

The Report of the Committee of Inquiry on the Case Involving Dr. Nancy Olivieri: A Fiduciary Law Perspective

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On October 26, 2001, 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.* was released to the public.¹ The Report was commissioned in 1999 by the Canadian Association of University Teachers (CAUT) following a protracted dispute precipitated by the desire of a physician-researcher to inform patients enrolled in clinical trials of what she believed was a potentially life-threatening effect of the treatment drug. The sponsor drug company, Apotex Inc. (Apotex), objected to the disclosure of this information by Dr. Olivieri and regarded it to be a breach of contract. Apotex threatened to bring legal action against Dr. Olivieri for any such disclosure.

At over 500 pages in length, the Committee of Inquiry Report is painstakingly comprehensive. The *Report* makes 31 recommendations directed at the following groups:

- clinical investigators;
- research ethics boards;
- industrial sponsors;
- universities and affiliated hospitals;
- the Association of Universities and Colleges of Canada (AUCC);
- the Canadian Association of University Teachers (CAUT);
- granting agencies (CIHR, SSHRC, and NSERC); and

- federal and provincial governments and regulatory bodies (including Health Canada and the Federal Minister of Health).²

In this comment we briefly summarize the facts as found by the Committee of Inquiry and describe earlier attempts to deal with the complex issues raised in the dispute. We then

set out and comment on the most significant recommendations made by the Committee of Inquiry in its Report. Finally, we refer to fiduciary law, which was not explicitly adverted to by the Committee of Inquiry. This body of law sharpens the focus considerably on the propriety of the

behaviour of the various parties to the dispute, including Dr. Olivieri. This is important because Dr. Olivieri and Apotex conducted themselves in much the same manner as do many other physician-researchers and sponsor companies who embark on industry-academic research. Fiduciary law is highly instructive about the limits of what may be agreed to by physician-researchers and sponsor drug companies when their agreements implicate the interests of patients who volunteer as subjects in clinical trials.

As governments have struggled to contain rising healthcare costs, there has been increased willingness within and by the public sector to rely on drug companies to fund clinical research. Without doubt, there are significant benefits associated with co-operative research arrangements between

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the private and public sectors,³ but there are also real risks.⁴ A prominent risk of industry-academic research is that when the interests of the research partners conflict, academic freedom to publish findings or publicly voice opinions is often sacrificed in order to promote commercial interests.⁵ There is also concern that industry-academic liaisons can jeopardize the interests of patients of clinicians who are engaged in academic research.

The case of Dr. Olivieri is a compelling and instructive example of just how industry-academic research relationships can adversely affect the interests of patients and both the professional and academic interests of clinical researchers. This is a serious problem because the impairment of professional duty and academic freedom in this context can profoundly undermine the trust Canadians place in their publicly funded healthcare institutions, the physicians who provide vital services to the public and the integrity of academic institutions.

Background

Our analysis proceeds on the basis of the facts found by the Committee of Inquiry. We do not vouch for these facts and caution readers that the various parties may have divergent views and interpretations of them. However, it is highly worthwhile to evaluate the legal implications that flow from the facts as found, given that they are not entirely unusual.

Dr. Olivieri is a renowned clinical researcher and expert in the treatment of β -thalassemia, a serious inherited blood disorder that manifests during childhood and is fatal if left untreated. She was involved in the early clinical development of a drug called deferiprone, also known as L1, which acts as a chelating agent to reduce abnormally elevated iron burden in the blood in affected individuals.

In 1989, pilot studies were commenced at the Hospital for Sick Children in Toronto (HSC) to evaluate the long term efficacy and safety of L1 in patients with β -thalassemia. The results suggested that L1 may be an effective treatment for the disease, however, to comply with regulatory requirements in the United States, additional randomized studies to test the drug's safety and efficacy were required. To fund such studies, Dr. Olivieri and her colleague Dr. Gideon Koren, then Associate Director for Clinical Research at HSC, approached Apotex. In 1993 a formal research agreement was entered between Apotex and doctors Koren and Olivieri.

Among other things, the 1993 agreement contained a confidentiality clause that gave Apotex the right to control communication of trial data for one year following termination of the trial. Specifically, the clause provides:

[a]ll information, whether written or not, obtained or generated by the investigators during the term of this agreement and for a period of one year thereafter, shall be and remain secret and confidential and shall not be disclosed in any manner whatsoever to any third party, except to an appropriate regulatory agency for the purpose

of obtaining regulatory approval for manufacture, use or sell L1 [sic] unless the information has been previously disclosed to the public with the consent of Apotex. The

investigators shall not submit any information for publication without the prior written approval of Apotex.⁶

On its face, this clause focuses exclusively on the commercial interests of Apotex. There is nothing in the clause that purports to protect or even address the patients' interests.

