

# Physicians' liability and drug formulary restrictions

Timothy Caulfield, Kerry Siminoski

In the United States, physicians, ethicists and lawyers have long struggled with the concerns associated with formal cost containment initiatives that actively interfere with physicians' prescribing practices.<sup>1-3</sup> Canadian physicians are beginning to experience similar forms of explicit pressure to contain costs. These external factors have the potential to expose physicians to a variety of liability concerns. For example, the imposition of fiscal restraint policies creates unique dilemmas regarding informed consent and the standard of care.<sup>4,5</sup> In this article, we use a specific example of a financially driven treatment paradigm designed by a third party, other than the physician or the patient, to illustrate the possible legal implications of such cost containment strategies.

A number of approaches have been used by drug programs of provincial health plans to limit expenditures, such as basing pricing on the lowest-cost alternative and the adoption of clinical practice guidelines.<sup>6,7</sup> The Alberta Ministry of Health and Wellness has gone a step further: it has created its own untested treatment paradigm for the use of bisphosphonates in the treatment of osteoporosis. The application of this paradigm to the treatment of postmenopausal osteoporosis will be used as an example of how formulary rules can create possible legal dilemmas. We recognize that there are many variations on this theme in provincial drug formularies across the country.

Through their action on osteoclasts, bisphosphonates reduce bone turnover, increase bone mineral density, improve bone strength and, thereby, reduce fracture incidence.<sup>8</sup> Etidronate, alendronate, and risedronate are 3 bisphosphonates approved for the treatment of osteoporosis in Canada. Etidronate is supplied in a kit along with calcium, and this kit is referred to by the Alberta Ministry of Health and Wellness as "etidronate/calcium."<sup>9</sup>

A discussion of the data regarding the efficacy of these drugs for the treatment of postmenopausal osteoporosis, their Health Canada-approved indications and Alberta Blue Cross coverage rules is provided in Appendix 1 (available on the *CMAJ* Web site at [www.cma.ca/cmaj/vol-166/issue-4/pdf/drugappendix.pdf](http://www.cma.ca/cmaj/vol-166/issue-4/pdf/drugappendix.pdf)). In brief, it is widely recognized that the body of data supporting the efficacy of etidronate for the treatment of postmenopausal osteoporosis is inferior to that supporting the efficacy of the other 2 drugs. Alendronate and risedronate have been shown to reduce vertebral fractures by 50% and hip fractures by at least 40% (see Appendix 1 for references). The effect of etidronate/calcium on hip fractures has never been studied. Health Canada has, however, approved etidronate/calcium as therapy for postmenopausal osteoporosis in a select sub-

group of women who meet specific clinical and bone density criteria. The Health Canada indications for alendronate and risedronate in the treatment of postmenopausal osteoporosis are virtually unrestricted.

The Alberta Ministry of Health and Wellness provides payment for medications under the Alberta Prescription Drug Program, which is administered by Alberta Blue Cross.<sup>10,11</sup> The Alberta Ministry of Health and Wellness instituted special eligibility criteria for alendronate in 1998. These criteria have remained in place with only minor changes.<sup>9</sup> In 2001, the same eligibility criteria were applied to risedronate.<sup>12</sup> The special authorization criterion of relevance to this discussion is as follows:

For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures. Special authorization is granted to a maximum of twelve months. The patient would start etidronate/calcium therapy at the beginning of the second year.

This criterion creates a specific treatment paradigm of one year with either alendronate or risedronate followed by mandatory subsequent treatment with etidronate/calcium. This medical treatment protocol appears to be arbitrary and violates the tenets of evidence-based medicine. Not only has it never been tested, it has never even been proposed in the osteoporosis literature. The comparability of this protocol to continuous alendronate or continuous risedronate is unknown, but there can be no reassurance that they provide the same results. The superiority of alendronate and risedronate to etidronate/calcium is implicit in the paradigm; otherwise, why bother with even one year of alendronate or risedronate?

