

**Date: 20060728**

**Citation: 2006 FC 933**

**BETWEEN:**

**Docket: T-698-04**

**LÉOPOLD DELISLE**

**Applicant**

**- and -**

**THE ATTORNEY GENERAL OF CANADA**

**-and-**

**MINISTRY OF HEALTH (HEALTH CANADA)**

**-and-**

**DIRECTOR GENERAL**

**THERAPEUTIC PRODUCTS DIRECTORATE (HEALTH CANADA)**

**Respondents**

**BETWEEN:**

**T-2138-04**

**DANY LAFOREST**

**Applicant**

**- and -**

**THE ATTORNEY GENERAL OF CANADA**

**-and-**

**MINISTRY OF HEALTH (HEALTH CANADA)**

**-and-**

**DIRECTOR GENERAL**

**THERAPEUTIC PRODUCTS DIRECTORATE (HEALTH CANADA)**

**Respondents**

**BETWEEN:**

**T-2139-04**

**LAURENT LÉGÈRE**

**Applicant**

**- and -**

**THE ATTORNEY GENERAL OF CANADA**

**-and-**

**MINISTRY OF HEALTH (HEALTH CANADA)**

**-and-**

**DIRECTOR GENERAL**

**THERAPEUTIC PRODUCTS DIRECTORATE (HEALTH CANADA)**

**Respondents**

**BETWEEN:**

**T-2140-04**

**DANIEL GRANDMONT**

**Applicant**

**- and -**

**THE ATTORNEY GENERAL OF CANADA**

**-and-**

**MINISTRY OF HEALTH (HEALTH CANADA)**

**-and-**

**DIRECTOR GENERAL**

**THERAPEUTIC PRODUCTS DIRECTORATE (HEALTH CANADA)**

**Respondents**

**REASONS FOR JUDGMENT**

**LEMIEUX J.**

I. Introduction

[1] There are four applications for judicial review, to be jointly examined, regarding some decisions by the federal authorities made under Health Canada’s Special Access Programme (the “SAP”) and especially the January 23, 2004 decision by the Director of the Senior Medical Advisor Bureau (the “Director”). The effect of this decision is two-fold:

- 1° it stated a public policy: access via the SAP to a product known as 714-X, a medication which has not been licensed by Health Canada, nor elsewhere, but whose sale has been authorized in Canada, since 1989 via the SAP following requests for access submitted by several physicians was thereafter to be limited. This policy required that significant evidence be included in all requests to the SAP before any new sales were authorized. It indicated that [TRANSLATION] “in view of this decision, it is unlikely that the SAP shall authorize sales of 714-X for new patients.” It provided for a one-year transitional period for the patients currently taking the product. They were to have access to the product on the advice of their physician if they experienced no adverse reaction. Future use of the product was to be submitted to a clinical trial;
- 2° this is Health Canada’s response to several requests for access to 714-X which were then still on hold.

[2] The respondents explain the scope of this decision in the following terms, that can be found in their memorandum of points and authorities:

[TRANSLATION]

2. This decision bears on the sales conditions via the Special Access Programme of a drug known as 714-X. Pursuant to a thorough review of the documentation, the Director concluded, on January 23, 2004, that there was no credible evidence establishing the effectiveness or the safety of this drug. The Director decided not to invoke the exceptional discretionary power conferred on him by section C.08.010 of the *Food and Drug Regulations*, which authorizes the sale of this drug to certain patients. The sale of this drug remains prohibited, in accordance with the *Food and Drugs Act* (hereinafter referred to as “FDA”) and the *Food and Drug Regulations* (hereinafter referred to as “FDR”).

...

24. On January 23, 2004, Dr. Brian Gillespie, Director of the Senior Medical Advisor Bureau, made a public policy decision regarding access to a new drug, 714-X. Pursuant to this public policy, the Director informed referring physicians that the new 714-X drug would no longer be accessible via the SAP, except for a one-year grace period for those patients whose referring physicians had already received an authorization. Furthermore, this decision was to be applicable to all access requests which had been on hold since August 2003.

...

26. The Director, however, did not rule out the possibility that 714-X might eventually be accessible to Canadians. The manufacturer shall be, however, required to request and obtain an authorization prior to undertaking clinical trials. These are obligations that the “FDA” and the “FDR” impose on all manufacturers of new drugs. [Emphasis added.]

[3] The respondents focus on Dr. Gillespie’s January 23, 2004 decision, claiming that said decision and all the issues raised by the applicants are inextricably interrelated;

[4] As to the applicants, their submissions not only bear on Dr. Gillespie’s decision, but also on the SAP’s decision with regard to access requests by each of their referring physicians: they argue that those decisions were made within a reasonable time or that it is unwarranted to deny them access to the drug in issue;

[5] The applicants raise several issues:

1. Want of jurisdiction

They submit that access decisions were the prerogative of the Assistant Deputy Minister of the Food Directorate, Health Products and Food Branch within the Department, who could not delegate that power or, if he could, that the decision in issue was made by the wrong person, or that it should have been made on a case-by-case basis and not applied uniformly, or that a new delegation of powers was required in view of changes within Health Canada's administrative structure.

2. Excess of jurisdiction

They submit that the SAP based sales authorizations of 714-X on requirements that went beyond the scope of the Regulations in several manners: (1) by requiring from referring physicians additional information on the product's effectiveness and safety that physicians do not have, (2) by asking for specific information that appeared in science magazines and pertained to the registration process, which is not part of the Regulations, and (3) by adopting a public policy going beyond the limits of its discretionary power;

3. Breach of legitimate expectation

They contend that the SAP's mandate, as described by Health Canada, includes a commitment to treat every request for access within 24 hours after it is received.

Not only was this policy deviated from in several cases, but in the case of two of the applicants, the delay in the response was unreasonable. The applicants also submit that, after 15 years of access, they had a legitimate expectation that their requests for access would be authorized.

4. The scope of the discretionary power

When construed in the light of their object, the Regulations creating the SAP provide for a restricted authorization power, exclusively based on the duties owed of the physician and his patient; there is nothing discretionary about it. The system thus created is that of access on demand.

5. Abusive and patently unreasonable use of discretionary power

The applicants claim that 714-X is not toxic and is effective. In establishing its public policy, Health Canada is said to have ignored evidence from patients, their physicians, Mr. Nassens, as well as the scientific theory that supports 714-X.

Furthermore, in its review of the issue of access to 714-X, the SAP acted arbitrarily in the evaluation and application of the evidence.

6. Violation of sections 7 and 15 of the *Canadian Charter of Rights and Freedoms* (the Charter)

[6] In my view, several of the issues raised by the applicants are essentially issues of statutory interpretation. The modern approach was reiterated by Mr. Justice Gonthier in *Barrie Public Utilities v. Canadian Cable Television Assn.* [2003] 1 R.C.S., who quoted the following excerpt from E.A. Driedger in his work, *Construction of Statutes* (2<sup>nd</sup> ed. 1983, p.87):

Today there is only one principle or approach, namely, the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament. [Emphasis added.]

[7] Only two sections of the Regulations, captioned “sale of new drug for emergency treatment,” relate to the SAP:

C.08.010. (1) The Director may issue a letter of authorization authorizing the sale of a quantity of a new drug for human or veterinary use to a practitioner named in the letter of authorization for use in the emergency treatment of a patient under the care of that practitioner, if

(a) the practitioner has supplied to the Director information concerning

(i) the medical emergency for which the drug is required,

(ii) the data in the possession of the practitioner with respect to the use, safety and efficacy of that drug,

(iii) the names of all institutions in which the drug is to be used, and

(iv) such other data as the Director may require; and

(b) the practitioner has agreed to

(i) report to the manufacturer of the new drug and to the Director on the results of the use of the drug in the medical emergency, including information

C.08.010. (1) Le Directeur général peut fournir une lettre d'autorisation permettant la vente d'une certaine quantité d'une drogue nouvelle d'usage humaine ou vétérinaire à un praticien nommé dans la lettre d'autorisation pour le traitement d'urgence d'un malade traité par ledit praticien, si

a) le praticien a fourni au Directeur général des renseignements concernant

(i) l'état pathologique urgent pour lequel la drogue est requise,

(ii) les données que possède le praticien à propos de l'usage, de l'innocuité et de l'efficacité de ladite drogue,

(iii) le nom de tous les établissements où la drogue doit être utilisée, et

(iv) les autres renseignements que le Directeur général pourrait lui demander; et

b) le praticien a consenti à

(i) faire part au fabricant de la drogue nouvelle et au

respecting any adverse reactions encountered, and

(ii) account to the Director on request for all quantities of the drug received by him.

(2) The Director shall, in any letter of authorization issued pursuant to subsection (1), state

(a) the name of the practitioner to whom the new drug may be sold;

(b) the medical emergency in respect of which the new drug may be sold; and

(c) the quantity of the new drug that may be sold to that practitioner for that emergency.

C.08.011. (1) Notwithstanding section C.08.002, a manufacturer may sell to a practitioner named in a letter of authorization issued pursuant to section C.08.010, a quantity of the new drug named in that letter that does not exceed the quantity specified in the letter.

(2) A sale of a new drug made in accordance with subsection (1) is exempt from the provisions of the Act and these Regulations. [Emphasis added.]

[8] The sale of a new drug via the SAP is not subject to the requirements of section C.08.002 of the Regulations.

[9] According to subsection C.08.002(1), it is forbidden to sell or advertise a new drug unless, upon request from the manufacturer, the Minister issues a notice of compliance.

However, subsection 30(1)(j) of the Act authorizes the Governor in Council to exempt a drug from any or all provisions of the Act and to prescribe the conditions of exemption;

Directeur général des résultats de l'usage de la drogue au cours de l'urgence, y compris les renseignements se rapportant à toute réaction défavorable qu'il aura observée, et

(ii) rendre compte au Directeur général, sur demande, de toutes les quantités de la drogue qu'il aura reçues.

(2) Le Directeur général doit, dans toute lettre d'autorisation fournie conformément au paragraphe (1), spécifier

a) le nom du praticien auquel la drogue nouvelle peut être vendue;

b) l'état pathologique urgent pour lequel la drogue nouvelle peut être vendue; et

c) la quantité de la drogue nouvelle qui peut être vendue audit praticien pour ledit cas urgent.

C.08.011. (1) Nonobstant l'article C.08.002, un fabricant peut vendre à un praticien mentionné dans une lettre d'autorisation fournie conformément à l'article C.08.010, une quantité de la drogue nouvelle nommée dans ladite lettre qui n'excède pas la quantité spécifiée dans la lettre.

(2) La vente d'une drogue nouvelle faite en conformité du paragraphe (1) n'est pas soumise aux dispositions de la Loi et du présent règlement.

[10] In order to enable the Minister to assess the safety and effectiveness of a new drug, the information demanded under subsection C.08.002(4) of the Regulations in support of such a request includes: 1) details of the tests to be applied to control the potency, purity, stability and safety of the new drug; 2) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended; and 3) substantial evidence of the clinical effectiveness of the new drug for the purposes and under the conditions of use recommended.

[11] Léopold Delisle currently has access to 714-X via the SAP. In his application for judicial review, filed April 2, 2004, Mr. Delisle seeks to:

[TRANSLATION]

5. **Purpose of application for judicial review:** The application for judicial review relates to the decisions of the respondent Health Canada, and more specifically, of the Director General of the Therapeutic Products Directorate, who refused requests from physicians on behalf of their patients to make the 714-X product available through the Special Access Programme (hereinafter referred to as “the SAP”) administered by the respondents. The application also seeks to order the respondents to allow the physicians’ requests, without any further requirements and conditions within 24 hours of receiving these requests, whether the patients concerned have been granted or not in the past a similar authorization for access to the 714-X product; [Emphasis added.]

[12] Although his physician has been requesting it since August 2003, Daniel Grandmont was never treated with 714-X. His application for judicial review, filed on December 1<sup>st</sup>, 2004, seeks to have the following order issued against Health Canada:

[TRANSLATION]

- (a) Not to deny access requests to 714-X made by his physician through the Special Access Programme (hereinafter referred to as the “SAP”) on grounds of insufficient information regarding the effectiveness or toxicity of 714-X;

- (b) To allow the applicant to have access to 714-X upon request from his physician through the SAP, beyond January 2005 and for as long as his physician deems it necessary; [emphasis added.]

[13] Laurent Légère, who currently has access to the 714-X via the SAP, is seeking the following relief in his application for judicial review, filed on December 1<sup>st</sup>, 2004:

[TRANSLATION]

**12. Relief sought**

- 12.1 The application for judicial review seeks to have the following order made against respondent Health Canada:
- (a) To respond to special access requests within twenty-fours and to avoid any unreasonable delay, such as the applicant has suffered, in processing requests for access;
  - (b) Not to deny any requests for access to 714-X made by his physician through the Special Access Programme (hereinafter referred to as the “SAP”) on grounds of insufficient information regarding the effectiveness or the toxicity of 714-X;
  - (c) To allow the applicant to have access to 714-X upon request from his physician pursuant to the SAP, after January 2005 and for as long as his physician deems it necessary; [emphasis added.]
- 12.2 . . .

