

# Commentary: An Independent Voice?: Conflicts of Interest and Research on Ethical, Legal and Social Issues

*Timothy Caulfield*

Over the past few months there have been a number of well publicized controversies that have highlighted the impact of industry funding on the nature and tone research results. There is, for example, mounting evidence that involvement with industry sponsors creates a bias toward the publication of positive results.<sup>1</sup> The impact of these studies has been punctuated by headline grabbing stories about safety issues with the popular drugs Paxil and Vioxx, and the possible suppression of negative results.

To date, however, there has been little discussion about the impact of research funding on the integrity of ethical, legal and social issues (ELSI) research. Unlike some areas of biomedical investigation, ELSI research, which includes a wide range of disciplines, rarely receives significant funds directly from industry sponsors. However, increasingly, the government funding agencies that support biomedical ELSI work have, rightly or not, embraced an explicit commercialization agenda. For example, the enabling legislation of the Canadian Institutes of Health Research (CIHR), Canada's primary public funder of biomedical research, states that the goals of the CIHR are to "encourag[e] innovation, facilitat[e] the commercialization of health research in Canada and promot[e] economic development through health research in Canada."<sup>2</sup> Genome Canada, a publicly funded national research program, requires all researchers to obtain matching funds, which will often come from the private sector, on a dollar for dollar basis.<sup>3</sup>

There are undeniable benefits to building close ties between academic researchers and industry. Commercial partners increase available research funds, may contribute to broader economic growth and provide the needed infrastructure to develop and disseminate new technologies. But these ties also come with a cost. Though the public clearly trusts academic researchers, that trust can be quickly lost. And there is evidence that involvement with industry is one of the surest ways to lose public trust.<sup>4</sup> One study, for example, found that most people "rest their assessment of credibility on the degree to which the person or institution is perceived to be at arm's length and independent of controlling and/or funding influencers. The source of the funding seems to be the critical test."<sup>5</sup>

Ideally, all researchers should have access to funds that are removed from an economic agenda. However, in a world where the biomedical research environment is becoming increasingly commercialized, the role of the independent ELSI scholar seems particularly important. ELSI work can provide an ongoing critical analysis of the biomedical research environment, thus helping to build public trust by ensuring that research is done in an ethically appropriate manner. ELSI researchers often serve on policy bodies and provide expert advice to government on socially contentious issues, such as stem cell research, the use of placebo controlled trials and human gene patents.<sup>6</sup> In these controversial areas, the mere perception of bias may compromise the



integrity and credibility of both the policy making process and the associated ELSI research.

My research is supported by grants from Genome Canada and the National Centres of Excellence programs (e.g., the Stem Cell Network).<sup>7</sup> Both programs have been wonderfully successful at funding large scale interdisciplinary projects. They provide unique opportunities for ELSI scholars and students to work closely with scientists, thus helping to ensure that ELSI research is informed by science and that scientists are sensitive to ELSI issues. In addition, these research bodies, as with the CIHR, have been tremendously supportive of ELSI work, funding large peer reviewed research projects, public engagement initiatives and national conferences and workshops.

However, the mere association with funding entities that have a mandate to facilitate the commercialization of research can produce a perception of bias that might diminish the perceived impartiality of even high quality ELSI work. This situation creates an “ELSI research” paradox. It would be irresponsible for agencies like Genome Canada and the Stem Cell Network *not* to support ELSI work – particularly given the socially sensitive nature of these research areas. But as the related technologies move from the lab to possible commercial product, the potential to create a conflict intensifies for all affiliated researchers.

How can we minimize the conflict of interest issues associated with ELSI research? First, a strong argument can be made that ELSI research teams should not have to seek additional “matching” funds for their publically funded research. Whether from industry or government, matching funds are often associated with a desire to achieve a particular research result. As such, matching funds can create real and perceived conflicts of interest.

Second, funding entities that also have a commercialization program need to develop specific and transparent governance structures that ensure ELSI research is, as much as practical, at arms length from the commercialization agenda.

Third, researchers should not be required to always justify work in the context of economic benefit. Indeed, there has been a good deal of Canadian ELSI research that has highlighted the social concerns associated with the commercialization process.<sup>8</sup> Though such work has clear social benefit, as demonstrated by the Vioxx and Paxil controversies, its direct commercial utility is less obvious.

Fourth, it is essential that the Canadian government continue to fund basic research in all areas of biomedical investigation.

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There seems little doubt that the research community will have an ever increasing role to play in the Canadian society. Many emerging areas of research – including nanotechnology, stem cell research and human genetics – have the potential to create new health benefits and economic opportunities. However, they also create innumerable ethical, legal and social challenges. All research associated with commercially promising areas should not have to be caught in the glare of market potential. Indeed, one way to help address the social issues inevitably associated with academic/industry partnerships is to ensure that clinicians, policy makers and the public can rely upon a critical analysis by truly independent academic researchers.

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1. American Medical Association, Featured Council on Scientific Affairs Report: “Influence of Funding Source on Outcome, Validity, and Reliability of Pharmaceutical Research” (4 June 2004), online: American Medical Association <<http://www.ama-assn.org/ama/pub/category/14314.html>>.
2. *Canadian Institutes of Health Research Act*, R.S.C. 2000, c.6.



3. Genome Canada, online: Genome Canada <<http://www.genomecanada.ca/index.htm>>.
4. C. DeAngelis, "Conflict of Interest and the Public Trust" (2000) 285 *Journal of the American Medical Association* 2237.
5. Pollara & Earncliffe, "Public Opinion Research into Biotechnology Issues Third Wave" (December 2000), online: <<http://biotech.gc.ca/docs/engdoc/3Wavexec-e.pdf>>.
6. Jocelyn Downie, "Contemporary Health Research: A Cautionary Tale" (2003) Special Edition *Health L.J.* 1.
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American Society of Law, Medicine and Ethics

June 13 - 15, 2005 Atlanta, Georgia

[https://www.aslme.org/aslmesecure/register/step1.php?conf\\_id=57](https://www.aslme.org/aslmesecure/register/step1.php?conf_id=57)

### **"First International Interdisciplinary Conference On Emergencies"**

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<http://www.ciiu2005montreal.com/appel.html>

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<http://www.cpha.ca/english/conf/conf.htm>

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