

T-698-04

COUR FÉDÉRALE

BETWEEN:

LÉOPOLD DELISLE

Plaintiff

-and-

LE PROCUREUR GÉNÉRAL DU CANADA

-and-

MINISTÈRE DE LA SANTÉ
(SANTÉ CANADA)

-and-

DIRECTEUR GÉNÉRAL
DIRECTION DES PRODUITS THÉRAPEUTIQUES (SANTÉ CANADA)

Defendants

T-2138-04

COUR FÉDÉRALE

BETWEEN:

DANY LAFOREST

Plaintiff

-and-

LE PROCUREUR GÉNÉRAL DU CANADA

-and-

MINISTÈRE DE LA SANTÉ
(SANTÉ CANADA)

-and-

DIRECTEUR GÉNÉRAL
DIRECTION DES PRODUITS THÉRAPEUTIQUES (SANTÉ CANADA)

Defendants

February 1, 2005

EVA WARSZAWSKI
Official Court Reporter

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T-2139-04

COUR FÉDÉRALE

BETWEEN :

LAURENT LÉGÈRE

Plaintiff

-and-

LE PROCUREUR GÉNÉRAL DU CANADA

-and-

MINISTÈRE DE LA SANTÉ
(SANTÉ CANADA)

-and-

DIRECTEUR GÉNÉRAL
DIRECTION DES PRODUITS THÉRAPEUTIQUES (SANTÉ CANADA)

Defendants

T-2140-04

COUR FÉDÉRALE

BETWEEN :

DANIEL GRANDMONT

Plaintiff

-and-

LE PROCUREUR GÉNÉRAL DU CANADA

-and-

MINISTÈRE DE LA SANTÉ
(SANTÉ CANADA)

-and-

DIRECTEUR GÉNÉRAL
DIRECTION DES PRODUITS THÉRAPEUTIQUES (SANTÉ CANADA)

Defendants

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CROSS-EXAMINATION ON AFFIDAVIT
DEPOSITION OF IAN MACKAY

APPEARANCES:

Me Michel Bélanger,
Me Jean-Sylvain Pelletier
Counsel for Plaintiffs

Me Carmela Maiorino,
Me André Lespérance,
Counsel for Defendants

February 1, 2005

EVA WARSZAWSKI
Official Court Reporter

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A. Mm-hmm?	
Q. [607] ... and submits some information he has about the product...	
A. Correct.	
Q. [608] ... and that he is granted the authorization to, his patient is granted the authorization to received the product, and after two (2) months, for instance, he comes with another request, because the period is lapsed, does he have to submit always the same data to get the same, the same positive answer?	172

- Q. [635] So you don't consider at all that some information could have been applied to similar cases in the future?
- A. No, we, as I mentioned before, and I underscore the fact that each request is...
- Q. [636] From scratch everything?
- A. Yes, yes, yes, definitely. I acknowledge, it is the source of frustration, not just with 714-X, with other physicians as well; however...
- Q. [637] It's not only frustration, I think it's...
- A. I, the...
- Q. [638] ... a strange way to manage...
- A. ... the regulations are clear...
- Q. [639] ... to say the least.
- Q. [640] ... the regulations are clear with respect to... 179

- Q. [641] Regarding 714, did you have any word to say on the cost of the product, how much the product was sold from the manufacturer to the client? 180

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- Q. [649] Okay, I was speaking with the physician of Léopold Delisle, the Plaintiff, Applicant. If his physician requests access to the 714 for Mr. Delisle, filling the form, always the same way, submitting the data, always the same data, will his physician be granted at every request the access to the product for his client? 183
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- Q. [691] Okay. How many vacations a year, how many weeks a year do you, do you leave the office, vacation time? 193
- Q. [776] No, actually, my question was: If the answer is not given in a very short delay, we're talking about very short delay here, twenty-four (24) hours, this is your target...
- A. Mm-hmm?
- Q. [777] ... if the answer is given in longer delay, what may be the cause, not the cause, what may be the consequence for the patient? 216
- Q. [842] Within the typical categories. And roughly would you say that, what is the percentage, actually, of drugs in the SAP that enters into the A), B), C) category, typical? 236
- Q. [855] We've mentioned before, and it's stated in your affidavit several times, that 714 entered the programme in nineteen eighty-nine (1989). At that time did, are you aware if Health Canada provided, or done a survey or some kind of research on

the safety of the product...

Me CARMELA MAIORINO:

I'll have to object...

Me JEAN-SYLVAIN PELLETIER:

Q. [856] ... and on the efficiency of the product, did they do some kind of survey anyway? 240

Q. [877] But would any new information from the manufacturer be pertinent and of interest for you to manage the product? . . 245

Q. [956] So. Do you know a researcher by the name of xxxxxxxxxxxxxxxxx, does that sound familiar to you?

A. No.

Q. [957] Do you know:
"Département de Pathologie et de Biologie Cellulaire, Faculté de Médecine, Université de Montréal."? . 266

Q. [967] It talks about la théorie somatidienne...

A. I understand that, yes.

Q. [968] ... I'm referring to Gaston Naessens as being the author of this theory. I would ask you to go to page 12, please, and eventually it may be appropriate, indeed, to get a translation. "Conclusion," if you may look at paragraph 3:

A. Yes.

Q. [969] ...
"Ces particules sont des éléments acceptés par la communauté scientifique. Elles ont été rapportées par un très grand nombre de groupes scientifiques et on s'accorde à leur attribuer des rôles physiologiques importants."

And a little above it's stated, the paragraph above, above the word "conclusion":

"Pour cela les investigations devraient être encouragés afin d'établir leurs caractéristiques et leur pertinence biologique in vivo. Quelle que soit la nature des phénomènes faisant intervenir les

microparticules en tant que marqueurs
ou participants, il est primordial de
poursuivre leurs études."
And I refer to paragraph, last paragraph of
page 11... 272

My questions were asked already, the
witness answered, and the point is simply
to deposit this document as evidence,
regarding the...
Me CARMELA MAIORINO:
Oh, you're seeking to file this into
evidence...
Me JEAN-SYLVAIN PELLETIER:
Absolutely.
Me CARMELA MAIORINO:
... for the judicial review application?
Me JEAN-SYLVAIN PELLETIER:
Sure, sure. 278



February 1, 2005

IAN MACKAY
Examination
Me Pelletier

- 14 -

In the year two thousand and five (2005), on this first (1st) day of February, PERSONALLY CAME AND APPEARED:

IAN MACKAY, born on October twenty-second (22nd), nineteen sixty-four (1964), domiciled and residing at sixteen (16) Ivy Crescent, Ottawa, Ontario, K1M 1Y2;

WHOM, after having been duly sworn to make a solemn affirmation, doth depose and say as follows:

EXAMINED BY Me JEAN-SYLVAIN PELLETIER
COUNSEL FOR PLAINTIFFS:

Q. [1] So just to specify my intervention today, I'm making this session on request of Maître Bélanger who feels his English, even though it's fair, he believes that his client would be best served by someone who humbly has a better knowledge of English language, which is me. So I've been involved in the case for only a few days, the case is rather complex, and lots of documents were filed by each party, so I believe that you'll be able to answer my questions

according to that premise. So if you have your affidavit...

A. I do.

Q. [2] ... before you...

Me CARMELA MAIORINO:

Sorry to interrupt, but before we begin I'd like, for the record, just to have my request on record of exclusion of witnesses for this cross-examination of Mr. Mackay.

Me JEAN-SYLVAIN PELLETIER:

Go ahead.

Me CARMELA MAIORINO:

My request is that...

Me JEAN-SYLVAIN PELLETIER:

That is?

Me CARMELA MAIORINO:

... the content of Mr. Mackay's deposition today not be disclosed and be confidential until the filing of the transcripts.

Me MICHEL BÉLANGER:

No, until you decide if you...

Me CARMELA MAIORINO:

Until, until the...

Me MICHEL BÉLANGER:

Jusqu'à temps que vous décidiez si vous

interrogez ou pas Monsieur Naessens auquel cas je verrai si je m'objecterai pas à la possibilité d'interroger à ce moment là, o.k.?

Me CARMELA MAIORINO:

Oui, ça revient à la même chose.

Me JEAN-SYLVAIN PELLETIER:

Okay?

Me CARMELA MAIORINO:

Go ahead.

Me JEAN-SYLVAIN PELLETIER:

That's all?

Me CARMELA MAIORINO:

Yes.

Me JEAN-SYLVAIN PELLETIER:

Thank you.

Q. [3] So, Mr. Mackay, you have your affidavit...

A. I do.

Q. [4] ... that you have signed, actually, it's the second affidavit, it's the amended affidavit, right, that you have signed on the thirteenth (13th) of January of this year?

A. That is what I have in front of me, correct.

Q. [5] Okay, so the questions will be based on this affidavit. So, Mr. Mackay, I understand that the Special Access Programme, that we'll be

calling SAP...

A. Yes?

Q. [6] ... exists since nineteen eighty-nine (1989); I'm correct?

A. No.

Q. [7] When did it start?

A. The regulatory amendment, which gives the authority to issue authorizations, was an amendment to the Food & Drugs Act in nineteen sixty-six (1966). The programme itself...

Q. [8] Nineteen sixty-six (1966)?

A. Nineteen sixty-six (1966), yes.

Q. [9] That created the SAP?

A. That created the authority which underpinned the actual operational programme, which has been called a number of things through the years, but the authority has remained the same since nineteen sixty-six (1966).

Q. [10] But am I right when I say that the actual programme as it is today, was created, indeed, in nineteen eighty-nine (1989), and at that time, I believe the name was EDRP, as stated in section 7 of your affidavit, Emergency Drug Release Programme?

A. Yes, that is the, the name of the programme was,

in nineteen eighty-nine (1989), was the
Emergency Drug Release Programme...

Q. [11] Right.

A. ... the Special Access Programme was a change in
name, which happened on or about nineteen
ninety-six (1996).

Q. [12] Okay. So you say that the SAP, let's call
it SAP...

A. Yes.

Q. [13] ... for the matter of the questions...

A. Right.

Q. [14] ... the SAP programme was created in, with
concrete effects, applicable effects, in
nineteen sixty-six (1966); is that what you're
saying?

A. Obviously I wasn't around at the time, but the
authority to provide special authorization under
special circumstances, as it exist in
legislation, was put in place in nineteen sixty-
six (1996). The programme has been run
organizationally in different ways, obviously,
for the last thirty (30) or forty (40) years,
and I'm only familiar with the time, of course,
since I've been working, since nineteen ninety-
two (1992).

- Q. [15] Okay, and when was the 714-X, because we're dealing here with a product called 714-X, when was that product included in the SAP programme? You understand when I say SAP, I mean I'm talking about the programme...
- A. I understand, yes, I understand.
- Q. [16] ... no matter what the name is actually, okay?
- A. I understand, I understand. The, I think in my affidavit I refer to this in...
- Q. [17] May I suggest paragraph 190?
- A. No, I would, I would suggest paragraph 100. The first release of 714-X, through the, what is now known as the SAP, was in nineteen eighty-nine (1989).
- Q. [18] Okay, okay, it's the same as 190 actually, first sentence...
- A. Sure, okay, I'll, I'll...
- Q. [19] ... remains the same.
- A. ... may I look at it just to be...
- Q. [20] That's fine.
- A. Correct.
- Q. [21] Okay. Now, can you give me information about the, briefly, in few sentence, if you can, what is the aim of the programme SAP?

A. The Special Access Programme has a mandate through the authority of the Food & Drugs Act and regulation, to provide emergency access to drugs which are not approved in Canada, provided the physician has undertaken and provided us with certain information, and after a consideration by the Special Access Programme, an authorization may be, may be granted. There are obligations which go along with the authorization, both on the part of the, of the physician involved, and responsibilities on the part of SAP, in terms of receipt of reports, and we have the authority to request accounting for quantities received and used. I have a, you asked me in two (2) or three (3) sentences, there is, of course, a large section of my affidavit which refers to the mandate and scope, and all the details of how the programme is organized, and managed, and operated.

Q. [22] There's a word that comes back sometimes in your affidavit, it's "compassion;" am I right?

A. I don't use it a whole lot, it's, I would have to go through it...

Q. [23] But that word is linked to SAP programme, isn't it?

- A. Not in regulation, no.
- Q. [24] Not in -- actually, regulation, when you refer to that, you refer to section C-08010 and C-08011; am I right?
- A. That's correct.
- Q. [25] And this is the only regulation concerning SAP programme?
- A. It is.
- Q. [26] When I say SAP programme maybe I'm redundant.
- A. I understand, yes. No, no, I understand, it's the authority...
- Q. [27] It's...
- A. ... it's the authority which underpins the programme, yes.
- Q. [28] That is it, there's no more authority on that in terms of regulation?
- A. That's correct.
- Q. [29] Okay. But in terms of the aims and the why's of the SAP, I recall reading in some documentation, I can look at it if you want to, but, anyway, there's a concept that comes back sometimes, which is compassion.
- A. Mm-hmm.
- Q. [30] Isn't compassion actually the, one of the

issue involved in the goal of the SAP programme?

- A. Well, the goal of the programme stems from the legislation. That word has been used in the past, but, of course, it does not stem from regulation, it is...
- Q. [31] Obviously not.
- A. Yes, but the word has been used in the past, but the word also is an emotionally charged word, and it has been excluded from any official documentation for the last little, for the last little bit. It was something, I think, that grew out of, I think, the organization of the programme, and, to a certain extent, much of the work that we undertake involves dealing with very sick patients, etc., and some people could interpret that as assisting, with assisting patients in providing access, some people could interpret that as compassion, yes. However, the word "compassion" can mean different things to different people.
- Q. [32] Right, but is a common sense, definition of compassion, a common sense, understanding of compassion, that's what I meant, compassion in the sense to help people, to...
- A. In its basic form, yes, yes.

- Q. [33] ... to intervene in all possible ways to give them a hand in whatever problem, health problem they could have?
- A. Again, I think that it's a, I think it's a definition that could mean different things to different people.
- Q. [34] Now, you say that you're unit head, in paragraph 2:...
- A. Yes.
- Q. [35] ...
"I am the unit head of Special Access Unit, clinical trials in Special Access Programme."
- A. That's correct.
- Q. [36] For how long have you been unit head?
- A. I've been unit head since...
- Q. [37] You refer, maybe you can look at your affidavit, your...
- A. I'm just look, I'm just looking, I should...
- Q. [38] ... curriculum vitae.
- A. Thank you.
- Q. [39] Maybe it would, it would appear there, I don't recall actually.
- A. Just want to be sure. I think I need to go back to my other... yes, from two thousand (2000).

Q. [40] Two thousand (2000), right.

A. Yes.

Q. [41] Now, you have deposited in evidence a document emitted by the sub-minister, I believe, confirm the authority, the Delegation of Authority, that's your annex B...

A. Yes.

Q. [42] ... in your, of your affidavit.

A. Yes.

Q. [43] You have that before you?

A. I do.

Q. [44] Just as a clarification, from A to H are different people that are allowed to sign on behalf of the deputy minister the letter of authorization. Paragraph A, the director; who's the director, are you the one?

A. I'm sorry, paragraph?

Q. [45] Paragraph A in the list.

A. Oh, A.

Q. [46] Yes, director.

A. The director?

Q. [47] Yes, who's the director, isn't it Mr. Gillespie?

A. Dr. Gillespie is the director of the Senior Medical Advisor Bureau, correct.

- Q. [48] Okay, and I understand actually from all the information you gave, that you are, in paragraph C, emergency drug coordinator; right?
- A. That's correct, it's the, this term is no longer used, the term that's now used organizationally is unit head, but the, but the position remains the same.
- Q. [49] Do you know if the Delegation of Authority was changed from nineteen eighty-nine (1989) up to today?
- A. I do not believe it has been.
- Q. [50] Now, I understand from your curriculum vitae, that you deposited as annex A, that you're not a physician?
- A. I'm not a physician.
- Q. [51] Now, in the regulation 010, we'll try to be a little concise, and 010, we're talking about new drug...
- A. Yes.
- Q. [52] ... programme is specifically, addresses specifically to new drug?
- A. Yes.
- Q. [53] Is there a definition in the law or on the regulation of new drug?
- A. Yes, there is.

- Q. [54] Where do you find that, do you know?
- A. I don't have the regulations in front of me, but new drugs is a particular section, division 8, I believe, off the regulations, refers to new drug, and in the beginning part of the preamble part of that division new drug is defined.
- Q. [55] In the 010 we're talking about the notion of the word "emergency."
- A. Correct.
- Q. [56] Is that, is that word defined somewhere in the law or regulation?
- A. I do not believe it is, but I'd have to, I'd have to acquaint myself with the regulations again, the definitions, but I don't believe it is.
- Q. [57] So would you like to inquire and come back to me on that, or your position today is that there's no definition of emergency?
- A. My recollection is that there is no definition for emergency in the regulations, but I would have to check, and I guess we can do that?
- Me CARMELA MAIORINO:
Sure.
- THE WITNESS:
- A. To double-check if it's in there.

Me JEAN-SYLVAIN PELLETIER:

Okay, so it'll be...

Me CARMELA MAIORINO:

That's undertaking...

Me JEAN-SYLVAIN PELLETIER:

... undertaking number 1?

Me CARMELA MAIORINO:

Right.

Me JEAN-SYLVAIN PELLETIER:

Roughly, what about a ten (10) day delay, is that...

Me CARMELA MAIORINO:

Yes, that's fine.

Me JEAN-SYLVAIN PELLETIER:

... sufficient? We're not talking about...

Me CARMELA MAIORINO:

Well...?

THE WITNESS:

A. Oh, yes, I...

Me JEAN-SYLVAIN PELLETIER:

Q. [58] ... you know, ten (10), roughly ten (10) days, okay?

A. No, that could be looked after quite quickly.

UNDERTAKING NO. 1: To verify if there is
a definition of
"emergency," re: C-
08010

Me JEAN-SYLVAIN PELLETIER:

Q. [59] Now, pertaining to annex B that we looked a few minutes ago, there's only one (1) director, Mr. Gillespie, or there are several directors?

A. If you're referring to this document, this document is referring specifically to the following positions found within the Bureau of Human Prescription Drugs, and at the time there was one (1) director.

Q. [60] What about today?

A. There are, the Bureau of Human Prescription Drugs was, it changed names in around nineteen ninety-five (1995), to the Bureau of Pharmaceutical Assessment, a change in name only, and there remained one (1) director, and, subsequently, the divisions that were contained, you can see these divisions identified in D through H...

Q. [61] Mm-hmm.

A. ... these divisions essentially have remained

the same, but they've been elevated organizationally to become bureau, and so there are now, there are now, under D and H, people who were formally chiefs, if you will, had become directors of bureau, but it is, it is, it's part of an organizational change within the Therapeutics Products Directorate, which was the Drugs Directorate...

Q. [62] But who is the, who is the main director, is there a main director?

A. There is a Director General of the Drugs Directorate, and...

Q. [63] That is paragraph A, Mr. Gillespie?

A. No, of the, the Drugs Directorate, and I apologize, these are organizational changes which are common in government, and they're hard to keep track of, but the Drugs Directorate became the Therapeutic Products Directorate, change in name.

Q. [64] But who is the director listed in paragraph A.

A. The director, the...

Q. [65] You mention Mr. Gillespie.

A. Dr. Gillespie is the director of the bureau, which most closely resembles in name the Bureau

of Human Prescription Drugs.

Q. [66] So what you're saying is that, if you refer only to the description of paragraph A, you can't say to me who is the director that this paragraph A refers to; am I correct?

A. The Delegation of Authority specifies the Bureau of Human Prescription Drugs, and that, as an organizational entity in name, does not exist any more, neither does the Drugs Directorate in name...

Q. [67] I understand that, but I'm talking about the people listed from A to H. You mentioned that the chief listed from D to H...

A. Yes?

Q. [68] ... have become directors now.

A. That's correct.

Q. [69] Are those people the directors...

A. Essentially, they're...

Q. [70] ... that we talk about in paragraph A?

A. I'm sorry, I missed that last question.

Q. [71] Are they, are the ex-chiefs that became director...

A. Yes?

Q. [72] ... the director that we speak about on paragraph A?

- A. No, these, the chiefs who essentially became directors, would become, would have become equivalent, i.e., colleagues of the director referred to in A. So five (5) people were promoted, and one (1) person was not promoted, if you will.
- Q. [73] Okay, and in terms of Emergency Drug Coordinator, paragraph C...
- A. That has not change.
- Q. [74] ... there's only one (1), and it's you, from...
- A. Yes, that's correct, it has changed in name, but that has remained the same.
- Q. [75] ... from two thousand (2000) up to today?
- A. No, it remains as of the date of this Delegation of Authority, the position and the functions of the Emergency Drug Coordinator are the same in nineteen eighty-nine (1989) as they are today. While there were other organizational changes, as I described, the SAP has remained as an entity.
- Q. [76] You are right, it's quite complex, and I'm not sure I'm following totally your point, but actually I'll skip the point, and I'll go to another question.

- A. In paragraph 7 the programme changed name from Emergency Drug Release Programme to Special Access Programme?
- A. Correct.
- Q. [77] In nineteen ninety-six (1996) it was only a change of name; right? All other aspects didn't change?
- A. Yes, the actual operations and functions remained the same. There was a, there was a movement and a consolidation of personnel that were operating the same programme in a sister Directorate, and it was placed under one (1) roof, but the functions, the telephone numbers and operations did not change, and it was at that time that the, that the, there was a change in name, and the change in name was necessary for a number of different reasons: 1) There were some other priorities within the branch in terms of naming, etc., but there was also the issue of, everything we were dealing with weren't necessarily drugs, we were dealing with blood products, etc., so we wanted to get rid of the word "drug" to more appropriately capture all the products that we were dealing with.
- Q. [78] I understand. Paragraph 4 of your

affidavit you state that:

"Since nineteen ninety-eight (1998) I have been responsible for managing the Special Access Programme, that devise, that receive, process, and considers requests from physicians seeking special access to a variety of new drugs."

A. Correct.

Q. [79] Do you have a list in your data files about those new drugs, variety of new drugs, from nineteen eighty-nine (1989) up to today?

A. From nineteen eighty-nine (1989)?

Q. [80] Yes?

A. There, we have a historical database of the drugs that are currently release, and that have been released through the programme, for as long as we've been keeping computer records which dates back to, into approximately nineteen eighty, excuse me, nineteen eighty-eight (1988) to nineteen ninety-nine (1999).

Q. [81] Okay, so you would have, you would have that list from nineteen eighty-nine (1989) up to today?

A. That list exists, that's correct.

- Q. [82] Okay, would that list also, it would, it would state the time that this specific product was accepted in the SAP, and also the time where this specific drug was excluded, or withdrawn, or ceased to be applicable under the SAP, do you have that information also?
- A. The list which exists details the first release of the drug.
- Q. [83] Right.
- A. We are careful, we try our best, it's difficult organizationally, but we try our best not to talk about the word "accept" the drug on the programme...
- Q. [84] Whatever...
- A. Right.
- Q. [85] ... whatever term that may be appearing there.
- A. So we would have records of the first release...
- Q. [86] Right.
- A. ... of the drug, and the last release of the drug. There are various reasons why drugs go off the programme, and so the last date of the authorization could reflect, could connect to a note in our database, which talks about the reasons why it is no longer available.