In 1996, whilst clinical trials were ongoing, Dr. Olivieri became concerned that L1 was potentially causing serious side-effects in patients. The Hospital for Sick Children's institutional Research Ethics Board (REB) was consulted. Dr. Zlotkin, the REB Chair, directed Dr. Olivieri, among other things, to amend the study information and consent form, report her findings to the Health Protection Branch and inform all physicians responsible for the care of patients receiving L1 of the potential risk.⁷ Apotex disagreed with Dr. Olivieri's evaluation of the risk and argued that there was insufficient evidence to support her concerns.⁸ Apotex threatened legal action against Dr. Olivieri if she informed her patients or others of the perceived risk. Nevertheless, and contrary to the wishes of Apotex, Dr. Olivieri followed the REB's directive. Apotex responded by terminating the ongoing trials at HSC,⁹ terminating Dr. Olivieri's consulting agreement and threatening to "vigorously pursue all legal remedies" against Dr. Olivieri.¹⁰

In the Fall of 1998 the Board of Trustees of the HSC arranged for Dr. Arnold Naimark to conduct a review of its policies and procedures governing clinical trials.¹¹ Within the HSC, medical and scientific staff were growing increasingly concerned over the Olivieri situation and the media attention it was receiving.¹² Moreover, the publication

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of a scientific paper by Dr. Olivieri, in which she suggested that L1 might be responsible for causing liver fibrosis in some patients,¹³ generated further interest and scrutiny.

The scope of Dr. Naimark's mandate was to conduct "an independent review to determine the facts and circumstances giving rise to the current controversy,"¹⁴ including matters pertaining to patient safety, conflicts of interest, and the release and publication of research information. The *Naimark Report* was released to the public in December 1998. Among this Report's findings is that Dr. Olivieri had failed to report to the REB, in a timely fashion, an unexpected risk identified during the course of a clinical trial.¹⁵ In its later *Report* the Committee of Inquiry refutes this finding.¹⁶

In January 1999 Dr. Olivieri was removed from her position as Director of the Hemoglobinopathy Program at the HSC. Simultaneously, she and a number of her colleagues were issued directives to not discuss their concerns publicly. Dr. Olivieri's legal counsel, pre-eminent scientists from abroad, the CAUT, the University of Toronto Faculty Association and the University of Toronto administration intervened in the matter. As a result, Dr. Olivieri was re-instated to her directorship and was given an assurance that she would receive financial support from the HSC in the event that legal action was brought against her by Apotex .

The Report of the Committee of Inquiry

As noted above, the CAUT first became involved in the present situation in August 1998. It was not until September 1999, however, that the Committee of Inquiry established by the CAUT commenced its investigation. The Committee of Inquiry members agreed to serve only if they could be guaranteed true independence and if their findings, irrespective of content, would be published. Some two years later, on October 26, 2001, the long awaited Committee Report was released to the public.

The Committee of Inquiry asserts that it had better access to relevant information than did Dr. Naimark's committee. Its *Report* makes reference to and relies on relevant documents that had not been previously available.¹⁷ Moreover, and importantly, unlike the Naimark committee, the Committee of Inquiry also had the benefit of Dr. Olivieri's participation and cooperation.¹⁸

In the Report, the Committee of Inquiry sets out what it regards to be the central issues. They are stated as follows:¹⁹

- the right of participants in a clinical trial to be informed of a risk that had been identified during the course of the trial by the investigator, and the obligation of the investigator to inform the participants of the risk; and
- the academic freedom of Dr. Olivieri to publish her findings on L1 and thus inform investigators administering the drug in other centres.

The first of these issues goes to the heart of the obligation of physicians to disclose to patients matters of material importance, including risks of treatment.²⁰ This duty implicates fiduciary law when non-disclosure of risks is motivated by the desire of physicians to advance their personal interests, including personal legal or research interests.²¹ The second issue implicates the time-honoured freedom of academics to publish research results even if publication damages commercial interests. The value and rectitude of this freedom are highlighted in the present case because of the potential beneficial impact that publication would have on patient populations enrolled in L1 studies at other centres.

Recommendations of the Committee of Inquiry

The *Report* contains 31 recommendations, most of which are general in nature and have broad application to clinical research generally. For the purpose of this comment, the most important recommendations are the following.

- Gag clauses are not permissible in clinical research contracts, protocols or investigator agreements; on the contrary, there should be express provision that the clinical investigators shall *not* be prevented by anyone from informing study participants, members of the research group, other physicians administering the treatment, research ethics boards, regulatory agencies, and the scientific community, of risks (or potential risks) to participants that the investigators identify during the research.²²
- Research ethics boards are to review all protocols, research contracts, investigator agreements and budgets to ensure that (1) they do not preclude a clinical investigator from informing interested persons of risks (or potential risks) to participants that the investigators identify during the research; and (2) conflicts are managed in ethically appropriate ways.²³