This regimen pressures patients and physicians, for the financial benefit of the insurance plan, to use etidronate/calcium for individuals for whom it is not approved by Health Canada. Indeed, the Alberta Ministry of Health and Wellness protocol mandates the use of etidronate/calcium by these patients in contravention of the Health Canada caution that "the Didrocal cyclic therapy should be considered only for the patient population described under Indications."<sup>13</sup>

## Legal issues

### *Informed consent*

Since the seminal 1980 Supreme Court of Canada case of *Reibl v. Hughes*, physicians have been legally obliged to disclose material information that a reasonable person in the patient's position would want to know.<sup>14-18</sup> At a mini-

mum, this disclosure obligation mandates the provision of information about the efficacy of a given procedure or drug and information about all reasonable alternatives. As was stated by the Alberta Court of Appeal in a 1998 case, “[a] patient should be advised of a known treatment which others in the same specialty consider superior, even if the doctor does not agree.”<sup>19</sup>

Given this case law, it can be argued that a physician should explain that there is a lack of scientific data to support the Alberta Ministry of Health and Wellness treatment paradigm and that it is the widely held view that alendronate and risedronate are superior to etidronate/calcium. Indeed, if a physician believes that the only reason the Alberta Ministry of Health and Wellness protocol is being followed is because of financial constraints, this should also be disclosed — it is information that a reasonable person in the patient’s position could expect to receive.<sup>4</sup>

More controversial, but still legally sound, is the possibility that physicians must also provide the patient with information about the private purchase of the clinically superior alternatives. Although there are a number of sound policy concerns (e.g., disclosure would facilitate the growth of a private tier of health care) and ethical arguments against the disclosure of private alternatives (e.g., it would be cruel to tantalize lower income patients with the possibility of an expensive alternative), withholding of material information for the good of the patient is only rarely justified in Canadian law.<sup>20,21</sup> Physicians should disclose information about private alternatives “because the option may be material to a patient’s choice between accepting the lesser care or seeking superior care elsewhere.”<sup>22</sup> As such, to reduce legal liability, physicians should err on the side of providing all relevant information.<sup>5,23</sup>

### **Fiduciary law**

In Canada, a physician’s fiduciary obligations (i.e., the legal obligations created by the special nature of the physician–patient relationship) require him or her to “act with utmost good faith and loyalty” in dealings with patients.<sup>21,24</sup> In this context, physicians should strive to do only that which is in the patient’s best interest, even at the expense of the physician’s interest or that of any other person or entity. In practical terms, this means that physicians should try to avoid actual or apparent conflicts of interest.<sup>25,26</sup> The Alberta Ministry of Health and Wellness protocol creates such a conflict, because it is a remuneration plan, conducted through physicians, that places the interest of third parties (i.e., the cost to the overall system) over the interests of the patient. The Alberta Ministry of Health and Wellness acknowledges that a “rationale behind limiting the coverage of a drug ... [is] when the cost impact to the drug program of an unrestricted listing is prohibitive....”<sup>27–29</sup>

Whereas financially driven access restrictions may make fiscal sense for the Alberta Prescription Drug Program, they pit the interests of the broader system against the

obligations a physician has to recommend the most appropriate treatment for his or her patient. At a minimum, the physician’s fiduciary obligation would necessitate a disclosure of this reality.

Although untested under Canadian law, there is also a possibility that fiduciary law compels the Alberta Ministry of Health and Wellness to act in the best interests of their subscribers.<sup>30</sup> This is an area that has attracted significant attention in the United States, where managed care organizations (MCOs) often have aggressive cost containment schemes.<sup>2,31,32</sup> In fact, the conflict between an MCO’s duty to patients and the desire to contain costs has led many US states to enact laws that mandate the disclosure of information about the nature of cost containment initiatives.<sup>3,33,34</sup> Given this trend, the Alberta Ministry of Health and Wellness should consider a disclosure policy that will inform their subscribers of the existence and impact of their cost-cutting initiatives.

### **Standard of care**

The Alberta Ministry of Health and Wellness protocol also creates issues regarding the standard of care. The legal standard of care is generally determined by a court through reference to what the medical profession views as the accepted practice for a given situation.<sup>35,36</sup> The standard of care is established on a case-by-case basis via the testimony of expert witnesses. Although codified guidelines, such as clinical practice guidelines, are often instructive, they are not determinative.

The Alberta Ministry of Health and Wellness treatment paradigm would not be considered a codified legal standard of care. Thus, what if a patient is injured while adhering to the Alberta Ministry of Health and Wellness paradigm? In such a case, could a physician use the existence of the Alberta Ministry of Health and Wellness protocol as an excuse for the provision of substandard care? For example, what if a patient fractures a hip, a potentially costly injury,<sup>37,38</sup> after switching from alendronate or risedronate to etidronate/calcium? No randomized, controlled study has ever shown that etidronate/calcium prevents hip fractures, whereas alendronate and risedronate clearly do.