Q. [87] Okay, undertaking number 2?

Me CARMELA MAIORINO:

First of all, I'd like to object under reserve for the request of the production of such documents because the, Mr. Mackay nor myself did not receive a request to produce documents during this cross-examination in accordance with Rule 91 of the rules, whereby we should have received a request to receive documents, to produce documents, so I'll have to object under reserve, and...

Me JEAN-SYLVAIN PELLETIER:

Do you have Rule 91 that I can just briefly take a look at it?

(OFF THE RECORD DISCUSSION)

Me JEAN-SYLVAIN PELLETIER:

Okay, so we briefly discussed the different information that could be available, under objection of my consoeur. So I'm coming back to this idea of submitting a database that we discussed previously, referring to the transaction concerning all drugs that were accepted under SAP from nineteen eighty-nine (1989) up to today. That's undertaking number 2 under reserve.

A. Now, you refer to...

Me CARMELA MAIORINO:

Under reserve of the objection.

Me JEAN-SYLVAIN PELLETIER:

Yes.

A. ... refer to drugs or transaction? Transaction refers to an individual authorization, or denial for that matter...

Q. [88] You have both, you have both database?

A. I understood the question that you asked me is whether or not we had a records of the transactions, which...

Q. [89] First of all, records of the drugs.

A. Yes, we do.

Q. [90] You do have that?

A. Yes.

Q. [91] Okay, so that would be undertaking number 2.

UNDERTAKING NO. 2: To provide the database showing the transactions concerning all drugs that were accepted under SAP from 1989 up

to today (under
reserve of objection)

Me JEAN-SYLVAIN PELLETIER:

Q. [92] And undertaking 3 would be, also under
objection, I believe...

Me CARMELA MAIORINO:

Right.

Me JEAN-SYLVAIN PELLETIER:

Q. [93] ... the, all the releases of those drugs
that would be another database, right, there's
another, a second database that you have?

A. Yes, it's a related but separate, separate
database, yes.

Q. [94] So undertaking number 3.

Me CARMELA MAIORINO:

And, for the record, I'm objecting to both based
on Rule 91, and also as to relevance, cause
you're seeking information as to all drugs and
not just on the 14-X.

UNDERTAKING NO. 3:

To provide a second
database showing all
the releases of all
drugs that were

accepted under SAP
from 1989 up to today
(under reserve of
objection)

Me JEAN-SYLVAIN PELLETIER:

Q. [95] Just referring to section, annex number B, as we discussed, the Delegation of Authority, can you tell me today how many people -- if you can't say it today maybe it'll be an undertaking -- how many people today can sign that letter of authorization that is described in the Delegation of Authority of nineteen eighty-nine (1989)?

Me CARMELA MAIORINO:

Can you, please, clarify your question?

Me JEAN-SYLVAIN PELLETIER:

Q. [96] How many people, there are eight (8) different titles that are listed, can you tell me how many people physically, concretely, are listed to those eight (8) descriptions?

Me CARMELA MAIORINO:

I'll have to object, perhaps you can limit your line of questioning to what pertains to the, to Mr. Mackay's role, who is the unit head of the

SAP. I don't see how he can be able to answer as to how many people can sign a Delegation, are encompassed in a Delegation of Authority and Programmes other than his own.

Me JEAN-SYLVAIN PELLETIER:

I think it's important to have an overview of the SAP Programme, and eventually we'll be going, because that's his perspective also that I'm following in his affidavit, a broad perspective at first, and then we'll focus eventually on the 714.

Me CARMELA MAIORINO:

I agree that it's very important to have an understanding of SAP Programme, but the SAP Programme is encompassed in part C of that Delegation of Authority, and not in the other subsections of that Delegation of Authority, so we'll object under reserve.

Me JEAN-SYLVAIN PELLETIER:

Okay, so I'll restrict my question to 714.

Q. [97] How many people in that list had the authority to sign a letter of authorization regarding the 714 product?

A. Well, I'm not a, I'm not an expert in Delegations of Authority, I do know that my

title is contained in that, or my job is contained in that, and that operationally, on a daily basis, I am the only person who authorizes or considers requests under the regulations, operationally speaking. You're talking about practical or physically, I am the only, I am the only person who undertakes that work at the present time.

Q. [98] So regarding 714, you're the only person that the Delegation of Authority is used for?

A. Operationally, I am the person who considers all requests that come in to the programme.

Q. [99] Since two thousand (2000)?

A. Well, I think I was doing it before then, but I became officially the head in two thousand (2000), I think my affidavit reflects that, but I had been doing that, I think in paragraph 4, since nineteen eighty-nine (1989) on an acting basis, nineteen ninety-eight (1998), excuse me, on an acting basis.

Q. [100] In paragraph 10 you talk about:

"The review conducted by the Bureau of Senior Medical Advisor."

Is that review deposited in your evidence?

Me CARMELA MAIORINO:

I'm sorry, paragraph...?

Me JEAN-SYLVAIN PELLETIER:

Ten (10).

A. Yes, the refer, the review referred to in paragraph 10 was the so-called Garber review was conducted...

Q. [101] Is it, is it deposited...

A. Yes.

Q. [102] ... is it part of your evidence...

A. Yes.

Q. [103] ... can you refer me specifically to which annex?

Me CARMELA MAIORINO:

For purposes of accelerating this, I have...

Me JEAN-SYLVAIN PELLETIER:

You do have?

Me CARMELA MAIORINO:

Yes, so in the interest to help the...

Me JEAN-SYLVAIN PELLETIER:

Well, if you have the answer, go ahead, I'll be please to...

Me CARMELA MAIORINO:

... can I just show it to the, to Mr. Mackay?

Me JEAN-SYLVAIN PELLETTIER:

Sure, absolutely, absolutely, go ahead.

Me CARMELA MAIORINO:

I'm showing him Exhibit M, and is this the review you're referring to?

Me JEAN-SYLVAIN PELLETTIER:

Feel comfortable to feed him.

Q. [104] Is it, so...?

A. It is Exhibit M to my, the original affidavit.

Q. [105] And in the amended affidavit they haven't changed, it's the same document as M?

Me CARMELA MAIORINO:

Yes.

Me JEAN-SYLVAIN PELLETTIER:

Q. [106] Right?

A. Cross-references back to the original, yes.

Q. [107] So you're referring to the memorandum of January eight (8) that was amended in the January two thousand four (2004), amended January twenty-third (23rd)?

A. That's correct.

Q. [108] That's it.

A. Okay. I should note at this time that there is a, I know there was some question about the two (2) dates. There was an organizational problem

with the appendices of the original January eighth (8th), that the author, Dr. Garber, corrected on January twenty-third (23rd), so the substance of the memorandum remained the same, but the organization of the, of the appendices changed slightly, I think it was the order, with the order of them, so it's important to note that, cause there was, there were two (2) dates, there was a revised, but the actual date of the January eighth (8th) was the, was the date, and the substance contained therein was used to undertake the, to finalize the letter, which eventually was issued to physicians in the latter part of January.

Q. [109] In paragraph 10 you say:

"As explained herein, it has been determined, taking account of the review conducted..."

Etc.

A. Mm-hmm.

Q. [110] Who is "it," who is that, is that you, specifically, personally, exclusively, or some other people?

A. I don't believe "it" is referring to a person, it's referring to the issue at hand, I don't

believe it's, I'm not referring to anyone, anyone in particular, I'm not referring to myself.

Q. [111] So who determined actually, if I put my question differently?

A. It was, paragraph 10 refers to a review that was undertaken by the Bureau of the Senior Medical Advisor, and...

Q. [112] I understand that, my question is: You say:

"It has been determined..."

A. Yes?

Q. [113] Who determined?

A. Dr. Brian Garber, as the appendix or the exhibit we just described, undertook that review, and Dr. Garber is a senior physician and risk manager within the Senior Medical Advisor Bureau.

Q. [114] So if I understand, Dr. Garber did the review, and also determined the rest of the paragraph; right:

"That unless sufficient evidence to support the emergency use of 714-X was provided by a physician,..."

Etc.

- A. Yes, he...
- Q. [115] So Garber did the review, and did also the determination?
- A. Dr. Garber made a number of recommendations, I'd have to familiarize myself with them again. That would be... Dr. Garber undertook the review for the purposes of reviewing the literature available, and the evidence, the scientific evidence available, which, about 714-X, and this memo then was considered by a number of people, including senior advisors within the Therapeutic Products Directorate, including Dr. Gillespie...
- Q. [116] And you?
- A. ... and myself.
- Q. [117] You were involved, yes?
- A. Yes, and there were others that would have been familiar with the, with the report as well, including Dr. Robert Peterson, who is the Director General of the Therapeutic Products Directorate.
- Q. [118] And the rest of paragraph 10 states that:
"It has determined taking into 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"

Right?

A. Mm-hmm.

Q. [119] Is this notion of:

"... sufficient evidence to support the emergency use of 714-X..."

appears in the law or the regulation at all?

A. C-010 speaks to the obligation of the physician who is requesting access to a particular drug, to provide data respecting the use, safety, and efficacy of the product as part of their application. Data respecting use, safety, and efficacy essentially is scientific evidence to support their decision to prescribe the drug.

Q. [120] That is your interpretation, isn't it?

A. Hmm...

Q. [121] Because the regulation doesn't state that.

A. The regulation states that the physician must provide data respecting the use, safety, and efficacy of the drug.

Q. [122] Mm-hmm, mm-hmm.

A. And as part of our discretionary authority, it

is incumbent upon us to ensure that that evidence is credible, and is sufficient for us to make a decision to authorize the drug.

Q. [123] And you apply this discretion in two thousand four (2004)?

A. We apply that discretion every day.

Q. [124] But referring to this paragraph 10, to determine that:

"Unless sufficient evidence to support the emergency use of 714-X was provided by a physician, access... should be limited"

That decision, that discretion was made in two thousand four (2004); am I correct?

A. No, this paragraph 10 describes the circumstance that we undertook a review to determine what was out there, there were a number of, there were, we knew there were, there was information that was being supplied to us, and we had questions about the volume of that information, the credibility of that information, and we then, Dr. Garber was asked to review this information, in terms of its volume and its credibility, to support the use of it in various indications for which the drug had been requested. This

paragraph was, is part of the overview, but it basically describes the circumstance where we said that we're not aware of any large body of data, credible data, that would ordinarily support the emergency use of a drug.

Q. [125] Where's that, is that an obligation in the SAP?

A. The physician is obligated to provide data respecting the use, safety, and efficacy, of that, of the drug that's being requested.

Q. [126] Did you ask the physician to supply that information?

A. Yes, the request form which physicians fill out, has that, has a specific question that's asked in that regard.

Q. [127] Okay, did you make a follow-up on those questions, on that specific question, I mean?

Me CARMELA MAIORINO:

Can you, please, clarify your question, did you...?

Me JEAN-SYLVAIN PELLETIER:

Q. [128] About the data that the physicians submit.

A. If you're talking about general terms, do we follow up, or you're talking about specific instances, or...

- Q. [129] Well, I'm talking about the data that you say that the physician was supposed to submit.
- A. Right.
- Q. [130] Did you make the follow-up on that, regarding 714?
- A. Requests that come to us, it's the obligation of the physician to supply us with information.
- Q. [131] Did they, indeed, supply information?
- A. Some provided information, that's correct, yes.
- Q. [132] What do you mean some, half of them, a third?
- A. I wouldn't, I wouldn't be able to recollect that.
- Q. [133] Would you be able to find the answer as an undertaking?
- A. Of information that was provided to, by us?
- Me CARMELA MAIORINO:
I'll have to object, it's a very, very wide question in terms of time frame. Are you referring to specific cases, are you referring to all SAP requests that were filed?
- Me JEAN-SYLVAIN PELLETIER:
No, no, I'm talking about 714.
- Me CARMELA MAIORINO:
All SAP requests...

Me JEAN-SYLVAIN PELLETIER:

We are, we are dealing specifically with 714.

Me CARMELA MAIORINO:

... for 714-X since nineteen eighty-nine (1989),
that's what you want to know?

Me JEAN-SYLVAIN PELLETIER:

Yes.

A. No, we would not have that, ready access to that
information.

Q. [134] Do you, do you keep files of the data that
are submitted by physicians under the 714
programme?

A. Seven fourteen (714) programme...

Q. [135] No, 714 access in the programme of SAP.

A. Requests that come to us are, come to us
generally by fax, and...

Q. [136] I'm talking about the data.

A. Yes?

Q. [137] Do you keep track of the data that are
submitted by physicians?

A. Physicians normally answer question 3.

Q. [138] We're talking about 714, right, let's...

A. I understand, yes, I understand, I understand.

Q. [139] ... let's stick to that only.

A. Yes, if you're referring to the requests in

general, physicians are obligated to provide us with that information. They do so by answering what we call question number 3, if you will, on our form...

Q. [140] Okay, so I'll repeat for the third time my question.

A. Yes.

Q. [141] Do you keep track of the information, the data that are submitted by the physicians in the SAP for 714?

A. Yes, and we do so in two (2) ways.

Q. [142] You do have that, do you have a database on that though?

A. No, we do not have a data, we do not have an electronic database, no.

Q. [143] Do you have a physical database?

A. We have historical records, naturally, on...

Q. [144] That means paper, paper type of...

A. That's correct.

Q. [145] Do you have a record of those information that are in that database?

A. A record of information...

Q. [146] A résumé?

A. No.

Q. [147] To your memory, how many data was

submitted by physicians regarding 714, in the request, in application of the regulation?

Me CARMELA MAIORINO:

Do you mean what type of data was...

Me JEAN-SYLVAIN PELLETIER:

How many?

Me CARMELA MAIORINO:

How...

Me JEAN-SYLVAIN PELLETIER:

Q. [148] How many different, how many times did physicians submit documents?

A. Well, physicians...

Q. [149] To your memory, if you can.

A. I don't, I would have no recollection, no specific recollection of each individual...

Q. [150] Can you, can you check that in your database?

Me CARMELA MAIORINO:

I'm not sure I understand the question really.

Me JEAN-SYLVAIN PELLETIER:

Q. [151] I'd like to know, I'd like to know how many physicians submitted data requested by the regulation, how many of them, and how many times, and what was that information supplied.

Unless you're telling me that all the

information is in your evidence that you submitted already, then I'll be satisfied with that answer, if this is your answer today; is it the case?

A. No.

Q. [152] So there are more data submitted by physicians than what you have submitted in your evidence; am I correct?

A. In basic terms, yes.

Q. [153] Okay, so that's the information I'd like to have, is it possible to have it?

A. The information that physicians submit to satisfy the regulations in data that support the use, safety, and efficacy, comes, and has come in all shapes and sizes, if you will. Some of them have been specific documents, and that would be the most common way in which physicians have provided this information...

Q. [154] Have you kept track of those documents, do you have still those documents in your files?

A. Some of those documents would have been, I have filed, some of those, other...

Q. [155] Okay, so would you be, would you be in a position to submit those documents as an undertaking?

- A. As I said, the range, the range of ways the physicians will answer that question, or meet that obligation, is varied.
- Q. [156] Okay, in terms of way, we're talking about what, documents that were faxed to you, documents that were sent to you, right, documents that were e-mailed to you, right, maybe?
- A. I don't believe we've received...
- Q. [157] No, what are the means, what are the ways?
- A. Generally requests that come to us come by fax.
- Q. [158] Okay, so I'm talking about the data that was submitted by the physicians.
- A. Right, correct.
- Q. [159] That is after the request was submitted by fax; right?
- A. No.
- Q. [160] No, at the same time?
- A. Usually at the same time.
- Q. [161] Okay, okay, great. So we're talking about what, faxes, that's it, that's the, that's the point?
- A. We're talking about requests that came to us with attachments, yes.
- Q. [162] Okay, by fax?

- A. Generally, yes, at least laterally, I mean...
- Q. [163] Okay.
- A. ... they were not always received by fax, yes.
- Q. [164] I understand, most of the time it's by fax; right?
- A. In the last four (4) years, yes.
- Q. [165] Okay, and before that what was it, by mail?
- A. By mail, by telephone...
- Q. [166] Okay, so in all those occasions you said that you kept track, and you have those documents in your files; right?
- A. We have historical records of all transactions, and all requests that have been authorized, yes.
- Q. [167] You have the records and you have the copies too; am I correct?
- A. Copy?
- Q. [168] The documents that were sent, you still have them, or they were destroyed?
- A. No, we would not destroy documents, they -- if documents existed, they would, they would generally be attached to, or appended to the original request, which would have gone to a central registry.
- Q. [169] Fine, okay, so I'd like to have a copy of

those documents that were submitted by physicians. Are there, are there many, can you give me an idea of how many were submitted, we're talking about dozens, or hundreds or thousands; do you have an idea?

A. You're talking about specifically 714-X?

Q. [170] Yes.

A. And you're talking about what time frame?

Q. [171] The, from the beginning?

A. You're talking thousands.

Q. [172] Thousands?

A. Thousands.

Q. [173] Okay, so I will restrict my undertaking to a résumé, actually, just statistics per year, how many were submitted per year?

A. How many...?

Me CARMELA MAIORINO:

How many SAP requests for 714-X?

Me JEAN-SYLVAIN PELLETIER:

Q. [174] No, no, no, how many documents were submitted by physicians per year; is that possible?

Me CARMELA MAIORINO:

I'll have to object under advisement, because, like I said, Rule 91 is very clear in terms of

requesting of documentation, direction to attend, so...

Me JEAN-SYLVAIN PELLETIER:

Well, I understand, I understand that all the undertakings are being under objections, unless you prefer to object every time, but I take for granted that this point will be clarified, and if...

Me CARMELA MAIORINO:

And beyond that I find this is a fishing expedition, this is not an examination on discovery, this is a cross-examination on affidavit, and you're requesting a wide range of documentation here, the witness just stated you're dealing with thousands of documents, and the work it'll entail to do a summary, I mean, we haven't even asked the question as to that.

Me JEAN-SYLVAIN PELLETIER:

So regarding my...

Me CARMELA MAIORINO:

So can you, please, can you, please, state exactly what your undertaking is?

Me JEAN-SYLVAIN PELLETIER:

Well, yes, actually, I'll repeat it, it's the data, we're talking about here numbers, not

necessarily documents, but numbers, figures, per year of how many, on how many occasions did physicians submit data with their request to have access to 714.

Me CARMELA MAIORINO:

On how many occasions did physicians submit their data?

Me JEAN-SYLVAIN PELLETIER:

Per year, yes.

Me CARMELA MAIORINO:

I'll also have to object as to the relevancy of that, because the relevancy, the question is not whether they submitted data, but whether the data is actually scientific and credible...

Me JEAN-SYLVAIN PELLETIER:

Well, that's not my point...

Me CARMELA MAIORINO:

... to support the access to the drug.

Me JEAN-SYLVAIN PELLETIER:

... that's not my point, I'm not, I haven't reached that detail yet.

Me CARMELA MAIORINO:

So how many, on how many occasions the physicians submit data in their SAP requests?

Me JEAN-SYLVAIN PELLETIER:

Yes.

Me CARMELA MAIORINO:

Can you specify as to what the nature of the...

Me JEAN-SYLVAIN PELLETIER:

Well, if he can, if he can discriminate
different types of information, if you can
discriminate, otherwise, just a bulk figure.
We're talking about there the information
submitted under the regulation.

Me MICHEL BÉLANGER:

1(A)ii.

Me JEAN-SYLVAIN PELLETIER:

Q. [175] Now, do you have before you section...

A. I don't have it before me, no.

Q. [176] ... 18010? I believe we're talking about
paragraph 1(A)ii. Is that it, this is the
information we're talking about; right?

A. This specifies the obligation of the physician
to supply us with that information, yes.

Q. [177] Okay, so my undertaking relates to this
paragraph specifically.

Me ANDRÉ LESPÉRANCE:

Just want to clarify, so you're asking
irrespective the nature of the data, just the

fact it could have attached something that is not a data on the face of it, but you just want the number of the time that the physician filled, I guess you answer part 3 of the request, and attached or submitted from their prospective data, that's what you want?

Me JEAN-SYLVAIN PELLETIER:

Under the obligation they have under paragraph 010 1(A)ii, that states:

"The data in the possession of the practitioner with respect to the use, safety, and efficacy of that drug."

Is that your clarification?

Me ANDRÉ LESPÉRANCE:

I just want to see, it's irrespective, so you're not asking Mr. Mackay to do analysis of the data, just the number of time...

Me JEAN-SYLVAIN PELLETIER:

- Q. [178] You have to, just the number actually, because I understand that we're talking about thousands of documents here; is that it?
- A. I stated earlier that with respect to the number of authorizations and, therefore, the possible number of documents would be into the thousands, yes, correct.

Q. [179] Okay?

Me CARMELA MAIORINO:

Yes, it's clear for me.

UNDERTAKING NO. 4: To advise on how many occasions physicians submitted data with their SAP requests for 714-X (under reserve of objection)

Me JEAN-SYLVAIN PELLETIER:

Q. [180] Dr. Mackay, am I, doctor, am I, am I correct when I say doctor...

A. No, you're not correct.

Q. [181] ... no, probably not, eh, I think it's Dr. Gillespie and other doctors, but, okay. Still paragraph 10 of your affidavit states that, we're talking about the notion of:

"Sufficient evidence to support the emergency use of the 714-X."

A. Mm-hmm.

Q. [182] Who came up with that notion, that it was requested to have:

"... sufficient evidence to support

the emergency use of 714."?

- A. Paragraph 10 refers to the so-called Garber review, which was undertaken by the Senior Medical Advisors Bureau, and that's the conclusion that was drawn.
- Q. [183] So this notion of sufficient evidence to support the emergency use of 714 was drawn by Dr. Garber?
- A. Dr. Garber undertook the review, and provided that review for the consideration of others, including myself, and Dr. Gillespie, and Dr. Peterson.
- Q. [184] Who came with the conclusion that, because there was insufficient evidence to support the emergency of 714, the programme should be limited?
- A. This was ultimately a decision by the Therapeutic Products Directorate, after receiving advice from Dr. Garber.
- Q. [185] Okay, and who is that decision, who took part of that decision?
- Me CARMELA MAIORINO:
I believe he already answered earlier.
- Me JEAN-SYLVAIN PELLETIER:
- Q. [186] Well, who are those people?

A. I described Dr. Peterson as being the Director
General...

Q. [187] So it's the same people you mentioned
before?

A. Yes.

Q. [188] Okay. The end of paragraph 10 you say:
"This position is based on a clear
absence of credible evidence to
support the safety and efficacy of the
714-X."

My question is, do you have any evidence that
the product is unsafe?

Me CARMELA MAIORINO:

I'll have to object. Are you asking this
question from a medical physician perspective,
cause Mr. Mackay stated earlier he's not a
physician, so...

Me JEAN-SYLVAIN PELLETIER:

I said, do you have evidence?; he'll answer
according to his knowledge.