- It is the research ethics board that should ensure that all sponsors and investigators understand that inappropriate confidentiality clauses are not acceptable.²⁴
- Universities and affiliated teaching hospitals should implement appropriate policies and practices to ensure protection of academic freedom.²⁵
- There should be a national, integrated approach for all research done in hospitals affiliated with universities. The Association of Universities and Colleges of Canada (AUCC) should develop, implement and enforce a policy governing industry-academia relationships that would apply to all faculties of medicine and affiliated teaching hospitals.²⁶
- The Canadian Institutes for Health Research (CIHR), the Social Sciences and Humanities Research Council (SSHRC) and the Natural Sciences and Engineering Research Council (NSERC) should require that universities and health care institutions receiving *any* funding from the granting agencies have in place policies to ensure that gag clauses are not contained in any clinical research contracts, protocols or investigator agreements; there should be express provision that clinical investigators shall not be prevented by anyone from informing study participants, members of the research group, other physicians administering the treatment, research ethics boards, regulatory agencies, and the scientific community, of risks (or potential risks) to participants that the investigators identify during the research. Failure to abide by the requirement could lead to the withholding of all CIHR, SSHRC and NSERC funds. The Councils should actively monitor compliance with this requirement.²⁷
- The *Tri-Council Policy Statement* should be amended so as to give further explicit and prescriptive direction to REBs on the need and ways to manage conflicts of interest.²⁸

We agree with the principles that underlie the recommendations made by the Committee of Inquiry. These principles include:

1. that physicians have an obligation to disclose perceived risks to their patients;
2. that fetters to the disclosure of information which physicians are duty-bound to disclose to patients must not be tolerated; and

3. that institutional structures should be established that encourage and facilitate the appropriate flow of information both from physicians to their patients and from physicians to their professional colleagues.

The Role of The Law of Fiduciary Obligation

In the context of fiduciary relationships, like the physician-patient relationship, many of the Report's recommendations articulate not only the values of fiduciary law, but its explicit prescriptions and proscriptions. It is unfortunate that the Report does not highlight this point. It is of considerable significance that many of the Report's recommendations go beyond ethics and good clinical practice and reflect the content of the existing law of fiduciary obligation. The willingness of all parties involved in clinical research to implement the Report's recommendations, as well as the speed of implementation, would undoubtedly be affected by an awareness that many of the Report's recommendations reiterate legal principles that already exist.

The Fiduciary Nature of the Physician-Patient Relationship and The Duty To Disclose Material Risks

Fiduciary law is a strict body of law that is often overlooked or misunderstood. It has a significant role to play in protecting vulnerable people.²⁹ This is especially true, we believe, of patients who enroll in clinical studies because they have serious conditions for which there are no treatments or for which standard treatments are deficient or ineffective. The fact that the doctor-patient relationship is a fiduciary one is indisputable.³⁰ That it retains its character as a fiduciary relationship in a clinical trial setting, while not absolutely certain, is very probable.³¹ That physician-fiduciaries must act in the best interest of their patients, and must communicate to them material risks of which they become aware, is trite law.³² Consent forms for participation in clinical trials, without exception, attest to the duty to disclose material risks and further, without exception, confirm that the duty of disclosure is a continuing duty that may be activated in the course of a trial if and when new risks are detected. A failure to disclose a material risk which is motivated by personal interest, such as the desire to have a clinical trial continue or to avoid contractual liability, is a breach of fiduciary duty.³³ It is also a breach of the undertaking made by clinical researchers in the consent forms signed by patients who participate in the trials. Physicians who fail to disclose risks to patients for improper

reasons clearly violate their professional obligations enunciated in the Hippocratic Oath. Such non-disclosure undermines the trust and confidence that is the essence of the doctor-patient relationship, and is also a breach of fiduciary obligation.³⁴

Third Party Liability For Participating In a Breach of Fiduciary Duty

An important point, not fully understood by the legal, medical or business communities, is that fiduciary law not only binds fiduciary actors, but also, in some circumstances, third parties who are not fiduciaries.

Third parties cannot with impunity, either through contract or otherwise, induce or facilitate or participate in a breach of fiduciary obligation. At least in some circumstances, fiduciary law regards as an actionable wrong the participation of non-fiduciaries in a breach of fiduciary duty. If this kind of legal wrong has application in the context of clinical research—and we think it does—then sponsor companies such as pharmaceutical companies are well advised, along with clinicians and academic institutions, to embrace the recommendations of the Report.

In law, third parties are guilty of knowingly participating in a breach of fiduciary duty if the following can be established:³⁵

(a) that there was a breach of fiduciary duty which involved the fiduciary taking an undue or wrongful risk, “which risk is known to be one which there is no right to take”;³⁶

(b) that the third party participated in the breach of fiduciary duty;³⁷ and

(c) that the third party was aware both of the existence of the fiduciary relationship and that it was participating in a breach of a fiduciary duty (which involved the taking of an undue risk which the fiduciary knew should not be taken).³⁸

With respect to the knowledge requirement under (c), third parties must have actual knowledge, or they must be reckless to the truth or willfully blind.³⁹ The application of these principles suggests that there is a credible case to be made that sponsor companies who negotiate contracts with clinical researchers that include gag clauses fettering the disclosure responsibilities of physicians, are guilty of participating in a breach of fiduciary duty.

(a) Did Dr. Olivieri Breach her Fiduciary Obligation?