[14] Dany Laforest was treated with 714-X, but no longer has access to it. Her application for judicial review, filed on December 1<sup>st</sup>, 2004, seeks to have the following orders made against Health Canada:

[TRANSLATION]

- (a) To allow her request for access to 714- X, which the respondent has omitted or refused to do within a twenty-four-hour deadline;
- (b) Where applicable, not to request that her physician submit any further information on the effectiveness or toxicity of 714-X than that provided in response to prior requests;

- (c) To enable the applicant to have access to 714-X, upon request from her physician in compliance with the SAP, after January 2005 and for as long as her physician deems it necessary; [Emphasis added.]

[15] In the alternative, assuming that Health Canada has complied with the enabling legislation, each applicant is seeking that the Court declare that sections C.08.010 and C.08.011 violate sections 7 and 15 of the Charter, in that they allow the responsible authorities to deny and delay treatment in an unreasonable manner, or to reject in an abusive and arbitrary manner and without reasonable grounds the requests submitted by physicians for access to 714-X, thus resulting in a deprivation of the liberty and security of the person under section 7, or discrimination under section 15.

## II. The SAP

[16] The SAP is a programme instituted by Health Canada to facilitate emergency access to unapproved experimental drugs for serious illnesses when conventional therapies have failed, are unsuitable, or unavailable. The programme started in 1966 under a different name. The Department describes as follows the SAP's mandate in its request for special access Guideline (applicants' brief, volume 1, page 62):

The Special Access Programme (the SAP) provides access to nonmarketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable. The SAP authorizes a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada. Drugs considered for release by the SAP include pharmaceutical, biologic, and radiopharmaceutical products not approved for sale in Canada.

The SAP does not authorize the use or administration of a drug - this authority falls within the practice of medicine, which is regulated at the provincial level. The SAP authorization does not constitute an opinion or statement that a drug is safe, efficacious or of high quality. The SAP does not conduct a comprehensive evaluation to ensure the validity of drug information or attestations of the manufacturer respecting safety, efficacy and quality. These are important

factors for practitioners to consider when recommending the use of a drug and in making an appropriate risk/benefit decision in the best interests of the patient. The SAP strongly encourages practitioners treating individuals with drugs obtained through the SAP to seek informed consent before treatment.

Practitioners are encouraged to contact individual manufacturers to confirm the availability of a drug as well as to obtain the most up-to-date drug information such as prescribing information and other data supporting the use of the drug. In all cases, the manufacturer has the final word on whether the drug will be supplied. The manufacturer also has the right to impose certain restrictions or conditions on the release of the drug to ensure that it is used in accordance with the latest information available. For instance, they may restrict the amount of drug released, request further patient information, etc. Inquiries concerning the shipping, cost and/or payment should be directed to individual manufacturers.

In seeking and receiving access to a drug through the SAP, the practitioner agrees to provide both the SAP and the manufacturer with a report on the use of the drug, including information on adverse reactions and, on request, account for all quantities of drug received. [Emphasis added.]

[17] The patient's referring physician is the one who requests access to 714-X (or any other new drug) by completing a Health Canada form. In addition to giving information on the medication, the patient and the exact medical condition he wishes to receive for this medication, since 2002, the physician must: (1) provide a clinical rationale, including about the patient's medical history, prognosis, other treatments attempted or ruled out; (2) justify why this drug is the best choice for the patient, for example it is a drug of choice, he is undergoing a first or second line therapy, there are no product alternatives; and (3) reference any sources of information available, such as specific medical literature, product monograph, etc., with respect to the use, safety and effectiveness of the medication he is ordering.

[18] The practitioner's consent on the form is as follows:

I, the practitioner, am accessing this non-marketed drug for use in the emergency treatment of a patient under my care in accordance with the *Food and Drug Regulations* (C.08.010).

I, the practitioner, am aware that by accessing this drug through the SAP, the sale of the drug is exempt from all aspects of the *Food and Drugs Regulations* including those respecting the safety, efficacy and quality.

I, the practitioner, agree to provide a report on the results of the use of the drug including information on Adverse Drug Reactions and, on request, to account for quantities of the drug received. [Emphasis added.]

[19] In its guidelines, Health Canada requests that the forms be faxed to the SAP and indicates that a complete form does not guarantee that a request will be authorized, as “additional information may be required during the review process.” Health Canada states that “every effort is made to process requests within 24 hours of receipt” but warns that “given the mandate of the Programme and the volume of requests received, the SAP adopts a triage system to ensure that requests for drugs for life-threatening conditions take precedence over other less urgent matters” and that “if a drug is new to the Programme, the total processing time may be extended” (applicants’ brief, at page 64).

[20] Another Health Canada document (applicants’ brief, at page 70) defines the SAP’s objective:

The Special Access programme (the SAP) allows practitioners to request access to drugs that are unavailable for sale in Canada. This access is limited to patients with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable. [Emphasis added.]

[21] In the same document, Health Canada responds as follows to the question: “Can the SAP be considered a fast-track approval process for medications?”:

No. The SAP is not intended to be a mechanism to promote or encourage the early use of drugs or to circumvent the clinical trials review and approval process or the new drug approval process, but rather to provide compassionate access to drugs on a patient by patient basis. [My emphasis.]

[22] In 1997, the House of Commons Standing Committee on Health (“Standing Committee”) reviewed the operation of the Emergency Drug Release Program (“EDRP”), the SAP’s precursor.

[23] In its report, the Standing Committee addressed the right of catastrophically-ill patients:

The concept of catastrophic rights holds that: “a catastrophically-ill patient has the right to be free from any paternalistic interference in electing, in consultation with his physician, any therapy whatsoever that does not cause direct harm to others.” (2) This concept is rooted in the principle of freedom. [Emphasis added.]

[24] This Committee acknowledged, however, that “the catastrophic right to try to save one’s own life is, unfortunately, neither straightforward nor simple in its application for this is a “positive” right, meaning that its fulfilment requires the participation of others,” in other words, it “imposes a corresponding duty on those who have drugs or on those who manufacture drugs.”

[25] In the Committee’s opinion, “the Act attempts to safeguard the health of Canadians by prohibiting the sale of drugs of unproven safety and efficacy.” It stated:

As such, the Act would disallow an individual's catastrophic right to an unproven therapy were it not for sections C.08.010 and C.08.011 of the Act's Regulations. These provisions establish the conditions for the Emergency Drug Release Program (EDRP); whereby, the Health Protection Branch (HPB) of Health Canada may authorize a pharmaceutical manufacturer to sell a drug, not approved for sale in Canada, to a physician for the emergency treatment of a specific patient. The program covers two therapeutic categories: investigational drugs and drugs approved in foreign countries. When the EDRP was established in 1966, it was largely used for this latter function; however, since the emergence of the AIDS epidemic approximately 15 years ago, the focus of the EDRP has shifted to the point where the authorization of experimental drugs for people who are catastrophically ill is the program's major function. While catastrophic rights do not have the force of legal recognition in Canada, the government’s action to facilitate the provision of unapproved medications “implicitly recognizes that critically-ill persons should be allowed to take much greater risks than would otherwise be acceptable.” [Emphasis added.]

[26] It cautioned, however:

Round Table participants identified a number of problems associated with compassionate access; however, its potential to slow the drug regulatory process was probably the greatest concern. There was strong concurrence that nothing must interfere with the rapidity of drug development, which brings the best treatment to the most people, and is therefore of paramount importance. The availability of compassionate access may lead to high drop-out rates from trials in progress or it may slow or limit recruitment to controlled trials . . . Not only did this slow the achievement of knowledge, but some volunteers were on drugs for three years without any evidence of a superior arm. There was considerable agreement that if compassionate access is to occur in parallel to clinical trials then creative solutions must be developed to protect the drug development process; but, it was also stressed that greater flexibility within the drug regulatory process is required in order to respond to the urgent need for drugs to treat immediately life-threatening conditions. [Emphasis added.]

[27] At page 10 of its report, the Standing Committee stated a consensus on the need for compassionate access:

From the briefs, presentations and five days of Round Table discussions, it appears that the provision of compassionate access to investigational therapies can and does have an impact on the drug development and evaluation process in Canada. In spite of this impact, however, not a single Round Table participant suggested that compassionate access programs should be curtailed in any fashion or that attempts to further liberalize the process should be avoided. . . . [Emphasis added.]

[28] Under the heading “Ethical aspect, overarching considerations,” at page 18, it was stated:

The five National Round Table sessions were characterized by a high level of agreement. Indeed, there was no stated disagreement to the concept of a catastrophic right. It was pointed out, however, that this right is only operational when the physician agrees with the choice of therapy; that is to say, an individual's right to an unmarketed therapy does not override the physician's equal right “to do no harm.” This ethical obligation, to do no harm, goes to the heart of the question of when it becomes appropriate to consider an unproven therapy as a possible candidate for compassionate access. Although a few participants held that there should be no risk limitations on access to experimental drugs, the majority opinion held that release of a therapy should only be considered when “an acceptable balance between efficacy and toxicity” has been demonstrated. (43) Further, it was firmly held that the rights of those with catastrophic illness have defined limits. On this point, Neill Iscoe of the Canadian Cancer Society stated that “the society believes in the right to self-determination but does not believe this right permits one person to exercise that right to the disadvantage or detriment of another individual.”(44) Specifically, it was felt that compassionate access, while necessary, should not be allowed to impede rapid drug development. [Emphasis added.]

III. 714-X

[29] The inventor of the 714-X product is a biologist, Gaston Naessens. He submitted an affidavit in support of each application for judicial review and was not cross-examined. 714-X was developed in 1975 and is sold by its manufacturer, CERBE Distribution Inc. (“CERBE”). Mr. Naessens is the owner. This product enhances the natural defenses and the immune system when it is introduced directly into the lymphatic system.

[30] 714-X has been accessible to the SAP since December 18, 1989. Gaston Naessens stated that, between that date and March 30, 2004, 1,499 Canadian physicians received 20 985 authorizations from Health Canada for 714-X, which is the equivalent of 440,685 injections and 30,513 treatments by inhalation provided for 4,051 Canadian patients.

[31] According to section C.08.001 of the Regulations, 714-X is a new drug because it has not been sold for a sufficient time and in sufficient quantity in Canada to establish its safety and effectiveness, a finding which is challenged herein.

[32] However, CERBE made no request for a notice of compliance in connection with this product. It should be noted that, until now, 714-X has not been subjected to any clinical trials. Based on the evidence submitted, this product is not authorized in the United States, or anywhere else.

#### IV. The challenged decision and related decisions

[33] On January 23, 2004, Dr. Gillespie wrote to several physicians to respond to their requests for access to 714-X and notified them of changes in the administration of the programme which would affect the processing of future requests for the product. He recalled that the SAP's mandate is to offer access to non commercial drugs to physicians who treat patients with serious or life-threatening conditions when conventional therapies have failed or have proven to be unsuitable. (I also note that Dr. Gillespie had sent a similar letter to a smaller number of physicians on January 19, 2004.)

[34] He cautions, however, that, as an emergency mechanism, [TRANSLATION] “the SAP is not designed to circumvent the clinical trial process or the review process of new medications, nor to promote or encourage the marketing or early use of drugs before their safety and effectiveness has clearly been shown.” [Emphasis added.]

[35] He lists Health Canada's efforts since 2001 to improve the SAP's operations. He mentions two initiatives:

[...]The first, a drug audit process, was implemented to monitor all drugs on the programme and identify those for which there are identified concerns of safety, efficacy or quality and/or there is limited data to support widespread access. The second, a quality initiative, was implemented to review the administration of the programme to preserve its use as an emergency mechanism in accordance with the SAP provisions of the *Food and Drugs Regulations*. [Emphasis added.]

[36] As to 714-X, Dr. Gillespie advises that this product [TRANSLATION] “has been identified from the start of the medication verification process as a product with limited data to support widespread access or long-term use, and with limited prospects.”

[37] Therefore, at the time, [TRANSLATION] “it was assigned some priority and it was added on to a list of products requiring sequential testing in an order of priority.” Shortly thereafter, a new form was introduced in connection with the Health Canada initiative on the quality of the programme. [TRANSLATION] “The most important change is the requirement that practitioners provide a clinical rationale for its use . . . and the sources of scientific information supporting this rationale.”