Me CARMELA MAIORINO:

As manager of SAP?

Me JEAN-SYLVAIN PELLETIER:

Yes.

Me CARMELA MAIORINO:

Okay.

Me JEAN-SYLVAIN PELLETIER:

Q. [189] You understood my question, Mr. Mackay?

A. I did.

Me CARMELA MAIORINO:

Can you, please, repeat your question?

Me JEAN-SYLVAIN PELLETIER:

Q. [190] Do you have, do you have any evidence that the 714 is unsafe?

A. I have knowledge that there are potential drug interactions that are associated with 714-X, which would constitute a safety issue. The blanket phrase "unsafe" is not something that we use in regulation specifically, we talk in general terms about the safety and efficacy of a product, but I have specific knowledge that there is the potential for drug interactions, or that have been associated with 714-X.

Q. [191] What is that information?

A. That information is contained in my affidavit, and it's information that originally came from information supplied by the manufacturer, with respect to how the product should be administered, and I'll have to figure out where

it is, just hang on a second.

(OFF THE RECORD)

THE WITNESS:

A. I'm referring to my affidavit, my original affidavit, and I believe I'm still in Exhibit M, I believe I am, just let me double-check... I am in Exhibit M, and it's...

Me JEAN-SYLVAIN PELLETIER:

Q. [192] Just a moment.

A. Yes, indeed.

Q. [193] Exhibit M?

A. Yes.

Q. [194] M as Mary?

A. M as Mary, yes. I think you have your finger on it, just, it's, it's...

Q. [195] Well, this is, to me, is, unless it's written wrongly, Exhibit M is the document...

Me CARMELA MAIORINO:

It's towards the end of that document...

THE WITNESS:

A. That's correct, it's...

Me JEAN-SYLVAIN PELLETIER:

Oh, at the end, oh, okay, okay...

THE WITNESS:

A. ... it's one of the appendices of this.

Me JEAN-SYLVAIN PELLETIER:

... I understand, okay, that was part of the memoranda?

Me CARMELA MAIORINO:

Yes.

Me JEAN-SYLVAIN PELLETIER:

Q. [196] Okay, so if you can precise the page?

A. So there is no page number per se, but if you skip to the back, skip to the... keep going, no, keep going... keep going, keep going, keep going... okay, yes, it's in around here. I am referring to this section that's entitled "Interactions With Other Health Products;" okay?

Q. [197] And where specifically?

A. The top of the information, the top part of the information, it says:

"The clinical observations have revealed certain exceptions to the case."

Q. [198] Just a moment, where are you actually?

A. The first paragraph refers to:

"Therapies that are generally referred to as non-conventional, complimentary..."

Etc., we're talking about interactions with

other treatments.

Q. [199] Okay, can you refer me to the section of the page?

A. I'm referring right to the top, the top paragraph.

Q. [200] Okay.

A. It's important to note right at the top of the page it's specifically stating "Interactions With Other Health Products."

Q. [201] Okay.

A. And if you refer, the best example, for instance, is under vitamin E, if you go down further.

Q. [202] Okay.

A. Vitamin E, yes, and refer down to the page, keep going down, keep going.

Q. [203] Okay.

A. Yes.

"It is not recommended to use 714-X and vitamin E supplements simultaneously."

And it goes into an explanation as to, in the words of the author:

"A potential for interaction."

In regulatory terms, this would be a potential

interaction, which is, by definition, a safety issue.

Q. [204] Okay, does that mean that the product is toxic, there's a risk in taking the product?

Me CARMELA MAIORINO:

I'll have to object, you're asking a line of questioning that is referring evidently to an expertise as to the toxicity...

Me JEAN-SYLVAIN PELLETIER:

No, I understand your point...

Me CARMELA MAIORINO:

... and that's not within the realm of Mr. Mackay's expertise...

Me JEAN-SYLVAIN PELLETIER:

Actually, I understand your point...

Me CARMELA MAIORINO:

... and Dr. Garber's review was very clear as to the, Dr. Garber's review, according to Mr. Mackay's testimony, was precisely to verify the state of the knowledge as to the safety, use, and efficacy of the drug, so...

Me JEAN-SYLVAIN PELLETIER:

But I'm addressing the fact that it's unsafe, and, as he said, it doesn't appear anywhere, because this term of unsafe...

Me CARMELA MAIORINO:

Right?

Me JEAN-SYLVAIN PELLETIER:

... is not used in their documentation.

Me CARMELA MAIORINO:

Right?

Me JEAN-SYLVAIN PELLETIER:

So he started to answer according to his knowledge, as a coordinator, or as a head of the, of your responsibilities, this is, this is what I'm looking after, according to your responsibilities, according to your knowledge of the application of SAP, specifically with the 714 product, this is, this is, I'm not looking for a medical advice. I understand your point, but it's, I think it's irrelevant.

Me CARMELA MAIORINO:

Well, go ahead with your questioning, the last question you asked...

Me JEAN-SYLVAIN PELLETIER:

Okay.

Me CARMELA MAIORINO:

... directly pointed towards the...

Me JEAN-SYLVAIN PELLETIER:

Q. [205] So my question was about the fact that, if

you had any information, you said, yes, you had information about the fact that the 714 was unsafe, and you referred to me this page that is titled "Interaction With Other Health Products"...

A. I think...

Q. [206] ... the document submitted by the fabricant, specifically vitamin E, okay? As you say:

"It is not recommended to use 714-X and vitamin E supplements simultaneously."

Do you have other information regarding the unsafety of 714-X?

A. I think I, just to clarify, I spoke to the issue of knowledge that I had, and I pointed you to an example, and I talked about the issue of an interaction, as it is so stated, as being a safety issue.

Q. [207] Okay.

A. I didn't declare anything safe or unsafe...

Q. [208] Right.

A. ... I talked about these sorts of generally...

Q. [209] It's a matter of principle, just...

A. ... generally refer to...

- Q. [210] ... in theory?
- A. Correct.
- Q. [211] Yes, okay, so what else, what other information you have about unsafety?
- A. I believe, I believe there are others that are noted in...
- Q. [212] Can you pinpoint that to me, please?
- A. Vitamin E -- vitamin B12...
- Q. [213] B12 in the same page?
- A. Same page, further down, shark and bovine cartilage.
- Q. [214] Okay.
- A. And this is the knowledge that I have that would point to a safety issue, as stated by the manufacturer.
- Q. [215] But you would agree with me that the manufacturer doesn't say that the product is unsafe in general terms?
- Me CARMELA MAIORINO:
I'll have to object, I mean, we're asking the witness to...
- (OBJECTION)
- Me JEAN-SYLVAIN PELLETIER:
Right, it goes by itself, okay.
- Q. [216] So besides this information that we looked

in the documentation, do you have other information about the unsafety of the product?

Me CARMELA MAIORINO:

I'll really have to object to this line of questioning, the safety, the safety...

Me JEAN-SYLVAIN PELLETIER:

Well, obviously your client doesn't know.

Me CARMELA MAIORINO:

No, I mean, we're drawing conclusions here, obviously, I understand why that comment, but the duty to prove the safety of the product does not incumb upon Mr. Mackay, it incumbs upon the manufacturer to prove the safety of a product, and upon, as the, as Mr. Mackay stated earlier on, C-08010, it's incumbent upon the physician to provide the evidence he has, the information he has as to the safety of the drug. So I object to this line of questioning.

Me JEAN-SYLVAIN PELLETIER:

Obviously, actually, I'm insisting, because I think paragraph 10, and, actually, this notion of safety comes back numerous times in the affidavit, so I think there's...

Me CARMELA MAIORINO:

Yes, and based on, Mr. Mackay testifies to that

as, in his affidavit, as to the evidence, the information he has to support the safety and efficacy that was submitted to him on behalf, by the physicians.

Me JEAN-SYLVAIN PELLETIER:

Not only on that base, also on the base of Dr. Garber's documents, or any other documents to his knowledge, that's...

Me CARMELA MAIORINO:

And I believe Mr. Mackay just answered.

Me JEAN-SYLVAIN PELLETIER:

- Q. [217] That he did not know, besides what we looked at, vitamin 12, vitamin E, and shark, bovine cartilage, there's no other information, to your knowledge, relating to the unsafety of the product; am I right?
- A. The issue of, the specific determination of something being unsafe, or safe, or efficacious, or not efficacious, is a very large question, which would encompass, which would, which would encompass a long and complicated decision making and information gather process. The specific, the specific obligations that I have, under the regulations, are to determine whether or not a physician has supplied us with that information,

and whether that information is acceptable to us. It is not to make a broad decision as to whether or not something is safe or unsafe.

Q. [218] Are you saying to me that Dr. Garber's document, that referred as section of annex M, as Mary, only referred to the documentation that were submitted by physicians to reach his conclusion?

A. No, his conclusion was based on a broad examination of information that he, in his position, would have ready access to, in addition to information that other physicians would have ready access to, so what information a reasonable physician could avail themselves of in making a decision to prescribe a product.

Q. [219] Do you know if Dr. Garber had access or looked at the documentation submitted by physicians regarding 714...

A. Dr....

Q. [220] ... to write his report?

A. Dr. Garber, in his report, and it's probably useful to go to it, talks about the scope of the information that he considered for his review, and it's probably self-explanatory. For instance, on page 3 of his review...

- Q. [221] Of his first or second?
- A. Of, sorry, of his, I'm taking the first one, and I don't believe it is...
- Q. [222] Page 3, yes?
- A. Yes. He refers to:
"A systematic review of published literature."
- Q. [223] Okay, in that, in that list do you see that he's consulted the documentation submitted by physicians with the requests?
- Me CARMELA MAIORINO:
I'll have to object to the measure, to the extent that the document speaks for itself in terms of what is...
- Me JEAN-SYLVAIN PELLETIER:
I understand, and I think you're right to object. I withdraw my question.
- Q. [224] Mr. Mackay, is it possible that actually the 714 is efficacious?
- Me CARMELA MAIORINO:
I'll have to object to that as well, I mean...
- Me JEAN-SYLVAIN PELLETIER:
- Q. [225] To your knowledge, is it possible that 714 is efficacious, even though there's no evidence on that?

Me CARMELA MAIORINO:

I'll have to object to that. The scope of Mr. Mackay's testimony here today is within the realm of the judicial review, and the crux of the case is whether the decision maker in this specific case acted under, within the realm of his authority, and whether the decision rendered was patently unreasonable or not. I don't see how Mr. Mackay's personal opinion as to the efficacy of the drug is relevant.

Me JEAN-SYLVAIN PELLETIER:

Actually, I think he should be answering...

Me CARMELA MAIORINO:

Perhaps you can...

Me JEAN-SYLVAIN PELLETIER:

... and, depending on his answer, you know, the answer will decide if it's pertinent or not...

Me CARMELA MAIORINO:

Perhaps if you rephrase your question, but...

Me JEAN-SYLVAIN PELLETIER:

... if he, if he doesn't know, I'll hear from him.

Me CARMELA MAIORINO:

Perhaps you can rephrase your question, but as it is posed, I object under reserve, because it

doesn't...

Me JEAN-SYLVAIN PELLETIER:

Okay.

Q. [226] Mr. Mackay, you've been having access to information on 714 since nineteen eighty-nine (1989) or two thousand (2000), I believe; am I correct?

A. I'm not sure I know what you, I know what, I'm not sure I understand what you mean by information. You said: "I've been having information,"...

Q. [227] Yes.

A. ... I don't understand that.

Q. [228] Since when you heard about 714-X, first time?

A. First time I heard about 714-X?

Q. [229] Yes?

A. I don't have any, it...

Q. [230] Roughly, could it be before nineteen eighty-nine (1989)?

A. No.

Q. [231] Would it be around nineteen eighty-nine (1989)?

A. No.

Q. [232] In two thousand (2000)?

- A. No -- two thousand (2000), yes.
- Q. [233] Yes, okay.
- A. You're talking eighty-nine ('89) you say? You said eighty-nine ('89).
- Q. [234] Eighty-nine ('89), yes.
- A. Yes, my answer was, no, and...
- Q. [235] Okay, so two thousand (2000)?
- A. Definitely...
- Q. [236] That would be, that would be the beginning of it, and from two thousand (2000)...
- A. No.
- Q. [237] ... from two thousand (2000) you...
- A. No, it's not the beginning of my knowledge, I had knowledge about 714-X prior to the year two thousand (2000).
- Q. [238] So when was that, that was my question?
- A. I don't have any specific knowledge, but it was likely, I was probably familiar with it within a short time after me beginning to work at the programme in nineteen ninety-two (1992), but I don't have any specific recollection, or any, of the date, or anything like that.
- Q. [239] Okay, from nineteen ninety-two (1992) up to two thousand four (2004), you had access, in your duties, to information about the 714-X; I'm

right?

A. Yes.

Q. [240] Am I right if I also say that you had access to numerous informations about 714-X in internal reports, exterior documents, whatever?

A. I would not label that as numerous, no.

Me CARMELA MAIORINO:

Can you, please, specify what you mean?

Me JEAN-SYLVAIN PELLETIER:

Q. [241] Okay, to your knowledge, to the best of your knowledge, can you give a rough idea of how many different sources of information you got about the 714-X, was it two (2) sources of information, was it ten (10), was it more?

A. I would have to, I would have no specific recollection of the number of documents...

Q. [242] Just give me an order of, about number.

A. Well, I think information that I would have been familiar with would come, would have come in different forms...

Q. [243] I'm talking about numbers, not the forms.

A. Right, okay, so...

Q. [244] Roughly, ten (10)?

A. Probably roughly ten (10) would be...

Q. [245] Roughly ten (10)?

- A. Yes.
- Q. [246] Do you consider on that information submitted by physicians with their requests?
- A. I'm sorry, could you repeat the question?
- Q. [247] Would you, in that ten (10) that you mention, roughly ten (10), would you include information that were submitted by physicians with the request for 714?
- A. Most of the documents that physicians would file, or refer to in their requests, I was familiar with.
- Q. [248] Okay, how many document that is?
- A. I think I just answered, it would be...
- Q. [249] Ten (10), it's the same?
- A. Approximately, approximately ten (10), but I have, but I'd have to go back to make a...
- Q. [250] Okay, but it's a, it's a round figure?
- A. A round figure, yes.
- Q. [251] Okay. So does that mean that only ten (10) physicians submitted documents regarding 714-X, that you are aware of?
- A. No.
- Q. [252] Why not?
- A. ...
- Q. [253] Do you understand my question?

A. I don't think I do, no.

Q. [254] I don't think you do. You said that you had about ten (10) different sources of information regarding 714.

A. That's correct.

Q. [255] You said that part of this ten (10) documentation, or ten (10) source of information, were documentation or data submitted by physicians...

A. Correct.

Q. [256] ... with their request for 714.

A. That's correct.

Q. [257] So my question is, then probably ten (10) or less documents or data were submitted by physicians with their requests; am I right?

A. I think I had mentioned earlier that the request, the information which physician, the information or packages that physicians file with requests, were familiar to us, and, in other words, in other words...

Q. [258] I'm not talking about familiarity, I'm talking about source of information.

A. If we're talking about, I think, when I speak about I was familiar with about ten (10) documents, there was about ten (10) documents

from ten (10) sources, ten (10) separate documents or ten (10) separate types of information, and these would be commonly, even though we had, obviously, hundreds, and over the course of the years, thousands of requests, the same documents...

Q. [259] Were presented redundantly?

A. ... were presented, yes, but in terms of the discrete differences, there were...

Q. [260] I understand.

A. ... there were about ten (10).

Q. [261] I understand, so those documents were redundant from one request to another?

A. They weren't redundant, they were submitted, they were, as I said before, they were commonly, the same documents were commonly used by various...

Q. [262] Submitted by different physicians; right?

A. That's correct.

Q. [263] Mr. Mackay, do you have evidence that the 714 is not efficient, according to your knowledge?

A. Once again, the determination of the efficacy of a product is not something that I would be in a position to determine, and in regulatory terms,

the pronouncement that a drug is efficacious involves the consideration of huge volumes of information.

Q. [264] I understand that, but I'm talking about, do you have information that in some cases the product worked?

Me CARMELA MAIORINO:

Mr. Mackay just answered your question.

Me JEAN-SYLVAIN PELLETIER:

No, he didn't, no, no, he didn't.

Me CARMELA MAIORINO:

He did.

Me JEAN-SYLVAIN PELLETIER:

He went far beyond my question. So I'm repeating the question:

Q. [265] Do you have information that in some cases the 714 did, indeed, work, and helped people in their, in their illness, and cured people maybe?

Me CARMELA MAIORINO:

I'll have to object to that. That's, you're asking questions that clearly point to medical expertise, and Mr. Mackay is not in a position...

Me JEAN-SYLVAIN PELLETIER:

Well, no, no, he's, he's responsible, he's the

coordinator.

Me CARMELA MAIORINO:

... but Mr. Mackay is not in a position to state whether...

Me JEAN-SYLVAIN PELLETIER:

He knows if the product, in some cases, has worked.

Me CARMELA MAIORINO:

So your question is whether he has knowledge, as unit head of the SAP, of evidence...

Me JEAN-SYLVAIN PELLETIER:

Q. [266] That in one (1), or two (2), or three (3) case, whatever, that, indeed, 714 did bring a relief or bring a cure; do you have that information, have you ever seen something like that?

A. I've seen testimonials, yes.

Q. [267] Okay. Where, of who?

A. There have been newspaper reports.

Q. [268] Do you recall what newspaper, have you kept track of that?

A. No.

Q. [269] No, okay. You don't recall when neither?

A. ...

Q. [270] The period?

- A. I think it would be fair to say that I was familiar with testimonies with respect to 714-X, shortly after I began working at SAP in nineteen ninety-two (1992), which was during a period that I've described in my affidavit, where there was some activity, there was, there was, there was newspaper interest, there was press interest surrounding it, so that would be my most specific recollection of timing...
- Q. [271] In the beginning. Do you have other information, what else, about the fact that 714 worked, or helped people, or people were cured with 714?
- A. I think the other specific recollection that I have that might be helpful would be my understanding and knowledge of the OCCAM's best case series review, which, by definition, involved the review of cases where the drug, where the product was purported to have had an effect.
- Q. [272] Okay.
- A. And so those would be the specific things that I could remember off the bat, so one is an earlier recollection, and the other is a latter recollection.

- Q. [273] What else do you have, do you have other sources that would confirm that 714 is efficient, efficacy?
- A. No, I have no evidence that would confirm the efficacy, as I referred to earlier, that the determination of efficacy is a large decision that does not fall in, within my scope of responsibilities.
- Q. [274] Did you recall receiving letters from physicians or patients about the effect, the beneficial effect of 714?
- A. From patients?
- Q. [275] Patients or physicians?
- A. Certainly over the years physicians would have reported to us on occasion...
- Q. [276] Do you, do you recall how many times roughly?
- A. No.
- Q. [277] So they would report positive effects of 714?
- A. I referred earlier that I was familiar with testimonials, and we would consider that a...
- Q. [278] We're talking about physicians.
- A. Right, we're, I'm familiar with those, yes.
- Q. [279] Physicians that had applied for 714 in the

SAP?

A. Yes.

Q. [280] Are you talking about those physicians?

A. I'm talking, I would have... yes, and I believe that there were documents that we filed, which, where physicians have talked about the, from their perspective, their experience with the use of the drug.

Q. [281] Do you have an idea of how many of those letters that you read, how many of them?

A. No, I have no specific...

Q. [282] Well, was it two (2), three (3), ten (20), twenty (20), hundred (100), give me a ballpark?

A. I think the best reference is in my affidavit, my most recently submitted affidavit, the amended affidavit?

Q. [283] Yes.

A. When we had, as a part of a latter effort, we had specifically requested physicians to, as to whether or not they had any information in their possession with respect to the use, safety, any new information that we may not be familiar with. So, in my affidavit, for instance, there is a letter from Dr. xxxxxxxxxx...

Q. [284] Okay, but besides, besides what you've

submitted as evidence that is already in the file, is there some other letters that you received from physicians regarding the beneficial effect of 714?

A. I have no specific recollection of any other letters, but we're talking about a fairly long period of time, and I was not the only person in the office who may have received them at the time, so.

Q. [285] I'm talking about your personal knowledge, obviously.

A. My personal knowledge, I don't have any specific recollection of any specific documents at this time about, about your question. I think, as I said, to be helpful, a specific example that I'm familiar with, and relevant to what we're talking about, is the, is the, for instance, a letter submitted by Dr. xxxxxxxxxxxxxx, which talks about her, in her words, and her experience with the, on behalf of two (2) or three (3) other doctors and their experience with 714-X.

(SHORT RECESS)

(UPON RESUMING)

Me JEAN-SYLVAIN PELLETIER:

Q. [286] Paragraph 14 of your affidavit, sir.

A. Fourteen (14)?

Q. [287] Fourteen (14).

A. Yes.

Q. [288] At the end you mention:

"The system, by statute, is
precautionary given that all drugs
carry some level of risk."

What do you mean by "statute," do you mean it's
in the law?

A. The, paragraph 14 refers to a general
explanation as to, of the Food & Drugs Act, and
the last statement refers exactly to exactly
what I mean. The system, the drug review
system, by statute, in other words, by
legislation, is precautionary.

Q. [289] Do you find the "precautionary" in the
law?

Me CARMELA MAIORINO:

That's not what Mr. Mackay...

Me JEAN-SYLVAIN PELLETIER:

No, actually, that's, I don't believe, but...

A. I'm providing a general, a general overview
of...

Q. [290] The perspective of the law...

A. Right.

Q. [291] ... is precautionary?

A. The, I think what I'm specifically referring to here is the, is the general prohibition within the act and regulations, which, for lack of a better phrase, assumes a drug is guilty before it is proven innocent, and so that would, I'm describing that as precautionary.

Q. [292] Paragraph 18:

A. Mm-hmm.

Q. [293] ...

"The Food & Drug regulations contains special rules respecting the review of new drugs by Health Canada."

Do you refer here to SAP?

A. No, paragraph 18 refers to the review of new drugs in general...

Q. [294] In general, okay...

A. ... in general...

Q. [295] ... so we're not talking about SAP here?

A. No, the...

Q. [296] Okay, thank you.

A. I should say, excuse me, that, other than to say, as we spoke earlier, the regulations

respecting SAP are found within the new drug regulations in division 8, and, as I say in my affidavit, new drug, and we talked about this earlier, is defined earlier in section 8.

Q. [297] Right, I saw that, okay.

A. In paragraph 26, when you say:

"Ultimately the system is designed to ensure that patients are protected from both real and potential risk."

This also refers to, not to SAP, but to general provisions of the law; right?

A. I'm referring specifically to the system, the regulatory system in general.

Q. [298] But not specifically to SAP?

A. No, I'm talking about the system in general.

Q. [299] And 27 is also the same answer, I believe.

"Consideration and monitoring of clinical trials and review of New Drug Submissions filed by sponsor seeking full market authorization."

This is, this is not referring to SAP specifically; right?

