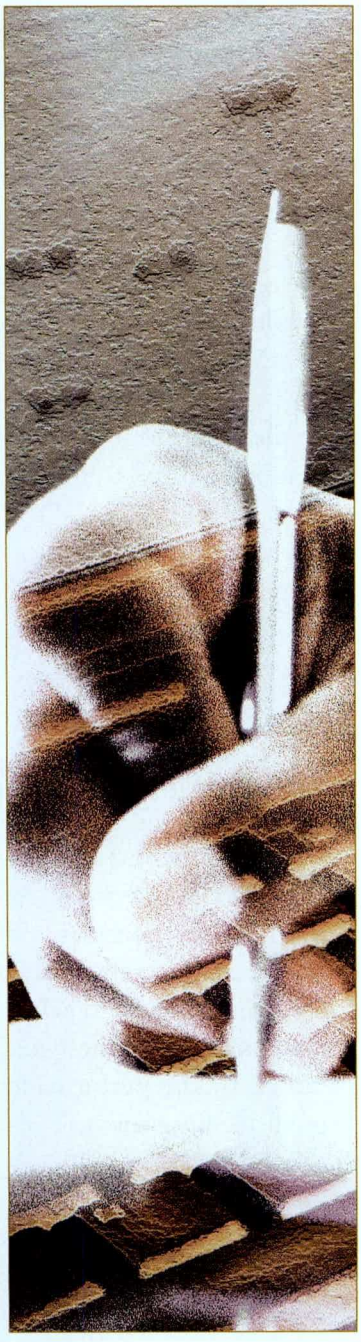
LEGAL FOCUS: British Columbia's proposed optician's regulation



The Canadian Association of Optometrists sought legal counsel regarding the proposed opticians regulation in British Columbia. Of interest to members, the following letter by Alan West, dated July 13, 2004, provides a relevant legal perspective to the issue of increasing the permitted scope of practice of opticians.
The document clearly provides an analysis of the proposed regulation from a legal position and touches on critical areas of concern, such as mitigation of risk and liability.
CAO is hopeful that the publication of the letter by Mr West will provide members with, not only a broader view of the serious issues relating to increased scope of practice of opticians, but that it will also be viewed as a useful resource.
In addition, CAO members are encouraged to visit www.opto.ca, "advocacy" section and CAO member website, "inside CAO". Members may also monitor this issue on the BCAO website, www.optometrists.bc.ca.

by Alan West
Gowling Lafleur Henderson LLP,
Barristers & Solicitors

Alan West is a Lawyer and Physician. He can be reached at *Gowling Lafleur Henderson* LLP in Toronto.
www.gowlings.com

Certain amendments have been proposed to the Opticians Regulation to the British Columbia Health Professions Act (the "amended regulation"). The effect of the proposed amendments is to increase the permitted scope of practice of opticians. Opticians will be permitted independently to perform refractive eye examinations (as opposed to merely filling the prescription of an optometrist or ophthalmologist, as is currently required).

One of the factors motivating the proposed amendment is the development of an automated, computerized refraction system, which enables opticians to perform 'refractions' without medical knowledge.

The problem with the proposal, as identified in many representations already made to the British Columbia Ministry of Health Services, is that performing a 'refraction' by way of an automated system does not

screen the patient for potential health problems—in contrast to the system currently in place, and in contrast to the system as it exists in every other jurisdiction in North America. As Dr. T. Peter Seland, Deputy Registrar of the College of Physician and Surgeons of British Columbia wrote in a letter dated April 19, 2004 to Mr. Daryl Beckett, Acting Director, Professional Regulation, Ministry of Health Services:

> *Autorefraction is certainly a safe and accurate procedure to guide the prescribing of eye glasses, as Minister Hansen has noted in his Press Release. The risk of harm arises from the context within which the procedure is done. Specifically, patients will, even with disclaimers to the contrary, often consider that a satisfactory autorefraction (i.e., yielding a prescription which provides good visual acuity) is an adequate testimony to their ocular health. All involved professionals acknowledge that this is manifestly not so.*

The letter then describes the history of two cases of patients who were fitted with glasses with the aid of autorefraction (with prescriptions signed by ophthalmologists who had not actually examined the patients), who subsequently discovered serious ocular health problems which had been missed by reason of the autorefraction procedure. The letter concludes by stating that it would be legally and ethically unacceptable to prescribe based on sight-testing data without a complete ocular examination, even if the patient consents to this procedure by way of a waiver accepting the risk. This position was stated in a College Policy entitled "Provision of Prescriptions for Ocular Refraction by Physicians in British Columbia", referenced in the letter.

