



# Centre expérimental de recherches biologiques de l'Estrie inc. (1974)

**GASTON NAESSENS**

President-Founder, Chairman  
Scientific Director

October 19<sup>th</sup>, 2006

## **Re: The Federal Court gives possibility to Canadian patients to access 714X through the Special Access Program (SAP)**

Dear Doctor,

Thanks for taking time to read this letter. You are receiving this document because you have obtained 714X in the past for one or more of your patients through the *Emergency Drug Program* (now called *the Special Access Program: SAP*).

Recent events have persuaded me to write you directly.

I am Gaston Naessens, the director of CERBE inc., a private laboratory that manufactures 714X (*Trimethylaminohydroxybicycloheptane Chloride*).

You will find attached my résumé (*Schedule 1a*) and a brief presentation of CERBE Inc. with the core values of our organisation in *Schedule 1b*.

Last July 28<sup>th</sup>, Mr. Justice François Lemieux of the Federal Court of Canada granted a request for judicial review undertaken by a group of 714X patients. The complete text of the judgment is available at the following address: [www.coalition-nationale-714x.com](http://www.coalition-nationale-714x.com).

**The judgment voids Health Canada's policy statement issued on or about January 19, 2004** (referred in the judgment as the "January 23, 2004 decision", *see Schedule 2*).

Paragraphs 172, 173, 174, 175, 176 and 177 of the judgment summarize Mr. Justice Lemieux's reasons for judgment (*see Schedule 3*).

Allow me to underline that I was never a part of the said lawsuit, even though I was asked to submit an affidavit in the file by the applicants' attorneys in January 2004 (*see Schedule 4*).

**That being said, several points raised in the Federal Court judgment by representatives of Health Canada concern me directly, either as the manufacturer of 714X, as a research biologist or simply as an individual.**

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Here are some comments related to questions, allegations and even certain ambiguities raised by Health Canada's representatives in the Federal Court Judgment.

## **My Comments as Manufacturer**

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I will first remind you that the *Special Access Programme* (SAP), formerly the *Emergency Drug Release Program*, finds its origin in the Canadian Food and Drug Act (in particular, sections C.08.010 and C.08.011 of the Regulations). A description published by Health Canada is supplied in *Schedule 5*. 714X was first introduced into this nationwide emergency program on December 19, 1989 (*see Schedule 6*).

Some 17 years later, Health Canada has authorized **21,096 courses** of 714X at the request of **1,498 Canadian doctors**, from all provinces, for the use of **4,039 patients** meeting the SAP's criteria. Statistics on the use of 714X under the SAP are found in *Schedule 7*.

According to this number of courses, to this day, **443,016 injections** have been authorized (at the rate of 21 injections per course). It is to be noted that, during all these years of use, **not one single report of an adverse event has been reported** to the manufacturer or even testified to before the Court by representatives of Health Canada or their attorneys. I recall that the injection protocol has been tested and provides a high level of safety and effectiveness if performed as recommended: not otherwise.

Let us review an essential element of the SAP as published by Health Canada in their document entitled "Special Access Programme (SAP) – Instructions for Making a Special Access Request" (*Schedule 5*):

"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. 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.**"

In this case, where more than 21,094 courses of 714X have been duly authorized by Health Canada **without any adverse event reports**, one must admit that, at the very least, the last 17 years show **the non-toxic nature of the product**.

As the manufacturer of the product, I can confirm the non-toxic nature of 714X because **it was intentionally designed to support the biological terrain**. Clinical observations from doctors having used 714X, in Canada or elsewhere, confirm this fact.

Results from animal toxicity tests conducted in 1978 by an independent laboratory also confirmed the non-toxic nature of 714X (*see Schedule 8*). (At that time, this test was requested by Mr. Fernand Séguin, on my behalf, in order to protect my anonymity.)

In some medical legal analysis performed in USA and in France, the non toxic nature of 714X was also reported.

Finally, over the years, several other independent laboratories (including high profile university laboratories) have also confirmed the non-toxic nature of 714X.

**As regards to the sterility of the product**, Health Canada conducted its own tests in 1990. You will find in *Schedule 9* the letter signed by the Federal Minister of Health at the time, Mr. Perrin Beatty, confirming the sterility of the product when 714X was first admitted to the Emergency Drug Release Program. This question is of extreme importance for you doctors to guarantee that the product you recommend for your patients is sterile.

