

CAUT

The Drug Trial: Nancy Olivieri and the Science Scandal that Rocked the Hospital for Sick Children

Miriam Shuchman. Toronto: Random House Canada, 2005; 464 pp; ISBN: 0-679-31084-3, hardcover \$34.95 ca.

Book Portrays Olivieri as More Villain than Victim

By Arthur Schafer

Dr. Nancy Olivieri is famous for raising doubts about an experimental drug with which she was treating thalassemia patients. Her principled stand, and the resulting scandal, led universities to offer researchers some protection against illegitimate drug company pressure. Medical journals changed their publication rules. Research hospitals changed their policies. She became an international icon.

Apotex, the drug company that tried to silence her, has attracted international opprobrium. The company threatened to sue Olivieri if she publicly revealed her fears about the inadequacy of their drug, deferiprone. She sued them for libeling her. They sued her for \$20 million for discrediting their drug.

Apotex claims still to believe in the virtue of deferiprone, but the company has been heavily criticized for conduct many have interpreted as placing profits ahead of patient safety. Apotex is not

alone in the dock of public opinion. Every week seems to bring some new scandal involving drug company suppression of negative data. Think of Prozac (Eli Lilly), Vioxx (Merck) and Celebrex (Pfizer). Public trust in drug company-sponsored research is plummeting.

Olivieri's hospital (the Hospital for Sick Children) and her university (the University of Toronto) have also taken a public drubbing for failing to provide her with effective support as she struggled with Apotex. Actually, not only was Olivieri denied effective support, she was fired from her position and experienced harassment of almost every kind. When it was discovered the university was negotiating with Apotex for a huge financial donation, people drew their own conclusions — and these were not flattering to the university.

Miriam Shuchman's book, *The Drug Trial*, is the fourth to be published on the Olivieri affair. The first was commissioned by the hospital. It singled out Olivieri for special criticism but was quickly shown to be based on misinformation. Next, CAUT commissioned a report from three eminent academics. Their book exonerates Olivieri while sharply criticizing the conduct of Apotex, the UofT and Sick Kids. Then spy novelist John le Carré joined the fray with a murder mystery, *The Constant Gardener*, casting Olivieri as heroic victim of drug company machinations.

Shuchman's book, by contrast, pays little attention to the central moral issues of academic freedom and drug company censorship. She concedes that Olivieri was right to go public with her data and that Apotex was wrong to threaten her. But Shuchman's focus is on Olivieri herself, as researcher, physician and person. The book

attempts to demonstrate that Olivieri is a bad scientist, a bad doctor and a bad person to boot.

Shuchman, a psychiatrist and medical journalist, goes to great lengths to discredit Olivieri, portraying her as a scientist who is blind to the truth about the drug she once favoured but now criticizes. The real scandal, the author claims, is that Olivieri's scientific doubts about deferiprone are not well founded. Shuchman also attempts to discredit Olivieri as a doctor who is so busy doing medical research she neglects her patient care duties, and as a person who swears frequently at hospital administrators, is tough on colleagues and too demanding of subordinates.

To persuade us that Olivieri got the science wrong, Shuchman quotes a large number of Apotex-funded scientists, who claim deferiprone will save lives. Unfortunately, most of the researchers on whose work Shuchman relies are scientific journeymen. By contrast, the leading blood researchers in the world — David Nathan, former president of the Dana-Farber Cancer Institute at Harvard and David Weatherall, Regius Professor of Medicine Emeritus at Oxford — both believe Olivieri got the science right. Since the liver scarring associated with deferiprone is a gradual process, we won't know for years which side of this scientific controversy is correct.

Shuchman claims thalassemia patients in Toronto have a higher death rate than patients in other places, and she insinuates this "could" result from "lack of access to" deferiprone. The conclusion to which she pulls the reader is clear. Olivieri is to blame. This sensational but dubious hypothesis is highlighted in the publisher's

publicity handout for the book. It's a slippery inference, however, since speculation that Toronto has a higher death rate than other centres is not supported by any good scientific evidence. Besides Shuchman herself acknowledges the lowest death rate in the world appears to be at University College Hospital, in London, and none of their patients receives deferiprone.