Making a binding covenant in a contract to not disclose without permission of a sponsor company that which fiduciary law requires be disclosed is, in our view, a breach of fiduciary duty. Fiduciaries have no right to fetter, let alone put beyond their legal control, the discharge of their fundamental fiduciary responsibilities. This latter conduct amounts to disloyalty because it creates a risk of serious harm. It places the disclosure decision in the control of an actor whose motivation is pecuniary and who has no duty of loyalty to affected patients. Moreover, physician-fiduciaries

should not, and perhaps as a matter of law cannot, delegate to others that which is in law their personal obligation, namely, to assess whether a risk is sufficiently material to be disclosed to their patients.⁴⁰

For these reasons we believe that the mere act of entering into a non-disclosure agreement with a sponsor company, as Dr. Olivieri did with Apotex, is a breach of fiduciary duty – assuming that the non-disclosure agreement is indeed lawful, which it may not be.⁴¹ It is a breach of fiduciary duty in the nature of taking an undue risk which physicians, almost certainly, must be aware that they should not be taking. To the extent that it is common for physicians to sign the kind of non-disclosure agreement that Dr. Olivieri signed, then it is common for physicians to violate their fiduciary obligations to their patients.

The duty to personally discern and communicate the existence of material risk is so fundamental to the practice of medicine, so central to the integrity of the physician-patient relationship, that physicians must be aware that it is improper to transfer to profit-seeking enterprises, that owe no duty of loyalty to patients, the right to determine what will and will not be disclosed to these patients. It follows that Dr. Olivieri very likely breached her fiduciary duty by signing the Apotex contract which contained the gag clause. Though the signing of the contract did not itself cause harm to the patients or make such harm inevitable, the breach ought not to be regarded as merely technical.⁴² The gag clause in the contract created a real risk of serious harm to a vulnerable patient population. Fortunately, in this case the potential harm was not visited on the patients.

Though Dr. Olivieri, as a fiduciary, should not have signed the contract containing the gag clause, from the point of view of fiduciary law, her post-contract behaviour was exemplary. Once a fiduciary duty is breached, fiduciaries have an obligation to minimize damage to those to whom

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they owe a duty and, if possible, reverse the breach.⁴³ To her credit, Dr. Olivieri discharged these consequential duties in the face of Apotex's strenuous objections and threats of a law suit. She did this by communicating her conclusions about the dangers of L1 treatment to her patients and, through publication, to her professional colleagues and to the public at large. In essence, she repudiated her contract with Apotex. At a minimum, by telling her patients about the dangers she had detected in the study, Dr. Olivieri properly discharged her professional duty and avoided a further, and much more serious, breach of fiduciary duty.

(b) Did Apotex Participate In Dr. Olivieri's Breach of Fiduciary Obligation?

Apotex was party to the original breach of fiduciary duty by Dr. Olivieri. It was a party to the contract containing the clause that violated Dr. Olivieri's duties to her patients. It was the beneficiary of Dr. Olivieri's contractual undertaking of non-disclosure. In all likelihood, and certainly if Apotex insisted on this undertaking as a condition of financing the clinical trial, it induced the breach. It did so with full knowledge that Dr. Olivieri was a physician-researcher, and with either actual knowledge or knowledge that would likely be imputed to it that Dr. Olivieri was a fiduciary with protective responsibility for her patients and that this responsibility extended to communicating to her patients material risks of treatment of which she became aware during the trial.⁴⁴ In other words, at the outset of their contractual relationship, Dr. Olivieri and Apotex improperly agreed to legally encumber Dr. Olivieri's ability to provide vital protection for her patients by communicating to them risks of treatment that she perceived to be material, or even life-threatening.

(c) Did Apotex Know that Dr. Olivieri was a Fiduciary and that it was Participating in a Breach of Fiduciary Duty?

Apotex, being a large pharmaceutical corporation, must have intimate knowledge of the industry in which it operates. Surely it is the recipient of expert advice and has in its employ and service numerous physicians and attorneys with first-hand knowledge of the obligations that physicians owe their patients. Research protocols routinely manifest an acute awareness of the paramount duty of physician-researchers to pursue and protect their patients' best

interests. It would be surprising if Apotex was not actually aware that physician-researchers owe fiduciary obligations to their patients.⁴⁵ Similarly, it would be surprising if Apotex was not actually aware of the fiduciary obligation that physicians have to disclose to their patients, fully, frankly and forthwith, the material risks which attend a course of treatment, whether standard or experimental. With respect to physicians engaged in medical research, Justice Hall of the Saskatchewan Court of Appeal has stated that:

[i]n my opinion the duty imposed upon those engaged in medical research to those who offer themselves as subject for experimentation is at least as great as, if not greater, than, the duty owed by the ordinary physician or surgeon to his patient. There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may be in ordinary medical practice.⁴⁶

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physician's duty of original and continuing disclosure. If, surprisingly, it cannot be said that sponsor companies appreciate the existence of the fiduciary obligation that physician-researchers owe patients, and/or that this includes a duty to disclose that which physicians conclude are material risks, then it would be plausible to suggest that these sponsor companies are indifferent to or willfully blind about the truth.

