

I beg to differ

C. David Naylor, Dean of Medicine at the University of Toronto, declares that the university and the Hospital for Sick Children (HSC) have “moved on” from the scandal surrounding the clinical trials of deferiprone at those institutions.¹ But, as other articles in the same issue clarify,²⁻⁴ several central issues remain unresolved.

Naylor relates that “[i]ncalculable amounts of time and money have now been spent on ... a dispute about a single drug that has, at best, uneven efficacy and uncertain toxicity.” Indeed, over several years, HSC’s administration authorized the spending of large amounts of public money on a series of expensive proceedings against me that relied on unfounded allegations by two senior professors in the Faculty of Medicine.⁵ The allegations were abundantly contradicted in documents available to these professors and to HSC at the time, and have now been dismissed by independent inquiries that declared my actions “commendable.”^{6,7}

Also using public money, university staff and professors made public unfounded allegations of research misconduct against me at an academic board meeting, in the University of Toronto Bulletin,⁸ in the press and, for a period of 18 months, on a university hospital Web site. These allegations have now, finally, been discarded by Dean Naylor himself. However, despite repeated requests to do so, the university has not repealed, in similar venues, the announcements that disgraced and defamed me publicly. Nor has the Dean or any member of the hospital administration addressed the conduct of the senior professors who advanced demonstrably incorrect testimony against me.

Subsequent to our taking a stand for patient safety and academic freedom, my colleagues and I have, for nearly 6 years, been subjected to unfair treatment by the university and hospital administrations.

We have spent our personal money in defending these rights and principles, in the face of “incalculable amounts” of public money spent by others.

Naylor states that deferiprone “has, at best, uneven efficacy and uncertain toxicity.” It is interesting that an observation that the university once termed controversial is now stated as fact. It was by taking this now-acceptable view of the efficacy and safety of deferiprone⁹ that I became the target of repeated threats of legal action by the drug’s manufacturer, Apotex Inc., and was sued by the company for \$10 million in a statement filed in Ontario Superior Court on June 19, 2000, an action still before the court.

Naylor next takes issue with clinical research in the hemoglobin disorders and suggests that genetic therapy is the future direction for the treatment of thalassemia: all this fuss, he claims, has focused on a “primitive” and “palliative” measure: iron chelation therapy. In fact, iron chelation therapy has been life-saving for my adult patients, allowing them extensions of life to age 40 and older, education opportunities, employment and health, including fertility — all of which would have been unknown to such patients 2 decades ago. Genetic therapy is not a clinical option, nor will it be for many years — not even for the richest thalassemia patients in the most advanced academic centres worldwide.

In the meantime, despite its “uneven efficacy and uncertain toxicity,” deferiprone is being administered to many patients with thalassemia in many parts of the world, in place of the effective, safe, somewhat onerous standard therapy with deferoxamine. In promoting deferiprone, Apotex has used the scientific opinions of the same senior professor who was the leading source of the unfounded allegations used by HSC as the basis for its actions against me.¹⁰

All of us, including the Canadian public, will be pleased to “move on”

once the central issues of disclosure of risks, academic freedom, due process, professional accountability, and redress for harm done have been resolved at their source.

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[The author responds:]

Nancy F. Olivieri’s unfortunate letter speaks little to broad principles for the future, and mostly to a search for personal redress and vindication as she defines it. She ignores the University’s progress in implementing

tough new standards for industry-sponsored research,¹ and the extensive efforts the University has made to mediate a resolution of her issues.

Olivieri's claims about the publicity surrounding the allegations by the Medical Advisory Committee [MAC] of the Hospital for Sick Children are misleading. The substance of the allegations was never publicized in the University of Toronto Bulletin. The MAC's referral of these matters for investigation ran 9 lines on page 2 of the Bulletin with a 15-point headline.² The story on the University's dismissal of the complaints ran 28 lines on page 3 of the Bulletin with a 30-point headline.³ It included my criticism of the hospital for publicizing the referral, a criticism repeated in *CMAJ*.⁴ Then-university president J. Robert S. Prichard confirmed to the University's Academic Board that the matter had been referred, after the referral had already been publicized. As Olivieri knows, a statement dismissing the MAC allegations was later read into the formal record of the Council of the Faculty of Medicine.

Olivieri protests that the CEO of the pharmaceutical company with which she became entangled is suing her for \$10M. In a fair and rational world, there would be no litigation surrounding this dispute. That said, the suit in question was initiated well after Olivieri had published her study and publicized her views of the drug. It arose from Olivieri's statements about the company's CEO. Moreover, a check through public court records shows that Olivieri has herself initiated lawsuits against officers of Apotex, academic colleagues, the hospital, the University, and media outlets, for claims in excess of \$20M.

Olivieri's comments about her personal legal costs side-step her role in initiating proceedings. They also demean the involuntary contributions to her legal costs made by over a thousand nonclinician colleagues who pay mandatory dues to the University of Toronto Faculty Association [UTFA]. In fact, the UTFA has spent hundreds of thousands of dollars on legal fees and

services for Olivieri and her supporters.

Olivieri seeks discipline against 2 colleagues "who advanced demonstrably incorrect testimony against me." But at times in this bitter dispute, Olivieri herself has advanced "demonstrably incorrect" allegations against others, including an allegation of forgery that was subsequently retracted publicly. Less understandable is her recent breach of confidential misconduct proceedings, causing dissemination of misinformation about a distinguished and neutral colleague.

On the efficacy and safety of L1, Olivieri wrongly assumes that the University has or had an official view. The drug's worth is for clinicians, researchers, and regulators to determine.

Olivieri alludes to deferoxamine therapy as "somewhat onerous"; "all this fuss," it seems, is about an intravenous pump infusion that must be given nightly to children. Not only is the need for an alternative obvious, but Olivieri's own L1 studies were directed to that end. I am therefore baffled by her personalized response to my comment that energy spent on this dispute could be better directed at research into other treatment options for the thalassemias.

In sum, Nancy F. Olivieri's letter sadly illustrates why a definitive resolution is needed to bring closure, if possible, for Olivieri and her allies, and underscores why the involved institutions are indeed moving on.

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Independent inquiry

Although we applaud the coverage¹⁻³ given in the Feb. 19, 2002, issue of the case of Nancy Olivieri, Apotex, the Hospital for Sick Children and the University of Toronto, the editorial "Questions of Interest"⁴ may have left your readers with serious misapprehensions.

The first of these concerns the independence of our Committee of Inquiry. When it became clear that a committee of inquiry into this case was needed, the Canadian Association of University Teachers (CAUT) was the only external body prepared to commission such an inquiry and to provide it with full independence. Because CAUT had taken a position on some matters arising in the case, and because this organization by definition serves the interests of university teachers, we agreed to serve on the committee only on the provision that we could be independent of CAUT or of any other person or organization. At the outset, we stipulated special arrangements to ensure our independence. CAUT agreed to these, and also undertook to have our report published exactly as submitted and in its entirety. Our report was delivered to CAUT on Oct. 26, 2001, at the same time as it was released to the public; the association had no advance copy. It is also worth noting that none of us sought appointment to this committee; we agreed to serve because of the important issues it raised, and did so for 2 years without remuneration.

Second, with respect to the participation of the various individuals involved in the case, we agree that it would have been ideal to have an inquiry in which all parties participated. However, it must be noted that the administrations of the University, the Hospital and Apotex declined our invitation to participate. The potential disadvantage of their nonparticipation was substantially offset by the access that we had to a large quantity of relevant correspondence and documents originating from the administrations of the university and the hospital, Apotex, and other nonparticipants. These thousands of documents included the 1998