The most plausible hypothesis for a surplus of deaths in Toronto, if indeed there is such a surplus, would be the severe underfunding of the Toronto thalassemia program, compared to centres such as University College Hospital. There are simply too few specialist thalassemia physicians in Toronto — a problem Olivieri and the thalassemia patients' association have both fought to rectify.

To fill out this story, Shuchman compiles a lengthy charge sheet against Olivieri. The most serious accusation is that Olivieri, through her negligence, was responsible for the death of a young patient, Sanchia Bulgin. Shuchman is unmoved by the fact that Olivieri was not the physician treating this patient, and that the responsible physicians failed to follow well-established guidelines. It's a bizarre accusation.

Shuchman greatly admires Gideon Koren, one of Olivieri's foes at Sick Kids, and spends pages describing his stellar virtues and research accomplishments. Only after these encomiums does she acknowledge, incidentally, that Koren was formally found guilty of both research misconduct, for plagiarizing Olivieri's work, and of sending anonymous hate mail to her supporters: "conduct

unbecoming a physician," in the language of the College of Physicians and Surgeons of Ontario.

Shuchman doesn't admire Olivieri, and so spends many pages describing the serious charges of unprofessional conduct which the hospital made against her. Then, almost sotto voce, Shuchman grudgingly acknowledges the college cleared Olivieri of all the charges and commended her for acting in the best interests of her patients.

This heavily biased style of presentation undermines the book's credibility. Credibility is a big issue here, because most of the hostile quotations are attributed to doctors and patients who are not identified. One of the few clearly identified patients has now gone on record as saying his words, as quoted in the book, were twisted beyond recognition. This patient insists he made clear to Shuchman that he considers Olivieri to be a highly ethical doctor who is utterly dedicated to her patients.

My confidence in Shuchman's journalistic reliability was further eroded when I came across a passage in which she "quotes" from a commentary I published in *The Globe*. I wrote none of the words she attributes to me.

As I was reading Shuchman's book, I was repeatedly struck by how dramatically her account of events is contradicted by a series of inquiries conducted by independent bodies — all public documents, all easily obtainable.

In order to refresh my memory I reread these documents: the Hospital for Sick Children Internal Review Committee's Report on the

Death of Sanchia Bulgin; the Hospital for Sick Children and University of Toronto's disciplinary proceedings against Dr. Gideon Koren for professional misconduct; the CAUT Report; the Ontario Health Professions Appeal and Review Board Inquiry into Complaints against Dr. Gideon Koren; and the University of Toronto's Disciplinary Proceedings against Dr. Gideon Koren for Research Misconduct. Procrustes would have genuinely admired Shuchman's sly way of dealing with inconvenient facts.

In the end, what really matters is that once Olivieri discovered preliminary evidence of deferiprone's toxicity, she was morally obliged to warn her research subjects, who were also her patients. Patient safety is a value which trumps all others. Olivieri did her duty, in the face of company threats and hospital harassment, for which she is rightly honoured. Her hospital and university saw the battle as a mere "scientific dispute." In consequence, they failed in their moral obligation to defend her academic freedom. They just didn't get it. Shuchman still doesn't.

Arthur Schafer is a professor of philosophy at the University of Manitoba, where he is director of the Centre for Professional and Applied Ethics. He has not received funds from any drug company or from any party to this dispute. He has appeared at three press conferences with Nancy Olivieri, at which his (unpaid) role was to analyse and evaluate the ethical issues raised by her dispute with Apotex, the Hospital for Sick Children and the University of Toronto. His article on the affair, "Biomedical conflicts of interest," was published in 2004 by the Journal of Medical Ethics.
