

The Olivieri dispute: No end in sight?

The story of the battle between Dr. Nancy Olivieri and the drug company Apotex is well known: the company produced an experimental drug, deferiprone, that was used to treat thalassemia, and it threatened to sue Olivieri if she published a study showing that the drug could be hazardous. The story made headlines in the summer and fall of 1998, when Olivieri accused her home institutions — the Hospital for Sick Children (HSC) and the University of Toronto — of failing to support her after the study appeared (*N Engl J Med* 1998;339:417-23).

That it's still in the news is testimony to the effective media strategies of the players involved, but its newsmaking potential also reflects the larger questions being asked. Do drug companies silence researchers in order to keep secrets? Have academic institutions put their interest in wealthy donors above all others? And are research subjects adequately protected from potential risks?

When attached to the story of Olivieri and Apotex, these questions attracted intense interest. It's the careful

deliberation of several different groups asked to consider her story, and address precisely these sorts of questions, that's put Nancy Olivieri back in the spotlight.

At the end of October, 3 professors released a 540-page report on her case (see pages 448 and 452). They had been commissioned to write it by the Canadian Association of University Teachers (CAUT), the group representing faculty unions across the country. CAUT was also heavily involved in funding Olivieri's legal and academic battles with the hospital, the university and the drug company, and all 3 parties declined to participate in the professors' investigation, although the professors billed themselves as independent of CAUT.

Their report, which largely favours Olivieri's position, suggests she should "receive redress" from the hospital for "unfair treatment she has received." The professors also attempted to address broader issues by calling for changes in Canada's Food and Drugs Act in order to prevent similar situations and by recommending that hospitals change the way they inquire about the conduct of individual staff physicians.

Olivieri says the report has fully vindicated her. In a commentary written for the *Globe and Mail*, she said the boards at HSC and the U of T need to "recognize that they have a duty to govern on behalf of the public." The hospital responded to the professors' report with a brief statement that it had already implemented new policies to govern research. It added: "This dispute is closed and attempts to revive it are counterproductive."

In November, a group that considers appeals of cases decided by the College of Physicians and Surgeons of Ontario (CPSO) ruled in Olivieri's favour. Olivieri and 2 colleagues had complained to the college in 1999 about Dr. Gideon Koren, a doctor and scientist at HSC who sent several "poison-pen" letters to them. Initially, the college termed the letters "unprofessional" but decided against sending complaints about them

to its Disciplinary Committee. The Health Professions Appeal and Review Board has now ordered the college to refer the case for a disciplinary hearing.

And in December, the college decided in Olivieri's favour on another issue. Leaders at the HSC had alleged that Olivieri might have committed ethical transgressions — for example, by performing liver biopsies that may not have been clinically indicated but were performed for the purposes of research. The allegations stemmed from a review the hospital commissioned in 1998, and the hospital's Medical Advisory Committee began to investigate them. Olivieri accused the committee of hearing witnesses in secret, refusing to let her counsel cross-examine witnesses and failing to respond to her lawyer's requests for information. The hospital then claimed that Olivieri had blocked their investigation, and in the spring of 2000 it asked the college to investigate her behaviour.

Privately, college executives expressed surprise that HSC involved them in the ongoing dispute. They couldn't decline to be involved, since the college is obliged to review every complaint. In December its review concluded that Olivieri "did not fall below a reasonable standard of care in any of the areas of concern raised." On the allegations regarding liver biopsies, it described Olivieri's practices as "not only reasonable but commendable in the circumstances." Shortly after the college announced its decision, the hospital told Olivieri it would not take the investigation further.

Although Olivieri appears to have won her battles with the drug company, the hospital and the university, she and her supporters are still pursuing grievances against the university and ongoing litigation with Apotex. In her newspaper commentary on the CAUT report, she concluded: "Not one of us believes that the [professors'] report represents the end of this struggle — that's still being fought, on several fronts." — Dr. *Miriam Shuchman*, Toronto



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Dr. Nancy Olivieri: this isn't over yet