[38] He concluded by announcing:

In the months after these procedures were introduced, the SAP received many 714-X requests that did not reference scientific data supporting the use, safety and efficacy of this product. The SAP responded to these apparent deficiencies through a routine fax-back procedure for incomplete requests. This process is used to identify specific request deficiencies, reference additional sources of programme information, . . . and outlines our minimal request standards. In addition, it offers practitioners an opportunity to consider a deficiency in light of the minimal requirements of the *Food and Drug Regulations* and resubmit a request, with additional information, for further consideration. Despite these efforts, the SAP continued to receive a large volume of 714-X requests with little or no data.

Based on a further review of evidence now available with respect to the use, safety and efficacy of this drug, as they relate to the emergency uses for which this drug has been requested, it has been determined that significant new evidence would have to be included in any SAP request before any further sales of 714-X could be authorized pursuant to requests made under section C.08.010 of the *Food and Drug Regulations*. Given this determination, it is unlikely that the SAP will authorize the sale of 714-X for new patients. During an interim period of one year, the SAP will take account of the special considerations relating to patients currently receiving the drug, who in the opinion of the practitioner have not experienced adverse effects from their ongoing treatment, and may continue to authorize requests made for such patients. The SAP then will revisit the merits of any such continued authorizations on the basis of reports filed on the previous use of the product, including any adverse events, in accordance with subparagraph C.01.010 (b)(i) [n'existe pas] of the *Food and Drug Regulations*.

The determination that has been made by Health Canada in this matter is consistent with that made by the U.S. National Cancer Institute (NCI) concluded that there have been no clinical studies (e.g. clinical trials, case series or case reviews) reported in peer-reviewed, scientific journals to support the safety or the efficacy of 714-X and it did not recommend the use of 714-X outside the context of well designed clinical trials. If you wish to pursue the use of 714-X, I recommend that you work with a manufacturer to develop and sponsor a clinical trial. A clinical trial would provide an opportunity to better understand the safety and efficacy of 714-X for specific indications and conditions. The regulatory review of the clinical trial would ensure that formal scientific and medical scrutiny is applied to the method of manufacturer of 714-X and the protocol and data supporting the use of 714-X in the proposed treatment. Most importantly, a clinical trial would ensure that the best interests of patients are protected through the required involvement of research ethics boards. [Emphasis added.]

## V. The SAP's evaluation of each applicant's file

[39] Following is a history of each applicant's treatment with 714-X and the progress of their physicians' request for access underlying the application brought before the Court. None of the applicants was cross-examined on the affidavit that they submitted in support of their application for judicial review.

### A. *Léopold Delisle*

[40] Mr. Delisle's evidence is not limited to his own particular case. He studied the cases of several other patients who used the product or wished to have access to it. He obtained access to other documents by submitting a request pursuant to the *Access to Information Act*;

[41] The applicant, Léopold Delisle, was diagnosed in 1989 with an immune system illness — mastocytosis. He stated that neither traditional medicine nor international research has found any medication to cure this disease. Between May 1994 and June 1997, he was treated

with experimental medication, not only unsuccessfully, but with adverse results. On July 23, 1997, he was given access to 714-X. Paragraphs 38 to 40 of his affidavit read as follows:

[TRANSLATION]

38. On October 21, 1997, my medical specialist noticed that my condition had improved, with a weight gain, a decrease in these signs and symptoms, the disappearance of a right-side inguinal hernia, which had been present since December 1995, and a significant decrease in my medication;
39. Since July 1997, I have administered myself several 714-X injections; in addition, I have received more than 714-X 100 treatments by inhalation in conjunction with these injections;
40. During this entire period, I observed no secondary side effects, except some painless redness on the site of the injections. The effects of 714-X have given me much more energy, fewer signs and symptoms of the illness, and have enabled me to substantially reduce my medication.. Furthermore, it has helped stabilize my immune system and, as such, has enabled me to have a better quality of life;

[42] He was authorized by an order of the Court to file a further affidavit in order to explain how the SAP reviewed his September 3, 2004 request for access, a request made, I emphasize, following Dr. Brian Gillespie's January 23, 2004 decision and following the filing of evidence contained in the first affidavit from Ian MacKay, Director of the SAP. The chronology of events is as follows:

- (1) on September 9, 2004, his physician received a letter from the SAP

[TRANSLATION] "rejecting my request on the grounds that the form is incomplete in that it lacks information." (Indeed, his physician's answer to question 3 on the clinical rationale was "documentation;" however, this question was asking for the available reference materials with regard to the safety and effectiveness of 714-X.)

- (2) in anticipation of a possible decision to extend access to the SAP for 2005, on December 1<sup>st</sup>, 2004, his physician received a letter from Dr. Gillespie asking him if he had scientific information establishing the effectiveness and safety of 714-X and more particularly, reminding him that his incomplete September 9, 2004 request for access remained unanswered;
- (3) on December 14, 2004, his physician submitted a new request for access;
- (4) on December 15, 2004, his physician responded to Dr Gillespie's December 1<sup>st</sup>, 2004 letter:

[TRANSLATION]

With respect to 714-X and the scientific data, I should tell you that my patient . . . submitted to me in December 2004, a letter from Dr Arthur B. Pardee of the Dana-Farber Cancer Institute, which confirmed scientifically what I had been observing for many years about 714-X. Notwithstanding the fact that there are no clinical trials on 714-X, it is very evident to me that this product has specific characteristics that are very beneficial to the immune system. Dr. Pardee's report clarifies the clinical observations I had made.

As to the September 2004 request on behalf of my patient L.D., your rejection and the further information required were irrelevant and unjustified, considering that in May 2004, you had authorized my request, which set forth facts identical to the ones submitted in September 2004. Furthermore, my patient has been using 714-X for several years and this medication is of great help to him. I support him in his wish to maintain its use.

Encl.: Dr Pardee's letter [Emphasis added.]

- (5) on December 15, 2004, Mr. Delisle's request for access to the SAP was granted.

[43] The enclosure is a letter dated August 9, 1999 from Dr. Pardee. It plays an important role in both parties' arguments, and shall be analysed further down.

B. *Laurent Légère*

[44] Laurent Légère's situation is analogous to Léopold Delisle's. He currently has access to 714-X. He complained about the delay incurred in the processing of his most recent request, the one submitted by his physician on November 13, 2003, and rejected, it appears, in December 2003 for insufficient information, but authorized in February 2004 following an exchange from his physician.

[45] In October 1994, after he was diagnosed with a carcinoma-type stomach cancer, his survival prognosis was six to eighteen months, and there was no conventional treatment for that type of cancer.

[46] His physician, who knew about 714-X, requested access to the SAP. The access was authorized. At the end of October 1994, he received treatments for eleven cycles, amounting to 231 consecutive injections. After nine months of treatment, he returned to work, [TRANSLATION] "to his physician's surprise" and discontinued using it for almost three years. In 1998, his physician obtained two cycles of treatment, and later, in 2001, he obtained 23 more. His health remained stable; he, again, discontinued 714-X treatments.

[47] In October 2002, he experienced a relapse and resumed his 714-X treatments until September 2003. He stated that his health improved once more "again, to the great astonishment of my medical specialists."

[48] His application before the Court relates to the request for access that his physician completed on November 13, 2003 and which, according to him, received no response, notwithstanding the fact that his physician attempted unsuccessfully to reach that office. He claimed that his wife tried twice to speak to the person responsible for authorizations, but “the receptionist refused to transfer the call.”

[49] Mr. Légère alleged that, in December 2003, he left a message on Mr. Ian MacKay’s voicemail, asking him to call him. “He never returned the call.”

[50] According to him, in December 2003, following his deputy’s intervention in Ottawa, Health Canada responded “denying him, however, access to 714-X based on a lack of information.” [Emphasis added.]

[51] Following the information provided by his physician in February 2004, this request was granted on March 11, 2004 “after a 199-day wait.” Due to this delay, he stated, the state of his health greatly deteriorated and he was morally very affected. He added that he was feeling “very anxious since Health Canada has informed his physician that he would be permanently denying him access to 714-X as of January 2005.” [Emphasis added.] Paragraphs 25 to 29 of his affidavit read as follows:

[TRANSLATION]

25. It is unthinkable that the Government of Canada would restrict access to a product that has kept me alive and has enabled me to work and pay income taxes during all those years. Furthermore, by personally paying for 714-X, I saved the country money. My health remained stable, I was able to return to work and to continue to pay income taxes, although I should have been dead since 1994;

26. By denying me access to 714-X, which, according to my physician, I need to remain healthy, the Government of Canada is causing me irreparable harm that could even prove fatal;
27. My physician and I can testify as to what 714-X has already done for me, as there exists no conventional treatment for the type of cancer I have;
28. My gastroenterologist confirmed that the 714-X treatment has worked. As he had never heard of a surviving case of carcinoma-type stomach cancer without surgical procedure or chemical intervention, he told me to consider 714-X as an interesting option that I should keep.
29. As he did not previously know about 714-X, but as he was very curious about the product, he asked the manufacturer, CERBE, for further information. [Emphasis added.]

### C. Daniel Grandmont

[52] Daniel Grandmont described his illness — a cancer known as adenocarcinoma, his two surgical procedures, in 1985 and 1990, and his remissions. He was never treated with 714-X, notwithstanding his having made several requests to the SAP, which, he claimed, were denied.

[53] In February 2003, his cancer relapsed; no surgery was possible and no treatment, available. While researching alternative treatments, he found out about 714-X and telephoned the CERBE. On August 6, 2003, his physician completed the access form. This request was returned to his physician on August 20, 2003 [TRANSLATION] “on grounds of insufficient information.”

[54] His physician was said to have then resubmitted the form to the SAP, with a note: [TRANSLATION] “Why this sudden change in attitude? 714-X is well known to the Canadian government. Please contact CERBE for available sources of information.” [Emphasis added.] On

August 26, 2003, his physician received a rejection letter from Dr. Gillespie

[TRANSLATION] “again on grounds of insufficient information.”

[55] Mr. Grandmont’s physician was then said to have told the applicant that he was concerned with Health Canada’s attitude [TRANSLATION] “since, for years, he had always completed his request for authorization in the same manner, and he told me he could not understand why I was unable to get it.” [Emphasis added.] Following his MP’s intervention and following a discussion Mr. Léopold Delisle was said to have had with an official at Health Canada, his physician would have accepted to submit another request for access on December 22, 2003. On February 11, 2004, his physician’s request for access was again denied.

[56] Paragraphs 29 to 33 of his affidavit read as follows:

[TRANSLATION]

29. Notwithstanding the fact that I met all the requirements of Health Canada to obtain this authorization to use 714-X, Health Canada always denied my physician’s requests for authorization;
30. No chemotherapy treatment is appropriate for the type of cancer I have, no radiation therapy is possible in my case, and no surgery may be contemplated;
31. Today, I suffer from left-side facial paralysis, I have great difficulty eating because I have trouble swallowing; I am deaf in my left ear, I have no voice left. I have great difficulty talking because I am out of breath. My eyelid moves with difficulty and my eyes are often dry. I am no longer able to make any physical effort;
32. The only alternative treatment remaining for me is 714-X, which has been highly recommended to me, especially by my physician and my medical specialist. 714-X is my only chance of survival;
33. The attitude, the rejections and the behaviour of Health Canada towards me have totally turned me off. The only thing I ask is the right to have a last chance, which Health Canada denies me, thus disregarding a request to that effect by my own physician; [emphasis added]

D. *Dany Laforest*

[57] Applicant Dany Laforest is 45 years old and had no health problems prior to 2000. In November 2000, her gynecologist found an abnormality in her right breast which tested positive following a mammography and a biopsy. After surgery, she received chemotherapy and radiotherapy, and, as a result, felt very weak.

[58] After doing some research and after contacting CERBE, on August 3, 2001, her physician was granted access to 714-X via the SAP. After eight cycles of treatment, feeling considerably better, she interrupted the treatment. Her last authorizations date back to December 4, 2002 and July 7, 2003.

[59] According to Ms. Laforest, on February 19, 2004, another request for authorization was submitted, but there was no response from the SAP. Ms. Laforest and her physician are still awaiting that response.

[60] She asserted that she never felt any adverse effects from the 714-X treatments, but rather experienced a sensation of well-being and of health improvement. She submitted that it is Health Canada's duty to respect requests made by physicians who, in her opinion, know more than anyone else what is good for their patients.

VI. Ian MacKay's June 8, 2004 affidavit

[61] As hereinabove mentioned, Ian MacKay is Director of the SAP. His June 8, 2004 affidavit is the main evidence relied on by the respondents in response to the applicants' evidence. He was cross-examined.