At a minimum, sponsor companies must know that gag clauses are inappropriate, disloyal to the patient population, and likely a breach of the duty of care of physicians. Whether, given this substantive understanding, they also know that these clauses are technically "a breach of fiduciary duty" is, in our view, of no moment. What we regard as critical and urge that the law embrace as the touchstone of liability, is consciousness of wrongdoing or sufficient disinterest or disregard of wrongdoing that it is just and fair that liability be visited on these companies.⁴⁷

Conclusion

As the foregoing analysis suggests, sponsor companies who insist on gag clauses in clinical-trial agreements are treading

on legally dangerous territory. They may well be conducting themselves unlawfully by inducing or participating in a breach of fiduciary duty. Along with the physician-researchers with whom they contract, sponsor companies could find themselves liable for harm caused by a failure to disclose information that physicians are duty-bound to disclose, or even by a delay in disclosure.

The potential liability of sponsor companies in this context may be somewhat surprising, especially if their objection to disclosure is based on a *bona fide* belief that no material risk has been made out.⁴⁸ Nevertheless it is entirely justifiable in principle. Such a belief does not cure the prior wrong of participating in a breach of fiduciary duty. It does not address the misdeed of contractually appropriating from physicians the right to determine which risks are communicated to patients.

Any legal system committed to deterring breaches of fiduciary duty must actively discourage those who knowingly substantially contribute to, benefit from, or induce the breach of duty. As Justice Gibbs of the Australian High Court stated in *Consul Development Pty Ltd. v. D.P.C. Estates Pty Ltd.*, if “the maintenance of a very high standard of conduct on the part of fiduciaries [is a goal of the law] . . . it would seem equally necessary to deter others from knowingly assisting those in a fiduciary position to violate their duty.”⁴⁹ This point seems to have resonance in the U.S. where “[i]n the last two decades . . . there has been an exponential growth of aiding-and-abetting litigation in a variety of contexts.”⁵⁰ It is to be hoped that with the benefit of hindsight provided by the Dr. Olivieri saga, sponsor companies and physician-researchers will not contribute to similar growth in Canada.

All parties and institutions who have an interest in clinical trials and in the well-being of human research subjects can benefit from the Committee Report. Understanding that the doctor-patient relationship is fiduciary in nature and that this has significant legal implications provides an even deeper insight into the issues raised by the Olivieri case. Fiduciary law is strict in its insistence that physicians live up to the high standard that the “trust accorded them requires.”⁵¹ That physicians may not ordinarily yield this personal responsibility to others—sponsor companies or even arbitration bodies intended to resolve issues that arise between clinical researcher and sponsor company—must be kept in mind in the development of personal and institutional policies governing clinical trials.

Ultimately, the public will be served if the Committee Report fosters debate in the medical, legal and commercial communities so that positive changes may be effected to

facilitate better, more ethical and legally compliant clinical research in Canada.

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1. J. Thompson, P. Baird & J. Downie, *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.* (Toronto: James Lorimer & Co. Ltd., 2001) [hereinafter *Report*]. The Report is also available online at: CAUT <<http://www.caut.ca/english/issues/acadfreedom/olivieri.asp>> (date: accessed December 11, 2001).
2. *Ibid.* For a concise summary of the Report and the recommendations made by the Committee of Inquiry, see pages 1-49. The recommendations are summarized on pages 40-46.
3. Whilst recognizing the potential pitfalls of industry-academia relationships, numerous authors recognize the importance of industry-academia arrangements, and desire to develop new and innovative ways to maximize the benefits and minimize the risks of such arrangements. See K.W. Bander & L.E. Rosenberg, “Building bridges between academia and industry: Forms; Foundations; Functions” (1997) 70 *Yale J. Biol. Med.* 213; M.G. Bergeron, “Industry-Academia synergism in research” (1995) 99 *Am. J. Med.* 79S; T. Caulfield, “The commercialization of human genetics: A discussion of issues relevant to the Canadian consumer” (1998) 21 *J. Consumer Pol’y* 483.
4. See J.A. Martin and L.K. Bjerknes, “The legal and ethical implication of gag clauses in physician contracts” (1996) 22 *Am. J. L. & Med.* 433 at 434. The authors point out that gag clauses contained in physician contracts with managed care organizations that attempt to dictate to physicians what types of treatment alternatives they may provide to patients violate the doctor-patient relationship in such a way that they infringe patient autonomy. Martin and Bjerknes suggest that such clauses are, in fact, illegal, unethical and against public policy. We argue that constraints on obligations owed by physicians to patients in the research context are analogous.
5. See D. Blumenthal *et al.*, “Relationships between academic institutions and industry in the life sciences - An industry survey” (1996) 334 *NEJM* 368; and D. Blumenthal, “Ethics issues in academic-industry relationships in the life sciences: The continuing debate” (1996) 71 *Acad. Med.* 1291.
6. *Report, supra* note 1 at 110. See footnote 31 therein which refers to the contractual agreement in “Notes to 5A: The Toronto L1 Trials”, LA-01 Contract, 930,423.
7. *Report, ibid.* at 134.