In other words, the government of British Columbia intends to enact legislation which it has been reliably informed by the province's own College of Physicians and Surgeons (among many others), will result in an unacceptable level of risk to the public.

This opinion addresses the legal liability issues raised by this unprecedented legislation.

Conclusions

❶ The proposed regulatory amendment will expose large numbers of British Columbia residents to potential harm. The available evidence indicates that tens of thousands of British Columbia residents within the age range affected by the proposed amendment have eye diseases of which they are unaware. As a result of the proposed amendment, they will not be screened adequately, and the provision made in the amendment for their protection is, on its face, inadequate.

❷ Opticians who rely on the proposed amendment to provide autorefraction services are likely to be found liable if injuries result from a failure to detect eye disease. The existence of the amended regulation will not protect opticians from civil liability. In my opinion, the provision of such services, in the absence of a proper medical or optometric examination, breaches the appropriate standard of care in the circumstances.

Discussion

There are two interrelated liability issues raised by the British Columbia government's proposed amended regulation:

- Whether the wording of the regulation adequately mitigates the identified risk to the public; and
- Whether the provision of autorefraction services in accordance with the amended regulation creates any liability issues for participating opticians.

Mitigation of Risk

The wording of the amended regulation is clearly intended to mitigate the anticipated risks to the public that result from the provision of autorefraction without adequate medical or optometric supervision. According to new subsection 6(2), an optician may only perform an assessment based on autorefraction in accordance with Schedule "A" to the regulation. Schedule "A" lists a series of limitations that are designed, in theory, to limit the risk posed by the performance of autorefraction without medical supervision. These limits are (in relevant part) as follows:

① The optician is required to provide written notice to the client, informing the client that the procedure in question is not an ocular examination, defining the

difference between the two, and stating the desirability of periodic medical examinations;

② The client must sign this notice, attesting to the fact that he or she has read and understood the information, is between the ages of 19 and 65, that to the best of his or her knowledge he or she does not have any of the diseases or conditions listed in the Schedule that would render him or her ineligible for autorefraction, and that he or she consents to the procedure;

③ If the autorefraction indicates a change in refractive error exceeding a specified number of diopters, an optician must refuse to dispense eyeglasses based on the assessment and instead recommend that the client seek for medical or optometric examination.

Unfortunately, these safeguards are wholly inadequate to protect the public against the entirely predictable and understood dangers of autorefraction without medical or optometric supervision.

First, the notice and waiver provisions in and of themselves are unlikely to successfully protect the client. This fact is apparently accepted by the legislative draftsmen themselves, who have excluded from the population eligible for autorefraction those clients aged less than 19 years and greater than 65 years. If the notice and waiver provisions were adequate to protect the population from the risks of undiagnosed eye diseases and conditions, there would be no need to restrict the age range of potential clients. Clearly, the government has indicated that for certain populations, the risk of failure to obtain a proper medical examination is too great—even if they are warned that autorefraction is different from a medical examination. In my opinion, in the context of a civil action for damages, this "precaution" in and of itself constitutes evidence of negligence of an optician who "prescribes" lenses without medical or optometric supervision.

The problem with that position is that there is considerable evidence that the population between the ages of 19 and 65 is also at risk. This point is made in an article entitled Prevalence of Asymptomatic Eye Disease, by Dr. Barbara E. Robinson. In that paper, Dr. Robinson describes a cross-sectional Canada-wide clinical study undertaken in order to determine the proportion of persons presenting for an eye examination who are unaware that they have an eye disease. One of her conclusions was as follows:

> *"[a]wareness of eye disease was also related to patient's age and time since last full eye examination. Older patients were more likely to be aware of the presence of an eye disease than younger patients were (Table 4). People whose last full examination prior to the current visit was 1 year or less had the highest probability of knowing about the eye disease." [emphasis added]*

Table 4, for example, indicates that in the 25 to 44 age range 44% of subjects were likely to know of the existence of an eye disease; the 65-85 age range, 58% were likely to know.

The figures also indicate that the risk for those within the category of persons eligible for autorefraction without medical supervision in accordance with Schedule "A" of the amended regulation is not trifling. On table 6, Dr. Robinson lists four major eye diseases and their prevalence by age. To provide some examples, in the 45 to 65 age range 8.57% of subjects had cataract/IOL opacification; 6.87% had glaucoma (or suspected); 1.31 % had diabetic retinopathy; and 2.02% had macular degeneration. Table 6 also lists levels of knowledge of disease by disease: for example, 50% of persons of all ages who have glaucoma are unaware of the fact.

