias. Horton now seemed to imply that commercial interests had gained a stronger presence and influence around the publishing table. His remark resonated against the backdrop of the Vioxx scandal which, at the time, was slowly unfolding. The scandal demonstrated in no uncertain terms how mixing commerce and medicine and relying on tainted information could prove deadly for the public. Vioxx was an oversight nightmare and public policy wake up call. It implicated institutions that were to ensure the integrity of medical data and the public interest. One of those institutions was the *NEJM*.

Vioxx and the Midas effect

In 2000, the *NEJM* published a clinical study (VIGOR) sponsored by the pharmaceutical company Merck (23). The article discussed the benefits of Vioxx – a drug used to treat arthritic pain. Vioxx was a commercial blockbuster and the VIGOR study contributed to its success. *The Wall Street Journal* (*WSJ*) reported that in June 2001 two doctors wrote a letter to the *NEJM* for publication – informing the journal that more adverse events associated with Vioxx existed than indicated by the VIGOR study (24). The higher rates of adverse events – heart attacks and strokes – were posted on the Food and Drug Administration (FDA) public website.

The *NEJM* rejected the letter for publication citing a lack of space. In August of 2001, one of the doctors – a pharmacist – called a radio show where Jeffery Drazen appeared, and "begged" him to correct the paper to reflect the actual adverse events associated with Vioxx (24). The concern was that, given the *NEJM*'s prestige and influence, the study would lead physicians to prescribe a drug that had deadly consequences. But Drazen dismissed the request saying: "We can't be in the business of policing every bit of data we put out" (24). Concerns about adverse events associated with Vioxx were also raised in 2001 in another leading medical journal (25). Tens of thousands of people died from taking Vioxx (26). And the question arose whether Merck had suppressed data over adverse events. Prior to pleading guilty to criminal charges, Merck withdrew Vioxx from the market in September 2004 (27). In December 2005, five years after publishing the VIGOR study, the *NEJM* published an expression of concern. It claimed the VIGOR study "did not accurately represent the safety data available to the authors when the article was being reviewed for publication" (28).

A question that kept cropping up was, why did the *NEJM* wait a year after Vioxx had been withdrawn from the market to publish its expression of concern over the VIGOR study (29, 30)? Drazen had suggested that it was the responsibility of the authors of the VIGOR study to have corrected the record. But commentators did not understand why the *NEJM* had not been more pro-active in investigating concerns over Vioxx, given that the VIGOR study clashed with what was posted on the FDA's website about Vioxx's adverse events (29, 30). The *WSJ* offered an explanation for why the *NEJM* published its expression of concern when it did. Emails made public through litigation over Vioxx in Texas revealed that the *NEJM* had timed its expression of concern to divert attention away from a deposition that might be embarrassing for the journal, should the information become public (24). An internal email between *NEJM* editors and a public relations consultant noted that the strategy "was playing out nicely".

The internal emails revealed that the *NEJM* sold more than 900,000 reprints of the tainted research article. Merck – the manufacturer of Vioxx – had bought most of them. The sale in the Vioxx reprints alone generated $697,000 or more in revenue for the *NEJM* (24).

The scandal also entangled institutional review boards (IRBs). Litigation revealed that another clinical study involving Vioxx (the ADVANTAGE study) was designed by Merck's marketing department (31). It was a seeding trial – designed solely to get doctors to prescribe Vioxx (32, 33). Seeding trials were identified as cause for public concern in the early 1990s in the *NEJM* by an FDA commissioner (34). They were characterised as not addressing a valid scientific or research question and were described as a marketing ploy to get a drug prescribed so that it could gain a market share. The ADVANTAGE trial was a successful marketing strategy that contributed to Vioxx being widely prescribed by physicians (33). But how could a seeding trial have received IRB approval? IRBs are mandated to assess the science behind a trial and to determine whether it is ethical or not. They are also supposed to ensure that research participants are informed of the purpose of a study and its possible risks and benefits. While IRBs involved in the trial were reportedly unaware of the actual purpose of the study, the ADVANTAGE trial demonstrated how marketing disguised as science had trumped the rights and welfare of research participants. It also illustrated that had it not been for litigation, the public would not have known that IRBs approved a study that was designed solely to promote financial interests. Who then was overseeing the public interest?