[62] In the introductory paragraphs of his affidavit, he explained the basis of Health Canada's decision to limit access to 714-X through the SAP:

8. The *Food and Drug Act and Regulations* provide a comprehensive scheme designed to protect the health of Canadians. As such, they prohibit the sale of drugs where their safety, efficacy and quality have not been demonstrated in accordance with the said *Act and Regulations*.
9. As explained herein, it has been determined, taking account of the review conducted by the Bureau of the Senior Medical Advisor within Health Canada, that, unless sufficient evidence to support the emergency use of 714-X was provided by a physician, access to 714-X through the Special Access Programme should be limited. This position is based on a clear absence of credible evidence to support the safety and efficacy of 714-X.
10. I have read the affidavit of Léopold Delisle and Gaston Naessens and they disclose unsubstantiated and unfounded claims.
11. In this affidavit, I will respond to these claims by explaining:
  - (a) the role of Health Canada as Canada's drug regulator;
  - (b) drug development in Canada;
  - (c) the scope and mandate of the Special Access Programme;
  - (d) the impact of the quality review of the Special Access Programme on 714-X;
  - (e) the impact of the prevailing consensus within the scientific community in Canada and the United States as to the lack of any evidence of the safety and efficacy of 714-X;
  - (f) the carefully considered steps undertaken by the Special Access Programme with respect to the availability of 714-X; [emphasis added.]

[63] I will not elaborate on the portions of Mr. MacKay's affidavit describing the role of Health Canada as a drug regulator, the development of drugs in Canada and the SAP's mandate.

[64] With regard to Health Canada's role, Mr. MacKay invoked the Regulations.

[65] Mr. MacKay explained that the system set up by the Regulations "is precautionary given that all drugs carry some level of risk . . . [and] emphasizes the need to take timely and appropriate preventative action, even in the absence of full scientific demonstration of cause and effect." In his opinion, the approval system for new drugs rests on the fact "that there is extensive uncertainty regarding the effects of drugs in humans. Promising treatments do not always work out." He acknowledged that "[n]o drug is totally effective and likewise no drug is completely safe. Thus, part of the regulatory review process weighs a drug's potential for benefit (degree of effectiveness) against its potential for harm, as compared with other current treatment options. The regulatory decision as to whether or not to approve a drug for the Canadian market is largely based on this risk/benefit assessment". [Emphasis added.]

[66] He identified the steps involved in the development and approval of a new drug: discovery of a new active pharmaceutical ingredient, laboratory and animal studies, and, ultimately, clinical trials on humans "to formally and systematically gather information on the safety and efficacy of a drug in humans, verify the claims made by a sponsor and the uncertainty regarding the harms or benefits of drugs in humans. Clinical trials are conducted by physicians, scientists and other health care professionals in controlled settings using good clinical practices."

[67] There are three types of clinical trials: (1) Phase I clinical trials “in which an experimental drug is usually given to a small number of healthy volunteers. The goals of a Phase I trial is to determine how the drug is absorbed, distributed in the body, metabolized and excreted, as well as to estimate the initial safety and tolerability of the drug at different dosages »; (2) Phase II clinical trials “are the initial trials to assess efficacy in patients for a specific indication, . . . they are also called therapeutic exploratory studies. Some of the information gained in Phase II trials includes the best dose and frequency of the drug, the target population . . . and the best outcome measures . . . to assess efficacy;” and (3) Phase III clinical trials “also called therapeutic confirmatory studies, is to demonstrate the safety and efficacy of the drug in the intended patient population under the intended conditions of use.”

[68] At paragraphs 49, 50, 51 and 52 of his affidavit, Mr. MacKay summarized his theory on the quality of the evidence required by Health Canada under the Regulations:

49. In summary, the regulatory approval process ensures that the manufacturer develops a drug which is well characterized, and that its production results in consistent pharmacologic properties. The process involves the systematic assessment and reporting of extensive information on the drug and its effects. Furthermore, it restricts the claims a manufacturer can make about a drug, limiting claims to those areas for which there is sufficient scientific evidence.
50. Universally, anecdotal evidence, which by definition is gathered without any experimental design, is insufficient to make informed decisions as to whether the benefits of a drug outweigh the risks.
51. Evidence and data gathered from well designed and executed non-clinical and clinical trials is considered credible when conducted by scientific and medical experts and subjected to scrutiny by peer review.
52. A physician’s impression from an individual patient cannot be extrapolated to form a scientific basis of support for widespread use of a drug. Classically this is referred to as anecdotal information. [Emphasis added.]

[69] Wit respect to the SAP, M. MacKay explained that:

- (1) the decision to authorize or deny access to the SAP is based “on the data supplied by the physician and other information it may have in its possession. The SAP carefully exercises this discretion by considering all information provided by the physician, the nature of the medical emergency, and the extent to which the data submitted in support of the request is credible and relevant to specified medical emergency” [paragraph 56] [emphasis added];
- (2) “A physician is responsible for initiating a request on behalf of a patient and ensuring that the decision to prescribe the drug for a specific indication is supported by credible evidence available in the medical literature or provided by the manufacturer” [paragraph 57];
- (3) “Health Canada also considers other information in its possession about the drug including the progress of clinical trials, safety information and the regulatory status of the drug in other countries” [paragraph 58];
- (4) “If the data submitted is insufficient, in order to render an informed decision, the SAP has the authority to request additional information respecting the use, safety and efficacy of the drug from the requesting physician” [paragraph 59];
- (5) “The sale of a drug is authorized for emergency use through the SAP when some credible evidence is available respecting the use, safety and efficacy. Typically drugs available through the SAP are either: a) the subject of clinical trials in Canada or elsewhere; b) authorized by Health Canada but not yet launched onto

the Canadian market, or c) authorized by one or more credible and competent regulatory agencies in other jurisdictions. 714-X does not fall within any of the aforementioned parameters” [paragraph 69] [emphasis added];

(6) “. . . SAP authorization does not constitute an opinion or statement that a drug is safe, efficacious or of high quality. The SAP does not conduct a comprehensive evaluation to ensure the validity of drug information or attestations from the manufacturer respecting safety, efficacy and quality such as that undertaken during review of clinical trial applications or new drug submissions” [paragraph 70];

(7) “Nevertheless, the SAP does manage risk within the context of its review and consideration of data supplied by a physician or provided by a manufacturer. This framework takes into consideration what is known about the risks and benefits of a product. The SAP considers, *inter alia*, the standards of manufacturing . . . , the package of product information provided by the manufacturer, whether the product has been reviewed by another regulatory jurisdiction or by Health Canada for purposes of a clinical trial or a new drug. The SAP also consults with medical and scientific experts within Health Canada to rule out any knowledge of serious safety issues or submission deficiencies, as was done in the case of 714-X” [paragraphs 72 and 73] [emphasis added].

[70] He enumerated and explained recent SAP initiatives to improve its operations: (1) in 1999, the SAP considered how a new drug was authorized under the SAP; (2) in 2001, the SAP implemented a verification process in order to determine the number of authorizations, the date

of the last authorization and the conformity to the regulatory regime or development required to secure a notice of compliance; (3) a third initiative on quality relates to the administration of the programme and the need to maintain it as an emergency mechanism in accordance with regulatory provisions. It is pursuant to this initiative that the SAP modified its form in 2002 to include a clinical rationale.

[71] Mr. MacKay examined the 714-X product and noted that it is “promoted by the manufacturer and patient advocates as a non-toxic immune modulator for use in the treatment of HIV, AIDS, cancer, and a variety of other diseases and conditions” [paragraph 86]. “Its use is recommended in the context of an unorthodox biologic theory whereby disease states are diagnosed and treatment regimens are proposed after examining whole blood samples with the aid of a specialized attachment to a standard light microscope” [paragraph 87].

[72] He noted that 714-X was never subjected to a clinical trial, or to a formal development plan leading to licensing by Health Canada, and that it had never received approval from a credible and competent regulatory board. “Hence its safety and efficacy has not been established” [paragraph 89] [emphasis added].

[73] CERBE never submitted a request for accreditation to Health Canada, or a request for a clinical trial. “Therefore, Health Canada has not had the opportunity to conduct a comprehensive regulatory review of the safety, efficacy or quality of 714-X” [paragraph 90] [emphasis added].

[74] As to a clinical trial for 714-X , in his view, “If such a trial were to be conducted, it would represent an avenue for limited and controlled access to the drug and at the same time generate credible data that would contribute to an objective understanding of the safety and efficacy of the drug » [paragraph 91] [emphasis added].

[75] He reviewed all the scientific information on 714-X: two pre-clinical studies, one in 1985 and one by Drs. Pardee and Huang in 1999, as well as the manufacturer CERBE’s data sheet, and stated that, in his opinion, it “describes potential drug interactions which presumably stems from specific reports of adverse events reported to the manufacturer or is a reasonable expectation from the manufacturer’s perspective . . . These identified risks alone refute the claim that the drug is non-toxic” [paragraph 95] [emphasis added].

[76] He commented on Gaston Naessens’ affidavit and, more particularly, on the mandate CERBE gave in 1998 to a Toronto consulting firm, Clinical Consortiums, to conduct complementary immunological tests on 714-X, which would be used to prepare a briefing paper for a clinical trial request. Under the direction of Dr. Lux, this firm retained the services of Dr. Van Alstyne, a virology and immunology specialist, who asked Dr. Pardee’s laboratory, which is associated with the Dana-Fiber Cancer Institute of Boston, to conduct immunological tests. Dr. Van Alstyne’s August 22, 2000 report summarized the results of the research conducted by Dr. Pardee and his colleague, Dr. Huang. According to Mr. MacKay, “Dr. Huang’s position is that the tests are preliminary and that the results are too premature. . .” [paragraph 94] [emphasis added].

[77] Gaston Naessens transmitted Dr. Van Alstyne's report to Health Canada. Mr. MacKay has attached as exhibit K to his affidavit a letter from Health Canada attorney to CERBE's attorney, notifying him that Health Canada could not review this report without a specific regulatory request.

[78] According to him, between 1988 and the early 1990s, 714- X was well known to patients suffering from AIDS "who, in the absence of any treatment options advocated for access to the drug on an emergency basis." Mr. MacKay concluded:

98. The unprecedented nature of the AIDS crisis challenged physicians, patients and government authorities to act in the public interest to permit limited access to 714-X. Hence, 714-X was first released through the SAP in 1989.
99. After the first and subsequent AIDS drugs were approved and marketed in Canada, interest in the use of 714-X as a treatment for AIDS waned precipitously. After 1992, interest in the product shifted from AIDS to cancer and a variety of other diseases.

[79] The initiatives implemented to improve the SAP's operations had an impact on 714-X: "the introduction of the new request form in 2002 and the more consistent review of requests revealed that requests for 714-X did not reference credible scientific data supporting the use, safety and efficacy of this product. As a result, 714-X was identified early in the audit process 2002 as a product for which there was limited, if any, data to support widespread access for any medical condition. At that time, it was assigned a relative priority and added to a list of products for further review and possible action" [paragraphs 100 and 101] [emphasis added];

[80] The SAP reacted to the absence of scientific information from physicians:

102 . . . through a routine fax-back procedure it employed to manage incomplete requests. This procedure is used to identify specific deficiencies and outlines our minimal request standards. In addition, it offers practitioners an opportunity to consider a deficiency in light of the minimal requirements of the *Food and Drug Regulations* and resubmit a request, with additional information, for further consideration. Despite these efforts, the SAP continued to receive requests for 714-X with little or no supporting data. [Emphasis added.]

[81] This deficiency worried the SAP, whose interest had increased, knowing that “the Office of Cancer Complementary and Alternative Medicines (OCCAM), National Cancer Institute, National Institute of Health” was contemplating a review of 714-X. He asserted that “the ongoing problem with request deficiencies and the new knowledge of the OCCAM review prompted Health Canada to take a closer review of the information submitted by physicians and credibility of scientific evidence available to support the use, safety and efficacy of the drug in humans.” A new policy for review of access requests to 714-X was put in place [emphasis added]:

105. As of July 2003, requests for 714-X received by the SAP were subject to normal processing except where the physician provided information that was insufficient to allow me to render a decision. Notwithstanding our growing understanding of what little data existed on the drug, most requests were processed provided that the physician quoted at least one source of information about the drug. In some cases, requests were returned and additional information or clarification sought from the prescribing physician. [Emphasis added.]

[82] That more thorough review showed “that the status of 714-X within the SAP represented an exception since the physicians clearly did not refer to credible data to support the safety and efficacy of the drug” [emphasis added];

[83] The study, led by a group experts from the OCCAM, in July 2003, included a meeting with CERBE and a review of five cases (four American and one Canadian) “where the drug reportedly had dramatic positive effects.”

[84] On or about September 11, 2003, Mr. MacKay knew that the OCCAM had concluded “that there was insufficient evidence to support NCI research following their Best Case Series review of 714-X. After considering the information from the OCCAM, we began to reconsider the release of the product through the SAP” [emphasis added] [paragraph 107].

