HOUSE OF COMMONS
CANADA

ANIMAL-SOURCED INSULINS: AVAILABILITY FOR DIABETICS

REPORT OF THE STANDING COMMITTEE ON HEALTH

Bonnie Brown, M.P.
Chair

June 2003

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THE STANDING COMMITTEE ON HEALTH

has the honour to present its

FOURTH REPORT

In accordance with its mandate under Standing Order 108(2), your Committee has conducted a study on the availability of animal-sourced insulins and reports its findings and recommendations.

THE COMMITTEE FOCUS

On 3 February and 29 April 2003 the House of Commons Standing Committee on Health heard from various witnesses about the availability of animal-sourced insulins versus recombinant human insulin. The witnesses represented the perspectives of affected individuals, the pharmaceutical industry and Health Canada. During the two sessions, Committee members were told quite clearly that animal-sourced insulins are essential to a certain proportion of diabetics and that their availability must be maintained.

Witnesses told the Committee members about individuals who were unable to adjust to the recombinant human insulin for controlling their diabetes. Endocrinologist testimony confirmed this concern and suggested that a small percentage of diabetic patients who have been on insulin derived from animals (specifically pig or cow) for an extended length of time may not be able to make the transition to the recombinant human form for a variety of physiological, immunological and undetermined reasons.

The Issues

A. Inadequate Medical Education

The Committee members are very concerned about the apparently limited knowledge held by physicians about animal-sourced insulins. Witnesses suggested that medical schools do not routinely educate students about this area of diabetes control and that the Canadian Medical Association does not include the option of animal-sourced insulins for diabetes in its guidelines. Witnesses emphasized that the animal-sourced insulins must still be actively marketed since they are indispensable to some diabetics.

B. Access Challenges

Groups representing affected diabetics are apprehensive that the animal products may be discontinued due to the proportionally small market as compared to the recombinant product. Health Canada reported that individuals can purchase bovine insulin from the United Kingdom through Health Canada's Special Access Program. However other witnesses suggested that this process is somewhat complicated as well as expensive to the patient.

C. Pharmaceutical Companies and Supply

The Committee members learned that although Nova Nordisk has discontinued its porcine insulin production, Eli Lilly intends to continue to provide porcine insulin in Canada. However, it has recently discontinued one of its animal-sourced products and is under no legal obligation to provide the animal products. The Committee members are pleased that while other pharmaceutical companies have stopped supplying animal-sourced insulins due to a diminishing market share, Eli Lilly has continued to honour its stated commitment to those individuals who require the animal product.

D. Committee Observations

The continuing reduction in availability of animal insulin products is a major concern for Committee members. While encouraged that Health Canada is actively working with Eli Lilly and patient groups on this issue, they would like proactive measures taken in order to ensure that the animal-sourced products remain available to those patients who require them. The Committee members want greater certainty that such products will be available at a reasonable cost. They also want improved education for physicians who provide medical care to diabetics.

LIST OF RECOMMENDATIONS

The Committee recommends that:

1. **Health Canada make the necessary adjustments to the Special Access Program such that**

   a) **any costs that place an undue burden on a patient are absorbed by the federal government and,**

   b) **the bureaucratic burden is reduced;**

2. **Health Canada report annually to the Standing Committee on Health through the House of Commons on the status of animal-sourced as well as human recombinant insulins;**

3. **Health Canada request significant advance notice from Eli Lilly, (for example, five years), on any change in the company's policy regarding the provision of animal-sourced insulins;**

4. **Health Canada, in partnership with the Canadian Food Inspection Agency, facilitate the work done by Eli Lilly through active support for various measures, including the provision of tissue for insulin purification through the relationship established between the Agency and the abattoirs;**

5. **Health Canada work closely with the Food and Drug Administration of the United States such that a concerted strategy is developed to ensure a North American supply of animal-sourced insulins; and**

6. **Health Canada work closely with the Canadian Medical Association, the Royal College of Physicians and Surgeons of Canada and other professional bodies to ensure that the use of animal-sourced insulins is an option considered in the education and subsequent practice of physicians.**

