

Report clears researcher who broke drug company agreement

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A new report has urged Canada's federal government to do more to curb attempts by pharmaceutical companies to influence the conduct and publication of clinical studies carried out by researchers into their products.

The report, commissioned by the Canadian Association of University Teachers, follows a four year dispute at the Toronto Hospital for Sick Children, centring on attempts by a drug company to prevent publication of results of a trial that were unfavourable in relation to one of its products.

The dispute began after researcher Dr Nancy Olivieri decided to break a confidentiality agreement with Apotex, a Toronto based pharmaceutical company that was sponsoring her research. She published results critical of the drug deferiprone, which she was testing in young patients with thalassaemia, in the *New England Journal of Medicine* (1998;339:417-23).

Dr Olivieri, former head of the hospital's haemoglobinopathy programme, was threatened with legal action by Apotex and also removed from her hospital post, though she was later reinstated (*BMJ* 1999;318:351).

Now a report into the affair, commissioned by the academic tenure and freedom committee of the Canadian Association of University Teachers in 1999, has exonerated her. It concluded that Dr Olivieri's academic freedom was violated when the pharmaceutical firm Apotex stopped the trials and threatened legal action if she went public with her fears about deferiprone.

Reacting to the report, Dr Olivieri said in an article in the Toronto *Globe and Mail* newspaper (2001;Oct 31:A15) that neither the hospital nor the university, "both anticipating large



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Dr Nancy Olivieri's "academic freedom was violated" when Apotex stopped the trials and threatened legal action

donations from Apotex, supported me in fulfilling my ethical obligations to my patients or my scientific obligations to the public."

She said the report confirmed that, after her announcement of her findings, she experienced "five years of personal vilifications, reprisals and harassment."

In major respects the report contradicts a previous report commissioned by the Hospital for Sick Children that said that the hospital had done nothing wrong, although it called for changes in hospital policies and procedures (*BMJ* 1999; 318:77).

In a news release (www.caut.ca) James Turk, executive director of the university teachers association, called for immediate action so that researchers' ethical duties, academic freedom, the rights of patients, and the public interest should "never again be compromised in this way."

Mr Turk said it was essential that medical faculty be given the same rights of academic free-

dom as all other faculties. He charged that the University of Toronto was currently in negotiations with its teaching hospitals over an alternative funding arrangement "that would strip clinical faculty of academic freedom."

One of the study's three authors, Jocelyn Downie of Dalhousie University, said her greatest concern was "the fact that this is not an isolated incident." She added: "These incidents are happening across the country. We have a clear need for national standards to be implemented and applied... so that people can be protected."

The Hospital for Sick Children issued a statement saying that it had already conducted "a full, thorough investigation" of the issues arising from the affair and noting that neither it nor the University of Toronto participated in the association's review.

"This dispute is closed and attempts to revive it are counter-productive," the hospital wrote in its statement (www.sickkids.on.ca). In the three years since

the completion of its own investigation the hospital had "implemented an entirely new policy structure governing clinical research in the hospital," it said. "The new policies ensure that the relationship between clinicians and those who provide financial support for research is clear."

The hospital said that the Canadian Association of University Teachers was an association representing faculty unions and did not represent doctors at the hospital. It added that the Canadian university teachers' association did not "have any standing when it comes to clinical research, patient care, personnel or human resources issues at Sick Kids or any other teaching hospital."

The University of Toronto's statement said the new study "does not add any substantial information on the case."

Susan Bloch-Nevitte, the university's public affairs director, said that since the report was commissioned by the hospital, the university had moved forward to implement its recommendations (www.newsandevents.utoronto.ca).

The University of Toronto "reached an agreement in March with its teaching hospitals to harmonise research policies and enforce stringent ethical guidelines and public accountability in research. Under the new agreement, peer review remains the cornerstone of excellence in research, and it notes that scientists should have the right to disseminate the results of their findings. No agreements will be negotiated that allow research sponsors to suppress or censor research results." □

The Report of the Committee of Inquiry on the Case Involving Dr Nancy Olivieri, the Hospital for Sick Children, the University of Toronto, and Apotex Inc is accessible at www.caut.ca/english/issues/acadfreedom/olivieri.asp