While the data used in this study is prevalence data derived from clinical studies, not population-based data and not specific to British Columbia, the numbers involved are quite similar to population-based studies in similar jurisdictions. The Framingham population study in the United States, for example, revealed that the incidence of glaucoma for the 55 to 64 age range was 7.2%; and other population-based studies in the US, Holland and Australia have found that 50% of cases of glaucoma were undiagnosed.

These figures indicate that the risk is not inconsiderable.

The problem is exacerbated by the design of Schedule "A" to the amended regulation. The regulation is intended to prevent persons with certain conditions from obtaining autorefraction. For example, paragraph

4(b)(i) of Schedule "A" states that clients with glaucoma are ineligible. A client is supposed to sign a waiver stating that "to the best of his or her knowledge", he or she "does not have an ocular disease specified in section 4(b) of this Schedule"—such as glaucoma. However, from the above study, it appears that half of the people who have glaucoma do not know it (with the chance being greater for those who are younger and thus within the accepted age range); and that some 6.87% of those aged 45 to 65 (and thus within the accepted age range) have the disease.

This indicates that at least 3.4% of clients aged 45 to 65 (and probably more) have glaucoma and are unaware of the fact. They could truthfully answer that "to the best of their knowledge" they have no eye disease. Unless the suggestion of the desirability of obtaining a proper medical or optometric examination motivates them (as apparently the government believes will not be the case for those over 65), this condition will go undetected.

According to statistics for the year 2001, the number of people in British Columbia between the ages of 45 to 64 was around one million. This means that some 34,000 persons (and probably more) in British Columbia may have glaucoma and are unaware of the fact, and will be put at risk of not being screened as a result of this amended legislation. That, of course, is just one disease out of many, for the selected age range.

In other words, the stipulation that the client must state that "to the best of his or her knowledge, the client does not have an ocular disease specified..." is completely worthless. Tens of thousands of British Columbians within the 'accepted' age range have eye diseases or conditions which ought to render them ineligible for autorefraction—and are unaware of this fact. Indeed, logically, if they were aware that they had an eye disease, they would likely be under medical care already.

Liability of Opticians

The question is whether the existence of a regulatory procedure can displace an allegation of negligence. Can a person who follows a legislative standard be found negligent?

The answer, unequivocally, is "yes".

The leading case on point is the decision of the Supreme Court of Canada in Ryan v. Victoria (City), [1999] 1 S.C.R. 201 at para. 29:

> *Legislative standards are relevant to the common law standard of care, but the two are not necessarily co-extensive. The fact that a statute prescribes or prohibits certain activities may constitute evidence of reasonable conduct in a given situation, but it does not extinguish the underlying obligation of reasonableness: see R. in right of Canada v. Saskatchewan Wheat Pool, [1983] 1 S.C.R. 205. Thus, a statutory breach does not automatically give rise to civil liability; it is merely some evidence of negligence. See, e.g., Stewart v. Pettie, [1995] 1 S.C.R. 131, at para. 36, and Saskatchewan Wheat Pool, at p. 225. By the same token, mere compliance with a statute does not, in and of itself, preclude a finding of civil liability. See Linden, supra, at p. 219. Statutory standards can, however, be highly relevant to the assessment of reasonable conduct in a particular case, and in fact may render reasonable an act or omission which would otherwise appear to be negligent. This allows courts to consider the legislative framework in which people and companies must operate, while at the same time recognizing that one cannot avoid the underlying obligation of reasonable care simply by discharging statutory duties. [emphasis added]*

Whether or not an optician owes a duty of care to customers is governed by the two-step test in Anns v. Merton London Borough Council, [1978] A.C. 728 (H.L.), at pp. 751-52, which was adopted by the Supreme Court of Canada in Kamloops (City of) v. Nielsen, [1984] 2 S.C.R. 2, and numerous subsequent decisions. The two stages of the test were restated as follows in Kamloops, at pp. 10-11:

> ① *is there a sufficiently close relationship between the parties (the [defendant] and the person who has suffered the damage) so that, in the reasonable contemplation of the [defendant], carelessness on its part might cause damage to that person? If so,*

② *are there any considerations which ought to negative or limit (a) the scope of the duty and (b) the class of persons to whom it is owed or (c) the damages to which a breach of it may give rise?*

The first step of the Anns/Kamloops test presents a relatively low threshold. To establish a prima facie duty of care, it must be shown that a relationship of "proximity" existed between the parties such that it was reasonably foreseeable that a careless act by (for example) the opticians could result in injury to the appellant.