[85] In October 2003, the SAP contacted the physicians whose requests for access to the SAP were under review to inform them about the OCCAM’s conclusions on 714-X. It said:

108. . . . I contacted several physicians and explained the importance and significance of the OCCAM review such that they could be informed and take account of this information in making requests for 714-X. I also explained that, we were undertaking a review of the drug with a view to determining the availability of evidence supporting the safety and efficacy of the drug.
109. Many of those contacted acknowledged the paucity of data respecting the safety and efficacy and while some argued that patients should have continued access, others expressed the ethical and professional dilemmas associated with prescribing such a drug. [Emphasis added.]

[86] Faced with this situation, Health Canada contemplated some alternatives “and, in consultation with Health Products and Food Branch’s Risk Management Committee, considered the merits of limiting access to the product . . . The merits of continuing to authorize the SAP requests for patients currently being treated with 714-X for the period of one year was also considered” [paragraph 111] [emphasis added].

[87] Health Canada undertook a systematic review of all the scientific literature published on 714-X and, to that end, gave Dr. Bryan Garber, a member of Health Canada's Senior Medical Advisor Bureau, a mandate whose scope Mr. MacKay describes as follows:

112. . . . This review considered, among other sources, published statements from authoritative bodies such as the National Cancer Institute, the Canadian Breast Cancer Research Alliance, and the MD Anderson Cancer Centre. The review concluded there is no credible scientific basis to support the use of 714-X for cancer or any other disease or condition.  
[Emphasis added.]

[88] On or about December 20, 2003, all requests for access to 714-X were put on hold "as the scientific review of information neared completion and as the SAP prepared to render decisions on pending requests and publish guidance for future applicants" [paragraph 113] [emphasis added].

[89] The SAP's statistics revealed that six physicians submitted to the SAP 75% of requests for access to 714-X, and that the other physicians submitted such requests once or twice.

[90] Following Dr. Garber's report in the wake of the OCCAM's conclusions on 714-X, Health Canada decided to limit access to the SAP with respect to 714-X, a decision announced by Dr. Gillespie in his January 23, 2004 letter, which was:

127 . . . sent to physicians in January 2004 was an official response to physicians who had pending requests to access 714-X in 2003 and early 2004 and was a guidance document sent to all physicians who had requested 714-X in 2003 and early 2004.

[91] Mr. MacKay's comments on this decision were as follows:

129. The letter indicated future requests for new patients would be denied unless significant new evidence was provided to support the use, safety and efficacy. With respect to pending requests for new patients, the letter constituted a denial for the reasons contained therein.
130. Special consideration would be given to both pending and future requests for repeat patients. The letter invited physicians to re-submit a new request making specific mention of the patient's experience on the drug and specifically whether the patient had experienced any adverse effects during therapy with 714-X. This approach would allow access to repeat patients on the basis of the follow-up reports provided by the requesting physicians and confirmation that the particular patient had not experienced adverse events from their ongoing treatment. Ongoing access will be revisited after one year on the basis of follow-up reports provided by the physician, during which time clinical trials may have commenced and/or conducted or the therapy abandoned.
131. In fact, physicians with pending requests for repeat patients did subsequently submit modified requests for these patients noting that their patients did not experience any adverse effects. Once received and these facts confirmed, these requests were authorized forthwith. On a couple of occasions, physicians did not specify whether their patients had adverse effects - in these cases we telephoned the physician or faxed the request back asking for that specific information. Once received, they were reviewed and considered in accordance with the new policy.
132. Health Canada carefully considered this issue and opted to grandfather patients who had taken 714-X in the past and who had not experienced adverse effects. This approach considered that the level of risk incurred differed for new patients compared with repeat patients.
133. Since January 23, 2004, all requests received by the SAP for special access to 714-X have been processed in a timely and uniform manner and in accordance with the guidance set forth in the letter sent to physicians in January 2004. As of this date, there are no pending requests for special access to 714-X.
134. Records show that since this letter was issued, the SAP has authorized 56 requests, for a total of 24 repeat patients on the basis of the patients' experience with the drug as provided. A total of 14 requests for new patients have not been authorized. [Emphasis added.]

VII. Mr. Ian MacKay's additional affidavits

[92] The purpose of the January 13, 2005 additional affidavits was to enable Health Canada to respond to the applicants' affidavits, save for Mr. Delisle's affidavit on which it had previously commented.

A. *Response to Léopold Delisle's December 20, 2004 affidavit*

[93] Mr. MacKay explained that, in August 2004, the OCCAM published an update of its review of 714-X. The OCCAM concluded: [paragraph 126]

The NCI's BCS Program review of the pertinent medical records, radiographic films and pathology specimens of 17 cancer patients who reportedly received 714-X has been completed. At this time, the judgment is that there is insufficient information to justify NCI-initiated research on 714-X as an anticancer therapy. The OCCAM is seeking authorization to solicit referral of other well-documented cases directly from U.S. cancer patients. If approved, such a solicitation will be posted on the OCCAM website. [Emphasis added.]

[94] The OCCAM conclusion "is exactly consistent with the discussions and correspondence between the SAP and OCCAM in 2003."

[95] In December 2004, the SAP asked 14 Canadian physicians who had access to 714-X and to CERBE if new information on the effectiveness and safety of the drug had been published since Dr. Garber's scientific review:

141. In anticipation of the end of the one-year period for repeat patients referred to in the letter sent to physicians in January 2004, the SAP wanted to confirm whether any data respecting the use, safety and efficacy of 714-X had been reported in the medical literature since the review undertaken . . . in December 2003 and whether they were involved with or aware of any efforts to initiate a program of formal drug development. To this end, the SAP had sent letters to physicians who had gained access to 714-X in

accordance with the terms set out in the original notice sent to physicians on January 23, 2004. This letter was sent to a total of 14 physicians. The letter was also sent to the manufacturer.

142. Responses were requested on or before December 10, 2004. To date the SAP has received four (4) responses. None of the responses was able to provide any credible scientific information supporting the use, safety and efficacy of 714-X. [Emphasis added.]

[96] The four responses were reviewed by Mr. MacKay:

143. . . . the response from Dr. Teresa Clark, on behalf of the Centre for Integrated Healing in Vancouver, added that they had not encountered any cases of adverse effects and found 714-X to be effective in some cancer patients helping to improve their survival from advanced metastatic disease. She provided no details on these cases and I assume that her conclusions about the efficacy of the 714-X have not been peer reviewed.
144. . . . he was not aware of any credible scientific information regarding the use of 714-X.
145. . . . the response from Gaston Naessens did not provide any credible scientific information respecting the use, safety and efficacy of 714-X and provided a review of interactions with OCCAM and an update to ongoing discussions with the National Institutes of Health in the United States. I am familiar with the process undertaken by the OCCAM and acknowledge the ongoing discussion between Mr. Naessens and the NIH [emphasis added].
- . . .
149. . . . the response from Dr. D. Dagenais included a short letter outlining his experience with 714-X and a copy of the letter from Drs. Pardee and Huang referred to herein at paragraphs 145 and 146.

[97] The SAP received from Gaston Naessens a copy of the letter from Drs. A.B. Pardee and L. Huang, “with which I am familiar. The letter comments on the non-clinical laboratory studies they conducted. The correspondents’ final paragraph is worthy of note” [emphasis added]. I set out hereunder the last paragraph of that letter:

146. . . . “we strongly feel that this agent deserves equal attention as other compounds in a peer-reviewed journal if positive scientific evidence comes up to support its *in vivo* function. Therefore we would like to write up our results and submit them to a peer-reviewed journal for consideration of publication. Only our data will be presented in the manuscript. We believe that our data will provide a foundation for future characterization of this compound. Once scientific characterization of this compound is

established, large scale clinical trials would be feasible and this agent could be available to more patients. [Emphasis added.]

[98] Mr. MacKay submitted that:

147. This confirms that the studies performed were very preliminary in nature and that, in the opinion of the authors, the drug must be subject to further in vitro characterization before clinical trials, including “first in human” studies can begin.
148. To date, I am not aware that these results were ever submitted for publication. [Emphasis added.]

[99] He concluded:

150. To date, no adverse events have been reported with the use of 714-X since January 2004 in patients who have gained continued access to the drug in accordance with the January 2004 letter sent to physicians. This fact, combined with the ongoing and as yet unresolved legal challenges to the regulator’s decision making respecting 714-X, the SAP will continue to consider requests from physicians treating repeat patients for continued access to the drug until such time as the courts render a decision or the matter is otherwise settled. Practitioners will be notified of this position. [Emphasis added.]

[100] Finally, he explained how the SAP processed the request for access from Mr. Delisle’s physician in September 2004:

152. . . . The request was screened by a clerk and not by a reviewer using standard operating procedures for handling requests. Clerks make the first decision as to whether the request is complete which includes a judgment call about the completeness of answers to all questions and fields on the form. In my absence, the clerk made the decision that the word “documentation” was normally not something that we accept as a substantial answer to question 3 of the form. The request was not denied but returned to the physician with an accompanying note requesting clarification and additional information.
153. The word “documentation” does not provide any indication of what information Dr. Dagenais may have had in his possession at the time he filed the request. It was clearly appropriate and indeed the regulator was obliged to request further information and clarification with respect to the information and data that the physician had in his possession.
154. . . .
155. A request form that is returned to a physician specifically states the reason for the clarification and specifically states that the request will not be processed. It does not constitute a denial. A denial is a decision that is based on a review of all the facts

submitted, including any clarifications sought and leading to the issuance of a specific letter of denial.

156. Once a request is returned, we rely on the physician to consider the notice and to respond to our request for clarification or additional information accordingly. Ordinarily, we do not follow up with the physician directly.
157. In this case, I have no records or recollection of any attempt made by Dr. Dagenais to communicate with my office in response to our request for additional information. It was only after reading the additional affidavit of Mr. Delisle dated November 5, 2004 that it became apparent that the request for information sent by my office in September 2004 had been considered by Dr. Dagenais as a denial. Hence, in addition to the standard letter sent to Dr. Dagenais in December 2004, . . . it was decided that an additional paragraph be added to the letter seeking clarification as to whether Dr. Dagenais intended to pursue the request on behalf of the patient.
158. An additional request was filed by Dr. Dagenais on December 14, 2004, which included additional information on 714-X. . . . The request was authorized the following day and processed in the usual way. [Emphasis added.]

*B. Response to the November 1, 2004 affidavit from Laurent L g re*

[101] Mr. MacKay acknowledged that Laurent L g re used 714-X prior to the implementation of Health Canada's new policy and explained the processing of the request for access received from him in November 2003:

165. . . . at a time when a notice respecting continued access to 714-X through the SAP to physicians who had filed requests was pending final review by senior Health Canada officials and was scheduled for distribution in December 2003. Given the anticipated short time frames the name of the physician who had filed the request was added to the mailing list of physicians to receive a formal response.
166. I can confirm that the Dear Health Care Professional Letter dated January 19, 2004 was sent to, and according to our records, received by Dr. J. Taylor on January 21, 2004.
167. A new request was received on March 11, 2004 and was authorized on the same day since it was in compliance with the parameters set forth.
168. The SAP has received a number of other requests throughout the 2004 and I therefore conclude that Dr. Taylor has had access to 714-X for the treatment of Mr. L g re in accordance with the parameters set forth in the letter of January 19, 2004. [Emphasis added.]

[102] He admitted that there were a number of problems within the SAP in processing requests for access, that he hoped would be resolved “. . . through the development of a custom and state-of-the-art information management system that will change the way in which requests are received, processed, considered and decided upon.”

[103] His most telling acknowledgment of the SAP’s administrative problems was as follows:

170. . . . During this period, the number of requests grew from a few thousand to a peak of 33,000 in 2002. Innovations were realized during this period but the programme also had to contend with period of time when the amount of paper was very unpredictable and would overwhelm the ability of staff to appropriately and adequately manage requests effectively. As manager, I am confident that my staff does everything they can to manage the paper appropriately, but on occasion, requests are misplaced, go missing, are misfiled or for a variety of technological reasons, are never received. We regret these incidents but believe that under the current conditions a certain small percentage of errors is unavoidable. When they are brought to our attention, we endeavour to solve problems expeditiously.  
 . . .

*C. Response to the October 28, 2004 affidavit from Daniel Grandmont*

[104] This affidavit confirmed the following facts: the request for access submitted by Daniel Grandmont’s physician on August 20, 2003 was “processed by staff members in the usual way. The request was denied on August 26, 2003, citing the request did not contain sufficient information with respect to the use, safety and efficacy of the drug” [paragraph 165].

[105] A new request was submitted on December 22, 2003. “Given that a formal response to all outstanding requests was imminent,” his physician’s name was added on to the list of those who received the January 19, 2004 letter [emphasis added].