Of course, the manufacturing methods insuring the sterility of the product have been maintained since 1990. To this day, I can confirm that 714X is manufactured and bottled in modern laboratories, equipped with state-of-the-art technology. A manufacturer's minimum professional ethics require that a sterile product be produced, and this I can confirm it.

As a manufacturer, I also want to underline the importance that **I attach to full compliance with the injection protocol proposed for 714X** (*see Schedule 10*). Application of this protocol, performed as described, is essential to insure optimal effectiveness of the product and it presents absolutely no risk. The educational material produced to support the patients have been done with professionals to make sure that all the steps of the procedure are fully explained.

Preparatory asepsis procedures and those related to the injection and the elimination of waste material are clearly indicated. They allow us to insure, both for the patients and their environment, complete respect of conventional hygiene standards.

**As the manufacturer of 714X, I strongly encourage self-injection (when conditions permit, of course). I consider it as the ultimate means for an individual to take charge of his or her quest for better health known as "empowerment". This is how 714X have been used since 1989, and I insist on this point to maintain the patient in a pro-active attitude.**

In 714X's technical data sheet, I warn patients against the simultaneous use of vitamin E and B-12 as well as all anti-angiogenic products with 714X. Here is the reason why: from my research work, I observed that these vitamin supplements, in high dosage (and not those minimal quantities found in food), can delay the optimal effects of the product. Here are the reasons for such precautions.

Vitamin B-12 accelerates cell division (especially erythrocytes) and it can also accelerate the multiplication of anarchic cells. Vitamin E can create a small protective coating on the somatidian forms thus delaying their elimination in the blood circulation. Anti-angiogenic products (such as shark, bovine or other cartilages) by their constricting action on the blood stream, can conflict with 714X's effect which attempts to liquefy the lymph.

**These preventive notices I indicate as the manufacturer flow from the very nature of the product, its particular mode of action as well as its intromission mode into the lymphatic circulation (large and small lymphatic circulation).**

## **My Comments as Research Biologist**

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You have undoubtedly understood that 714X's uniqueness emanates from a completely different vision of human biology. This view is based on the existence of a small living particle in human blood, discovered in the 1950's, and that I have named "somatid". You can find at *Schedule 11* the Somatidian cycle in blood.

The living nature of this particle observed in the blood using optical microscopy was confirmed in November 2003, at the University of Montreal when replication of my work was done in a cellular biology laboratory at the Medicine Faculty.

Contrary to Health Canada's allegations dealing with the somatidian theory (that they qualify as 'non-orthodox'), I am no longer the only person who has observed the somatids. I may not travel the conventional road, but I do act in a step-by-step way, in a process that is most respectful of Science's fundamental principles.

I also note that my laboratory, CERBE inc., has been accredited as a private research institution under the Income Tax Act since 1997. Since that date, I have regularly submitted research and development work dealing with human blood and microscopy that have all been accepted.

In conclusion, 714X is a health product that acts on the somatidian cycle to reestablish the biological terrain's homeostasis, therefore acting on the causes of biological disturbances and not only on suppression of symptoms.

### **My Comments as an Individual**

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Over the last 17 years, I have tried on **several occasions** to establish a harmonious dialogue with Health Canada.

From 1989 to 1992, I have provided the product for free of charge (I even paid the shipping fees!) hoping to received results from the use of this product (as required by law). However, data have never been obtained from Health Canada.

At the end of 1994, after 5 years experience under the Emergency Drug Release Program, I asked for a meeting with agents of Health Canada (Emergency Drug Release Program). At that time, Health Canada's civil servants responded that they were not there to compile data nor statistics, and they refused to meet me.

In 2001, after obtaining interesting results following "immuno-assay" tests conducted on 714X by the Dana-Farber Cancer Institute in Boston, Health Canada again refused to meet me. At that time, Dr. Arthur Pardee, an eminent molecular biology researcher, had scientifically confirmed all the potential of 714X without knowing its content or its provenance (*see Schedule 12*). Never was I able to discuss intelligently about the Somatidian theory with Health Canada.

Once again, in December 2004, at the express request of Dr. Brian Gillespie, the doctor responsible for the SAP, I supplied new explanations on the evolving 714X file (in the United States and elsewhere). Unfortunately, this undertaking led nowhere and the meeting solicited at that time never occurred (see Schedule 13).