APPENDIX A
LIST OF WITNESSES

Associations and individuals	Date	Meeting
Department of Health	03/02/2003	18
Julia Hill, Acting Director General, Biologics and Genetic Therapies Directorate, Health Products and Food Branch		
Georges Nadon, Pharmaceutical Consultant, Non-Insured Health Benefits Program, First Nations and Inuit Health Branch		
Harold Rode, Acting Manager, Vaccines Division, Health Products and Food Branch		
Ian MacKay, Unit Head, Special Access Unit, Clinical Trials and Special Access Programme, Senior Medical Advisor Bureau, Therapeutic Products Directorate, Health Products and Food Branch		
Supriya Sharma, Director, Marketed Biologicals and Biotechnology Products Division, Marketed Health Products Directorate, Health Products and Food Branch		
Maureen Thompson, Manager, Diabetes Program, First Nations and Inuit Health Branch		
Society for Diabetic Rights		
Colleen Fuller, President		
Brenda Johnson, Vice-President		
University of Ottawa		
Jan T. Braaten, Endocrinologist, Associate Professor, Department of Medicine		
Eli Lilly Canada Inc.	29/04/2003	31
Carlo Di Fonzo, Associate Vice President, Regulatory Affairs and Quality Compliance		
Loren Grossman, Vice President, Research and Development		
Terry McCool, Vice President, Corporate Affairs		
Canadian Diabetes Association		
Diane Allingham, Executive Assistant, Public Policy and Government Relations		
Alexis Mantell, Senior Manager, Strategic Communications and Media Relations		
Department of Health		
Julia Hill, Acting Director General, Biologics and Genetic Therapies Directorate, Health Products and Food Branch		
Ian MacKay, Unit Head, Special Access Unit, Clinical Trials and Special Access Programme, Senior Medical Advisor Bureau, Therapeutic Products Directorate, Health Products and Food Branch		
Supriya Sharma, Director, Marketed Biologicals and Biotechnology Products Division, Marketed Health Products Directorate, Health Products and Food Branch		

REQUEST FOR GOVERNMENT RESPONSE

Pursuant to Standing Order 109, the Committee requests that the Government table a comprehensive response to this report.

A copy of the relevant Minutes of Proceedings (*Meeting Nos. 18, 31, 36 and 39, including this report*) is tabled.

Respectfully submitted,

Bonnie Brown, M.P.
Chair

DISSENTING OPINION

Standing Committee on Health
Report on Animal-Sourced Insulins: Availability for Diabetics

Svend J. Robinson, MP

The New Democratic Party dissents from this report. While we support some of the recommendations of this report, we feel that the report does not deal sufficiently with the issue of the safety of biosynthetic insulin.

My New Democrat colleagues and I acknowledge and value the dedication and hard work of my fellow Committee members in holding hearings with a variety of important witnesses on the subject of animal and biosynthetic insulins. Like my colleagues, I want to thank all of the witnesses who appeared before us. Their evidence was of great value for its depth and insight. Unfortunately, the committee neglected to invite several national and international experts who were recommended by the Society for Diabetic Rights, and who could have contributed critical evidence, which would have addressed concerns with the safety of biosynthetic insulin.

In its report, the Committee has taken some important steps towards ensuring that Canadians have continued access to animal-sourced insulins; however, it does not go far enough. The following are the key areas in which we believe that the report must be strengthened:

1. The report suggests that biosynthetic or recombinant human insulin is a safe alternative to animal-sourced insulins, without acknowledging the very serious health concerns of a significant minority of patients who use these products. While the report refers to the fact that some people who have been on animal-sourced insulins have been unable to make the transition to biosynthetic insulins, it is silent on the issue of diabetic patients who have similar problems but had never used animal-sourced insulins prior to being placed on biosynthetic insulins. The government must ensure that Health Canada conducts comprehensive post market surveillance of biosynthetic insulin. In addition, product monographs should accurately reflect independent scientific evidence. With regard to the product monographs for Eli Lilly's biosynthetic human insulin products, there are concerns that the company has neglected to include information that shows there may be a link between arthritis-type symptoms and biosynthetic insulin, even though this link was established in one of their own sponsored studies. The government must also ensure that Health Canada informs physicians that natural insulin, either beef or pork, is available to patients who present these painful and debilitating symptoms.

2. Furthermore, the government should direct Health Canada to conduct research studies into incidents of hypoglycemia unawareness resulting from biosynthetic insulin. This condition may be the result of a highly dangerous adverse reaction,

but data on its prevalence have not been adequately accumulated or considered. A recent article published in *Diabetes Care* reported on the results of a trial (continuous glucose monitoring) which found, unexpectedly, that 62.5% of Type 1 diabetics and 46.6% of Type 2 diabetics are unaware of hypoglycemia when it occurs. Of these, nearly 74% of hypoglycemic events occur during the night. It is highly unlikely that the subjects in this study were using pork insulin, and even less likely they were using beef insulin. A simple follow-up study could determine if there is any difference if patients are placed on Eli Lilly's NPH pork insulin (which has been shown to be among the least stable of the animal insulins), Semilente pork insulin (available in Europe from Novo Nordisk) or on Ultralente beef insulin (available in England).