[106] On February 2, 2004, his doctor submitted a new request “which appeared to be the same request as was filed on December 22, 2003. Because the request was filed subsequent to the issuance of the January 19, 2004 letter, it was formerly processed and identified as a new patient and therefore denied. According to our records, the denial was sent on February 5, 2004” [emphasis added] [paragraph 169].

*D. Response to Dany Laforest’s affidavit*

[107] He acknowledged that a request for access was sent on February 19, 2004 “and appears to have been successfully sent from Dr. C. Fournier to the SAP. Despite an exhaustive search, I can confirm that we have no record of having received this request on or about the above date” [paragraph 165].

[108] He added: “I do not recall nor does my staff recall receiving a call from Dr. Fournier’s office following up on the said request. I can confirm that the Dear Health Care Professional Letter dated January 19, 2004 was sent to, and according to our records, received by Dr. Fournier’s office on January 20, 2004.”

## VIII. Analysis

### A. *The review standard*

[109] The review standard depends on four contextual factors: (1) the presence or absence in the statute of a privative clause or of a right to appeal; (2) the administrative body's expertise in comparison to the reviewing court on the issue in dispute; (3) the purpose of the act and of the specific provision; and (4) the type of issue — of law, of fact, or of mixed law and fact.

[110] In this case, the Act includes no privative clause and does not provide for a right to appeal the decisions. However, the judicial review of the Director's decision is provided for under section 18.1 of the *Federal Courts Act*.

[111] Health Canada undoubtedly has more expertise than the Court if the decision or the issue in dispute requires specialized knowledge or experience in a particular area, when it comes to assessing the safety or the effectiveness of a drug and the scientific credibility of the evidence. (See Madam Justice Layden-Stevenson's opinion in *Reddy-Cheminor Inc. v. Canada (Attorney general)*, 2003 FCT 542).

[112] The third factor is the general object of the statutory scheme within which the administrative decision-making is taking place. With respect to this factor, Madam Justice Layden-Stevenson in *Reddy-Cheminor Inc.*, *supra*, wrote:

¶ 55 . . . Parliament has legislated that persons suffering from particular ailments and relying on particular products to alleviate those ailments must be assured that their reliance is not misplaced: *Wrigley Canada v. Canada* (1999), 164 F.T.R. 283 (T.D.), aff'd. (2000), 256 N.R. 387 (F.C.A.). The intent of the Regulations is to provide a process for approval of new drugs to be marketed in Canada that is “. . . in the interest of, or for the prevention of injury to the health of the purchaser or consumer”: *Apotex 2*. Put another way, a drug manufacturer, under the scheme of the Regulations, must satisfy the Minister of the safety and effectiveness of a new drug before selling it in Canada: *Merck & Co. v. Canada (Attorney General)* (1999), 176 F.T.R. 21 (T.D.). The Regulations vest complete and exclusive discretion in the respondent Minister to determine the requirements of a new drug submission in terms of the information or evidence to be provided by the manufacturer. The discretion must be exercised on consideration of factors that are relevant to the purposes of the Act and Regulations: *Apotex 2*. In my view, the purpose of the FDA and the Regulations passed pursuant thereto applies to all submissions for new drugs whether in the form of a NDS or an ANDS. Regarding the polycentric characteristics, Blanchard J., in *Bristol-Myers Squibb Co. v. Canada (Attorney General)* (2002), 22 C.P.R. (4<sup>th</sup>) 345 (F.C.T.D.) stated:

The purpose of the notice of compliance provisions of the Food and Drug Regulations is to protect public health by assuring a certain level of safety and efficacy for drugs. As such, the decision that a new drug submission has satisfied the *Food and Drug Regulations* is a polycentric one, given that it involves the implementation of “social and economic policy in a broad sense”. [*Pfizer Canada Inc. v. Minister of National Health and Welfare et al.*, (1986) 12 C.P.R. (3d) 438 (F.C.A.)] [emphasis added].

[113] Because it creates an exception to the statutory scheme under the Regulations, it is important to analyze the provision relating to the SAP;

[114] In its Instructions for Making Special Access Requests, Health Canada stated that the SAP enables physicians who treat patients with serious or life-threatening conditions to have access to drugs unavailable on the market when conventional therapies have failed, are unsuitable, or unavailable.

[115] In another document, Health Canada acknowledged that access to drugs via the SAP is limited to patients with serious or life-threatening conditions for humanitarian or emergency reasons;

[116] In its report, the Standing Committee considered that the SAP's humanitarian element was important, as was the rapid development of a medication, and that access to a medication that has not proved itself required that no treatment be applied until after the analysis has shown [TRANSLATION] "an acceptable balance between efficacy and toxicity;"

[117] The fourth factor pertains to the nature of the problem. As

Madam Justice Layden-Stevenson stated in *Reddy-Chemicor Inc., supra*:

¶ 50 . . . When the finding being reviewed is one of pure fact, this factor will militate in favour of showing more deference towards the decision-maker's decision. An issue of pure law militates in favour of a more searching review. Regarding questions of mixed fact and law, this factor will call for more deference if the question is fact-intensive and less deference if it is law-intensive. [Emphasis added.]

[118] Madam Justice Layden-Stevenson's decision was appealed. The Federal Court of Appeal dismissed the appeal (see *Reddy-Cheminor, Inc. v. Canada (Attorney General)*, 2004 FCA 102).

I quote paragraphs 8 and 9 of Mr. Justice Evans' reasons:

¶ 8 Second, I agree with Laydon-Stevenson J. that the pragmatic and functional analysis indicates that the decision under review is entitled to a high degree of deference. The drug approval process is a complex and technical area of public administration with a direct impact on the health of Canadians. Determining whether two products contain "identical medicinal ingredients" requires scientific understanding and regulatory experience, rather than knowledge of the law or legal principles.

¶ 9 Third, like the Applications Judge, I am not persuaded that it was either patently unreasonable, or unreasonable simpliciter, for the Minister to conclude that only drugs comprising the same chemical entities contain "identical medicinal ingredients", even though the active ingredients of drugs may deliver the same chemical substance to the body with the same therapeutic effects. [Emphasis added].

[119] Applying these principles herein, I hold:

- (1) The applicants' alleged errors regarding the violation of the Charter, the decision-maker's want of jurisdiction, the relevant factors in the exercise of

discretionary power and the scope of this power, as well as a violation of procedural fairness based on a breach of legitimate expectancy, must be assessed in accordance with the standard of correctness.

- (2) As long as the decision challenged was based on an assessment of the evidence, the weighing of that evidence, or if it is alleged that that decision is based on an erroneous finding of fact, that decision is reviewable according to paragraph 18.1(4)(*d*) of the *Federal Courts Act*, which reads as follows:

18.1(4) The Federal Court may grant relief under subsection (3) if it is satisfied that the federal board, commission or other tribunal

...

(*d*) based its decision or order on an erroneous finding of fact that it made in a perverse or capricious manner or without regard for the material before it;

18.1(4) Les mesures prévues au paragraphe (3) sont prises si la Cour fédérale est convaincue que l'office fédéral, selon le cas :

[...]

*d*) a rendu une décision ou une ordonnance fondée sur une conclusion de fait erronée, tirée de façon abusive ou arbitraire ou sans tenir compte des éléments dont il dispose;

The standard under this section is the equivalent of the patently unreasonableness standard.

[120] When the applicants reproached Dr. Gillespie for having ruled out evidence on the effectiveness and safety of 714-X, this argument must be examined in view of the standard provided for in section 18.1(4)(*d*).

B. A few principles

1. Discretionary power

[121] In *Baker v. Canada*, [1999] 2 S.C.R. 817, Madam Justice L’Heureux-Dubé explained, at paragraph 52 of her reasons, the concept of discretionary power:

¶ 52 The concept of discretion refers to decisions where the law does not dictate a specific outcome, or where the decision-maker is given a choice of options within a statutorily imposed set of boundaries. As K. C. Davis wrote in *Discretionary Justice* (1969), at p. 4:

A public officer has discretion whenever the effective limits on his power leave him free to make a choice among possible courses of action or inaction.

It is necessary in this case to consider the approach to judicial review of administrative discretion [page 853], taking into account the “pragmatic and functional” approach to judicial review that was first articulated in *U.E.S., Local 298 v. Bibeault*, [1988] 2 S.C.R. 1048, and has been applied in subsequent cases including *Canada (Attorney General) v. Mossop*, [1993] 1 S.C.R. 554, at pp. 601-607, *per* L’Heureux-Dubé J., dissenting, but not on this issue; *Pezim v. British Columbia (Superintendent of Brokers)*, [1994] 2 S.C.R. 557; *Canada (Director of Investigation and Research) v. Southam Inc.*, [1997] 1 S.C.R. 748; and *Pushpanathan, supra*.

[122] Paragraph C.08.010(1) of the Regulations states that the “The Director may issue a letter of authorization authorizing the sale of a quantity of a new drug . . . ”

[123] As held by Mr. Justice McIntyre in *Maple Lodge Farms v. Government of Canada*, [1982] 2 S.C.R. 2, relying on the reasons of Mr. Justice Le Dain’s, who was then a member of the Federal Court of Appeal, section 28 of the *Interpretation Act* requires that the word “may” be interpreted as referring to an option, unless the context indicates otherwise.

[124] In *Maple Lodge Farms, supra*, the Supreme Court of Canada teaches us how the courts should construe statutes that grant a discretionary power, and it lists errors which warrant the quashing of a discretionary administrative decision. Mr. Justice McIntyre wrote as follows:

¶ 9 In construing statutes such as those under consideration in this appeal, which provide for far-reaching and frequently complicated administrative schemes, the judicial approach should be to endeavour within the scope of the legislation to give effect to its provisions so that the administrative agencies created may function effectively, as the legislation intended. In my view, in dealing with legislation of this nature, the courts should, wherever possible, avoid a narrow, technical construction, and endeavour to make effective the legislative intent as applied to the administrative scheme involved. It is, as well, a clearly-established rule that the courts should not interfere with the exercise of a discretion by a statutory authority merely because the court might have exercised the discretion in a different manner had it been charged with that responsibility. Where the statutory discretion has been exercised in good faith and, where required, in accordance with the principles of natural justice [page 8], and where reliance has not been placed upon considerations irrelevant or extraneous to the statutory purpose, the courts should not interfere. This approach has been followed by Le Dain J. and I accept and adopt his words, at p. 514, where, though he had earlier noted that the appellant's view of the policy guidelines was not unreasonable, he said: . . .

In the present case the Minister, acting through the Office of Special Import Policy, appears to have adopted, as the reason for refusing the supplementary import permits sought by the appellant, the considerations which are disclosed in the passages quoted above from the letters of the Agency to the appellant. These considerations relate to the quantity of eviscerated chicken available and the over-all requirements of the market. Having regard to the terms of section 5(1)(a.1) of the *Export and Import Permits Act* and the description or definition of the product in Item 19 of the Import Control List, the proclamation establishing the Agency, and the Canadian Chicken Marketing Quota Regulations, I am unable to conclude that these considerations are clearly extraneous or irrelevant to the statutory purpose for which chicken was placed on the Import Control List and to which the exercise of the Minister's discretion must be related.  
[Emphasis added.]

## 2. Guidelines

[125] It is obvious that, in January 2004, Health Canada established guidelines with regard to its discretionary power on access to 714-X through the SAP. Two classes were created: the old patients, those who had been treated with the product, and the new patients, those who had not been.

[126] Although administrative law acknowledges the usefulness of guidelines as to the exercise of discretionary power, it also sets forth its limits. I quote again from the reasons of

Mr. Justice McIntyre in *Maple Lodge, supra*:

¶ 8 It is clear, then, in my view, that the Minister has been accorded a discretion under s. 8 of the Act. The fact that the Minister in his policy guidelines issued in the Notice to Importers employed the words: "If Canadian product is not offered at the market price, a permit will normally be issued; . . ." does not fetter the exercise of that discretion. The discretion is given by the Statute and the formulation and adoption of general policy guidelines cannot confine it. There is nothing improper or unlawful for the Minister charged with responsibility for the administration of the general scheme provided for in the Act and Regulations to formulate and to state general requirements for the granting of import permits. It will be helpful to applicants [page 7] for permits to know in general terms what the policy and practice of the Minister will be. To give the guidelines the effect contended for by the appellant would be to elevate ministerial directions to the level of law and fetter the Minister in the exercise of his discretion. Le Dain J. dealt with this question at some length and said, at p. 513:

The Minister may validly and properly indicate the kind of considerations by which he will be guided as a general rule in the exercise of his discretion (see *British Oxygen Co. Ltd. v. Minister of Technology* [1971] A.C. (H.L.) 610; *Capital Cities Communications Inc. v. Canadian Radio-Television Commission* [1978] 2 S.C.R. 141, at pp. 169-171), but he cannot fetter his discretion by treating the guidelines as binding upon him and excluding other valid or relevant reasons for the exercise of his discretion (see *Re Hopedale Developments Ltd. and Town of Oakville* [1965] 1 O.R. 259).