I must admit that after multiple efforts to establish an harmonious line of communication with agents of Health Canada, after 17 years, it is still non-existent.

## Conclusion

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714X will soon be 30 years old. For that occasion, I am preparing a document that will synthesize the scientific path undertaken since 1949 (either in microscopy or haematology) which path led to the filing of the Somatidian Theory before the *Académie des Sciences de Paris* in 1963.

The document will gather in one text all relevant evidence countering Health Canada's unfounded allegations suggesting that I have done nothing over the last several years and that I act without any development plan. Quite to the contrary, I have followed, for well over 50 years, a very precise and rigorous development plan.

At 82 years old, I continue to work with great pleasure and determination, with the firm intention of helping people.

You will understand that several steps were necessary to conceive 714X as it stands today.

I first had to fabricate a microscope and study live blood for several years. Following that, I confirmed the existence of the somatid, I isolated it, cultured it to authenticate its living nature and then established its cycle. Finally, I was able to fine tune non-toxic health products capable of acting on the somatidian cycle, 714X being the last born of these products.

Based on the experience I have gathered over the last 17 years relating to Health Canada's lack of overture to innovative and non-toxic products such as 714X, **it would serve no purpose at this time to undertake a conventional homologation process.**

From my understanding of these rules, it is impossible for 714X to be approved according to the existing rules. This situation is true for 714X and also for several other products. The actual homologation process must be thoroughly reviewed from top to bottom, above all the resistance of the guardians of the *statu quo*.

**Who** at Health Canada will be my "peer" in its investigation? **Who** at Health Canada (or at its American equivalent, the FDA) will approve 714X while at the same time ignoring or not understanding the Somatidian Theory which forms the underpinning of 714X? **Who**, in these regulatory agencies will have enough courage to greet new ways of addressing the origin of disease? These questions remain without any answers for now.

I conclude hoping that you will remember, in the light of Mr. Justice François Lemieux's July 28<sup>th</sup> judgment, **that compassion must characterize the SAP** and that 714X will remain accessible and available to Canadians, for new patients as well as ancient patients.

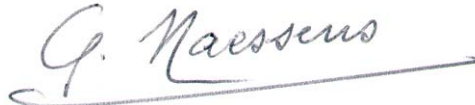
**From this moment onward, all attempts by Health Canada to "diplomatically discourage" Canadian doctors from using 714X for their patients can be considered disrespectful of the judgment.**

Here is an extract from an article published in the peer-reviewed journal *The Lancet* which perfectly reflects my thoughts at this point of my life: (*Schedule 14*)

« We have become used to the idea that innovation is slow and expensive and must be surrounded by elaborate controls at every point to prevent possible unethical behaviour toward people or animals. We have also become used to the idea that improvements will be marginal, as in cancer or cardiovascular disease, and therefore that everything must be done on a sufficiently large scale to ensure that small advances will not be missed. The structures of government and institutional controls have ensured that the effort required to get something done has become enormous, and costs have increased extraordinarily. **Those who do try to forge clinical innovation are repeatedly made to feel as though they are in some way immoral.**»

Again, I thank you for taking the time to read this letter, to better understand the issues encompassing 714X and, I remain available to answer your questions.

Please receive, Dear Doctor, my most sincere regards.

A handwritten signature in cursive script that reads "G. Naessens". The signature is written in black ink and is positioned above a horizontal line that extends to the right.

Gaston Naessens

GN/bc

Enclosures

## SCHEDULES

- 1a. Gaston Naessens' résumé
- 1b. The Naessens Group and its core values
2. Health Canada policy issued on or about January 19, 2004
3. Federal Court judgment (July 28, 2006)
4. Lauzon Bélanger, S.E.N.C. (January 26, 2004)
5. SAP description as published by Health Canada
6. First authorizations issued by Health Canada (December 19, 1989)
7. Statistics (from 1989 to September 30, 2006)
8. Research report done by Bio Research Laboratories (September 18, 1978)
9. Letter signed by Mr. Perrin Beatty, Health Canada (January 25, 1990)
10. How to administer 714X
11. Somatidian cycle as seen in blood
12. Letter signed by Dr. Arthur Pardee (August 9, 1999)
13. Letter signed by Dr. Brian Gillespie (December 1<sup>st</sup> 2004) and our December 9, 2004 response
14. The Lancet article signed by D. Horrobin: "*Effective clinical innovation: an ethical imperative*"