A. This is within a section of my affidavit which I talk about drug development in Canada, so I'm talking about the broad activities undertaken by

Health Canada, and I refer to three (3) specific activities, the review of clinical trials, the review of New Drug Submissions, and post -- and those two (2) things, I'm sorry, there are only two (2) things.

Q. [300] So I'm repeating my question because I don't believe you answered it. Paragraph 27 does not refer specifically to SAP then?

A. No.

Q. [301] Thank you. To your knowledge, Mr. Mackay, did Health Canada conduct at all any research to, besides Mr. Garber's document that was submitted, besides that, did Health Canada conduct any research on 714-X?

A. Can I ask what you mean by research?

Q. [302] Well, the general term of research.

A. No.

Q. [303] No, so the only document that were, the only study or research made by Health Canada on 714, was Dr. Garber's in two thousand four (2004)?

A. If you're referring to Dr. Garber's report as being research, that's not what I would consider to mean research when we're talking about drug development.

Q. [304] Well, okay, let's use the term research in the broad sense, and I include Dr. Garber's document as a research, or study, or...

A. If you're considering Dr. Garber's study as research, then Health Canada conducted a review, which you're terming research.

Q. [305] That's Dr. Garber's review?

A. Yes.

Q. [306] And that is the only one on 714-X done by Health Canada; I'm right?

A. I'm just having difficulty with the term "research", I'm used to using the term "research" in the context of...

Q. [307] I understand...

A. ... of scientific research, so.

Q. [308] ... I understand your dilemma.

A. Yes.

Q. [309] I'm talking about research, or study, or similar terms.

A. Mm-hmm.

Me ANDRÉ LESPÉRANCE:

Or review, maybe I can...

Me JEAN-SYLVAIN PELLETIER:

Review, well, thank you for the term, I mean, it's...

Me JEAN-SYLVAIN PELLETIER:

Or analysis?

Me JEAN-SYLVAIN PELLETIER:

... we're not, I'm not scientific...

A. Okay, that's okay, I just, I'm just...

Q. [310] ... I'm only a lawyer, I'm sorry.

A. Yes, my background just forces me into that,
into that definition.

Q. [311] I understand.

A. I think the, my, an example, if you're talking
about that broad sense, there was an analysis
done with respect to 714-X in the early nineties
(90s), where a research bureau, a scientific
research bureau undertook a chemical analysis of
the, so...

Q. [312] Okay, that is submitted in your, in your
evidence; right?

A. Yes, it is.

Q. [313] Okay, what else besides that?

A. The Garber review would certainly encompass
that.

Q. [314] It's submitted already, yes?

A. There have been, there have been analysis,
analysis done with respect to advertising, and
the appropriateness of advertising, by our, by

our compliants...

Q. [315] Advertising the 714-X?

A. Yes.

Q. [316] Is that submitted in your evidence?

A. No, it is not.

Q. [317] And can you carry on on that, what was that about, advertising?

A. There was, it wasn't, it was not something that I undertook, but Health Canada has a compliance function, whereby it ensures whether or not advertisement, and sales, and other things, are compliant with the Food & Drugs Act and regulation. One (1) major component and prohibition of the regulations state that no person shall advertise a drug unless it is approved, for instance.

Q. [318] Okay, that's in the general law; right?

A. That's right.

Q. [319] That doesn't apply specifically to SAP, but just in general, okay. What else besides this marketing thing?

A. I don't know, I think that's a legal question you're asking, I'm not in a position to agree or disagree with...

Q. [320] Okay, fine.

- A. ... with respect to...
- Q. [321] Okay, besides this study, or whatever term you used about marketing points, is there, is there other documentation, or research, or study, or review, whatever, that was done by Health Canada on 714?
- A. I am, I am aware of discussions, but, again, the issue of review, etc., that would have predated my coming to the programme, in and around the time I describe where there was media attention, etc., and I am aware that a meeting took place, and, but I have no idea of what analysis may have taken place, but naturally in the course of meetings, one prepares for meetings, and, but that predates me...
- Q. [322] Okay, besides that meeting, actually, regarding that meeting, do you recall if there were any document...
- A. No, as I said...
- Q. [323] ... previous or after that meeting, kind of a résumé of the...
- A. No, it...
- Q. [324] ... discussions?
- A. ... it predates me, but I, but I do, I'm told that a meeting took place.

Q. [325] Do you know if that meeting, after that meeting a document was issued as a résumé of the meeting?

A. I do not know.

Q. [326] You do not know. Okay, besides that?

A. I think I refer to, in my affidavit, to an issue that -- I'll have to find it if you give me a moment. I may not be able to find it right away, but I can describe it in general terms. There was an issue that arose four (4) to five (5) years ago, when it became, when we became aware that the product 714-X, pursuant to authorizations that we issued, were being sent directly to patients, and that was an issue which we examined at the time about the appropriateness of it, about the legal appropriateness of it, because the regulations state that the sale has to be between the manufacturer and the physician, and we had concerns about drug being sent directly to patients, and there was a, there was an analysis at the time as to, as to the appropriateness of that, the knowledge that we had about that, and what was the appropriate course of action. So in general terms about issues that we were

dealing with, again, I would not, I wouldn't use the word "research," but if you're talking about a review or an examination of that issue, that happened at the time.

Q. [327] Okay, regarding this direct sale to patients, do you know how it occurred, or why it occurred?

A. Why the sales were taking...

Q. [328] Yes.

A. ... place directly to the patients?

Q. [329] Yes, you don't know?

A. No, I don't.

Q. [330] Do you recall having requests from physicians, asking that the product be sent directly to their client, instead of being sent directly by the manufacturer to the client?

A. I don't have any specific recollection of that...

Q. [331] You don't recall that?

A. ... the letters, the authorizations which we issued, and the legislation is clear, the regulations are clear, that the sale, the manufacturer has an obligation to sell it to the physician. And so we believe it is the manufacturer's obligation to do so.

Q. [332] Do you recall having received a request from physician, one (1) or several, requesting that the product be sent directly from the manufacturer to the client, and not from the manufacturer to the physician requesting?

Me CARMELA MAIORINO:

He already answered that question.

Me JEAN-SYLVAIN PELLETIER:

No, he didn't.

Me CARMELA MAIORINO:

He did.

Me JEAN-SYLVAIN PELLETIER:

Q. [333] Your answer was no or yes?

A. I spoke...

Q. [334] You don't, you don't recall any requests from physicians that the product be sent directly from the manufacturer to the client?

A. I can't specifically recall what prompted the review about which I spoke earlier, what, how it came to our knowledge that the drug was being sent directly to patients. So I have no specific, I have no specific recollection of that, but...

Q. [335] Is it possible that it occurred?

Me CARMELA MAIORINO:

Objection, that's hypothetical, you're asking him if it's possible that it occurred.

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Q. [336] Mr. Mackay, I'll show you a document here, a list of documents, the first page heading "Health Canada," dated January twenty-ninth (29th), nineteen ninety-eight (1998), addressed to Dr. Naessens, title "Letter of Authorization." Saying:

"Notwithstanding section C-08002, you are authorized to sell to Dr. xxxxxxxxxxxx."

And this document is signed by Mary E. Carman?

A. Carman, C-A-R-M-A-N.

Q. [337] And do you know this person?

A. I do.

Q. [338] She says:

"Being director of Bureau of Pharmaceutical Assessment."

Is this person part of the annex B that you have submitted, which is the Delegation of Authority, is she part of that list?

A. I referred earlier to organizational changes,

and specifically changes to names.

Q. [339] Right?

A. The Delegation of Authority specifically states the Bureau of Human Prescription Drugs. I stated earlier that that entity changed names to the Bureau of Pharmaceutical Assessment, on or about nineteen ninety-five (1995)...

Q. [340] Can you, can you...

A. ... but that organizationally the director would be refer, would be...

Q. [341] Right, they were promoted you said; right?

A. No, that was the person that stayed the same.

Q. [342] Okay...

A. So, yes.

Q. [343] ... unfortunately for her. Can you refer to annex B, please, and tell me in the list of annex B that we looked before, where that person, director of Bureau of Pharmaceutical Assessment, is being listed?

Me CARMELA MAIORINO:

He just stated...

Me JEAN-SYLVAIN PELLETIER:

Q. [344] No, I would like him to look, have this document before him, and pinpoint to me...

A. I stated earlier...

- Q. [345] ... from A to H, tell me from A to H where is she, this person, in that list?
- A. A.
- Q. [346] A, so she is director?
- A. Correct.
- Q. [347] But director states in singular, there's no S at the end, it doesn't state the directors; you agree with me?
- A. ...
- Q. [348] That refers to one (1) single person, the director?
- A. It refers to a position entitled "the director."
- Q. [349] That's your interpretation; right?
- A. ...
- Q. [350] Okay, now, regarding the page 2 of the document submitted, the other document has titled "Clinique Médicale des Haut Bois," dated January twenty-sixth (26th), nineteen ninety-eight (1998), addressed to M.C.A. Franklin, Ph.D; do you know this person?
- A. Yes, her name is Claire Franklin.
- Q. [351] And how is she involved in the SAP?
- A. She was the former director of the Bureau of Human Prescription Drugs.
- Q. [352] So if, have you ever seen this document

before?

A. I have no recollection of having seen this document, no.

Q. [353] Now, the second paragraph of the letter addressed by Dr. xxxxxxxxxxxxxxxx, states, and it's in bold:

"Comme il demeure à l'extérieur, il aimerait que deux (2) viales lui soit envoyées chez lui"

Me CARMELA MAIORINO:

I'll have to object to this line of questioning, I don't see the relevancy as to whether, as to this line of questioning, it has absolutely no bearing on the, on the crux of the case, as to whether...

Me JEAN-SYLVAIN PELLETIER:

Well...

Me CARMELA MAIORINO:

... the drug was, the drug was actually sent directly to the physician or to the, to the patient...

Me JEAN-SYLVAIN PELLETIER:

Okay, actually...

Me CARMELA MAIORINO:

... it's absolutely irrelevant.

Me JEAN-SYLVAIN PELLETIER:

... it's not that pertinent, you're right, but actually your client mentioned that some drugs were sent directly to the client, and I want to...

Me CARMELA MAIORINO:

It was in response to your line of questioning as to whether...

Me JEAN-SYLVAIN PELLETIER:

Yes, yes.

Me CARMELA MAIORINO:

... whether there was any analysis at large whatsoever with respect to 714-X, and in response to that question he searched and searched for all the different reviews that could have been undertaken with respect to 714-X, but...

Me JEAN-SYLVAIN PELLETIER:

And I asked him specifically if that, actually that occurrence could have been caused or explained by a request from a physician to send the product directly to the client, and he said he didn't know, so this document would really complete his answer, so I would, I would deposit the document.

Me CARMELA MAIORINO:

I object.

Me JEAN-SYLVAIN PELLETIER:

Under the same objection, the same 91...

Me CARMELA MAIORINO:

I object under...

Me JEAN-SYLVAIN PELLETIER:

... Rule 91?

Me ANDRÉ LESPÉRANCE:

No.

Me CARMELA MAIORINO:

No, not under Rule 91, I object with respect to the absence of relevancy of this document, and your question with respect to the, whether a, whether the manufacturer sent the drug directly to the physician or not. I don't see that at all relevant with the scope of the case before the Court, which is to...

Me JEAN-SYLVAIN PELLETIER:

Well, actually...

Me CARMELA MAIORINO:

... which is to determine whether the decision maker acted within the scope of the legislation, whether the decision rendered was patently unreasonable or not.

Me JEAN-SYLVAIN PELLETIER:

I just want to make clear that the Court doesn't understand that the process was not well followed by either the physician or the manufacturer, because he states that the products were sent directly to the clients, and the way he presented it, he's saying a derogation to the usual set rule, and I want to clear that up so that the tribunal doesn't interpret his position as a default in the, in the position of the manufacturer.

Me CARMELA MAIORINO:

I'll object under reserve, and if the witness recalls...

Me JEAN-SYLVAIN PELLETIER:

How would you like to quote it, I don't know what type of, just, it's just legal matters, quelle cote on met?

Me CARMELA MAIORINO:

Vous voulez faire ça en engagement?

Me JEAN-SYLVAIN PELLETIER:

Sous réserve, non, non, non, pas d'engagement...

Me CARMELA MAIORINO:

Oh, sous réserve, oui.

Me JEAN-SYLVAIN PELLETIER:

... sous réserve, c'est quoi la cote?

(OFF THE RECORD DISCUSSION)

Me JEAN-SYLVAIN PELLETIER:

Exhibit 1 de l'interrogatoire.

Me CARMELA MAIORINO:

Oui.

Me JEAN-SYLVAIN PELLETIER:

C'est en liasse, documentation, correspondance
entre Santé Canada et...

Me MICHEL BÉLANGER:

Dr. xxxxxxxxxxxxxxxxxxxx.

Me JEAN-SYLVAIN PELLETIER:

... Dr. xxxxxxxxxxxxxxxxxxxx.

EXHIBIT NO. 1: Correspondence between
Health Canada and Dr.
xxxxxxxxxxxxxxxxxxxx, en liasse

Me JEAN-SYLVAIN PELLETIER:

Q. [354] Paragraph 51, Mr. Mackay. You talk about
"anecdotal evidence." Do you have a reference
that defines, how do you define anecdotal
evidence?

A. I think I define it in 51 as:

"Information gathered without
experimental design."

And that generally it's insufficient to make
informed decisions about the big questions,
about whether the benefits of a drug might
outweigh the risks of a drug.

- Q. [355] So this is your own definition of
anecdotal evidence, if I understand?
- A. I define it here, but I qualify it by saying
universally I think this would be adopted by
many within the scientific community. Others
may have different, different definitions, I'm
describing, I'm trying to describe it from my
perspective, what I understand would be the
generally accepted definition in the scientific
world.
- Q. [356] And you mention that the big question, as
you say, as to whether the benefit of a drug
outweighs the risk; right? This big question,
to quote your own words, refers to the regular
market, regular market drug, this is the test
for the regular market; right, not to SAP,
that's my question?
- A. No, I think I refer in the, in the, in my, in
paragraph 51, it's insufficient to make informed

decisions as to whether the benefits of a drug outweigh the risk. That could...

Q. [357] Does this apply to SAP also?

A. Definitely.

Q. [358] It does?

A. Yes.

Q. [359] How do you say that?

A. The regulations require me to make an informed decision as to whether or not the information submitted by the practitioner is sufficient, within the realm of discretion, to permit authorization.

Q. [360] Within the realm of your discretion?

A. Correct.

Q. [361] And based on which criteria?

A. C-010 and 11 describe discretionary authority for the regulator to make a decision with respect to whether or not authorization is warranted, based on information provided by the practitioner.

Q. [362] That is paragraph A. You have the regulation before you?

Me CARMELA MAIORINO:

No, I don't actually.

(OFF THE RECORD)

Me JEAN-SYLVAIN PELLETIER:

Q. [363] So referring to paragraph, the regulation
08010...

A. Yes?

Q. [364] ... can you tell me in that regulation
where you would apply your discretion?

A. It is inherent in the word "may."

Q. [365] And where is that word situated, can you
pinpoint it to me?

A. It's the third word of the, in the first
paragraph.

Q. [366] Okay:

"May issue a letter if..."

Right?

A. Yes.

Q. [367] A, then it goes on, A(i), (ii), etc.?

A. Correct, correct.

Q. [368] And in A do you see any, what words give
you some discretion of application?

A. Well, A is a subparagraph of 1, and, therefore,
those are the things which are considered, and
as to whether or not the director will or will
not issue a letter of authorization.

Q. [369] Okay. Besides the word "A" that you
mentioned, are there other discretion that you

would apply in the rest of the application of the regulation?

- A. Paragraph, under A, paragraph (iv), Roman numeral (iv), implies further discretion on the part of the director to require additional data as the director may require, I think it's self-explanatory.
- Q. [370] And what are the criterias to apply this subparagraph (iv), in which circumstances, other words, the director may require other data?
- A. It's a provision that's not used very often, but it is used on occasion when there is question about either the volume of, the amount of information submitted as for two (2)...
- Q. [371] Submitted by the practitioner?
- A. By the practitioner.
- Q. [372] In a specific case?
- A. In a specific case, yes.
- Q. [373] Okay.
- A. And, or whether there may be some question with respect to the credibility of it, there could be a contradiction. For instance, an example might be a physician who files data in possession, in their possession, but that data talks about a clinical trial where the drug did not work, for

instance, where there's an inherent contradiction in what they're submitting to us, that would support the use, safety, and efficacy of the drug, and so we may go back to the physician and clarify, and request additional information that they may have in their possession.

Q. [374] So who exercise this discretion in this specific case that you mention, is it you?

A. Because I am the authority which looks at and reviews requests, if I determine that the information is insufficient, I may consult, I consult regularly with experts in the bureau, in a number of bureaus actually, and if I have questions, and if there's some, something which still doesn't make sense, I may go back to the physician to acquire additional information, using and, using the authority inherent in subparagraph (iv).

Q. [375] Those criteria that you apply to exercise your discretion, are those, are they written somewhere?

A. We have, we have, we have standard operating procedures that we use to...

Q. [376] Are those, are those standard procedures

deposited as evidence in your file?

A. No, I make reference to them though in my amended affidavit.

Q. [377] But they're not deposited?

A. I don't believe they are deposited, no, I make reference to them.

Q. [378] And they exist, indeed?

A. Indeed, they exist.

Q. [379] Undertaking? I'd like to have all information, written information, that are used to apply your discretion in paragraph, subparagraph (iv) of the regulation.

UNDERTAKING NO. 5: To provide all the written information used to apply discretion in subparagraph (iv) of the regulations (under reserve of objection)

Me JEAN-SYLVAIN PELLETIER:

Q. [380] Now, who sets those written criterias?

A. Those standard operating procedures evolve, and have evolved over the course of the history of

the programme.

- Q. [381] So what does that mean evolves, it means it changed; right?
- A. Well, any procedure, procedures or operational sort of operations, will evolve over the course of time.
- Q. [382] Okay, do I understand from your answer that the criterias that were applied for your discretion in two thousand four (2004), for instance, are different than those applied in two thousand (2000), and different than nineteen ninety-eight (1998), or so?
- A. I'm not sure of the time frames you refer to, but I think I speak at length in my affidavit about process improvements beginning in and around the year two thousand (2000), so there's no question that the standard operating procedures that were applied now, were different from those that were applied earlier, and I go in at great lengths to talk about operational changes at SAP, improvements, process improvement, quality improvements, these are all standard fare in any organization trying to better itself all the time, and quite common in government, and SAP was a part of that, to try

every day to do a better job.

Q. [383] And at all times those procedures would have been rewritten?

A. I can only speak for, I can only speak for the time when I was responsible for the programme and those procedures.

Q. [384] Okay.

A. Certainly part of the issue was earlier on, and I attest to this in my affidavit, was that there was a good operational understanding with how things happened, but it wasn't always documented, and that was what the review in two thousand (2000) sought to do, was to, one of the major initiatives, which is, which I speak to very directly in my earlier submitted affidavit, the operational challenges that we had, and what we were going to do to correct those.

Q. [385] So when you submit the undertaking that we've discussed, will you be submitting the last written procedure, or you'll be able to submit also the anterior, the past written procedures, so that we can follow the evolution of the changes that you stated?

A. Yes, I have ready access, clearly, to the current operational...

- Q. [386] Okay, so that'll be done quickly.
- A. ... that's...
- Q. [387] Would you have access to past procedures too?
- A. I do have access to at least one (1) major iteration prior to mine, yes.
- Q. [388] Do you recall what was the date of the change that caused the new procedure? Roughly, if you can't, we'll look at the documents as such.
- A. Sorry, your question again?
- Q. [389] When was the procedure changed?
- A. My affidavit describes identifying operational issues in and around two thousand (2000), and the efforts undertaken between two thousand (2000) and today, and ongoing, to change those procedures. The current procedures were developed over the last two (2) to three (3) years, the prior procedures would have been in place many years before that.
- Q. [390] Okay, all the documents you'll be submitting will have dates, obviously...
- A. I...
- Q. [391] ... to follow the time frame.
- A. I'd have to go back and familiarize myself with

the earlier iteration, but I'm sure it must have a date...

Q. [392] Hopefully it will.

A. ... yes, I would, I would hope it'll have a date...

Q. [393] Now, let's go back to the regulation; where else do you have a discretion to apply? We were at 1A(iv), now if we go lower in this description of the regulations, where else will you have a discretion to apply?

A. Under B.

Q. [394] Yes?

A. Roman numeral (ii) under B, this is an undertaking that the practitioner has to make, the practitioner has agreed to, to account to the director on request. So we can, we can request off the practitioner an accounting for all the quantities received by the physician.

Q. [395] So it's your discretion to ask or not to ask; right?

A. That's correct.

Q. [396] Is it the same for (i), or one (1), B(i):

"The report to the manufacturer of the new drug, and to the director, on the results of the use of the drug."

Etc.

A. I think...

Q. [397] This is where discretion to be applied
there also?

A. No, this implies a specific obligation on the
part of the physician...

Q. [398] To give you report...

A. ... to do it.

Q. [399] ... every time?

A. That is their obligation.

Q. [400] Did they do it?

A. No.

Q. [401] Why?

A. Every time?

Q. [402] Yes?

A. No.

Q. [403] Why?

A. You'd have to ask physicians that question.

Q. [404] Did you, did you try to enforce this
provision?

A. We make it as clear as we can in our letter of
authorization that that is their obligation.
With respect to adverse drug reactions, it's
well known in the regulatory community, Canada
and elsewhere, that physicians don't do a good

job...

Q. [405] I'm talking about SAP, just concentrate and stick to SAP, please.

A. I am, I'm, what I'm trying to describe is the general circumstance where physicians do not and have not submitted reports to us, but that this is not uncommon in the, in the field of adverse drug reaction reporting universally, it's a chronic problem that regulators and other agencies deal with, and SAP is not unusual in that regard.

Q. [406] Am I right if I say that it was your obligation to do a follow-up on this obligation of the practitioner?

Me CARMELA MAIORINO:

I'll have to object. What is the relevance as to whether that was his obligation or not?

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

I'm asking...

Me CARMELA MAIORINO:

I object.

Me JEAN-SYLVAIN PELLETIER:

... if it's his obligation.

Q. [407] Whose obligation was it, yours or the

practitioner?

Me CARMELA MAIORINO:

I object, I object as to the relevancy of the questioning.

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Okay.

Q. [408] Out of, tell me, how many requests were made for 714 over all the years?

A. I don't have a specific number at my fingertips.

Q. [409] Are you able to say how many out of those, we're talking about hundreds or thousands requests?

A. Definitely talking thousands.

Q. [410] Thousands, okay, out of those thousand request, do you have an idea of the proportion of the physicians that submitted, indeed, the report that is requested by the regulation?

A. No, I don't.

Q. [411] You don't know at all, give me a rough figure, ten percent (10%), fifty percent (50%) that did?

Me CARMELA MAIORINO:

I'll have to object as the relevancy of that.

Me JEAN-SYLVAIN PELLETIER:

I'm asking just to give him a rough figure,
ballpark.