3. The government must direct Health Canada to develop, with the guidance of the Committee, an improved system to assist physicians, pharmacists, other health professionals and patients in reporting adverse drug reaction cases related to biosynthetic insulin to the Canadian ADR Monitoring Programme. Such guidance is required because it appears that those involved in diabetes care are unaware that persistent, inexplicable and severe hypoglycemia is an unacceptable and adverse effect, and very different than the more typical and symptomatic experience with low blood sugar of which most patients who use insulin are familiar.

4. Unfounded assertions were made during the Committee's hearings that no efforts were being made in other countries to maintain the availability of animal-sourced insulins. This is fallacious, as there are European nations which have assured the availability of as many as seven different types of pork insulin for diabetic patients. The government should therefore direct Health Canada to ensure that physicians and patients are aware of the availability of animal-based insulins, both in Canada and internationally, through a concerted campaign to raise awareness. An "It's Your Health" bulletin is inadequate. Furthermore, the government should direct Health Canada not to work only with one pharmaceutical company to ensure that Canadians have on-going access to affordable animal-sourced insulins, both beef and pork, but rather to facilitate access to these products from other producers, either nationally or internationally.

5. The government should amend the *Food and Drugs Act* so that drugs are approved based on medical need. The drugs which are approved must represent better value and be shown that they do not compromise safety. The *Act* should give Health Canada the necessary authority to require companies to maintain the safest and most effective versions of important pharmaceutical drugs on the market in the event that cheaper or lower-quality substitutes are developed. The health of Canadians must not be jeopardized by pharmaceutical companies seeking to derive greater profits by substituting inferior products for ones proven safe and effective. In this regard, the government should adopt higher standards of evidence for approval of new drugs, including a requirement

that studies relating to quality of life, mortality, and morbidity be conducted prior to granting approvals.

These are the key areas in which we believe the report should be strengthened.

MINUTES OF PROCEEDINGS

Wednesday, June 4, 2003
(Meeting No. 39)

The Standing Committee on Health met *in camera* at 3:48 p.m. this day, in Room 269, West Block, the Chair, Bonnie Brown, presiding.

Members of the Committee present: Bonnie Brown, Jeannot Castonguay, Raymonde Folco, Betty Hinton, Hélène Scherrer, Carol Skelton and Yolande Thibeault.

Acting Members present: Dominic LeBlanc for Brenda Chamberlain, Alan Tonks for Stan Dromisky and Gérard Binet for the Hon. Hedy Fry.

In attendance: *From the Library of Parliament*: Nancy Miller Chenier and Sonya Norris, research officers.

Pursuant to Standing Order 108(2), the Committee resumed its study on First Nations and Inuit Dental Health.

The Committee resumed consideration of a draft report.

It was agreed, - That, the Committee adopt the English version of the draft report, as amended, and that the French version be redone; and that the Chair designate some members of the Committee to approve the revised French translation.

It was agreed, - That, pursuant to Standing Order 109, the Committee request that the Government table a comprehensive response to this report.

It was agreed, - That the Chair be authorized to make such typographical and editorial changes as may be necessary without changing the substance of the report.

It was agreed, - That the Committee meet with members of a delegation from the United Kingdom on June 10, 2003 at 9:00 a.m.

It was agreed, - That the Committee meet with members of a delegation from Germany on June 12, 2003 at 9:30 a.m.

Pursuant to Standing Order 108(2), the Committee resumed its study on issues concerning synthetic insulin.

The Committee resumed consideration of a draft report.

It was agreed, - That, the Committee adopt the draft report, as amended, as the fourth report of the Committee to the House.

It was agreed, - That, pursuant to Standing Order 109, the Committee request that the Government table a comprehensive response to this report.

It was agreed, - That the Chair be authorized to make such typographical and editorial changes as may be necessary without changing the substance of the report.

It was agreed, - That, pursuant to Standing Order 108(1)(a), the Committee authorize the printing of brief dissenting and / or supplementary opinions as appendices to this report, immediately after the signature of the Chair, and that the opinions be sent to the Clerk of the Committee in electronic form in both official languages on or before 3:00 p.m. on Monday, June 9, 2003.

It was agreed, - That the Chair, or her designate, be authorized to present the report to the House.

At 4:48 p.m., the Committee adjourned to the call of the Chair.

José Cadorette
Clerk of the Committee