Although there is little Canadian case law that directly deals with this particular issue, there are reasons to believe that a court would not be sympathetic to a plea that this is the provincial protocol. In the case of *Law Estate v. Simice*, for instance, a widow sued several physicians because of the death of her husband as a result of a ruptured aneurysm. In the physicians’ defence, it was suggested that a CT scan was not provided in a timely manner because of constraints imposed by the provincial health insurance scheme. The court did not accept this “economic defence” and went on to conclude that “if it comes to a choice between a physician’s responsibility to his or her individual patient and his or her responsibility to the medicare system overall, the former must take precedence in a case such as this.”<sup>39</sup>

US jurisprudence is also instructive. For example, in the case of *Wickline v. State of California*, the court concluded: "While we recognize, realistically, that cost consciousness has become a permanent feature of the health care system, it is essential that cost limitation programs not be permitted to corrupt medical judgement."<sup>1</sup>

## Conclusion

We understand that in an age of ever-expanding health care costs, some form of economic restraint is inevitable and even desirable. In the eyes of the law, however, the physician's primary duties remain focused on the patient. Because health reform programs often ask (or force) physicians to curtail costs for the good of other members of society, this patient-focused ethic is strained to the point of becoming a liability issue.

Although the example presented here is relatively extreme, we believe that the concepts have much wider applicability to the ever-expanding intrusions of managed care into medical practice. Physicians will increasingly need to develop legally sound strategies to accommodate the external pressures placed on the clinical decision-making process. This includes being aware of and revealing when access to testing, choice of tests and decisions about therapy are influenced by third-party financial motives that may conflict with the best interests of the patient.

This article has been peer reviewed.

Mr. Caulfield is Canada Research Chair in Health Law Policy and Associate Professor, Faculty of Law and Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Alta. Dr. Siminoski is with the Endocrine Centre of Edmonton and Medical Imaging Consultants, Edmonton, Alta.

*Competing interests:* In 1998, Mr. Caulfield received research funds from Merck Frosst to assist in the production of an article that reviewed broader issues than this one, but which did deal with cost containment mechanisms. This article was produced as part of a project, called Health Care Reform and the Law, funded by a research grant from the Alberta Law Foundation. Mr. Caulfield has given talks at a conference of which Merck Frosst was a primary sponsor. Dr. Siminoski has acted as a consultant for and has received research grants and honoraria for speaking from Procter and Gamble and Merck Frosst.

*Contributors:* Both authors contributed to the conception of the article, the research and the writing of the article.

*Acknowledgements:* Mr. Caulfield's research is supported by the Alberta Law Foundation and the Alberta Heritage Foundation for Medical Research.

