

September 5, 2003

The Honourable Anne McLellan, P.C., M.P.
Minister of Health
Health Canada
Tunney's Pasture
Ottawa, Ontario, K1A 0K9

Fax number: (613) 943-0044

**Re: Non-corrective ("plano") contact lenses
Sold Through Unlicensed Facilities**

Dear Minister:

We wish to thank you for your decision earlier this year to conduct a risk assessment of non-corrective contact lenses and the potential for health risk when sold through unlicensed facilities. Most plano lenses are coloured, tinted or patterned. We have been working with the consultant and with officials in your department to ensure that the best information possible is presented within the timeframes specified. We are writing at this time to highlight our concerns and our positions on this important matter to the eye care professions in Canada.

1. A system for collecting injury data in Canada has not been established.

While we recognize the importance of injury data in the context of a risk assessment, we feel it is important to point out that there is no system in Canada for the collection of specific injury data. All our associations have initiated a call for information from the professions and some injury data has been collected in the past few months. However, it is early days for the professions in collecting this kind of information. Additionally, the professions are already overburdened with patient demand and reporting responsibilities.

Related to this concern is our understanding that emergency room doctors and hospitals and other health facilities were not consulted in the course of the investigation. It is a fact that some eye incidences related to contact lens use will show up first in an emergency health service setting. So it is not valid to conclude that incidence data solicited from some eye care professionals only (operating in a non-hospital setting) represents a survey of the universe of potential incidences related to contact lens use.

2. The evidence in the United States is clear and there is wide concern.

The Food and Drug Administration (FDA) has in place a mandatory manufacturing reporting system for contact lens incidences. The FDA data has been made available to the Canadian assessors. Additionally, the Association of Regulatory Boards of Optometry (ARBO) in the U.S. conducted incidence surveys and the data is again clear. From January to July this year, 90 incidents were reported. All were the result of contact lenses issued without a valid prescription. Six incidences resulted in serious eye injury. Some of the incidences and the injuries were attributed to plano lenses. All injuries were due to lenses sold without a valid prescription.

The U.S. Department of Transportation is also concerned about the distribution of plano lenses, without a valid prescription and through non-licensed facilities. It is a fact that these lenses are not fitted to the eye; they sit very flat on the eye as a result. On many individuals, this results in a

"swimming" contact lens that can blur and impair vision, particularly peripheral vision. This can be a hazard when driving.

3. The issue is professional-dispensing, not plano lenses per se.

Contact lenses issued with a valid prescription and sold through licensed facilities will include training and instructions on proper care and handling. Professional dispensing also ensures that contact lens wearers have a professional point of reference should questions arise about health and safety issues. It is in the public interest to ensure there is always a relationship between an eye-care professional and the contact lens wearer. It is in the public interest to ensure that there is always professional prescribing and dispensing of all contact lenses.

4. From a Health Perspective, plano and corrective lenses are the same.

The health of the eye does not differentiate between a plano or corrective contact lens. In both cases, a person is placing a foreign object on the cornea. This object, if not properly fitted by a professional and cared for by the individual wearer, can damage the eye. Professional dispensing and prescribing reduces the risk of health incidences and health injury. This is a fact of health care delivery. When dealing with medical devices or pharmaceuticals, professional dispensing is mandatory. Why would eye care be any different than any other aspect of primary health care?

5. The issue is potential for injury, not necessarily injury

Eye care professionals are surprised at the extent to which "injury data" seems to be a requirement of the risk assessment. The issue should be "potential for injury" not injury. Why would we require incidences of serious eye injury in Canada to justify professional dispensing of medical devices? The fact is that improperly fitted, instructed and prescribed contact lenses (plano or not) create potential for eye injury. It is the role of health and safety regulations to create an environment where medical device risk is minimized.

6. Risk Assessment and risk management are about reducing risk, not eliminating risk.

It is a fact that, even with professional dispensing, there is a risk of eye damage from plano or corrective lenses. A wearer is using their fingers to place a foreign object directly on the cornea of the eye. Managing risk means reducing the potential for damage. The potential for damage is significantly reduced with professional dispensing. The eye professions believe that reducing risk for all contact lenses (whether plano or corrective), through professional prescribing and dispensing, should be a consistent policy of Health Canada.

7. The U.S. FDA is committed to professional dispensing of plano and corrective contact lenses

Just as in Canada, there are issues around the legal status of plano lenses in the United States. However, the U.S. government has publicly stated concerns about improper care and instructions, about the colour tints in the coloured plano lenses, about traffic safety given their vision-distorting features, etc.

The U.S. Food and Drug Administration is committed to professional dispensing. The U.S. government is taking actions, within the confines of their Statute, to ensure that this is the case. European imports of plano lenses are rigorously subject to the full extent of the FDA rules as they stand today. Plano lenses are not legally distributed without a valid prescription in the United States.

The U.S. is also promoting a small legislative change in order to ensure the same regulatory regime for both plano and corrective contact lenses.

The eye care professions in Canada do not understand why the Canadian government is not taking the same approach.

8. There are legal remedies currently available to ensure professional dispensing of all contact lenses.

On the basis of legal advice from the Department of Justice, Health Canada has determined that plano lenses are not medical devices as defined in the Food and Drugs Act. While legal opinions may vary on this matter, there remain federal legislative and regulatory remedies available to ensure that plano lenses are professionally prescribed and distributed. The eye care professions believe these remedies should be adopted and put in place immediately.

Indiscriminate distribution of plano contact lenses represents a significant risk to Canadian eye care health. This risk can be minimized through professional prescription and dispensing and enforced by federal regulation.

9. The new Canada Health Protection Act may provide a long -term solution.

The professions do not anticipate that this Statute will become law in sufficient time to address the issue of risk in respect of indiscriminate distribution of plano lenses. At the same time, we anticipate participating in the consultations for this new amalgamated Statute. In the long term, the new Statute does provide an opportunity to create a normalized regulatory outcome for both plano and corrective contact lenses.

While the consultation documents do not address the plano and corrective lens issue, we are confident that the Health Canada consultations will do so. As mentioned, we look forward to participating in the debate.

In conclusion, the eye care professions in Canada are pleased that Health Canada is completing a risk assessment on plano contact lenses sold through unlicensed facilities. We believe that regardless of the extent of Canadian injury data, the conclusions will be clear. There must be a consistent regulatory regime in place for both corrective and plano contact lenses- a regime which results in professional prescribing and dispensing. It is in the public interest to ensure that eye injury risk is minimized.

Yours sincerely,

CAO

COS

OAC

c.c. Charles Ethier, Director General, Product Safety Program
Lindsay Mish, Cosmetics Division