8. *Ibid.* at 147. On this point, the Committee of Inquiry found that “Apotex obfuscated the issue by framing it as a scientific difference of opinion” and noted that Apotex “did not have the expertise to disagree with Dr. Olivieri on the matter of the medical risk to patients.”
9. *Ibid.* at 26. Apotex refused to reinstate the clinical trials at the HSC despite recommendations made to it by its own Expert Advisory Panel that it should do so. Dr. Olivieri was able to continue to treating patients who were enrolled in clinical trials at the HSC and who appeared to be doing well on L1 under Health Canada’s Emergency Drug Release program.
10. *Ibid.* at 139.
11. *Ibid.* at 273ff. Dr. Naimark is a former president of the University of Manitoba and a member of the Board of Directors of the CIBC. Dr. Naimark’s appointment as reviewer was mired in controversy from the outset because of perceived conflicts of interest. Dr. Olivieri and her supporters refused to cooperate in the Naimark review because, in their opinion, Dr. Naimark (and the two associate reviewers appointed by him) lacked sufficient independence. In response to the controversy, the Medical Scientific Staff Association (the MSSA) passed a motion asserting that “the process of the independent External Inquiry into all aspects of the Apotex affair must be open, consultative and independent.” To ensure independence, the MSSA also asserted that “three or more reviewers with relevant expertise, chosen by consultation between the parties is necessary.” Ultimately, this advice was not heeded and two associate reviewers were appointed without Dr. Olivieri’s approval. It should be noted that subsequently, the Committee of Inquiry determined that “[s]enior medical administrators did not effectively involve themselves in the dispute between Apotex and Dr. Olivieri, and offered no effective assistance to her during the first two and one half years. The Hospital did not take effective action to ensure that its responsibilities were fulfilled (until January 1999).” *Ibid.* at 154.
12. K. Foss & P. Taylor, “Volatile mix meant trouble at Sick Kids” *The Globe and Mail* (22 August 1998) A1; M.P. Valpy, “Salvage group tackles Sick Kids image disaster” *The Globe and Mail* (2 November 1998) A1; J. O’Hara, “Whistle Blower” *Maclean’s*, vol.111, No. 46 (16 November 1998) 65; CAUT, “Research Ethics vs. Corporate Interests: Investigator’s Disclosure Fuels Ethics Debate” *Bulletin Online* 45:7 (September 1998), online: CAUT <http://www.caut.ca/english/bulletin/98_Sept/lead.htm> (date accessed: 29 November 2001).
13. N.F. Olivieri *et al.*, “Safety and Effectiveness of Iron-Chelation Therapy with Deferiprone for Thalassemia Major” (1998) 339 NEJM 417. See also K Kowdley & M.M. Kaplan, “Iron-chelation therapy with oral deferiprone - toxicity or lack of efficacy?” (1998) 339 NEJM 468. Kowdley and Kaplan do not discount the possibility that deferiprone was the cause of liver damage occurring in some of Dr. Olivieri’s study patients. They do suggest, however, that there were too many confounding factors that need to be addressed in subsequent clinical studies.
14. A. Naimark *et al.*, *Report of the L1 Clinical Trials Review*, online: HSC <<http://www.sickkids.on.ca/L1trials/default.asp>> (date accessed: 29 November 2001) [hereinafter *Naimark Report*]. The recommendations of the *Naimark Report* have been implemented by the HSC on the basis of a *Research Policy Implementation Committee Final Report*, online: HSC <<http://www.sickkids.on.ca/taskforcereport/default.asp>> (date accessed: 29 November 2001).
15. *Ibid.*, Part IV: Issues and Findings, Patient Safety, at 1.1. See also *Report, supra* note 1 at 26, wherein the Committee of Inquiry notes that as a result of the *Naimark Report*, the Board of Directors of the HSC sought advice from the Medical Advisory Committee (MAC) of the HSC to inquire into Dr. Olivieri’s conduct. In April 2000, the MAC publicly reported that they were referring the allegations against Dr. Olivieri to the College of Physicians and Surgeons of Ontario and to the University of Toronto for investigation.
16. *Ibid.* at 9. The Committee of Inquiry notes that “the documentation shows that Dr. Olivieri fulfilled all reporting obligations she actually had, and put the patients’ right to be informed ahead of concerns of possible legal action against her by Apotex.”
17. *Ibid.* at 14. The Committee of Inquiry notes that “important documents became available [to it] that were not considered by the previous reviews” and that such documentation included “documentation from Dr. Olivieri and her supporters” (*ibid.*).
18. *Ibid.*
19. *Ibid.* at 5.
20. See *Halushka v. University of Saskatchewan* (1965) 53 D.L.R. (2d) 436; 52 W.W.R. 608 [hereinafter *Halushka* cited to D.L.R.].
21. See M. M. Litman, “Fiduciary law and for-profit and not-for-profit health care” in B. von Tigerstrom & T. A. Caulfield, eds., *Meeting the Challenge: Health Reform and the Law* (Edmonton: University of Alberta Press, forthcoming 2002) at n. 53 and accompanying text.
22. *Supra* note 1 at 40 (Recommendation 1).
23. *Ibid.* at 42 (Recommendation 10).
24. *Ibid.* at 42 (Recommendation 11).
25. *Ibid.* at 43 (Recommendation 16).
26. *Ibid.* at 44 (Recommendation 21).
27. *Ibid.* at 45 (Recommendation 25).