Me CARMELA MAIORINO:

I don't see how, I don't see how it's relevant
as to how many physicians, or what percentage of
physicians actually submitted...

Me JEAN-SYLVAIN PELLETIER:

I think it's quite relevant, and that's why you
object probably.

Me CARMELA MAIORINO:

No, I'm objecting because I don't see the
relevancy. Perhaps you can explain to me the
relevancy, and I'll withdraw my objection.

Me JEAN-SYLVAIN PELLETIER:

Well, we're right on the spot about the
regulation specific to SAP on 714, I'm asking
questions directly about the link between the
people responsible to apply the programme SAP,
and the physicians that were making the request
to have access to the product. I think it's
very relevant.

Me CARMELA MAIORINO:

But the adverse reporting, how is that relevant?

Me JEAN-SYLVAIN PELLETIER:

I think it's part of the whole, the whole
debate.

Me CARMELA MAIORINO:

Not at all, the debate is whether...

Me JEAN-SYLVAIN PELLETIER:

I think it is.

Me CARMELA MAIORINO:

... the...

Me JEAN-SYLVAIN PELLETIER:

We're talking about here, we're talking about
the report that talks about adverse reaction,
eh, we're talking about results...

Me MICHEL BÉLANGER:

Or results on the use.

Me JEAN-SYLVAIN PELLETIER:

"Results on the use of the drug,
including information respecting any
adverse reactions."

I think it's damn important, rather the
opposite.

Me CARMELA MAIORINO:

So I object, I object under reserve.

THE WITNESS:

A. You asked me, I think, the question of...

Me JEAN-SYLVAIN PELLETIER:

Q. [412] Yes.

A. ... of the proportion, or how many, I do not have any specific knowledge, and...

Q. [413] Okay, can you inquire on that, as an undertaking? Okay?

Me CARMELA MAIORINO:

Just for clarification, you'd like to know the proportion of doctors that...

Me JEAN-SYLVAIN PELLETIER:

Yes, of physicians that submitted the report requested by section B(i) with their request.

Me CARMELA MAIORINO:

Section B(i)?

Me JEAN-SYLVAIN PELLETIER:

Section B(i), yes.

Me CARMELA MAIORINO:

During which time frame?

Me JEAN-SYLVAIN PELLETIER:

From the beginning to the end.

UNDERTAKING NO. 6: To advise the proportion of physicians that submitted the report

requested by section
B(i) with their
requests (under
reserve of objection)

Me JEAN-SYLVAIN PELLETIER:

Q. [414] Mr. Mackay, as the person responsible to answer to the requests of the physicians to have access to the product, wasn't it important to have information about the results, and about the adverse reactions of the product?

Me CARMELA MAIORINO:

I maintain my objection as to the relevancy of this line of questioning, as to the...

Me JEAN-SYLVAIN PELLETIER:

I think it's dramatically pertinent, we're talking about a drug, we're talking about people responsible for the health of the population, we're talking about the, he explained all the way in his affidavit that any drug has risks, and there are adverse effects, and there are beneficial effects, and there's a need to find the equilibrium between the two, this is what the affidavit talks about. I think if I ask him the question that those reports, are those

reports important to him, regarding information from the physicians on the results, and on the adverse reactions. So my question is:

- Q. [415] Isn't that important information for the SAP?
- A. Practitioner has an obligation, and any reports we receive are important to us, yes.
- Q. [416] But wasn't it important to have as much as possible data regarding the results, and the adverse reactions from the doctors, the physicians, on the 714 usage?
- A. Clearly, it would have been to everyone's advantage, I think, for the physicians to meet their obligations. I described to you earlier that physicians do not meet their obligations to report, as part of a larger chronic problem about reporting from...
- Q. [417] Okay, I'll repeat my question, Mr. Mackay. Is it important for you, as the coordinator, the person responsible to answer the physicians, isn't it important for you to know if there are results, what are the results of the product, and if there are any adverse reactions?
- Me CARMELA MAIORINO:
He just answered the question...

Me JEAN-SYLVAIN PELLETIER:

No, he didn't.

Me CARMELA MAIORINO:

... he said the practitioner has the obligation
and the reports are important...

Me JEAN-SYLVAIN PELLETIER:

Yes?

Me CARMELA MAIORINO:

... he stated that previously.

Me JEAN-SYLVAIN PELLETIER:

Well, he didn't answer the question.

Me CARMELA MAIORINO:

He stated it, he did...

Me JEAN-SYLVAIN PELLETIER:

I'm sorry, no, he didn't.

Me CARMELA MAIORINO:

... he said the reports are important, he said
it.

Me JEAN-SYLVAIN PELLETIER:

That's not the answer, that's not the answer to
the question.

Me CARMELA MAIORINO:

Your question was: Isn't it important
information...

Me JEAN-SYLVAIN PELLETIER:

For you.

Me CARMELA MAIORINO:

... for SAP?.

Me JEAN-SYLVAIN PELLETIER:

To have as much information as possible on the results, and on the adverse reactions.

A. For what purpose?

Q. [418] I don't know, you tell me.

A. If you're talking about the general decision making from day-to-day, the bulk of the consideration is given, as specified earlier on in 10, data in respect:

"Data in the possession of the practitioner with respect to the use, safety, and efficacy of that drug."

If we had specific information that came to...

Q. [419] Not if, my question is: Is it important...

Me CARMELA MAIORINO:

Let him finish his answer, please.

Me JEAN-SYLVAIN PELLETIER:

Well, he's evading.

Me CARMELA MAIORINO:

Please finish your answer, Mr. Mackay.

THE WITNESS:

A. If we have information, specific information about adverse drug reactions, that's very important to us.

Me JEAN-SYLVAIN PELLETIER:

Q. [420] If you have this information?

A. If we have that information, it's very important to us, and on occasion, in a general sense, SAP does receive information, sometimes very disconcerting information respecting adverse drug reactions encountered with the use of SAP products. That is what we call a big red flag, and we have to act on that.

Q. [421] Tell me, tell me more about 714 specifically, did you get any big red flag from practitioners?

A. No...

Q. [422] You didn't?

A. ... I think I referred to that earlier, yes.

Q. [423] Okay. And you say that this information is very important, is that right, important information on the results and the adverse reaction?

A. I described the information that might come to us as the result of the use of the drug, and

information respecting adverse events, as important to us. I described as very important specific, very disconcerting information that might come to us about an adverse drug reaction, such, for instance, as a death, if there was death on a drug on SAP...

Q. [424] Yes.

A. ... and the physician connected that death to the drug in the report...

Q. [425] Yes?

A. ... that would be what we call...

Q. [426] I understand.

A. ... a red flag.

Q. [427] But regarding 714, do you know if there were internal instructions, or an internal policy, to gather as much information as possible from the physicians regarding section B(i)...

A. No...

Q. [428] ... since they were obliged to do so?

A. There was no specific direction with respect to 714-X.

Q. [429] So you didn't care at all about having information from the physicians on that topic, on those two (2) topics?

- A. I described the information as being important to us.
- Q. [430] When you receive it?
- A. When we receive it, yes.
- Q. [431] But I don't, I don't see in your answer that it was important for you to gather information; am I right?
- A. We did not have the ability to, with the number of requests that we had, to complete the loop, if you will, on that for all drugs.
- Q. [432] What do you mean, I'm talking about 714...
- A. Right.
- Q. [433] ... stick to 714, please.
- A. Okay.
- Q. [434] You didn't have the ability, what does that mean, you didn't have the personnel, you didn't have the resources, you didn't have the money, what does that mean, no ability?
- A. Well, with respect to the physician's obligation, we relied on the physician to report to us, it was their obligation, they undertook it as part of their request to us, and we specifically were expecting reports. When physicians did not report, it was not possible, given the number of authorizations during the

time frame that I'm familiar with, to go out looking for reports...

Q. [435] Why not?

A. ... nor is there a specific obligation to do it, it's important, but there's no specific obligation on my part to go out to get it. The obligation is on the practitioner to report.

Q. [436] Okay.

A. Which is different, I might add, from even the circumstance where, in the general adverse drug reaction scenario, where physicians are not obligated to do so.

Q. [437] But in that case they were?

A. On SAP they are...

Q. [438] Actually...

A. ... so it is their, it's very important to note that it is their obligation to do so.

Q. [439] Though you requested, positively, and with pressure actually, the enforcement of paragraph A(ii), that the information was submitted about data in the possession of the practitioner with respect to the use, safety, efficacy, and this information was not anecdotal evidence, obviously; I'm right? This was information about the product in general...

Me CARMELA MAIORINO:

Are you referring...

Me JEAN-SYLVAIN PELLETIER:

Q. [440] ... not about their own patient?

Me CARMELA MAIORINO:

... are you referring to the information received or the information requested.

Me JEAN-SYLVAIN PELLETIER:

Requested, and received probably.

Q. [441] If I understand your perspective, Mr. Mackay, you insisted, definitely, and it shows everywhere in your affidavit and the evidence you submitted, to receive from the physician supplemental data, in some cases, about the use, safety, and efficacy of the drug 714, but you never inquire specifically, or methodologically, or in a very enforced way, to get report on the results of the use of the product, nor on any adverse reactions, specifically from the physician with his patient?

A. Mm-hmm, I think a part is important probably to note that our request form, the request form which physicians use to file a request with us, and I can't recall whether that's an exhibit of mine or not... suffice to say there is a request

form, you're probably familiar with it.

Q. [442] Mm-hmm, yes.

A. The request form is a standard sort of government-looking form. Front page has basic information about the physician, the patient, the amount of drug required. The second page of information asks a number of questions, and in answer to those questions physicians, I don't have any specific recollection with 714-X, but in general physicians will, particularly, for instance, if it's a repeat patient, if a patient had been on a particular drug in the past...

Q. [443] Right?

A. ... they may have described their experience with it...

Q. [444] Right?

A. ... and why it is, and so there are three (3) questions which are asked, which physicians have the opportunity to describe why it's the best choice for their patient, I forget the exact questions...

Q. [445] Do they talk about the results and the adverse reactions?

A. They might.

Q. [446] They might...

A. They might.

Q. [447] ... have you, have you been taking,
compiling this information over the time?

A. No.

Q. [448] Why not?

A. Even if we did compile it, there's always the question, and it gets back to the part earlier in my affidavit in 51 where we talk about anecdotal evidence. Ultimately, particularly information with respect to efficacy, is definitely considered anecdotal, so even if we had a perfect data set, it still would not be enough, it's still ultimately anecdotal. The only way that we can get to an answer with respect to how efficacious the drug is, how safe the drug is, is by applying an experimental design and gathering information...

Q. [449] The whole kit...

A. Right.

Q. [450] ... if I may say, if I may say?

A. Right.

Q. [451] Okay, the big, the big machine, okay...

Me CARMELA MAIORINO:

Well...

THE WITNESS:

A. Yes.

Me JEAN-SYLVAIN PELLETIER:

Q. [452] ... as you describe, with all the tests,
and rulings, and...

A. I think...

Q. [453] ... sponsoring, and so on, okay?

A. Yes, I think in my affidavit I describe in
detail that this is a stepwise process, where
over the course of, you start small and you
gradually, you gradually amass information and
data that would ultimately support the safety
and efficacy of drug for a specific indication.

Q. [454] Okay, Mr. Mackay, if I, if I gather, let's
say, for instance, one thousand (1,000), if I
gather information on the results and the
adverse reaction of one thousand (1,000)
patients, is this still anecdotal evidence?

A. Yes, it is.

Q. [455] It is, okay.

A. And it seem counterintuitive...

Q. [456] But, but...

A. ... it seems counterintuitive, and...

Q. [457] No, I understand...

A. Yes.

Q. [458] ... I understand. I don't say I agree, but I understand.

A. Okay.

Q. [459] And your testimony is that to gather information on the results, even though we're talking about thousands of people, thousands of reports, it was not important enough to build some kind of data, some kind of sum-up of information that you could have used, or could have requested, on the results and on the adverse reactions? So you didn't, you didn't exercise your discretion to that level; I'm right?

A. As I said before, my understanding, and my read in my affidavit speaks to question, speaks to item B as being an obligation on the part of the practitioner, not discretion on my part.

(LUNCH RECESS)

(UPON RESUMING)

Me JEAN-SYLVAIN PELLETIER:

So we're back from lunch.

Q. [460] Mr. Mackay, in paragraph 51, before, just before lunch we discussed briefly about the matter of anecdotal evidence. You mentioned at one point that when you collect data from

physicians regarding the effect of the drugs that are used under the SAP, it's some example that you stated is that if a physician reports to you a death of his client using a drug under the SAP, would you consider that as anecdotal evidence?

A. I specifically said earlier, I think, that if a physician reports a death, and connects...

Q. [461] To the...

A. ... the use of the drug...

Q. [462] Right.

A. ... to the death...

Q. [463] Then you raise a red flag?

A. That's a red flag.

Q. [464] Okay, now, do you consider that as an anecdotal evidence?

A. It is a report of an adverse drug reaction, it is anecdotal in the sense that it's not, it wasn't collected in a experimental design, etc., but classically speaking, such series of events all have to be looked at in the event that it may be a trigger for some larger issue. It usually, it usually demands a full-fledged inquiry on the part of the physician, and you would then probably go back to see whether you

had any other reports of that, to see whether there was a trend, and I emphasize the word "trend," because it is anecdotal. And, so, yes, it is anecdotal.

Q. [465] It is anecdotal, indeed?

A. It is anecdotal, yes.

Q. [466] Now, what I understand from your answer is that an anecdotal event as such, depending on the context, can have no impact or major impact; I'm right?

A. Well, it can be a significant event, it can be a significant event, and it can, it can identify a trend.

Q. [467] Significant impact, is that, that was my question, it can have a significant impact or...

A. On..?

Q. [468] On whatever reaction, depending on the answer, or the event that is reported. In the case that we have as an example, someone died. That is, that is an anecdotal event which has an important impact; I'm right?

Me CARMELA MAIORINO:

Sorry, just to clarify, is it...

Me JEAN-SYLVAIN PELLETIER:

I'm just, no, I'm just...

Me CARMELA MAIORINO:

... is it impact on the access to the drug, or
is it impact on...

Me JEAN-SYLVAIN PELLETIER:

No, impact on your services, impact on the
people managing SAP.

A. It's a significant red flag.

Q. [469] Okay.

A. Yes.

Q. [470] Now, we're talking about an adverse
effect, obviously, someone's dead, but what
about...

A. If it was a death, yes.

Q. [471] Yes, if it was. Now, would it be the same
for the opposite, like someone reports a patient
who was about to die, who was cured by the same
product on SAP, would it raise the same impact?

A. No, it doesn't actually. Generally speaking in
regulation, significant adverse events are, it's
part of the precautionary approach I've
described earlier, and I describe at length in
the affidavit, where you're always presuming
something is bad before you can show that it's
good, so evidence, and all negative evidence is
weighted more heavily than positive evidence.

- Q. [472] Okay, how is treated a positive evidence anyway?
- A. Pardon me?
- Q. [473] How is treated, is there, is there a kind of a follow-up on a dramatic positive event that is reported by a physician?
- A. No.
- Q. [474] Not at all?
- A. No.
- Q. [475] And what if that event is redundant, like five (5) physicians report that their patients were cured with the product, do you have some, does it create some reaction inside management of SAP?
- A. No.
- Q. [476] Not at all either?
- A. No.
- Q. [477] Why?
- A. Because, as I said...
- Q. [478] Same answer?
- A. ... because it's...
- Q. [479] Because you...
- A. ... because it's anecdotal, and the weight of, the weight of evidence, the weight of negative evidence outweighs the weight of positive

evidence, although I do, it is, it is, it is anecdotal. It comes back to the central question of drug regulation, is that drugs are presumed guilty...

Q. [480] I understood that...

A. ... before they're, before they're...

Q. [481] ... understood that, but even though, even though the negative impact outweighs the positive impact, even though it outweighs it, does it mean there's any positive impact reported several times, to come back to my example, would not at all create any movement, or any questioning, or inquiries, or whatever, from the SAP management?

A. No.

Q. [482] Not at all either?

A. No, again, no, no.

Q. [483] Okay.

(OFF THE RECORD)

Me JEAN-SYLVAIN PELLETIER:

Q. [484] Paragraph 54, you come with like any question, when you say at the end of paragraph 54, page 14:

"As to whether the benefit of a drug outweighs the risks and vice versa."

Right, this is like the proportion, as you mentioned before, between the risk factor and beneficial factor. Does this criteria or equation apply to SAP products, or it's only for the main market product?

A. It's only for the what?

Q. [485] Open market.

Me CARMELA MAIORINO:

The witness responded to this question before lunch.

Me JEAN-SYLVAIN PELLETIER:

Q. [486] So he answered. Can you just repeat your answer then, I'm sorry, to ask you the same question. I presume the answer was, no, it wouldn't apply to SAP?

A. The paragraph 54 speaks for itself, is that I'm responding to something specific, and the question is is anecdotal evidence is insufficient to make informed decisions.

Q. [487] To, as you say, as to whether the benefit of a drug outweighs the risks and vice versa, and my question was, this notion of outweighing is related to SAP or not?

A. It can, it can encompass SAP, but it's also a general statement with respect to informed

decision making. Another way to describe that would be informed decision making, or evidence based decisions, or you're making a decision not because you think or you hope or you wish, it's based on evidence to make a serious decision as to whether to approve a drug, to release it through SAP, to prescribe a drug, etc., the whole issue, the issue of 54 is responding to a paragraph basically talking about informed and evidence based decision making.

Q. [488] Paragraph 56, now we're into the SAP.

A. Yes.

Q. [489] You say:

"Regulatory authority to permit the sale of unapproved new drugs for emergency purposes was established in nineteen sixty-six (1966) through an amendment."

The amendment only regulates the sale of the product; right? Would the amendment apply if the product was not sold, was not sold but given?

A. As, if you, paragraph 56 refers to a summary of the authority to permit the sale, sale is defined in regulation as being a transaction

with or without consideration.

Q. [490] Oh, in what regulation?

A. It's...

Q. [491] Other regulation than the...

A. ... sale is defined in the...

Me ANDRÉ LESPÉRANCE:

Defined in the Act.

Me JEAN-SYLVAIN PELLETIER:

Q. [492] It's in the Act?

A. Yes.

Q. [493] Okay, definition of sale is in the Act?

A. Yes.

Q. [494] It includes kind of...

A. Whether or not for consideration, so for free or for money.

Q. [495] Paragraph 57, and on, you mentioned a new term that appears here, "the regulator." I believe that regulator means the person responsible to apply SAP...

A. Yes.

Q. [496] ... in general, or are we talking about you specifically?

A. I'm talking in general terms, I'm a regulator in general terms...

Q. [497] With the SAP?

A. Yes, I could have easily used the present tense there.

Q. [498] And when we speak about regulator, we're talking about the people responsible to manage SAP; is that correct?

A. Yes, that's what I'm referring to, yes.

Q. [499] Okay. Paragraph 59, page 16 on the top...

A. Mm-hmm.

Q. [500] ... you mention:

"Health Canada also considers other information in its possession about the drug, including the progress of clinical trials, safety information, the regulatory status of the drug in other countries."

To your best knowledge, do you, do you know if you got, if you have in file a request, an inquiry to have information about 714 from other countries?

A. Do I have a request on file?

Q. [501] Did you, did you, do you have information in your file...

A. Mm-hmm?

Q. [502] ... about 714 coming from other countries?

A. Yes.

Q. [503] From which country and what documentation?

A. In my original affidavit and the Garber, so-called Garber report...

Q. [504] Okay, some, okay, this is all... I should have specified, that is not already deposited as evidence on your part. In other words, the evidence you deposited, is that total information you gathered in your files regarding 714, Canadian or other countries?

Me CARMELA MAIORINO:

Do you mean, just so, I'm not sure...

Me JEAN-SYLVAIN PELLETIER:

Q. [505] Beside the information you deposited as evidence, do you have other information...

Me CARMELA MAIORINO:

In terms of literature available...

Me JEAN-SYLVAIN PELLETIER:

Yes, on 714...

Me CARMELA MAIORINO:

... on 714-X...

Me JEAN-SYLVAIN PELLETIER:

... yes, yes.

Me CARMELA MAIORINO:

Okay, coming from any other country. Basically, are you familiar with any other literature on

714-X...

Me JEAN-SYLVAIN PELLETIER:

Not familiar, if he has in his file literature
as such from other countries.

A. Hmm...

Q. [506] If you're not sure, you can take a, a...

Me ANDRÉ LESPÉRANCE:

Undertaking?

Me JEAN-SYLVAIN PELLETIER:

Q. [507] ... undertaking, merci. Okay?

A. Yes, I'm just trying to think back. There is, I
should say there is a, there is a historical
file on 714-X, which predates me, which would
have contained, again, those newspaper articles
I referred to, etc., earlier, prior to me coming
onto the scene. There could very well be some
information that stem from other countries in
there, but I don't have any specific
recollection, or recall anything in particular,
but we can...

Q. [508] Can check that?

A. Yes.

Q. [509] What number were we at, 5?

Me CARMELA MAIORINO:

I don't know, maybe 6 or 7.

Me JEAN-SYLVAIN PELLETIER:

Sept (7)?

(OFF THE RECORD DISCUSSION)

Me CARMELA MAIORINO:

Just to clarify your last question, are you referring to scientific information, scientific literature that may come from...

Me JEAN-SYLVAIN PELLETIER:

No, all sorts of literature, all sorts of documentation that comes from other countries, and I'd like to have the, an index, and a copy of the document. If any, actually it may not be very heavy.

UNDERTAKING NO. 7: To verify if there is any information, literature, documents coming from any other country regarding 714-X, and if so, to provide an index and a copy of same (under reserve of objection)

Me JEAN-SYLVAIN PELLETIER:

Q. [510] Mr. Mackay, paragraph 62, please. You state, the first sentence:

"When a requester satisfies the SAP that there is a plausible scientific basis for the emergency use of the drug, notice of such authorization is transmitted to a specific manufacturer."

I understand from all the evidence deposited, that this plausible scientific basis for the emergency, and other conditions of the regulation, were, indeed, followed and fulfilled from the beginning of the programme in nineteen eighty-nine (1989) up to two thousand three (2003), when you started to question the access to the programme; I'm right?

Me CARMELA MAIORINO:

Well, just for clarification, Mr. Mackay was with the programme as of ninety-two ('92), so...

Me JEAN-SYLVAIN PELLETIER:

No, he was with the programme as, you started in two thousand (2000), so there's one (1) year maybe he was, he wasn't present.

A. No, I started in nineteen ninety-two (1992), I

was acting in nineteen ninety-eight (1998), and I had the job I currently have as unit head in two thousand (2000).

Q. [511] Okay, no, I'm sorry, sorry, I confused.

So according to the good statistics, starting from nineteen ninety-two (1992).

A. Well, I can only assume that any, I was not, I did not make all the decisions along the way, I described when I was responsible for decisions, and there were others responsible for decisions along the way over that period of time, and I can only assume that they were undertaken in good faith, taken in good faith.