The issue was central to a Senate investigation into Vioxx where the FDA received public scrutiny. The FDA had approved Vioxx and the Senate investigation wanted to know why a drug that killed tens of thousands of people should be allowed on the market. Dr David Graham, Associate Director of Drug Safety at the FDA testified that the FDA's handling of Vioxx was the worst preventable public health disaster in its history (35). Senior FDA management tried to discredit and silence Dr Graham from speaking to the Senate committee and from publishing an article that publicly disclosed adverse events associated with Vioxx (36, 37). Why?

The FDA had undergone a shift in culture – from being focused on drug safety to approving drugs faster for the market place. Promoting both drug safety and economic interests created an internal cultural tension within the FDA that originated with the Prescription Drug User Fee Act (PDUFA). The Act

was created in 1992 in response to industry and consumer requests to have drugs reviewed more quickly for the market. The PDUFA allowed the FDA to collect fees from drug manufacturers for the drug approval process. The regulator was being paid by the regulated. Commercial COI had become institutionally embedded in the FDA and industry interests gained a stronger presence and influence at the agency. As Graham put it: "The industry is paying the piper and calling the tune" (37).

The FDA had been captured by special interests. Senior FDA management viewed industry as their primary clients and sought to ensure that drugs were approved quickly, despite safety concerns being raised by reviewers.

Graham was not the only reviewer that FDA management tried to silence over concerns about the safety of drugs being quickly approved (38). Nor was Vioxx the only drug approved by the FDA that negatively impacted the public. There were a number of such drugs (38). Scientists at the FDA wrote newly elected President Obama to reform the agency which they claimed had become corrupted (39). Concerns over commercial COI at the FDA and the agency being too close to industry clients and serving their interests at the expense of the public good remain alive (36,40).

The FDA commissioner Dr Lester Crawford who had approved Vioxx left the agency after the scandal and worked for Merck, Vioxx's manufacturer. He became a senior counsel for Merck's PR firm, Policy Directions Inc. Dr Crawford later pleaded guilty to criminal charges for fraud and was fined $90,000 (41). He had broken federal COI rules by falsely reporting that he had sold stock in companies regulated by the FDA.

The Vioxx scandal tarnished gatekeepers' reputations and reinforced the view that commercial COIs were ubiquitous and a detriment to the health and safety of the public.

Concluding remarks

Natarajan's concerns on the corrupting influence of commercial conflicts on the integrity of medical publishing are neither idle nor idiosyncratic. The Vioxx scandal fortifies Natarajan's concerns and shows that they are justified and well founded. The anger that Natarajan's colleagues expressed over his concerns about commercial COI and the *NEJM* was misdirected. Getting mad at or trying to silence the messenger does not make a problem go away – as Dr Graham and other FDA reviewers can attest. Nor does suggesting that concerns over commercial COI are exaggerated as a recent editorial (42) and series of articles in the *NEJM* assert (43–45). The problem is real, and as previous editors of the *NEJM* have recently noted, should not be downplayed (15). Indeed, as the Vioxx scandal illustrates, the stakes are too high to either downplay or turn a blind eye to the problem of commercial COI. What is disconcerting is that the conditions that gave rise to the Vioxx scandal remain intact (36, 46). How could this be in light of a Senate investigation into Vioxx? What measures did politicians put in place in the wake of the Vioxx scandal to tackle commercial COI? And if they have not been effective, then we need to better understand what has continued to nourish and sustain the status quo. We also need to know what is required to better align medical journals and oversight institutions with the public interest. These questions need to be taken up and answered in another paper.

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Ethics of dental health screening

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Abstract

Screening is the detection of disease at a point in its natural history when it is not yet symptomatic. In the natural history of dental caries, for example, the incipient lesions are at a reversible stage, which is a pre-symptomatic or an unrecognised symptomatic disease. Ideally, this is the stage during which screening should identify the risk of dental caries; however, presently, the so-called dental screening employed identifies the clinical cavitation of the tooth, which is very obvious to the individual. The individual already knows that he/she has dental caries and needs treatment, which the screening personnel (dental doctor) explains again during the screening procedure. Is it ethical to call such an event screening? The mushrooming of dental teaching hospitals has promoted regular screening of dental diseases among the communities and schoolchildren through their community dentistry-related activities. More often, it is a dental "check-up" that is carried out on the pretext of screening for dental diseases. Though the basic intention of this activity is to promote awareness of dental diseases and promote good health,

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