28. *Ibid.* at 46 (Recommendation 26).
29. Litman, *supra* note 21 at n. 11 and 12, and accompanying text
30. See *Norberg v. Wynrib* [1992] 2 S.C.R. 226, 92 D.L.R. (4th) 449 at 485-86 [hereinafter *Norberg* cited to D.L.R.]: whilst recognizing that the doctor-patient relationship can be “conceptualized in a variety of ways” Justice McLachlin (as she then was) notes that “the most fundamental characteristic” is its “fiduciary nature.”
31. See *Parslow v. Masters* [1993] 6 W.W.R. 273, 15 C.C.L.I. (2d) 13 (Sask. Q.B.) wherein Justice Hunter concludes that a physician-patient relationship is a fiduciary relationship even though, on the facts of that case, the physician, Dr. Masters, was hired by a third-party insurer to provide an assessment about the medical condition of the insured, Ms. Parslow. Accordingly, even if third party interests are driving the process, as with sponsored clinical research, the physician in all likelihood has fiduciary duties. As well, first principles suggest that these duties exist if patients can be said to reasonably expect that their physician, as clinician and researcher, will serve their interests loyally. See Litman, *supra* note 21 at n. 18 and accompanying text. Most specifically, *Halushka, supra* note 20, supports the proposition that clinical researchers owe their patients fiduciary obligations. At 443-44 Justice Hall states that:

[i]n my opinion the duty imposed upon those engaged in medical research, as were the appellants Wyant and Merriman, to those who offer themselves as subject for experimentation, as the respondent did here, is at least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient. There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice. The researcher does not have to balance the probable effect of lack of treatment against the risk involved in the treatment itself. The example of risks being improperly hidden from a patient when it is important that he should not worry can have no application in the field of research. The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent. The respondent necessarily had to rely upon the special skill, knowledge and experience of the appellants, who were, in my opinion, placed in the fiduciary position described by Lord Shaw of Dunfermline in *Nocton v. Lord Ashburton* [1914] A.C. 932 at

936.

32. *Ibid.* See also *Arndt v. Smith* (1995), 126 D.L.R. (4th) 705 at 713 (B.C.C.A.) per Lambert J. wherein the duty of disclosure is tied into fiduciary obligation in the following terms:

the duty of disclosure of materials risks or of special or unusual risks is not like an ordinary duty of care in negligence, because it is not set by the standard of a reasonable medical practitioner, but is more similar to a fiduciary duty of disclosure, where the standard is set by utmost good faith in the discharge of an obligation by a person in the position of power and control to a person who is vulnerable, in a position of dependency, and is known by the doctor to be in a position of reliance.

The decision of the British Columbia Court of Appeal was reversed without comment on this observation by Justice Lambert: [1997] 2 S.C.R. 539; 148 D.L.R. (4th) 48. See also Litman, *supra* note 21 at n. 53, citing the case of *Moore v. Regents of the University of California*, 793 P. 2d 479, 271 Cal Rptr. 146 (S. Ct. 1990) [cited to Cal Rptr.] at 150 wherein Justice Pannelli notes that: “a physician must disclose personal interests unrelated to the patient’s health, whether research or economic, that may affect the physician’s professional judgment.” See also M.V. Ellis, *Fiduciary Duties in Canada*, (Scarborough, Ont.: Carswell, 2000) at 1-5 - 1-6 where the duty of disclosure is introduced as a general fiduciary duty and at 10-3 - 10-12 where the duty of disclosure of physicians is discussed. See also the comments of the Supreme Court of Canada on the duty of lawyers to disclose: *Canson Enterprises Ltd. v. Boughton Co.*, [1991] 3 S.C.R. 534, 85 D.L.R. (4th) 129.

33. *Ibid.*
34. See *Kenny v. Lockwood* (1932), 1 D.L.R. 507, O.R. 141 at 155 (C.A.) wherein Hodgins J.A. states that the relationship between physician and patient is one in which “trust and confidence must be placed in the physician.” For examples of situations in which Canadian courts have looked to the Hippocratic Oath, and/or other ethical standards concerning physician (or other professional) conduct, see *Norberg, supra* note 30 at 498; *Hodgkinson v. Simms* (1994), 117 D.L.R. (4th) 161, 3 S.C.R. 377 at 412; *R. v. Dymont* (1988), 55 D.L.R. (4th) 503; 2 S.C.R. 417 at 432-34; *Harry v. Kreutziger* (1978) 9 B.C.L.R. 166 95, D.L.R. (3d) 231 at 241 (B.C.C.A.). The Hippocratic Oath is available online at: CUNY <<http://www.humanities.cuny.edu/history/reader/hippoath.htm>> (date accessed: 28 November 2001). For a Canadian interpretation of the Hippocratic Oath, see also

Canadian Medical Association, *Code of Ethics* (1996) 155 CMAJ 1176A.