Q. [512] Just remind me when you started to be responsible for decisions, two thousand (2000)?

A. I became unit head in two thousand (2000).

Q. [513] So that's the time when you became responsible for answers; right?

A. Yes, I was, I was in an acting position before that, but there was a, but the real work with respect to these authorizations began in two thousand (2000).

Q. [514] Still paragraph 62 states, second sentence:

"SAP authorization permits the sale of

a specific quantity of the drug to a
specific physician for a specific
patient."

A. Mm-hmm.

Q. [515] What is the specific quantity that is
authorized?

Me CARMELA MAIORINO:

Can you, please, specify in respect...

Me JEAN-SYLVAIN PELLETIER:

Q. [516] In general, do you have criterias or
parameters that you use to apply or define the
specific quantity of the drug?

A. Right. The specific quantity stems from the
regulations that, if you look in C-08011, it
talks about that the letter of authorization
must specify a quantity.

Q. [517] Right?

A. So that's where the authority comes from. The,
a quantity that is ultimately authorized is,
first of all, something that's requested by the
physician based on a dosage for a period of
time.

Q. [518] So at first the physician specifies the
quantity?

A. Yes, they'll say they want a, they want a dose

once a day for, or twice a day, whatever the case may be, for two (2) months.

Q. [519] Does it occur, indeed, that some physicians ask for two (2) months quantity?

A. Yes.

Q. [520] Two (2) months?

A. I'm talking about in general terms about all SAP requests, they...

Q. [521] No, I'm talking about 714, let's stick to 714.

A. Okay.

Q. [522] Did it occur, indeed, that some physicians asked for two (2) months period quantity of drugs, for 714?

A. They, the requests that we've dealt with for 714-X through the years would have spanned a range of quantities, depending on...

Q. [523] From what to what?

A. I don't, I can't remember right now.

Q. [524] Okay, so you take undertaking?

A. I can say, we'll do an undertaking, it would range from one (1) or two (2) vials, to a range of twelve (12) vials, and, as I said, it depends on the dosage that the physician...

Q. [525] I would appreciate if you could check that.

Me CARMELA MAIORINO:

How is this relevant, the quantities, to the crux of the case?

Me JEAN-SYLVAIN PELLETIER:

Let me finish my questions, and probably you get the answer after that, okay?

Me CARMELA MAIORINO:

So I'm objecting under reserve then, the follow-up of the questions, because at this point in time I don't see how the quantity of the drug is relevant to the core of the case, the quantity and authorizations of the quantity...

Me JEAN-SYLVAIN PELLETIER:

Well, we're talking about regulation, regulation, as he says, indeed, specifies that it's a granted authority.

Me CARMELA MAIORINO:

But I really thinks it's important to bring you back to the heart of the matter, I don't see how it's relevant, that's what I'm saying, so I object...

Me JEAN-SYLVAIN PELLETIER:

Well, the heart of the matter is that people are in need to have this drug, and that the SAP managers, including our fellow here, to our

perspective, do not exercise their authority in discretion, according to what should be done, to allow those people to have access to the drug, and survive, because we're talking about here a matter of life or death. This is the issue. So I think all questions relating to how this whole process is being managed by people of SAP, regarding any kind of impact on the Canadians that are requesting this drug to survive, I think this is dramatically positively...

Me CARMELA MAIORINO:

Well...

Me JEAN-SYLVAIN PELLETIER:

... pertinent, absolutely, and I think it's alright to ask questions.

Me CARMELA MAIORINO:

We got to keep in mind that the case we have at bar is a judicial review, and the ground of review is patently unreasonable, so we got to keep within the scope of that, so...

Me JEAN-SYLVAIN PELLETIER:

The ground of review is what?

Me CARMELA MAIORINO:

The ground of review for a judicial review in the case at bar, is that the decision maker must

have rendered a decision that is patently unreasonable in order for it to be judicial...

Me JEAN-SYLVAIN PELLETIER:

Well, with great respect...

Me CARMELA MAIORINO:

... subject to judicial review.

Me JEAN-SYLVAIN PELLETIER:

... with great respect to your opinion, I mean, this could be also debated before the tribunal...

Me CARMELA MAIORINO:

So...

Me JEAN-SYLVAIN PELLETIER:

... in terms of what, to what degree the evidence has to be presented before the Court so that the review be granted.

Me CARMELA MAIORINO:

Nevertheless, I maintain my objection under reserve of, and the undertaking is noted.

Me JEAN-SYLVAIN PELLETIER:

Okay, we'll debate that later on.

UNDERTAKING NO. 8: To advise what the
range of quantities
was that was requested

by physicians for 714-
X (under reserve of
objection)

Me JEAN-SYLVAIN PELLETIER:

Q. [526] Now, besides the request of the physician on a certain quantity, what other criteria are considered to allow a specific quantity? Let's take of example a physician requesting quantity for one (1) year period to have the, to have access to the drug for his patient.

A. Mm-hmm.

Q. [527] How would you react to that, would you say yes or no?

Me CARMELA MAIORINO:

I'll have to object under reserve as well with this question.

Me JEAN-SYLVAIN PELLETIER:

Q. [528] Please?

A. You're asking a hypothetical question...

Q. [529] Oh, sure, I mean, unless you can answer my question otherwise.

A. Right. The first part of your question was to do with criteria that we have, and what, and then your second part...

- Q. [530] With quantity...
- A. Right, and...
- Q. [531] ... referring to quantity now.
- A. Correct, and then your second part of your question was what we would do for, in the case of 714-X for a year...
- Q. [532] An extreme example, correct, okay.
- A. So the criteria we apply, because we operate an emergency programme, it's assumed that the emergency is generally over a short period of time.
- Q. [533] Why do you assume that?
- A. Because it's an emergency.
- Q. [534] Why, why wouldn't be an emergency before three (3), or four (4), or six (6) months, or a year?
- A. I'm not finished my answer yet.
- Q. [535] Okay, you assume that?
- A. We assume that the period is short, and the SAP is designed to provide limited access...
- Q. [536] Limited access, where do you find that?
- A. Inherent in the word "emergency."
- Q. [537] This is your definition of it?
- A. It is.
- Q. [538] Okay. So in your definition of emergency,

necessarily it has to be for a short period of time; right?

- A. It is, it is my firm belief that SAP is to be used, in exceptional circumstances...
- Q. [539] But short period of time?
- A. For relatively short periods of time, yes, there is...
- Q. [540] Okay, do you...
- A. ... I believe there is, I believe there is a range, depending on the drug that's being used, and how it is used, the condition that it's being used for, and the dosing that is requested by the physician. If you have a circumstance, so we have, you asked whether we have criteria, we have a general criteria that we will authorize, provided it's consistent with the, with the prescribed dosing. In other words, if the, if the manufacturer suggests this be dosed at twice a day, or, etc., if a physician came and said we want to administer this a hundred (100) times a day, then we'd say, well, there's something funny with that, you're moving outside of the realm of...
- Q. [541] This is the per diem dosage, or the daily dosage, if you want, okay?

A. Yes, but ultimately, it ultimately would calculate to be a quantity, and so, clearly, if you're talking about extremes, if you saw someone who was looking for ten thousand (10,000) vials of something, and they want to use it for six (6) months, that's going to raise an obvious question as to how much drug is actually required, and what the, and what the, what the recommended dosing is from, information from the manufacturer.

Q. [542] But in your case it could be possible that your discretion, indeed, grants the request, if you're, if you analyze the circumstances, and your conclusion comes to, yes, it's, it goes according to our criterias, you would allow, or you could allow, indeed, such a long period, isn't it?

Me CARMELA MAIORINO:

I object to this question, it's a hypothetical question...

Me JEAN-SYLVAIN PELLETIER:

He came with the hypothesis, not me.

Me CARMELA MAIORINO:

Well, you should...

Me JEAN-SYLVAIN PELLETIER:

So he started the idea on that.

Me CARMELA MAIORINO:

... the whole line of questioning as to the quantity, and there's no specific...

Me JEAN-SYLVAIN PELLETIER:

We're on it, we're right on to it.

Me CARMELA MAIORINO:

We're very far from it...

Me JEAN-SYLVAIN PELLETIER:

Oh, absolutely not...

Me CARMELA MAIORINO:

... very, very far from it.

Me JEAN-SYLVAIN PELLETIER:

... we're talking about quantities, I, we just spoke about per diem, he spoke about how many dosage a day, and that was spoken about thirty (30) seconds ago. I think we're on the spot.

A. The issue, the central, what I believe is the central point of your question was whether we have criteria, and we generally apply, in general we will authorize what a physician will request, provided it's within the range that a manufacturer might suggest...

Q. [543] Is that, is that all, only on that range,

or other criterias?

A. No, I'm not finished.

Q. [544] Okay.

A. And if that range exceeds six (6) months, we will generally, we will generally limit it to six (6) months, and that allows...

Q. [545] Okay, who decided on a six (6) month period?

Me ANDRÉ LESPÉRANCE:

Just one point, allow the witness to finish the question, and I know...

Me JEAN-SYLVAIN PELLETIER:

Yes, okay, because...

A. The six (6) month, the six (6), you asked whether or not we have criteria, etc., and that is...

(OFF THE RECORD)

THE WITNESS:

A. This is an...

Me JEAN-SYLVAIN PELLETIER:

Q. [546] I'm sorry, I'm sorry, okay, I just hope that we didn't have to move.

A. Criterias, the question...

Q. [547] I'm sorry, go ahead.

A. ... the question was whether we have criteria.

Q. [548] I interrupted you again.

A. The criteria we apply is generally we'll consider up to a six (6) month supply, provided it's consistent with the dosing recommendations from a company. Generally speaking, within, within the practice of medicine, we also know, and we hear from physicians that any person's medicines, any person's drugs are reviewed on a regular basis, no physician will give you a prescription for an unlimited period of time. And so we believe that our criteria is consistent with what happens within the practice of medicine, where drugs are reviewed, and the use of drugs is reviewed on a regular basis, and that gives the opportunity for the physician to consider how well the drug worked or didn't work, whether there are adverse events, and then to consider a subsequent authorization, a subsequent request to us. So it doesn't preclude someone from having access to something for a longer period of time, but it just divvies it up into discrete units, whereby there's an opportunity to review, and to give consideration to the use of what is ultimately an unapproved product, where the safety and efficacy of that

product has not been definitively established, and it's in everyone's best interest that the system be set up such, that there's discrete units of consideration for these exceptional purposes.

Q. [549] Okay, regarding the six (6) month period...

A. Mm-hmm?

Q. [550] ... who decided about the six (6) month period, who decided about this period?

A. This has been something that's been of longstanding, it, no, it absolutely predates me in terms of decision making.

Q. [551] In the management of SAP?

A. Yes.

Q. [552] So if I understand your point, a physician may ask for a six (6) month period access to the 714, and he would be granted the authorization; am I right?

A. Well, again, that's a hypothetical, there's a lot of question, there's a lot of consideration given to each individual request.

Q. [553] Did it ever occur?

A. For a six (6) month period of time?

Q. [554] Yes?

- A. I have no specific, the number of requests that I would have considered over the years, and the number of 714-X, I would have no specific recollection of...
- Q. [555] You don't recall at all?
- A. I don't recall...
- Q. [556] Over the years how many authorization have you been granting...
- A. I think we asked that question...
- Q. [557] ... of 714?
- A. ... I think you asked that question...
- Q. [558] Thousands?
- A. We answered that, and we took an undertaking, I think, to confirm that.
- Q. [559] Yes, okay. And you don't recall if -- what was the longest period then that you granted for the access of 714?
- A. I have no recollection.
- Q. [560] You don't know?
- A. I don't know.
- Q. [561] That'll be part of the undertaking; right?
- A. I think the undertaking that we agreed to was the number of authorizations that we had, we had issued over a period of time, we didn't...
- Q. [562] Okay, so can you add then to, in that

undertaking, the period of time?

A. Our computer records may not reflect those specific points, it'll reflect the quantity.

Q. [563] Is the, was the...

A. But our computer records...

Q. [564] ... is the quantity used in a standard way by patients, to your knowledge? Actually, my real question is: From the quantity can you extrapolate or make a small calculation, and actually get to the period of time that it was used?

A. Not with...

Q. [565] Or that was granted?

A. ... not with the computer records that we would have access to for the entire length of time.

Q. [566] Can you do that yourself?

A. Pardon me?

Q. [567] Could you do that yourself with the numbers you have and the information you have?

A. What I'm saying is I don't believe we could do that. We have, we would have, we have transaction records of the, of the total number of authorizations, which we've given you an undertaking, and within those records it would contain the quantity of each authorization.

- Q. [568] And from that you cannot extrapolate or try to find the actual period of usage of the product?
- A. No, for one thing, the physician, even if the physician had of stated something in the first place, it may or may not have been the time and the dosage that was actually used, could have been adjusted along the way by the physician, we would have no knowledge of that.
- Q. [569] And to your personal experience, what was the usual, if I may say, period of time that the product was granted for, per time, every time, you know?
- A. Early on, before it was my responsibility for considering these, there was a, there was generally a two (2) vial limit, requests that would come in for two (2) vials...
- Q. [570] I'm sorry, what's a vial again, vial is...?
- A. A vial is a quantity of, the 714-X was sold in the form of a vial, it was a...
- Me CARMELA MAIORINO:
Tubes.
- THE WITNESS:
- A. Viales, viales, with...

Me JEAN-SYLVAIN PELLETTIER:

Q. [571] Viales?

A. Yes, thank you, thank you.

Q. [572] I don't know, yes, vial?

A. Yes.

Q. [573] So to extract for the...

A. Correct.

Q. [574] ... needles?

A. Correct. So in general the requests would come in, and they were authorized two (2) at a time...

Q. [575] And how long...

A. ... for many years.

Q. [576] ... how long is one (1) vial?

A. It depends on, ultimately, what the physician chose in terms of a dosage.

Q. [577] To your knowledge, was there a standard dosage?

A. There were standard dosages that were described by the manufacturer, but what was actually ended up being used on a, on a patient, I would not know.

Q. [578] And do you have patients that received from SAP supply of 714 for long period of time, in terms of more than six (6) months, more than

a year?

A. Hmm...

Me CARMELA MAIORINO:

I'll have to object, the witness answered previously that they normally evaluate these on a six (6) month basis.

Me JEAN-SYLVAIN PELLETIER:

But maybe he can answer the question that is presented otherwise. He was started to, to answer.

Me CARMELA MAIORINO:

He didn't start to answer.

Me JEAN-SYLVAIN PELLETIER:

Well, almost.

Q. [579] So do you have patients that were on 714, granted authorization to use 714 under the SAP for long period of time, when I say long, I mean one (1) year, or two (2) year, or three (3) year period?

Me CARMELA MAIORINO:

More than six (6) months, that's what you're saying?

Me JEAN-SYLVAIN PELLETIER:

Q. [580] Well, depending, one (1), two (2), three (3) years, do you recall any data on that?

- A. You asked me a question earlier as to whether or not I had any, what was the outside time frame of the longest I would have authorized, and I said I did not know that.
- Q. [581] Okay, so that'll be part of the undertaking, okay.
- A. As I said, the information...
- Q. [582] I'm sorry, I may, I may overlap some points that we already discussed, it's just that...
- A. The undertaking that we've agreed to is the total number of requests, and what we have, we have access to the number of vials, for instance, that were released for each individual authorization. Working backwards to actually what in, what any individual patient received, is not information in my possession.
- Q. [583] In the treatment or the management of your requests by physicians, do you open one (1) file per patient, or one (1) file per physician, how does it work?
- A. We have a request, we talked earlier about the request form, a request form constitutes a request, and that...
- Q. [584] Okay, but where do you put those requests,

you said the request was sent to you by fax usually.

A. Laterally, laterally...

Q. [585] And the answer, your answers were done by fax also. Once the fax is being received and treated, and managed, according to...

A. Yes.

Q. [586] ... to your criterias, what would you do with the fax, you would garbage it?

A. No.

Q. [587] Where would you put it, you had a file that you put it in probably?

A. Yes, I described earlier that there's a central...

Q. [588] Okay, so those files, so those files, physical paper file...

A. Yes?

Q. [589] ... do you have one (1) file per patient?

A. No.

Q. [590] Do you have one (1) file per physician?

A. One (1) file for requests, they are, they are catalogued...

Q. [591] Are they classified in there?

A. They are, they are catalogued according to the date of authorization or denial.

- Q. [592] Okay, okay, chronologically?
- A. Correct.
- Q. [593] And you don't make any categories per physicians at all, you don't have that, nor paper categories, or electronic categories, by computer?
- A. No, they are tracked, they are tracked by, each transaction, whether it's approval or a denial...
- Q. [594] Okay?
- A. ... are tracked according to the physician who made the request.
- Q. [595] So those are separate files, you have one (1) file for acceptance, and another file for denials; right?
- A. Well, it's the decision making, I'm just saying there's...
- Q. [596] Okay, but I'm talking about management of files, okay?
- A. Right.
- Q. [597] There's paper files and there's computer files?
- A. Correct.
- Q. [598] I understand that every paper file that is entered in SAP programme, is also, all the

information in there is being computerized; am I right?

A. Not all information is computerized.

Q. [599] But most of the information concerning a request, the name of the patient, the name of the doctor, the quantity, the date, and so on?

A. We call it basic tombstone information...

Q. [600] Yes?

A. ... and I don't know what proportion of the total information, but it's a, it's a portion of the information which comes in by fax, ends up into the electronic file as the transaction, a database that we spoke about earlier.

Q. [601] So regarding the paper file, you don't segregate, you don't discriminate, you don't separate the files? If I would go at your, at your office, for instance...

A. Mm-hmm, mm-hmm, yes?

Q. [602] ... and see the paper files that you have...

A. Yes.

Q. [603] ... how would it be presented, I would have to have...

A. Chronologically.

Q. [604] Chronologically?

A. Correct.

Q. [605] Only?

A. Correct.

Q. [606] So if a physician requests a demand for
714...

A. Mm-hmm?

Q. [607] ... and submits some information he has
about the product...

A. Correct.

Q. [608] ... and that he is granted the
authorization to, his patient is granted the
authorization to received the product, and after
two (2) months, for instance, he comes with
another request, because the period is lapsed,
does he have to submit always the same data to
get the same, the same positive answer?

Me CARMELA MAIORINO:

I'll have to object, this is totally
hypothetical.

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

No, no, it's not hypothetical.

Me CARMELA MAIORINO:

It's very hypothetical, if a physician submits a
request...

Me JEAN-SYLVAIN PELLETIER:

Yes?

Me CARMELA MAIORINO:

... and then submits it again, I mean, give me a concrete example.

Me JEAN-SYLVAIN PELLETIER:

Okay, well, actually, take off the "if" and put it "when."

Q. [609] When a physician submits a request for the 714, and he's already submitted such requests in the past...

A. Mm-hmm.

Q. [610] ... do you request or require the same data about the product that he's already submitted in the past? You understand my question?

A. I understand your question. The physician is required, I should preface it by saying that, and I spoke earlier about that, we consider each individual request discrete from another.

Q. [611] Totally discrete?

A. Yes.

Q. [612] Notwithstanding at all past requests from the same physician, for the same patient, for the same conditions, same emergency?

- A. That's correct.
- Q. [613] So every request that enters is treated like from scratch, totally new?
- A. Yes, and the reason why I can say that with confidence is that there are a lot of physicians who are frustrated with us.
- Q. [614] I would, I bet they would be.
- A. And the reason why they're frustrated with us is because they believe, like in the rest of the world, if someone had a repeat, if you will...
- Q. [615] Yes?
- A. ... at a pharmacy, sometimes the physician will write a script and say: "I'll give it to you for two (2) months with repeats."
- Q. [616] Yes.
- A. The physician doesn't have to write a new script. So they take it to the pharmacist and they get repeats, etc. We don't operate that way in the sense that, again, the implied mandate of SAP is for, is for an emergency and implies a short period of time, so what we're saying is that: "We'll give you a quantity of drug for a relatively short period of time, and you can come back to us if you want, but you have to evaluate, you have to fill that form out

again to essentially pull the emergency bell again.

Q. [617] And fill the, yes, I understand, fill the form...

A. Fill the form out again, yes.

Q. [618] ... and supply the same documentation that we've...

A. Well, things...

Q. [619] ... supplied already maybe five (5), or ten (10), or fifteen (15) times already?

A. The onus is on the physician to supply us with information in their possession. Within six (6) months, it could be, I don't like answering hypothetical question, but it could be the same information the physician applies, but in that period of time new information could become available that's in the possession of the, of the physician, and, quite commonly, a competent physician would want to do that, they would want to go looking for a new update for information. Information in the area of drugs changes on a daily basis.

Q. [620] Do you check for update information on 714?

A. ...

- Q. [621] You understand my question?
- A. In the context of an individual request?
- Q. [622] Yes? Do you check...
- A. The onus is on the physician to supply us with information in their possession.
- Q. [623] How do you know that it's an update of information, if you don't check at all any kind of information on 714?
- A. The onus is on them to provide what they have, and for us to determine, based on what they provided, whether or not we're comfortable with authorizing, or whether we're in a position to deny their request.
- Q. [624] Do you check the information that is submitted by physicians?
- A. What do you mean by check?
- Q. [625] Do you look at it?
- A. Yes.
- Q. [626] And what is done with it?
- A. It's part and parcel of the decision making, as to whether or not that information meets the criteria of the physician whose obligation it is to provide us with information in their possession.
- Q. [627] So if I understand the way you manage the

information, and the formulas, and the request that you make to physicians, a physician may be granted the authorization to use the product because he has sufficient, to your perspective, to your evaluation, sufficient data about the product?

- A. Mm-hmm.
- Q. [628] And what if another physician for another patient, with the same emergency condition, does not supply the same, or does not supply information at all, for the same context, the same illness, he would not be granted, is that what I understand well, he would not be granted the authorization to use the product?
- A. If the request came in without any information, for instance, question 3 not answered well or at all, I describe in my affidavit at length the procedures that we use to return the request to the requesting physician, in either saying to them that they haven't answered question 3, and/or they've not provided us with information, and specific direction as to what to do.
- Q. [629] So he will not be granted the authorization, even though it's the same illness, for the same context for the patient?

- A. What I understood your question to be is whether or not, if they provided, if they have not provided...
- Q. [630] Right.
- A. ... information in their possession...
- Q. [631] Right, but the illness is the same, the context...
- A. Correct.
- Q. [632] ... the urgency, and so on, is all the same...
- A. Correct, yes.
- Q. [633] ... objectively...
- A. Yes, it goes back to the regulations, the physician has an obligation to report...
- Q. [634] Okay.
- A. ... to file with the request data in their possession.
- Q. [635] So you don't consider at all that some information could have been applied to similar cases in the future?
- A. No, we, as I mentioned before, and I underscore the fact that each request is...
- Q. [636] From scratch everything?
- A. Yes, yes, yes, definitely. I acknowledge, it is the source of frustration, not just with 714-X,

with other physicians as well; however...