In this case, there is no question that sufficient proximity is created.

The second step of the Anns/Kamloops test requires that it be determined whether any factors exist that would eliminate or limit the duty found under the first branch of the test. This approach recognizes that while the test of "proximity" may be met, liability does not necessarily follow. The existence of a duty of care must be considered in light of all relevant circumstances, including any applicable statutes or regulations. Thus, a legislative exemption from liability can negate a duty of care in circumstances where that duty would otherwise arise.

In this case, the amended regulation does not purport to limit the liability of opticians.

Conduct is negligent if it creates an objectively unreasonable risk of harm. To avoid liability, a person must exercise the standard of care that would be expected of an ordinary, reasonable and prudent person in the same circumstances. The measure of what is reasonable depends on the facts of each case, including the likelihood of a known or foreseeable harm, the gravity of that harm, and the burden or cost which would be incurred to prevent the injury. In addition, one may look to external indicators of reasonable conduct, such as custom, industry practice, and statutory or regulatory standards.

In each case, the risk of foreseeable harm resulting from a lack of screening is established by the evidence:

❶ Likelihood of a known or foreseeable harm. As attested to by numerous letters from self-regulatory bodies all over North America, including the College of Physicians and Surgeons of British Columbia described above, and as further demonstrated by the analysis of the clinical trial data, clearly, the likelihood of foreseeable harm is high;

❷ Gravity of that harm. Untreated eye diseases are clearly a grave matter;

❸ Burden or cost that would be incurred to prevent the injury. The "burden or cost" is minimal—simply to maintain the regulation that now exists;

❹ Custom and industry practice. The current custom and industry practice is to require a medical or optometric examination.

❺ Statutory or regulatory standards. As will be described in further detail, following the procedure as outlined in the proposed amendment is in breach of other established statutory standards.

The "notice" provisions found in Schedule "A" to the proposed amended regulation do not conform to the elements of informed consent to a medical procedure, as described in the Health Care (Consent) and Health Care Facilities (Admission) Act, RSBC 1996, Chapt. 181 as follows:

Elements of consent

❻ An adult consents to health care if

a. the consent relates to the proposed health care,

b. the consent is given voluntarily,

c. the consent is not obtained by fraud or misrepresentation,

d. the adult is capable of making a decision about whether to give or refuse consent to the proposed health care,

e. the health care provider gives the adult the information a reasonable person would require to understand the proposed health care and to make a decision, including information about

i. the condition for which the health care is proposed,
ii. the nature of the proposed health care,
iii. the risks and benefits of the proposed health care that a reasonable person would expect to be told about, and
iv. alternative courses of health care, *and*

f. the adult has an opportunity to ask questions and receive answers about the proposed health care.

In particular, it can hardly be said that the client will be informed of the "... risks and benefits of the proposed health care that a reasonable person would expect to be told about", as required by paragraph 6(e)(iii) of the Act, merely by informing the client of "the distinction between an autorefraction and an ocular examination" and "the desirability of periodic ocular examinations and recommending that an eye health exam be obtained in addition to the sight-test", as required by section 1 of Schedule "A".

Summary

The chances are very good, given the large numbers of persons involved, that many cases of otherwise avoidable injury will occur as a result of opticians relying on the proposed amended regulation. In my opinion, those injured will have a good case in negligence against the opticians involved. Given the existence of class proceedings in British Columbia, there is a good chance that, ultimately, a class action will be launched.

In my opinion, this may lead to serious insurance issues. Insurers of opticians may refuse to cover this risk, or increase premiums to allow for this risk. If insurers do decide to cover the risk, and adopt a "wait and see" attitude in evaluating the risk, they are likely to find that the risk does not increase incrementally; as noted above, there is a good chance that clients who are injured will organize a class proceeding. This means that the risk is likely to crystallize as a single event.

Even if there is no class action, a drastic increase in lawsuits may result in a discontinuance of insurance coverage. The insurance programs involved are, I understand, "claims made" programs: that is, of the type which only cover liabilities for claims made during the currency of the insurance contract. This means that opticians will not be covered for claims made after insurance is cancelled. There is little chance that any insurance company would be likely to provide alternative policies or "tail coverage" in this case.

The result may be that the injured citizens of British Columbia will be left without recourse. The injuries expected, which may result in blindness, will no doubt prove extremely expensive; the cost will be borne by the people of British Columbia, either directly or by way of payments for social services.