In any case, the words employed in s. 8 do not necessarily fetter the discretion. The use of the expression "a permit will normally be issued" is by no means equivalent to the words "a permit will necessarily be issued". They impose no requirement for the issue of a permit. [Emphasis added.]

[127] However, according to the case law, if a guideline is set forth, (1) it must be based on criteria that are relevant to the exercise of discretionary power, that is to say, related to the object of the law (*Maple Lodge Farms Limited v. Government of Canada* [1981] F.C. and 500 (A.C.)) and (2) it must be in conformity with the enabling statute (*Ramsaroop v. University of Toronto* [2001] O.J. No. 2103);

[128] It is helpful to quote some excerpts from the reasons of Mr. Justice Doherty of the Court of Appeal for Ontario in *Ainsley Financial Corporation et al v. Ontario Securities Commission* [1994] 21 O.R. (3d) 104.

The authority of a regulator, like the Commission, to issue non-binding statements or guidelines intended to inform and guide those subject to Regulations is well established in Canada. The jurisprudence clearly recognizes that regulators may, as a matter of sound administrative practice, and without any specific statutory authority for doing so, issue guidelines and other non-binding instruments.

...

Non-statutory instruments, like guidelines, are not necessarily issued pursuant to any statutory grant of the power to issue such instruments. Rather, they are an administrative tool available to the regulator so that it can exercise its statutory authority and fulfil its regulatory mandate in a fairer, more open and more effective manner. While there may be considerable merit in providing for resort to non-statutory instruments in the regulator's enabling statute, such a provision is not a prerequisite for the use of those instruments by the regulator.

...

Having recognized the Commission's authority to use non-statutory instruments to fulfil its mandate, the limits on the use of those instruments must also be acknowledged. A non-statutory instrument can have no effect in the face of contradictory statutory provision or Regulations: *Capital Cities Communications Inc.*, *supra*, at p. 629; H. Janisch, "Reregulating the Regulator: Administrative Structure of Securities Commissions and Ministerial Responsibility" in *Special Lectures of the Law Society of Upper Canada: Securities Law in the Modern Financial Marketplace* (1989), at p. 107. Nor can a non-statutory instrument pre-empt the exercise of a regulator's discretion in a particular case: *Hopedale Developments Ltd.*, *supra*, at p. 263. Most importantly, for present purposes, a non-statutory instrument cannot impose mandatory requirements enforceable by sanction; that is, the regulator cannot issue de facto laws disguised as guidelines, Iacobucci J. put it this way in *Pezim* at p. 596:

However, it is important to note that the Commission's policy-making role is limited. By that I mean that their policies cannot be elevated to the status of law; they are not to be treated as legal pronouncements absent legal authority mandating such treatment.

(See also the judgment of the Court of Appeal of Saskatchewan in *Fairhaven Billiards Inc. v. Saskatchewan Liquor and Gaming Authority* [1999] No. 307 and Mr. Justice Blanchard's decision in *Thamotharan v. Canada (M.C.I.)* [2006] FC 16.)

### 3. *Limitations on the exercise of discretionary power*

[129] For over 40 years, administrative law has recognized that a discretionary power is not an absolute and untrammelled power. In *Roncarelli v. Duplessis*, [1959] S.C.R. 121, Mr. Justice Rand is of the opinion that “there is always a perspective within which a statute is intended to operate.”

[130] A discretionary power may not be used to achieve a goal opposed to the object of the law. Rather, its exercise must be based on considerations relevant to the object of the statute at issue. This exercise must promote the scheme, the underlying policy and the object of the law. Following is the analysis by Mr. Justice Binnie on this point in *Canadian Union of Public Employees, supra*:

¶ 93 The exercise of a discretion, stated Rand J. in *Roncarelli*, “is to be based upon a weighing of considerations pertinent to the object of the [statute’s] administration” (p. 140). Here, as in that case, it is alleged that the decision maker took into account irrelevant considerations (e.g., membership in the “class” of retired judges) and ignored pertinent considerations (e.g., relevant expertise and broad acceptability of a proposed chairperson in the labour relations community).

¶ 94 In this case, the “perspective within which a statute is intended to operate” is that of a legislative measure that seeks to achieve industrial peace by substituting compulsory arbitration for the right to strike or lockout. The “perspective” is another way of describing the policy and objects of the statute. In the language of Lord Reid in *Padfield v. Minister of Agriculture, Fisheries and Food*, [1968] A.C. 997 (H.L.), at p. 1030:

... if the Minister, by reason of his having misconstrued the Act or for any other reason, so uses his discretion as to thwart or run counter to the policy and objects of the Act, then our law would be very defective if persons

aggrieved were not entitled to the protection of the court. [Emphasis added.]

Lord Reid added that “the policy and objects of the Act must be determined by construing the Act as a whole and construction is always a matter of law for the court” (p. 1030). See also: *Air Canada v. British Columbia (Attorney General)*, [1986] 2 S.C.R. 539; *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817, at para. 56; *Mount Sinai Hospital Center v. Quebec (Minister of Health and Social Services)*, [2001] 2 S.C.R. 281, 2001 SCC 41; G. Pépin and Y. Ouellette, *Principes de contentieux administratif* (2<sup>nd</sup> ed. 1982), at p. 264; D.J.M. Brown and J. M. Evans, *Judicial Review of Administrative Action in Canada* (loose-leaf), at para. 13:1221. [Emphasis added.]

[131] However, Mr. Justice Binnie gives a word of caution:

¶ 107 The *HLDA* contemplates the appointment of “a person who is, in the opinion of the Minister, qualified to act.” The Minister is a senior member of the government with a vital interest in industrial peace in the province. His work in pursuit of that objective in the hospital sector, supported by his officials, should not be micro-managed by the courts. Still, as Rand J. said in *Roncarelli, supra*, at p. 140, the discretionary power is not “absolute and untrammelled.” The discretion is constrained by the scheme and object of the *HLDDA* as a whole, which the legislature intended to serve as a “neutral and credible” substitute for the right to strike and lockout.

#### 4. *Abuse of discretionary power*

[132] The Supreme Court of Canada further analyzed the concept of discretionary power in *Mount Sinai Health Center v. Quebec (Minister of Health and Social Services)*, [2001] 2 S.C.R. 281. In that case, the challenged decision was that of the Minister who denied the Health Center a modified permit to legalize hospital services it had been providing for several years and which the Quebec government was aware of.

[133] In Mr. Justice Binnie’s opinion, the issue was “whether the Minister’s decision was patently unreasonable in light of all the circumstances. This issue goes to the substance of the decision as opposed to the process by which it was reached.” [paragraph 52] [emphasis added].

[134] The concept of abuse of discretionary power originated in English administrative law.

Mr. Justice Binnie stated:

¶ 53 I mentioned earlier the “abuse of discretion” exception to the customary deference paid to ministerial decision making as noted by Dickson J. in *Martineau v. Matsqui*, *supra*, and reported by Sopinka J. in *Reference re Canada Assistance Plan*, *supra*. Their concern was with procedural fairness. However, the English courts have long extended “abuse of discretion” to substantive decision making which they call “Wednesbury unreasonableness” after *Associated Provincial Picture Houses, Ltd. v. Wednesbury Corp.*, [1948] 1 K.B. 223 (C.A.). The *Wednesbury* case was cited with approval in *Baker v. Canada*, *supra*, at para. 53. See generally H. W. MacLauchlan, “Transforming Administrative Law: The Didactic Role of the Supreme Court of Canada” (2001), 80 Can. Bar Rev. 281, at p. 285 et seq. ¶

[135] Referring again to *Baker v. Canada*, *supra*, Mr. Justice Binnie explained why he rejected some developments under English law:

¶ 60 Resort to the doctrine of “unreasonableness” to test the validity of substantive decisions was elaborated in *Baker v. Canada*, *supra*, at para. 53:

A general doctrine of “unreasonableness” has also sometimes been applied to discretionary decisions: *Associated Provincial Picture Houses, Ltd. v. Wednesbury Corporation*, [1948] 1 K.B. 223 (C.A.). In my opinion, these doctrines incorporate two central ideas – that discretionary decisions, like all other administrative decisions, must be made within the bounds of the jurisdiction conferred by the statute, but that considerable deference will be given to decision-makers by courts in reviewing the exercise of that discretion and determining the scope of the decision-maker’s jurisdiction.

¶ 61 *Baker v. Canada* went on to hold that the Minister and immigration officials had given insufficient weight to the impact of the decision on Ms. Baker and her Canadian-born children. This is part of the traditional *Wednesbury* test, as pointed out in *Coughlan*, *supra*, where Lord Woolf M.R. noted, at para. 58, that the test under *Wednesbury* “will be rationality and whether the public body has given proper weight to the implications of not fulfilling the promise” [emphasis added]. He went to say at para. 81: “We would prefer to regard the *Wednesbury* categories themselves as the major instances (not necessarily the sole ones) . . . of how public power may be misused.” On that basis he subsumed “unreasonableness” into the global English concept of administrative unfairness.

¶ 62 Where Canadian law parts company with the developing English law is the assertion, which lies at the heart of the *Coughlan* treatment of substantive fairness, of the centrality of the judicial role in regulating government policy. In *Coughlan*, it is said, at para. 76, that the decision to withhold substantive relief under the doctrine of legitimate expectation can only be justified if there is an overriding public interest. Whether there is an overriding public interest is a question for the court. [Emphasis added.]

¶ 63 In Canada, at least to date, the courts have taken the view that it is generally the Minister who determines whether the public interest overrides or not. The courts will intervene only if it is established that the Minister’s decision is patently

unreasonable in the sense of irrational or perverse or (in language adopted in *Coughlan*, at para. 72) “so gratuitous and oppressive that no reasonable person could think [it] justified.” This high requirement is met here where the unreasonableness, as in *Baker v. Canada*, turns on the singular lack of recognition of the serious consequences the Minister’s sudden reversal of position inflicted on the [page 318] respondents who were caught in the transition between the old policy (50 short-term care beds are in the public interest) and the new policy (50 short-term care beds must be coupled to enhanced diagnostic and treatment facilities). [Emphasis added.]

## IX. Discussion and conclusions

### A. *Discretionary or non-discretionary power*

[136] No doubt that sections C.08.010 and C.08.011 of the Regulations grant the Director a discretionary power to authorize or not the sale of a new drug;

[137] As Madam Justice L’Heureux-Dubé noted in *Baker, supra*, the concept of discretion refers to decisions where the law does not dictate a specific outcome, or where the decision-maker is given a choice of options within a statutorily imposed set of boundaries;

[138] The language and structure of the provision, the selection of the word “may,” the nature of the power – exempted from the requirements of the Regulations – and the purpose of the power, based partly on humanitarian considerations, demonstrate an intention to give the Director much leeway in granting, or not, a request for access to a new drug for the emergency treatment of a patient;

[139] In this case, my colleague Madam Justice Tremblay-Lamer ruled on an application from Léopold Delisle seeking an interlocutory order whereby the respondent was to grant the special access requests for 714-X submitted by physicians without any further requirements and conditions, and within 24 hours of receiving said requests without distinction, whether or not the patients had already received such an authorization. My colleague refused to make the order for several reasons (see *Delisle v. The Attorney General of Canada et al.*, 2004 FC 788).

[140] In her opinion, the use of the word “may” at paragraph C.08.010(1) of the Regulations vested the Director General with a discretionary power to issue, or not, a letter of authorization for the sale of a new drug via the SAP. She wrote:

¶ 12 Thus, section 8.010 of the Regulations creates a discretionary authority, and not an obligation, to issue authorizations for special access. In the case at bar, the applicant is asking that the Court order the respondents to issue authorizations for special access. It is obvious that the relief sought by the applicant is a *mandamus*. But the case law on this point is well established. The Court may, in the context of an application for *mandamus*, order the performance of a public duty but it cannot dictate the appropriate result when the authority conferred by the enabling provision is discretionary (*Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742 (F.C.A.), *aff'd* [1994] 3 S.C.R. 1100; see, to the same effect, *Martinoff v. Canada*, [1994] 2 F.C. 33 (C.A.); *Kahlon v. Canada (Minister of Employment and Immigration)*, [1986] 3 F.C. 386 (C.A.)). [Emphasis added.]

[141] She added:

¶ 14 Finally, this Court cannot order the respondents to accept requests for access to 714-X “[TRANSLATION] without further requirements or conditions”. Such an order would be illegal, since it would be in violation of the provisions of the Regulations, which stipulate certain conditions that must be met by a physician requesting access before the Director General can exercise his discretion. [Emphasis added.]