Q. [637] It's not only frustration, I think it's...

A. I, the...

Q. [638] ... a strange way to manage...

A. ... the regulations are clear...

Q. [639] ... to say the least.

Q. [640] ... the regulations are clear with respect
to...

Me ANDRÉ LESPÉRANCE:

I object to this line of question. I mean, this
is a legal issue, and you'll debate it.

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

I know, I know.

Me ANDRÉ LESPÉRANCE:

Maître Pelletier, we have different perspective
on this one...

Me JEAN-SYLVAIN PELLETIER:

I know, so, that's why we're here.

Me ANDRÉ LESPÉRANCE:

That's it.

Me JEAN-SYLVAIN PELLETIER:

Q. [641] Regarding 714, did you have any word to
say on the cost of the product, how much the
product was sold from the manufacturer to the

client?

Me CARMELA MAIORINO:

I'll have to object, that's totally irrelevant,
objection...

Me JEAN-SYLVAIN PELLETIER:

We're talking about sales...

Me CARMELA MAIORINO:

... objection under advisement, I -- no need to
answer that, it's completely irrelevant, unless
you can show me how the cost of the drug is
relevant to the issue at bar, it really is not
relevant.

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

I'll skip it.

Me JEAN-SYLVAIN PELLETIER:

Q. [642] When a physician applies for a request for
the product 714, for the same patient, for the
same period, the same criteria, with the same
literature submitted, and he was accepted
already once, can a denial occur at a future
request? If all the information is submitted
the same way, with the same literature, the
formula filled the same way, for the same
patient, same period, everything is the same,

and he was granted the authorization once, or twice, or three (3) times, can a denial occur afterwards?

Me CARMELA MAIORINO:

Maître Pelletier, I object to this line of questioning, it's completely hypothetical. Submit Mr. Mackay with a concrete factual background of a specific case, we have four (4) judicial review applications that are filed, with four (4) specific cases, I don't see how, I don't...

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Because you don't like my, you don't like my -- it's not a hypothesis, I'm asking a question.

Me CARMELA MAIORINO:

It's completely...

Me JEAN-SYLVAIN PELLETIER:

Q. [643] When, when a physician is filling the same form for the same patient, same context, same emergency, and he's got granted authorization once, or twice, or three (3) times, this physician, can he take for granted that future requests will be answered positively also?

Me CARMELA MAIORINO:

I object, there's four (4) judicial review applications, with four (4) different applicants, and four (4) different factual situations that you could refer to, in terms of understanding whether the decision makers, the decision making power within the scope of those four (4) judicial review applications fall within the scope of the law.

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Q. [644] Léopold Delisle's physician...

Me CARMELA MAIORINO:

Mm-hmm.

Me JEAN-SYLVAIN PELLETIER:

Q. [645] ... was granted the access to the product; right? Do you know that?

A. The name of the physician, just for clarity?

Q. [646] Let me inquire.

Me MICHEL BÉLANGER:

xxxxxxxxxxxxxxxxxxxx.

Me JEAN-SYLVAIN PELLETIER:

Q. [647] xxxxxxxxxxxxxxxxxxxx is the name. Does this sound familiar to you?

A. The name is familiar to me.

Q. [648] Yes.

(OFF THE RECORD DISCUSSION)

Me JEAN-SYLVAIN PELLETIER:

Q. [649] Okay, I was speaking with the physician of Léopold Delisle, the Plaintiff, Applicant. If his physician requests access to the 714 for Mr. Delisle, filling the form, always the same way, submitting the data, always the same data, will his physician be granted at every request the access to the product for his client?

Me CARMELA MAIORINO:

I'll have to object. Even though you're referring to Mr. Delisle, it's if, you can ask specifically what happened in the case of Mr. Delisle, rephrase your question. I mean, it's clearly hypothetical, if his physician, or, you know, we have a specific factual context of Mr. Delisle.

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Okay, I'll change my process, anyway.

Q. [650] For the same introductory context, same doctor, same patient, Mr. Delisle, same physical emergency, same dosage, when it is accepted once or three (3) times, because in his case, do you

recall, indeed, that Mr. Delisle got access to the product numerous times. Is he right to take for granted that he will be having access to the product on other occasions when the documents are submitted the same way with the same data?

Me CARMELA MAIORINO:

I object, I object under advisement once again because it's, clearly it's a hypothetical line of questioning. I have no problem if you want to inquire as to what transpired with respect to Mr. Delisle's situation, with respect to the SAP request that he filed in, that is within the context of his judicial review application, no problem.

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Q. [651] Mr. Delisle got access to the 714 on numerous occasions, as we discussed. On December two thousand three (2003) he was denied access to the product, December two thousand three (2003) he was denied access to the product; can you explain why he was denied access, even though the same patient, same context, same product, same physician, same data?

- A. I first of all have to confirm in my records whether or not there was a denial...
- Q. [652] Okay.
- A. ... and you'd have to provide me the date, or the approximate date on which you argue that...
- Q. [653] December two thousand three (2003).
- A. December two thousand and three (2003). I will have, I'll take an undertaking to confirm whether or not a denial was issued by SAP in December two thousand and three (2003) for the said doctor.
- Q. [654] Either September or December.
- A. Two thousand three (2003)?
- Q. [655] Two thousand three (2003)?
- A. I can add September two thousand and three (2003).
- Q. [656] In September two thousand four (2004), okay, I'd like you to check those two (2) dates, the two (2) period of time.
- A. I think I can, I'll have to take an undertaking for the December two thousand and three (2003), the two thousand, the September two thousand and four (2004), I speak to that transaction, and how that transaction was handled, in my affidavit.

UNDERTAKING NO. 9: To confirm if a denial
 was given to Dr.
 xxxxxxxxxxxxxxxxxxxx for Léopold
 Delisle in December
 2003

Me JEAN-SYLVAIN PELLETIER:

- Q. [657] Okay, whereabouts?
- A. It's beginning in, it's under a whole section titled, on page 39, point 151 it begins, wherein I respond to Monsieur Delisle's affidavit of December the twentieth (20th), two thousand and four (2004), and points 151 through 158...
- Q. [658] That's the, that's the...
- A. ... describe...
- Q. [659] ... episode with the clerk?
- A. Pardon me?
- Q. [660] That's the episode with the clerk?
- A. That describes the, that describes the events in and around September two thousand and four (2004) and subsequently, and I draw your attention specifically to point 51, 52, wherein I specifically described that, and the words are very important here:

"There was no denial issued."

A denial, from our perspective, is a specific record with a specific letter, and no such denial was issued.

Q. [661] But there was a delay; right?

A. The request that came to us was returned to the physician.

Q. [662] Why?

A. I describe in my, in my affidavit the reasons and the events of those, of those times.

Q. [663] That is described in paragraph 152?

A. One fifty-two (152) and 153.

Q. [664] So in 152 you state, you state that:

"The request was screened by a clerk
and not by a reviewer."

Right?

A. That's correct, yes.

Q. [665] Why was it screened by a clerk?

A. That is part of our standard operating procedures.

Q. [666] All the requests are being screened by clerk first?

A. All requests that come in come in by fax, and we have a standard operating procedure as to how they are processed, and the first part of the processing is a screening by our front line

staff.

Q. [667] That's the clerk?

A. Correct.

Q. [668] What does he check?

A. They will check to see whether, I think I describe in here:

"Make the first decision as to whether the request is complete, which includes a judgement call about the completeness of all answers to all questions and fields on the form."

Q. [669] Including supplemental data that is requested?

A. Correct, in particular, if question 3, which is, connects back to the regulations, which is the question in which the physician will provide data in their possession with respect to the use, safety, and efficacy of that product, if that question is not answered at all, or if there is a brief answer, then the clerk will make the judgement call as to whether to send it back, looking...

Q. [670] So he exercise discretion on that topic?

A. My answer describes this, it:

"Includes a judgement call about the

completeness of answers."

Not about the...

- Q. [671] So he has, he exercise kind of a discretion?
- A. They screen the request to see whether or not, if you will, all of the blanks are filled in, and they make a judgement call as to whether or not ones that are empty, or are one (1) or two (2) words, or whatever, are sent back to the physician, requesting a more fulsome answer to their question.
- Q. [672] Based on the filling of the form?
- A. Based on the filling of the form.
- Q. [673] What about based on the data that is required?
- A. No, they do not make a, this is not a decision, this is not an authorization or it's not a denial, and I make that specific point in paragraph 152, it is not a denial.
- Q. [674] Okay, and what is the role of the reviewer that you state on paragraph 152?
- A. The reviewer, and is another word to describe me, the person who brings their mind to the actual information that's provided in the form.
- Q. [675] So you review?

A. Yes.

Q. [676] Once the file is complete, according to the clerk, you review it?

A. Right, the reason why I use "reviewer" in this context, is I make, I made specific reference to standard operating procedures, and then our standard operating procedures, for clarity, we define the difference between a clerk and a reviewer.

Q. [677] Do I understand that this standard operating procedure is written?

A. Yes, I believe we had an undertaking already to provide it to you.

Q. [678] It's already undertaken, thank you. Page 40 on the top, you say:

"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."

A. Mm-hmm.

Me CARMELA MAIORINO:

Sorry, where are you?

Me JEAN-SYLVAIN PELLETIER:

Page 40 on the top, it's...

Me CARMELA MAIORINO:

Oh, okay, right, mm-hmm.

Me JEAN-SYLVAIN PELLETIER:

... the first line, the first words, first sentence.

Me CARMELA MAIORINO:

Mm-hmm, got it.

Me JEAN-SYLVAIN PELLETIER:

- Q. [679] Now, the clerk made that decision in your absence; why do you stipulate in your absence?
- A. I think it's an important point because, while I say that the clerk can make the judgement call, or whatever, sometimes if there's, if they have a question or if they'll come to me, and they'll say: "Ian, I'm not sure whether this is, does this sound right to you, is this the kind of thing you want to take a look at?," so this occurs frequently throughout the day. If I'm not there, then the judgement, if I'm not there, because I'm the main reviewer, then they make, they make a judgement call in my absence to send it back. I often come to the same conclusion, but in the course of working in our area we frequently consult each other before making a decision to send something back, in the event

that they might see something, they may not see something that I might see, I might know something that they don't know, and just to double-check before they send something back.

Q. [680] And you take vacations sometimes?

A. I do.

Q. [681] You go travel outside the country sometimes?

A. ...

Q. [682] Do you leave the country sometimes during the year?

A. I do.

Q. [683] And when you're not there at the office, what happens, who's taking the decision?

A. I delegate that authority to a, another senior officer in my employ.

Q. [684] Who's that?

A. It can be one (1) of three (3) people.

Q. [685] And what are their titles?

A. They are -- their titles?

Q. [686] Yes?

A. They are...

Q. [687] Functions, yes?

A. ... that are special access officers.

Q. [688] Are those people listed in annex B?

A. No.

Q. [689] They're not?

A. They're assuming my duties in my absence.

Q. [690] And they have authority, your authority actually, to accept or refuse a request?

A. In my absence, that's correct.

Q. [691] Okay. How many vacations a year, how many weeks a year do you, do you leave the office, vacation time?

Me CARMELA MAIORINO:

I object, how is this, how is this relevant in terms of...

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Well, it's pretty relevant, I want to see what period of time he's not there, how often is he not there.

Me CARMELA MAIORINO:

And how is that relevant to the four (4) JR applications that are filed?

Me JEAN-SYLVAIN PELLETIER:

Well, if he's not there to exercise his discretion, and other people exercise his discretion, I want to know for how long.

Me CARMELA MAIORINO:

The question is whether the, how was the discretion exercised for the four (4) JR applications that are filed.

Me JEAN-SYLVAIN PELLETIER:

Actually, we've been discussing either specifically on the case of Mr. Delisle, or some other cases eventually, or in general, regarding the application of the SAP, how is the SAP, the SAP managed. He's the decider, and I want to know when, he's told me already that when he's not there, someone else takes the decision at his place, and I want to know at what frequency or how long is he not there.

Me CARMELA MAIORINO:

The scope of the JR is not the inquisition of the SAP, but the verification as to how the SAP exercised its discretionary authority in the four (4) JR applications that are filed, so I maintain my objection.

Me JEAN-SYLVAIN PELLETIER:

Q. [692] Paragraph 66 you give some figures about the year two thousand and four (2004), page 17.

A. Yes.

Q. [693] They're all statistics in Léopold

Delisle's affidavit; have you seen those statistics also on the product, and statistics appearing in the legal procedure that supports, that is joined to this affidavit, do you recall seeing this, these numbers, figures?

Me CARMELA MAIORINO:

Perhaps you can refer him specifically to the...

Me JEAN-SYLVAIN PELLETIER:

Yes, I'll try to find it, and I'll let you know.

(OFF THE RECORD)

Me JEAN-SYLVAIN PELLETIER:

I am referring to... I'm not sure we have the same document, affidavit dated April twenty-third (23rd), two thousand four (2004), do you have that one? Cause I think there's two (2)...

Me CARMELA MAIORINO:

Twenty...?

Me JEAN-SYLVAIN PELLETIER:

April twenty-third (23rd)?

Me CARMELA MAIORINO:

I have May thirty-first (31st), two thousand four (2004), affidavit of...

Me JEAN-SYLVAIN PELLETIER:

Maybe actually they, I'm looking for data regarding the number of injections. You

probably, you probably will have that, let me see... okay, it's going to be here. Have you read the, you obviously read the affidavit of Léopold Delisle, dated April fifth (5th), two thousand four (2004), is that the one you have?

Me CARMELA MAIORINO:

I have May thirteenth (13th), two thousand four (2004), the affidavit filed in support of the judicial review.

(OFF THE RECORD DISCUSSION)

Me JEAN-SYLVAIN PELLETIER:

- Q. [694] I would like to briefly look at the affidavit by Gaston Naessens submitted in the evidence, the affidavit signed on March thirty-first (31st), two thousand four (2004); Mr. Mackay you have this document before you, you do?
- A. March thirty-first (31st), I'll just double-check for my own purposes... March thirty-first (31st), two thousand four (2004), yes, I have it right here.
- Q. [695] Okay, you have read this affidavit, obviously? Let's skip "obviously," but you have read it?
- A. Yes, some time ago, yes, yes.

- Q. [696] Some time ago, okay. Tell me how is your French for the reading, is it, is it strong enough to read the document in French, and understand by yourself?
- A. Read out loud?
- Q. [697] No, no, no, understand what you read, no, no...
- A. I will try. If I feel that I'm compromised, I'll ask for an authoritative translation.
- Q. [698] Okay, in that, in that specific case what happened, do you recall if you used a translator to help you out...
- A. Yes, the...
- Q. [699] ... or you read it by yourself, and understood..
- A. ... I read it by myself first of all, and there were a number of people that, not a number of people, there was, there were one (1) or two (2) people who were very skilled in French that assisted me in the areas that I, that I felt that I needed help, yes.
- Q. [700] For, okay, specific items, but in general...
- A. In general I read through it myself, definitely, yes, yes.

Q. [701] Okay. Now, Mr. Naessens, in his affidavit, stipulates some data, figures in paragraph 30.

A. Yes.

Q. [702] Thirty (30), three-oh (30).

A. Yes, yes.

Q. [703] Have you, can you take a look at this paragraph specifically?

A. I have it in front of me, yes.

Q. [704] You have it before you?

A. Mm-hmm.

Q. [705] Can you confirm to me that if those figures are true?

A. No.

Q. [706] You cannot?

A. No.

Q. [707] Can you check that?

A. I can check some of those, I can verify some of those figures, but I cannot verify all of those figures.

Q. [708] Which can't you?

A. I would not know the number of injections, I would not know the number of treatments, and it would be difficult for me to confirm unique patients, four thousand...

A. In general we are responding to urgent requests, and, where possible, all of our literature and documentation, and we work toward this over a course of many years, to work towards an operation that works towards fast processing of requests.

Q. [714] Give me an example, or a few examples of urgent requests, as you say.

A. Hmm...

Q. [715] Are the, if I may help you out, is the case of Léopold Delisle considered an urgent request?

A. We talked earlier about urgency meaning different things to different people, urgency also has a scale. The specific question you asked me is giving me an example of a, of an urgent request from our perspective, I'll give you...

Q. [716] A very specific example, this is not a hypothesis.

A. Right. So the example of...

Q. [717] Mr. Delisle.

A. ... example of Mr. Delisle. On the scale of things that we normally see, it would probably rank in the bottom third.

- Q. [718] What does that mean?
- A. It means that there are other requests that we receive on a regular basis, which would be comparatively more urgent.
- Q. [719] Like he would be on the lower third, you say, so there would be mid-third...
- A. I'm describing a scale to you...
- Q. [720] Yes?
- A. ... of things, of requests, and the reason why products are requested, and the seriousness with which the request is made.
- Q. [721] Okay, why do you consider Mr. Delisle in the third bracket, the non-urgent urgency?
- A. I didn't describe it as non-urgent, I described it as within a...
- Q. [722] The lower third?
- A. Right, I described it, a scale of urgency.
- Q. [723] But lower third, if I'm right, if I understand your words, means it's not that urgent; is that it?
- A. It's not as urgent as the top third...
- Q. [724] Right, so...
- A. ... I'm trying, describing a scale.
- Q. [725] ... it's a less urgent urgency?
- A. I'm describing a scale.

- Q. [726] Okay, so why do you say that Mr. Grandmont's request is in the low urgency scale?
- A. I did not comment on Grandmont.
- Q. [727] I'm sorry, Grandmont, no, no, Delisle, I'm sorry, cause I have that before me. Delisle, why do you say that Delisle is in the low urgency scale?
- A. I'm describing to you my experience of the range of products we release, and the range of indications for which those products are used, and in my experience there's a range of urgency.
- Q. [728] You don't answer my question, Mr. Mackay. My question was Mr. Delisle, why do you put Mr. Delisle's position in the lower scale for urgency?
- A. Because there are...
- Q. [729] You understand my question?
- A. ... there are on any given day requests which are more urgent, and so...
- Q. [730] On a given day?
- A. On a given day and a given time frame, yes.
- Q. [731] Could be day, could be weeks; is that...
- A. Yes, it's best to describe it in days, because that's the, our process occurs on a daily basis.
- Q. [732] Okay, do I understand that Mr. Delisle's

request could be one day urgent in the high scale, and the other day urgent in the low scale?

A. My affidavit is clear with respect, we aim to process all of the requests, I used the word "all"...

Q. [733] Mr. Mackay, will you, please answer the question about Mr. Delisle, please. You don't need to refer to the affidavit for that answer, please.

A. So could you repeat the question.

Q. [734] Why, are you saying that Mr. Delisle's position, or Mr. Delisle's request, one day could be in the high scale of urgency, top urgency for that day, and the next day, or two (2) days later, the same request of Mr. Delisle could be positioned, according to your discretion, in the lower scale of urgency?

A. On any given day it could vary as to where it would be, yes, because it is relative to the other requests that must be processed on that day.

Q. [735] Who evaluates the urgency of a request?

A. There are a number of people, the physician calling, or requesting, can indicate the urgency

on the form...

Q. [736] I'm sorry, I'm going to repeat my question. In the management of SAP...

A. Yes?

Q. [737] ... your people that you work with...

A. Yes?

Q. [738] ... everyday, who is, who is in charge of evaluating the urgency of a request when it comes in?

A. The first people to see the request are the clerks.

Q. [739] And so they evaluate this urgency or not?

A. There are, there could be clear indications on the form as to the urgency of the request.

Q. [740] Okay, for that same day again?

A. For that same day, correct, as they, as they come into the program.

Q. [741] Okay, so the process is: The clerk sees it first...

A. Correct.

Q. [742] ... and in the same day transfers it to you; is that it?

A. We aim to process all requests within twenty-four (24) hours.

Q. [743] You don't answer my question, Mr. Mackay.

Me ANDRÉ LESPÉRANCE:

Yes, he does.

Me JEAN-SYLVAIN PELLETIER:

Q. [744] The fair, no, no, the first, the first
thing, the clerk sees the document...

Me ANDRÉ LESPÉRANCE:

Sorry...

Me JEAN-SYLVAIN PELLETIER:

Q. [745] ... the first person who sees the request
is the clerk...

A. Correct.

Q. [746] ... and on the same day he transmits to
you this formula, this request?

A. We have a process, we have a, we have a standard
operating process whereby they screen, we
described that earlier...

Q. [747] Mr. Mackay, will you, please, answer yes
or no.

Me CARMELA MAIORINO:

Let him, let him...

Me JEAN-SYLVAIN PELLETIER:

I mean, he doesn't answer...

Me ANDRÉ LESPÉRANCE:

He does, maybe you...

Me CARMELA MAIORINO:

He told you that you that the aim, that's the
aim...

Me JEAN-SYLVAIN PELLETIER:

Maybe, maybe I'm too early, okay, I'm sorry,
maybe I'm too...

Me ANDRÉ LESPÉRANCE:

No, no, it's just a question...

Me JEAN-SYLVAIN PELLETIER:

... rushed to get your answer.

Me ANDRÉ LESPÉRANCE:

Yes...

Me JEAN-SYLVAIN PELLETIER:

Maybe.

Me ANDRÉ LESPÉRANCE:

No, no, but the point, I think it's been said
many times, he aims of doing the same day,
twenty-four (24) hours is the aim...

Me JEAN-SYLVAIN PELLETIER:

But, no...

Me ANDRÉ LESPÉRANCE:

Maybe you should ask him whether he achieved the
objective.

Me JEAN-SYLVAIN PELLETIER:

No, no, no, I have...

Me ANDRÉ LESPÉRANCE:

Well, what's your question?

Me JEAN-SYLVAIN PELLETIER:

... a very specific about Mr. Delisle...

Me ANDRÉ LESPÉRANCE:

Oh, okay, but then talk about Delisle.

Me JEAN-SYLVAIN PELLETIER:

... mais oui, mais oui, it's about, you know...

Me ANDRÉ LESPÉRANCE:

Then maybe you should explain...

Me JEAN-SYLVAIN PELLETIER:

What do you mean I should talk about Delisle, I'm been speaking for the last ten (10) minutes about Delisle. I mean, she doesn't want me to go for hypothesis, well, I stick to truth, true facts, I mean, but he doesn't answer.

Q. [748] Anyway, go ahead, I'm sorry, maybe I interrupt you too early.

A. I'll try to make it clear, and I'm trying to provide the context of what would happen on a given day, and what would happen with Monsieur Delisle's request. If there are, if there are no requests that come in, for instance, in the top end, bleeding disorders, people on operating tables, and various things like that...

- Q. [749] Oh, you're talking about top end, do you have a list of what is described or defined as top end?
- A. I described to you earlier there's a range of urgency.
- Q. [750] Well, yes, but tell me about this list...
- A. No, we do not...
- Q. [751] ... is it, is it written?
- A. No, we do not...
- Q. [752] It's not written.
- A. ... have a list, as I described earlier, that clerks make the first call as to whether -- first of all, we aim to look after everything within twenty-four (24) hours, which is fast.
- Q. [753] Okay.
- A. Within that twenty-four (24) hours, and we achieve that, we achieve that to a certain degree, we clearly don't achieve it to a hundred percent (100%), but we clearly achieve it to a large degree. Within that period of time there can be urgent requests, where judgement calls have to be made with respect to how fast the drug, the request has to be considered, for a whole variety of reasons.
- Q. [754] But...