## References

1. *Wickline v. State of California*, 228 Cal. Rptr. 661 (Cal. Ct. App. 1986).
2. *Pegram v. Herdrich*, 120 S. Ct. 2143 (2000), rev'g 154 F3d 362 (7th Cir. 1998).
3. Anderlik M. Efforts to regulate physician financial incentives. *Health Law Perspectives* Houston: University of Houston; 1998. Available: [www.law.uh.edu/healthlawperspectives/Managed/990120Efforts.html](http://www.law.uh.edu/healthlawperspectives/Managed/990120Efforts.html) (accessed 2002 Jan 7).
4. Wolf S. Toward a systemic theory of informed consent in managed care. *Houston L Rev* 1999;35:1631.
5. Caulfield T, Ginn, D. The high price of full disclosure: informed consent and cost containment in health care. *Man L J* 1994;22:328.
6. Thomas M. The change of cost: reference-based pricing and the statins. *Can J Cardiol* 1999;15:535-8.
7. Yakabowich MR, Keeley G, Montgomery PR. Impact of a formulary on personal care homes in Manitoba. *CMAJ* 1994;150:1601-7.
8. Russell RG, Rogers MJ. Bisphosphonates: from the laboratory to the clinic and back again. *Bone* 1999;25:97-106.
9. *Alberta Health and Wellness Drug Benefit List Quarterly Update* Part I summary of changes: drug products with changes to criteria for coverage. 2001;Jan 1:2.
10. *Guidebook on government and related programs*. North York (ON): Canadian Wholesale Drug Association; 1999. p. 1-4.
11. Drug review process. *Alberta Health and Wellness Drug Benefit List*. 2000:1-5-1-6.
12. *DBL Report* Issue 19, April 2001.
13. Didrocal. In: *Compendium of pharmaceuticals and specialties*. 36th ed. Toronto: Canadian Pharmacists Association; 2001. p. 448-50.
14. *Reibl v. Hughes* (1980), 114 D.L.R. (3rd) 1 (S.C.C.).
15. *Ciarlariello v. Schacter*, [1993] 2 S.C.R. 119.
16. *Health Care Consent Act*, S.O. 1996, c.2.
17. Picard EI, Robertson GB. *Legal liability of doctors and hospitals in Canada*. 3rd ed. Scarborough (ON): Carswell; 1996.
18. Dickens BM. Informed consent. In: Downie J, Caulfield T, editors. *Canadian health law and policy*. Toronto: Butterworths; 1999. p. 131.
19. *Seney v. Crooks*, [1998] A.J. No. 1060 (Q.L.).
20. *Meyer Estate v. Rogers* (1991), 78 D.L.R. (4th) 307 (Ont. Ct. (Gen. Div.)).
21. *McInerney v. MacDonald*, [1992] 2 S.C.R. 138.
22. Dickens BM. Informed consent. In: Downie J, Caulfield T, editors. *Canadian health law and policy*. Toronto: Butterworths; 1999. p. 133.
23. Miller F. Denial of health care and informed consent in English and American law. *Am J Law Med* 1992;18:37.
24. *Norberg v. Wynrib* (1992), 92 D.L.R. (4th) 449 (S.C.C.).
25. *Henderson v. Johnston* (1956), 5 D.L.R. (2d) 524 (Ont. H.C. Div. Ct.).
26. *Cox v. College of Optometrists of Ontario* (1988), 65 O.R. (2nd), 461 (Ont. H.C. Div. Ct.).
27. The rationale behind special authorization (SA). *DBL Report* Issue 9, October 1997.
28. Walker R. Shift to no-name drugs saving Albertans millions. *Calgary Herald* 1997 Mar 28; Sect B:1.
29. Walker R. Preventive drug cost alarms doctors. Medication may add millions to bill. *Calgary Herald* 1997 Nov 3; Sect B:1.
30. Litman M. Fiduciary law and for-profit and not-for-profit health care. In: Von Tigerstrom B, Caulfield T, editors. *Meeting the challenge: health care reform and the law*. Edmonton (AB): University of Alberta Press. In press.
31. *Shea v. Eesensten*, 107 F3d 625 (8th Cir. 1997).
32. Gostin L. Managed care, conflicts of interest, and quality. *Hastings Cent Rep* 2000;30:27.
33. Khanna V, Silverman H, Schwartz J. Disclosure of operating practices by managed care organizations to consumers of health care: obligations of informed consent. *J Clin Ethics* 1998;9:291.
34. Miller T, Sage W. Disclosing physician financial incentives. *JAMA* 1999; 281:1424.
35. *Crits v. Sylvester* (1956), 1 D.L.R. (2nd) 502 at 508 (Ont. C.A.), aff'd [1956] S.C.R. 991.
36. *ter Neuzen v. Korn*, [1995] 10 W.W.R. 1 (S.C.C.).
37. Goeree R, O'Brien B, Pettitt D, Cuddy L, Ferraz M, Adachi J. An assessment of the burden of illness due to osteoporosis in Canada. *SOGC Journal* 1996; Suppl:15-24.
38. Cauley JA, Thompson DE, Ensrud KC, Scott JC, Black D. Risk of mortality following clinical fractures. *Osteoporos Int* 2000;11:556-61.
39. *Law Estate v. Simice* (1994), 21 C.C.L.T. (2d) 228 (B.C.S.C.), aff'd [1996] 4 W.W.R. 672 (B.C.C.A.).

**Correspondence to:** Mr. Timothy Caulfield, Associate Professor, Faculty of Law and Faculty of Medicine and Dentistry, 461 Law Centre, University of Alberta, Edmonton AB T6G 2H5; fax 780 492-9575; [tcaulfld@law.ualberta.ca](mailto:tcaulfld@law.ualberta.ca)

A review of the evidence for the efficacy of bisphosphonates in the treatment of osteoporosis written by Anthony B. Hodzman, David A. Hanley and Robert Josse will appear in a forthcoming issue of *CMAJ*.