35. The elements of liability are drawn from existing case law pertaining to liability for participating in a breach of trust. The leading Canadian case is *Air Canada v. M & L Travel Ltd.* [1993] 3 S.C.R. 787, 108 D.L.R. (4th) 592 [hereinafter *Air Canada* cited to S.C.R.]. Based on the fact that trustees are fiduciaries, the rules for participating in a breach of trust set out in the *Air Canada* case can be regarded as merely a specific application of the general rules which govern liability for participating in a breach of fiduciary duty. In Australia, the High Court has been explicit in its recognition of the viability of the action of participating in a breach of a non-trust fiduciary duty. See *Consul Development Pty. Limited v. D.P.C. Estates Pty. Limited*, (1975) 132 C.L.R. 373 at 397. In the U.S., though the majority of states recognize claims for aiding and abetting a breach of fiduciary duty, there is considerable diversity in the liability rules. See S. Pietrusiak, Jr., "Changing the Nature of Corporate Representation: Attorney Liability For Aiding and Abetting The Breach of Fiduciary Duty" (1996) 28 St. Mary's L.J. 213 at 240-41.
36. *Air Canada*, *ibid.* at 826.
37. *Ibid.* at 809-10 and 827.
38. *Ibid.* at 811-13 and 827-28.
39. *Ibid.* at 811.
40. Fiduciaries may not delegate their fiduciary responsibilities. Though there are exceptions to this rule, clearly a delegation to a sponsor company would be improper. See D. Waters, *The Law of Trusts in Canada*, 2nd ed. (Toronto: Carswell, 1984) at 696 where it is stated that:

The rule adopted by equity towards persons occupying fiduciary positions was that such a person cannot delegate his duties, whatever they are. The Latin maxim was clear and succinct; *delegatus non potest delegare*, and the prime type of delegate to whom the rule referred was the trustee. The reasoning behind the rule "that trustees who take on themselves the management of property for the benefit of others have no right to shift their duty on other persons," and this includes both third party agents and co-trustees.

Patients enlist the personal skills and judgement and other characteristics important to them in choosing their physicians. If anything, the rationale behind the non-delegation rule is even stronger in the physician/patient context than it is for the trustee/beneficiary relationship. See also E.E. Gillespie, *The Law of Trusts* (Concord, Ont.: Irwin Law, 1997) at 134-36.

41. See S.M. Waddams, *The Law of Contracts*, 4th ed. (Toronto: Canada Law Book, 1999) at 399ff; and J. Beatson, *Anson's Law of Contract*, 27th ed. (New York: Oxford University Press, 1998) at 398ff. Arguably the clause in the clinical trial agreement concerning non-disclosure may be held contrary to public policy on the basis that its very existence fetters the pre-existing obligation owed by Dr. Olivieri to her patients. Although the law on public policy is not entirely certain, a court, under these circumstances, may strike the entire agreement or deem such a clause severable from the contract as a whole. See also Martin & Bjerknes, *supra* note 4.
42. Even if this breach were to be regarded as "merely technical," any subsequent failure by Dr. Olivieri to communicate to her patients materials risks of which she had become aware, would transform the initial "technical" breach into a substantive breach. Again, on the facts, this never occurred.
43. *Blueberry River Indian Band v. Canada (Department of Indian Affairs and Northern Development)* [1995] 4 S.C.R. 344, (1995) 130 D.L.R. (4th) 193 at 232. The Court inferred that under the circumstances, the Department of Indian Affairs, the fiduciary, had an obligation to correct the error whereby Indian lands were wrongfully conveyed. The Indian band was vulnerable and unable to correct the error itself. Accordingly, the Department of Indian Affairs was obliged to use its power to rectify the error.
44. *Infra*. See discussion of this point, below, under the next heading "*Did Apotex Know that Dr. Olivieri was a Fiduciary and that it was Participating in a Breach of Fiduciary Duty?*"
45. It may be significant that Apotex appears to be the targeted beneficiary of the gag clause. See *Air Canada*, *supra* note 35 at 812 where Justice Iacobucci states that "[i]f the stranger received a benefit, this may ground an inference that the stranger knew of the breach." However, he goes on to state that, "[t]he receipt of a benefit will be neither a sufficient nor a necessary condition for drawing of such inference" (*ibid.*).
46. *Halushka*, *supra* note 20.
47. See *Air Canada*, *supra* note 35 at 808 where Justice Iacobucci states, "[w]hether personal liability is imposed on a stranger to a trust depends on the basic question of whether the stranger's conscience is sufficiently affected to justify the imposition of personal liability."
48. It is a nice question whether a sponsor company may lawfully negotiate a gag clause which precludes clinical researchers from divulging any information, including risks, which they are not required in law to disclose to their patients. Perhaps, but only perhaps, this is possible in law. Certainly this kind of clause is



neither advisable nor ethical. Given that the determination of what is a material risk is a judgement call which a physician (and no one else) must make, a gag clause that permits physicians to disclose only material risks without consent ought to be regarded as unlawful. This is because such a provision may have a chilling effect on the discharge of a physician's fiduciary obligation. Physicians should not be put in a position where they have to weigh closely whether a risk is or is not material and therefore whether it can be divulged without legal sanction.

49. *Supra* note 35 at 397.
50. Pietrusiak, *supra* note 35 at 239.
51. *Norberg, supra*, note 30, wherein Justice McLachlin states at 486: “[r]ecognizing the fiduciary nature of the doctor-patient relationship provides the law with an analytic model by which physicians can be held to the high standards of dealing with their patients *which the trust accorded them requires*” [emphasis added].