[142] I concur with these reasons;

B. *Want of jurisdiction*

[143] In reply, the applicants' counsel correctly downplayed his argument that the January 23, 2004 decision was invalid because it was taken by Dr. Gillespie, who did not qualify as Director General under sections C.08.010 and C.08.011, that define the Director as "the Assistant Deputy Minister, Health Products and Food Branch, of the Department of Health."

[144] In this case, on August 14, 1989, Albert Joseph Liston, Assistant Deputy Minister, authorized certain persons "who may, from time to time, occupy the following positions within the Bureau of Human Prescription Drugs, Drugs Directorate . . . to sign on my behalf any letters of authorization issued pursuant to section C.08.010 of the *Food and Drug Regulations*."

[145] Two of the officials mentioned in the delegation of authority are the Director of the Bureau of Human Prescription Drugs and the Emergency Drug Coordination within the Bureau. The parties acknowledge that the Bureau of Human Prescription Drugs, Drug Directorate, has become the Senior Medical Advisor Bureau, which Dr. Gillespie heads, and the Emergency Drug Coordination is the one responsible for the Emergency Drug Release Program, which is now the SAP, and which Mr. MacKay heads.

[146] The Canadian doctrine and case law make it clear that the maxim *delegatus non potest delegare* is not a rule of law, but simply a rule of interpretation which, unless there is a provision to the contrary, authorizing a judge to conclude, from the nature of the powers assigned, as well

as from the history and the spirit of the Act, that there may be an implied delegation or subdelegation of discretionary power (see *Peralta v. Ontario*, [1988] 2 R.C.S. 1045, confirming the judgment of the Ontario Court of Appeal (1985), 16 D.L.R. (4<sup>th</sup>) 259, and the work of Professor Garant, *Droit administratif*, 5<sup>e</sup> ed. 2004, Editions Yvon Blais, at pages 219 and 220.)

[147] I also quote from the Supreme Court of Canada judgment, *The Queen v. Harrison*, [1977] 1 S.C.R. 238, at page 245:

Thus, where the exercise of a discretionary power is entrusted to a Minister of the Crown it may be presumed that the acts will be performed, not by the Minister in person, but by responsible officials in his department: *Carltona, Ltd. v. Commissioners of Works* . . . The tasks of a Minister of the Crown in modern times are so many and varied that it is unreasonable to expect them to be performed personally. It is to be supposed that the Minister will select deputies and departmental officials of experience and competence, and that such appointees, for whose conduct the Minister is accountable to the Legislature, will act on behalf of the Minister [page 246], within the bounds of their respective grants of authority, in the discharge of ministerial responsibilities. Any other approach would but lead to administrative chaos and ineffectiveness. It is true that in the present case there is no evidence that the Attorney General of British Columbia personally instructed Mr. McDiarmid to act on his behalf in appealing judgments or verdicts of acquittal of trial courts but it is reasonable to assume the "Director, Criminal Law" of the Province would have that authority to instruct.

[148] In *Ahmad v. Public Service Commission*, [1974] 2 F.C. 644, at page 651, the Federal Court of Appeal confirmed the principles of *Carltona Ltd. v. Commissioners of Works*, [1943] 2 All E.R. 560 (C.A.).

[149] In my opinion, in 1989, Mr. Liston was empowered to sub-delegate the administrative discretionary power to authorize access to the Emergency Drug Release Program, now called the SAP, and of which Dr. Gillespie and Mr. MacKay became the delegated officers. Admittedly, as administrator of the SAP, Mr. MacKay is heading a team. The evidence, however, shows that his subordinates in this case did not make the final decisions with respect to the applicants on access

to the SAP and that their intervention was limited to ensuring that the requests were in accordance with the administrative requirements. Furthermore, management of the SAP is subject to written administrative procedures (Standard Operating Procedures);

[150] With respect to the processing of each of the applicants' request for access, the evidence shows that the decisions for or against access were made either by Dr. Gillespie or Mr. MacKay;

C. *Excess of jurisdiction*

[151] The applicants deny that the SAP may require from physicians further information regarding the safety and effectiveness of 714-X. In their opinion, subparagraph C.08.010(1)(a)(iii) of the Regulations should be construed according to its plain meaning, that is, the data to be provided is [TRANSLATION] “the data in the possession of the physician [emphasis added] with respect to the use, safety and efficacy of that drug.”

[152] This is an argument without merit. It rules out the construction recognized in *Barrie Utilities, supra*. It completely ignores subparagraph C.08.010(1)9(a)(iv) of the Regulations, which provides that physicians must submit to the Director General “such other data as the Director may require.” The words “other data” may not be limited, as the applicants submit, to data other than use, safety and effectiveness, which are limited under subparagraph (ii) to data “in the possession of the practitioner.” Nothing in those provisions suggests such restrictions, that would, on the other hand, deviate from the object of the Act, which is to ensure the

protection of the health of Canadians by banning the sale of medication whose safety and effectiveness are not proven. Furthermore, such a construction of the Regulations would bar the exercise of discretionary power assigned to the SAP's administrators by limiting the documentation required to make an informed decision.

D. *Legitimate expectation*

[153] The applicants' legitimate expectation argument is two-fold:

- (1) the SAP's failure to comply with its promise that requests for access would be processed within 24 hours; and
- (2) after having approved authorization requests for 714-X in accordance with the regulations for more than fifteen years, the SAP created a legitimate expectation that it had to abide by with respect to the litigants, whether these were the patients or the referring physicians, who relied on this product as an alternative to ineffective treatments. The applicants submitted that the administration could not deny access to 714-X without new, concrete data leading to the conclusion that the product was toxic. They submit that Health Canada's position is that it has no evidence that 714-X is effective in treating various cancers. The applicants respond that Health Canada has no evidence that the product is ineffective. In these circumstances, Health Canada was absolutely not justified in withdrawing 714-X from the SAP.

[154] I cannot accept the applicants' arguments. The SAP's guidelines do not guarantee that each request for access shall be processed within 24 hours of receipt. The SAP's guidelines acknowledge that further information may be required during the review process and simply stated that "[E]very effort is made to process requests within 24 hours . . ." The guidelines also mention a number of factors in the SAP's mandate that could impede its efforts.

[155] At paragraph 32 in *Mount Sinai Hospital Center v. Quebec (Minister of Health and Social Services)*, *supra*, Mr. Justice Binnie stated that the scope of the doctrine of legitimate expectation "was shut only against substantive relief" and, at paragraph 29, that "the expectations must not conflict with the public authority's statutory remit."

[156] In my opinion, the application of the doctrine of legitimate expectation, as proposed by the applicants, would provide substantive, and not procedural, relief, notwithstanding the considerable efforts deployed by the applicants' attorney in attempting to persuade me that the legal basis of the disputed decision was substantive, that is, the evidence rules.

E. *The reasonableness of the January 23, 2004 decision*

[157] The applicants challenge the quality of the evidence required by Health Canada. They submit that this evidence is the type of evidence required for licensing, which is inappropriate with respect to the SAP.

[158] I must reject that argument. During his cross-examination, Mr. MacKay clearly indicated that the level of evidence required to persuade the SAP to issue a letter of authorization is much lower than what is required to obtain a notice of compliance, but that evidence of effectiveness and safety was not considered unacceptable. As he stated:

I'm describing here the discretion, that you don't need to back up a truck, but you need something, and what you send us has to be credible information to support the emergency use of that product within the context of the physician's request. Page 92 So you know when we're talking about emergencies here, we're talking about emergencies and we're talking about levels of evidence, we're not talking about truck loads we're talking about plausible basis that would be generally supported within the scientific and medical community, and in the context of emergency, that threshold no one would expect to be ridiculously high, but nevertheless, there is a threshold.

[159] That position is highly reasonable when construing the provisions of the SAP in light of the overall framework of the Regulations and of the legislative intent, at subsection C.08.010(1)(a)(ii), regarding the effectiveness, use and safety of a medication accessible through the SAP;

[160] The applicants' submissions on the assessment of the evidence are without merit.

[161] At paragraph 85 in *Canadian Union of Public Employees, Local 301 v. Montreal (City)* (1997) 1 S.C.R. 793, at page 844, the Supreme Court of Canada stated as follows:

85 We must remember that the standard of review on the factual findings of an administrative tribunal is an extremely deferent one: *Ross v. New Brunswick School District No. 15*, [1996] 1 S.C.R. 825, per La Forest J., at pp. 849 and 852. Courts must not revisit the facts or weigh the evidence. Only where the evidence viewed reasonably is incapable of supporting the tribunal's findings will a fact finding be patently unreasonable. An example is the allegation in this case, viz. that there is no evidence at all for a significant element of the tribunal's decision: see *Toronto Board of Education, supra*, at para. 48, per Cory J.; *Lester, supra*, at p. 669, per McLachlin J.. Such a determination may well be made without an in-depth examination of the record: *National Corn Growers Assn. v. Canada (Import Tribunal)*, [1990] 2 S.C.R. 1324, per Gonthier J., at p. 1370.

F. *Unreasonable delay*

[162] Laurent Légère complains that the SAP did not grant him access to the SAP within a reasonable time. It appears that Dany Laforest was still awaiting a decision when she filed her application for judicial review;

[163] In Laurent Légère's case, there was a delay due to what the SAP considered insufficient information in his request;

[164] The Federal Court of Appeal in *Apotex Inc. v. Canada* [1994] 1 FC 742 ruled that the Regulations vest Health Canada with the discretionary and exclusive power to set forth the conditions relating to the information and evidence required from the manufacturer when introducing new drugs;

[165] Because, in this case, the delay was caused by the applicant, there was no unreasonable delay;

[166] As to Dany Laforest, Mr. MacKay, upon cross-examination, acknowledged that her physician had submitted a request for access in early 2004. He also admitted that, from time to time, requests had been lost. Based on the balance of probabilities, my opinion is that Dany Laforest's request for access was lost by the SAP;

G. The January 23, 2004 public policy

[167] The public policy on 714-X announced by Dr. Gillespie is, in fact, a set of guidelines relating to the SAP's exercise of discretionary power.

[168] The case law is clear on such guidelines:

(a) they are a unique tool, as the decision-maker announces, by and large, the type of considerations which will guide him in exercising this power;

(b) however, the decision-maker may not impede the exercise of his discretion by considering this statement of policies as compulsory or binding, to the exclusion of all other valid or relevant reasons why he exercises his decision power.

[169] In this case, what prompted the SAP to restrict access to the 714-X product was the lack of reliable evidence on its effectiveness and safety.

[170] The SAP officials concluded that, with respect to 714-X, the SAP had become a mechanism used by the manufacturer to circumvent the general requirements of the Regulations.

[171] Such considerations, in my opinion, are not unrelated to the reasons why the SAP was created.

[172] But the analysis must go further. The issue is to determine whether the guidelines set out on January 23, 2004 unduly fettered the discretionary power granted to the SAP through the Regulations. In other words, was the January 23, 2004 policy mandatory? In my opinion, it was and, consequently, it is invalid for the following reasons:

[173] Firstly, the SAP was created in an attempt to strike a balance between access to medication that has not yet proven itself and humanitarian reasons in the case of an illness for which the conventional treatments were ineffective or inadequate. In my opinion, the January 23, 2004 public policy does not reflect the balance sought by Parliament, because it does not take into consideration humanitarian or compassionate concerns.

[174] Secondly, the public policy requires a clinical trial for 714-X before any discretionary power may be exercised.

[175] Thirdly, with regard to new patients, the access door, for all intents and purposes, is shut. All requests for access on hold for new patients were denied on January 23, 2004 because they had not been treated with 714-X. The humanitarian factor was not taken into account.

[176] Fourthly, the same fate awaits the old patients at the end of the interim period.

[177] My finding is not harmful for Health Canada and the SAP. It simply requires a weighing of the valid objectives of the public policy against the humanitarian factor.

[178] In these circumstances, there is no need to consider the argument relating to the Charter.

[179] I hereby order that these reasons be filed in files T-698-04, T-2138-04, T-2139-04 and T-2140-04.

“Francois Lemieux”

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Judge

Certified true translation  
François Brunet, LLB, BCL

**FEDERAL COURT**

**SOLICITORS OF RECORD**

**DOCKETS:** T-698-04, T-2138-04, T-2139-04, T-2140-04

**STYLE OF CAUSES:** LÉOPOLD DELISLE *ET. AL.*  
v.  
PGC *ET. AL.*

**PLACE OF HEARING:** Montréal, Quebec

**DATE OF HEARING:** July 4 and 5, 2005

**REASONS FOR ORDER BY:** The Honourable Mr. Justice Lemieux

**DATED:** July 28, 2006

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