A. And...

Q. [755] Oh, sorry.

A. ... on any given day, that scale of urgency would move. It's like any other operation, if you have an ice storm in the city, then the police are not going to get to everyone at the same time, and they will have to prioritize, based on whether people are hurt, whether they're not hurt, whether it's a fender bender, and so we would operate a similar kind of triaging system, depending on what happens on any given day.

Q. [756] And depending on the illness of the patient?

A. Is one (1) factor. And this only comes into play, to a certain, because we do process the vast majority within a short period of time, so there's never, there's rarely a question. However, there are burning urgent requests. For example, I had a request the other day where something had to be looked after within minutes, there's frequently things that have to be looked after within minutes.

Q. [757] For the 714?

A. Not for 714, I'm describing the urgency, I'm

describing, I'm describing the urgency and the, and the alarm bell, are the emergency that the physician is describing.

Q. [758] In that evaluation of the urgency, you mentioned one of the factor is the illness; right?

A. It's one (1) factor, yes.

Q. [759] I'm referring you to affidavit of Mr. Delisle of April the fifth (5th), two thousand four (2004).

Me CARMELA MAIORINO:

We only have the affidavit...

Me JEAN-SYLVAIN PELLETIER:

I'm still wrong, I'm still off the...

Me CARMELA MAIORINO:

... May thirteenth (13th), two thousand four (2004), that's the one we have.

Me JEAN-SYLVAIN PELLETIER:

Okay, do you mind if I just borrow it for a second...

Me CARMELA MAIORINO:

Sure.

Me JEAN-SYLVAIN PELLETIER:

... I mean, we'll just clear it out, because the information is probably all the same?

Me CARMELA MAIORINO:

I don't think I have any annotations.

Me JEAN-SYLVAIN PELLETIER:

Q. [760] Mr. Mackay, paragraph 17 of Léopold
Delisle's affidavit, he states:

"En mille neuf cent quatre-vingt neuf
(1989), je fut diagnostiqué porteur
d'une maladie du système immunitaire
appellée mastocytose."

You remember reading that?

A. I do.

Q. [761] Do you know what mastocytose is?

A. I understand this is the diagnosis as, I
understand exactly as it says, that this is the
diagnosis...

Q. [762] But do you know what that is, do you know
what type of illness it is?

A. I don't have intimate knowledge of it, but I
understand it to be a chronic serious condition.

Q. [763] Okay. Daniel Grandmont's affidavit,
paragraph 11.3...

A. Yes, paragraph what again?

Q. [764] Eleven point three (11.3). Just a sec....

A. That doesn't make sense to me.

Q. [765] ... no, no, no, no, no, just a moment.

Okay, Grandmont...

Me CARMELA MAIORINO:

Which paragraph?

Me JEAN-SYLVAIN PELLETIER:

Paragraph 4, page number 2.

Me CARMELA MAIORINO:

Paragraph 4, page number 2?

Me JEAN-SYLVAIN PELLETIER:

Yes, you have that?

Me CARMELA MAIORINO:

Yes.

Me JEAN-SYLVAIN PELLETIER:

Q. [766] The individual states that at the age of
twenty (20), I'll translate in English...

A. Thank you.

Q. [767] You're welcome. At the age of twenty (20)
he's been diagnosed with a cancer called
carcinome adenoïd cystic. Now, do you know what
that is in terms of illness?

A. Clearly, it's a cancer.

Q. [768] Oh, thank you very much...

A. Yes.

Q. [769] ... do you know what type of cancer?

A. Well, it's adenocarcinoma of some type.

Q. [770] Oh, very bright. Now, do you know

carcinome adenoïd cystic, what type of cancer
carcinome is?

A. ...

Q. [771] You're pretty good.

A. I'm not sure I understand the question, what
type...

Q. [772] What type, do you know specifically the
type of cancer called carcinome adenoïd cystic,
do you know something about this type of cancer
specifically?

A. Not sitting here, no.

Q. [773] Okay, regarding Dany Laforest...

Me ANDRÉ LESPÉRANCE:

I just want to make a comment, Maître Pelletier,
and it comes back to relevancy. At no point in
the record and in the decision making, the
special access was refused because of the nature
of the disease. That's not part of the
decision, and it's not part of the...

Me MICHEL BÉLANGER:

No, but it has been postponed for weeks.

Me ANDRÉ LESPÉRANCE:

.. the nature, but that's not the reason, so you
have, that's the point I'm making, your question
has to link with the ground of review, the

ground of review is why you attack the decision, and it's nowhere in the record that the decision not to grant special access, it's because of the nature of the disease. We recognize, for the record, that these, those are serious disease, so it, if you wanted to have an admission in the file, we'll have it, so I'm just trying to save us time here, it's not relevant to recognize the importance of the disease. It's all people, you're talking about cancer, people that may die, he can admit it for the matter of the record, that's not relevant, it's admitted, you may argue on it, and that's not the reason why we are here today.

Me JEAN-SYLVAIN PELLETIER:

Well, I think you made the point, and I'm not going to go further...

Me ANDRÉ LESPÉRANCE:

That's it.

Me JEAN-SYLVAIN PELLETIER:

... I think you just, with the information you just gave us, I mean, if you, indeed, consider these as admitted, so we'll skip it.

Me ANDRÉ LESPÉRANCE:

The witness testify on it, he mentioned that

those...

Me JEAN-SYLVAIN PELLETIER:

Okay, okay.

Me ANDRÉ LESPÉRANCE:

... in the respect of Mr. Delisle, this was a serious disease. It's, you're talking about the efficacy and the safety of the product, and evidence thereof, that's the issue.

Me MICHEL BÉLANGER:

And abused discretion, yes, too.

Me JEAN-SYLVAIN PELLETIER:

Q. [774] Mr. Mackay...

Me ANDRÉ LESPÉRANCE:

That's...

Me JEAN-SYLVAIN PELLETIER:

This is discussions.

Q. [775] Mr. Mackay, you mentioned the matter of urgency to justify the fact that you had a operational target of twenty-four (24) hours to answer the request. Can you give us example of longer delays as consequence?

A. Mm-hmm. Paragraph 67 I outline a number of reasons why a request may be delayed.

Q. [776] No, actually, my question was: If the answer is not given in a very short delay, we're

talking about very short delay here, twenty-four (24) hours, this is your target...

A. Mm-hmm?

Q. [777] ... if the answer is given in longer delay, what may be the cause, not the cause, what may be the consequence for the patient?

Me CARMELA MAIORINO:

I object, the question is way too, too, it's unclear, what may be the consequence to a patient, which patient?

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Q. [778] For Mr. Laurent Légère, for instance, are you aware of some consequence that could occur to him if there's a delayed answer, or of Mr. Delisle, are you aware of any consequence they could suffer, or Mr. Laforest, or Mr. Grandmont, monsieur or madame, I don't know.

Me MICHEL BÉLANGER:

Monsieur.

Me JEAN-SYLVAIN PELLETIER:

I think it's monsieur, yes.

Q. [779] What is your answer?

A. I'm not specially aware of what the consequences may be.

Q. [780] Do you care about those consequences in the treatment of the programme?

Me CARMELA MAIORINO:

I'll have to object, that's absolutely irrelevant whether he cares or not.

Me JEAN-SYLVAIN PELLETIER:

I think it's absolutely relevant.

Me CARMELA MAIORINO:

How is that?

Me JEAN-SYLVAIN PELLETIER:

We're talking about a programme who's based on the principle of...

Me CARMELA MAIORINO:

The, but the judicial review is not based on whether Mr. Mackay factually, personally, emotionally cares about the consequence. The issue at bar is whether the discretion was exercised according to the law.

Me JEAN-SYLVAIN PELLETIER:

But the whole programme is based on the concept of compassion, and I want to know, in his perspective, if...

Me CARMELA MAIORINO:

That's not what Mr. Mackay testified earlier to.

Me JEAN-SYLVAIN PELLETIER:

That's what he said about it, but, anyway, I want to, I want to see if he has this...

Me CARMELA MAIORINO:

I object to the question.

Me JEAN-SYLVAIN PELLETIER:

... this perspective when he managed the programme. Under objection, under...

Me CARMELA MAIORINO:

I object under advisement.

Me JEAN-SYLVAIN PELLETIER:

Under advisement, what does that mean?

(OFF THE RECORD DISCUSSION)

Me CARMELA MAIORINO:

I'll take the objection under reserve.

Me ANDRÉ LESPÉRANCE:

And ask your question again.

Me CARMELA MAIORINO:

Ask your question again.

Me JEAN-SYLVAIN PELLETIER:

Q. [781] Do you, when you managed the programme, do you consider the impact of a late answering for the four (4) people that have stipulated, do you consider the impact of going beyond the twenty-four (24) hour target to give an answer?

A. I think that in my affidavit I specifically address the issue in terms of... allow me just to try to locate it... you can refer to paragraph 160 of the main affidavit, paragraph 60 of my affidavit.

Q. [782] One sixty (160)?

A. Right. This is basically talking about the period of time wherein, there's no...

Me CARMELA MAIORINO:

One sixty-one (161), sorry.

THE WITNESS:

A. I'm sorry, one sixty-one (161), I'm sorry, I didn't see the...

Me JEAN-SYLVAIN PELLETIER:

Q. [783] One sixty-one (161)?

A. One sixty-one (161) on page 42 of my affidavit. This is a paragraph which describes the period of time wherein there were delays. We acknowledge those delays, those are not, those are for the record. We also acknowledge, within this, the debate that we had within the programme as to what the appropriate course of action should be when you have outstanding requests, but at the same time you have an ongoing review with respect to the credibility

and the availability of information that physicians were providing, and the availability of information to support the use of this drug in emergency contexts.

Q. [784] But...

A. And so in my, in my, in my affidavit, describing a debate clearly shows, I think, clearly shows that this was something that we considered, and were trying to balance in the best way possible, and that particular paragraph describe that the delays that were incurred could not have been envisaged in the beginning, we were hoping to be able to respond more quickly, but there was an important due diligence process underway whereby we had to make sure we had covered all possible bases with respect to the availability and credibility of information to support the use of the drug, and until such time as we completed that review, there were delays incurred, and that's a matter for the record, and we attest to that without, without reservation.

Q. [785] Could you have continued a review, but answer promptly also, could you have done the two (2) simultaneously?

A. Yes, there were physicians who were, there were

physicians who were advised that there were delays, and that a response, a fulsome response was forthcoming from the department, and I think it was well-known, I know I spoke to physicians directly, I know my front line staff spoke to physicians directly, when there were inquiries as to what the reason for the holdup was. And we were very forthcoming with individual requests, with individual inquiries about that, and that we had every intention of trying to resolve the issue as quickly as we could through a single communication to everyone as to what was happening, what a conclusion, what the conclusion was when we reached it, and how that would impact on further processing of requests.

Q. [786] If I... yes, sorry, go ahead.

A. It's just, it's clearly fair to say that this was delayed beyond what we had originally hoped, but due diligence sometimes takes a bit longer than you had hoped, but it's important to make sure you're covering all the bases when you're dealing with important matters such as the evidence to support the use and safety of a drug in the context of an emergency.

Q. [787] If I understand what you're just saying to

me, you suspended the answers, positive answers or negative answers, anyway, you suspended the answers, because you were doing a review or a due diligence; is that right?

A. I did not use the word "suspend."

Q. [788] You did not answer, at least.

A. No, as I said, there were, there were, this...

Q. [789] You informed physicians that there would be a delay?

A. Many physicians were informed that there would be a delay, absolutely.

Q. [790] Okay, but actually you did not treat the request during the time you were doing the review or the due diligence?

A. No, that's not true. My paragraph 160 describes that there was a period of time when the review began, from the time the review began, and the consideration began, to the time the review was complete, where there were delays; there were some that got through...

Q. [791] Okay, how long does that last?

A. That lasts approximately from the end of July through to the date of the letter of, which was dated...

Q. [792] December?

A. No, it was dated January the nineteenth (19th),
two thousand and four (2004).

Q. [793] So for seven (7) month period, roughly?

A. I would describe the end of July, not being
seven (7) -- no, yes, to January, approximately,
yes.

Q. [794] So during seven (7) months you suspended
all access to 714...

A. No.

Q. [795] ... am I right?

Me CARMELA MAIORINO:

I'll...

Me JEAN-SYLVAIN PELLETIER:

He answered, he answered.

Me CARMELA MAIORINO:

Okay, I just would like to point out that the
affidavit is clear in answering your question,
at paragraph, the beginning of paragraph 161,
which says:

"The vast majority of requests..."

I'd just like to point that all.

Me MICHEL BÉLANGER:

Not all.

Me CARMELA MAIORINO:

Says:

"The vast majority of requests..."

Me JEAN-SYLVAIN PELLETIER:

Where do you see that?

Me ANDRÉ LESPÉRANCE:

"... were processed."

THE WITNESS:

A. Well, this is, you have to go back to the beginning of 60, and this is talking about the tabular listing, describing the delays.

Me JEAN-SYLVAIN PELLETIER:

Q. [796] Okay, so the vast majority were processed, so that means...

A. The vast majority of requests referred to in the tabular listing. I'm responding to the, I'm on page, I'm on point 160...

Q. [797] Above...

A. ... which is in the category of response to Exhibit 13 of the affidavit of Léopold Delisle. So the time frame of that tabular listing, I describe in 161:

"The vast majority of requests
summarized in Volume 1..."

Q. [798] Why couldn't you process all requests in that period? Could you have processed, actually, all of the requests during that

period, even though you say that you were doing a review, or a due diligence?

A. It's there for the record:

"Throughout the review SAP debated what the most appropriate approach should be with respect to processing a request."

Q. [799] But does that mean you had to...

A. This...

Q. [800] ... you had to not process some of the requests?

A. I'm going to provide a contextual answer, and then a specific answer. The contextual answer is the regulators often challenge with dealing with new information, and how that may impact on a particular circumstance where access to a drug may be available on the market, or available through SAP, or...

Q. [801] Was it the case that you had new information?

Me CARMELA MAIORINO:

Can you, please, let him finish answer, he was in the midst of talking.

THE WITNESS:

A. I think the context is important...

Me JEAN-SYLVAIN PELLETIER:

He talks, he talks a lot, I mean, it's hard to find...

Q. [802] Okay, sorry, carry on.

Me CARMELA MAIORINO:

Go ahead, Mr. Mackay, finish your answer.

THE WITNESS:

A. The, I think the context is important because the regulators often challenged with new information, and dealing with that on the run, and there's always a debate as to whether or not you stop everything until the review is complete because, or whether you continue everything until the review is complete, or whether you do something in-between, and there's all that the regulators challenged with that. In this particular instance, when the review began in the end of July through to the beginning of, through to December, and then a final decision announced on January the nineteenth (19th), we debated that issue, and there were some requests that went through that were, relatively speaking, good requests, and there were requests that came to us that were relatively poor requests. Which, it's important to note, is a

standard thing on a daily basis, we get good requests, we get ho-hum requests, and we get poor requests, and we have to deal with those on any given time.

Me JEAN-SYLVAIN PELLETIER:

- Q. [803] What do you mean by poor request?
- A. A poor request, it's not filled out properly, it's illegible, it's not complete, there's no documentation, it's not signed, there's a whole range of reasons why you would put something into a poor category. In the context of these requests, we clearly were talking, it's no secret, we were talking about the availability of information, and the obligation of the physician to provide evidence respecting the use, safety, and efficacy of it, and once we began to look at these more closely, carefully, we were finding that the requests were ranged, there was a range, there were good requests, there were bad requests, and the requests in-between, and that's the reason why some were processed in that period of time, and others were held pending a final decision. And I think that's clear in this portion of my affidavit.
- Q. [804] At the end how did you evaluate the

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request? Did you finalize, actually, the final opinion was that all requests were bad requests, according to the new criterias?

Me CARMELA MAIORINO:

Sorry, can you, please, specify during which time frame?

Me JEAN-SYLVAIN PELLETIER:

After January two thousand four (2004).

- A. The January nineteenth (19th) letter, dated January nineteenth (19th), two thousand and four (2004), letter, was a response to all of the outstanding requests. In addition, it was also sent to physicians who had accessed the product over the past year or so, and who could very well have had patients who were on 714-X, so we were trying to catch the group of physicians who were interested in using or continuing to use 714-X. So that response constituted, and that was clear in my affidavit, is that this constituted a response, and it provided direction to physicians who had outstanding requests as to what they should do, and it also provided direction to physicians who had patients on it, and who may want to file additional requests for continued access to the

product for a period of time that we specified.

Q. [805] Paragraph 68 of your affidavit, please.

A. Sixty-eight (68), yes?

Q. [806] Yes. Just read it, I'll have one (1) question for you.

A. Do you want me to read it?

Q. [807] Well, yes, unless you remember by heart.

A. Not into the record?

Q. [808] What?

A. Do you want me to read it into the record?

Q. [809] No, no, no, no, read it...

A. Oh.

Q. [810] ... read it...

Me MICHEL BÉLANGER:

In your head.

Me JEAN-SYLVAIN PELLETIER:

Q. [811] ... in your heart.

A. Yes.

Q. [812] Is the mandate described in paragraph 68 written somewhere in the law or the regulation?

A. No, it is not.

Q. [813] What is the origin of this description of the mandate?

A. The origin is stemmed, I think it was probably initially coined in and around say nineteen

ninety-five (1995), at a time when there was a review of the Special Access Programme, a regulatory review of the Special Access Programme, and at the time there was increasing attention on the department to try to describe regulatory activities in a transparent way. Prior to that regulators may have quoted regulations to people, perhaps even on the telephone, which really didn't mean much, and so this was an appropriate way to describe the programme for a large audience.

Q. [814] Is this mandate written somewhere at all?

A. It is published as a way, it's a description of the programme which is published in a number of areas, yes.

Q. [815] In what document, for instance?

A. It is published in the Compendium of Pharmaceuticals and Specialties each year, which is a large reference document that every physician and every pharmacist has within reach in Canada.

Q. [816] And you're saying that the origin of this wording comes from a reflection made within your service in nineteen ninety-five (1995); I'm correct?

A. It was in and around nineteen ninety-five (1995) when I believe this was coined. It's been tweaked since, as you would expect any literature to be, to be updated, to describe the programme in general terms, as to what we are there for. It's one way to, it's, whether it's media interviews, whether it's other interactions and other communications, it's a way to generally describe the programme, and the aims of the programme.

Q. [817] Does the mandate, the description of the mandate, did it change since nineteen ninety-five (1995), or it's always been the same?

A. ...

Q. [818] This is a description that you give in your affidavit...

A. Right.

Q. [819] ... in two thousand five (2005), ten (10) years after those events...

A. Right.

Q. [820] ... that you relate to.

A. Yes.

Q. [821] Between nineteen ninety-five (1995) and two thousand five (2005), I believe, maybe you'll correct me if I'm wrong, that it hasn't

changed, it's always been the same?

A. The general mandate as described has not changed, the wording may have changed...

Q. [822] But it remains to the same probably, isn't it?

A. This is a statement that I'm comfortable with, and that we've used for many years to generally describe the programme.

Q. [823] Sixty-nine (69), I'll let you read it.

(OFF THE RECORD)

THE WITNESS:

A. I'm familiar with it.

Me JEAN-SYLVAIN PELLETIER:

Q. [824] ...

"SAP is not a mechanism..."

Etc.

A. Mm-hmm.

Q. [825] Where, is this, is this coming from the law or the regulation, what SAP is not?

A. Mm-hmm, you'll know the regulations describe the exceptional nature of SAP, it describes that...

Q. [826] The regulation you're talking about is the one that...

A. C-08010 and 11.

Q. [827] Okay.

A. ... describes that authority as exceptional, I don't think anyone would argue, when you look at that it's designed for emergency purposes, and I think the wording is very crucial at the beginning of that, it says, not, you know:

"Notwithstanding the basic prohibition which is in place, that no person shall sell..."

In exceptional circumstances, at the discretion of the director, you can sell. And so it clearly implies that there is a, there is a, the basic prohibition still is in place, and the...

Q. [828] What do you mean it implies, who says that it implies?

A. Well, it says...

Q. [829] You say so?

A. ... it says:

"Notwithstanding..."

It says:

"Notwithstanding..."

Q. [830] And you conclude, you conclude, it's your interpretation that it implies, isn't it?

A. It's my interpretation that there is a, that the regulations on whole, provide a comprehensive framework for the regulation of drugs in Canada.

- Q. [831] Okay, so paragraph 69 is your own composition, if I may say?
- A. I wrote this, but it is wording and it is sentiments that is, that are well accepted within my, within my organization, and I would probably argue is well accepted within the drug development community, as reflected by the fact that...
- Q. [832] Of course, the drug community, definitely. Okay...
- A. I describe the drug development community...
- Q. [833] No, no, I understand that.
- A. Yes, yes.
- Q. [834] Paragraph 71.
- A. Mm-hmm.
- Q. [835] I'll let you read it.
- A. I'm familiar with it.
- Q. [836] Thank you. You mention:
"Typically drugs available through SAP are either A), B), C)."
What does that mean, where does that come from, what's the origin of this description?
- A. I'm, this is within the context of the mandate and scope of SAP, and I'm trying to provide some context about the programme and, typically, the

drugs that are available through it, and the profile of those drugs that are typically available through the programme.

Q. [837] Where do you get those discrimination, A), B), C)?

A. Those are, those are my descriptions off the drugs that, with which I am familiar over the course of my time at the Special Access programme.

Q. [838] So I understand that, typically, to be available through SAP, a drug has to fall within either A), B), or C), and you add at the end:

"That 714 does not fall within any of the aforementioned parameters."

A. Mm-hmm.

Q. [839] How come, how come 714 is still, anyway, it was for fifteen (15) years in the SAP programme, if it doesn't fall within one of those, A), B), C)?

A. Yes, I did not, in this I do not describe that it has to, I just said typically the drugs that are available through are.

Q. [840] Yes, but you also mentioned 714 does not fall, this is very affirmative.

A. Yes, but I'm describing that, I'm just

describing facts.

- Q. [841] Okay, so the 714 is not a typical drug to be in this, in this SAP programme; is that it?
- A. My affidavit is clear, I describe typically the drugs that are available, and how I might categorize those, and 714-X does not fall within those categories.
- Q. [842] Within the typical categories. And roughly would you say that, what is the percentage, actually, of drugs in the SAP that enters into the A), B), C) category, typical?
- Me CARMELA MAIORINO:
I'll have to object, what is the relevancy as to what is the percentage of drugs that fall within A), B), and C)?
- (OBJECTION)
- Me JEAN-SYLVAIN PELLETIER:
Actually, I should, I should ask him a question before that.
- Q. [843] How many drugs, I think you mentioned it somewhere in your affidavit, how many drugs are in the SAP programme in two thousand four (2004), I think you had a figure somewhere?
- A. I think I did somewhere... okay, at paragraph 66, I don't think I provided the exact number of

drugs that we released in two thousand and four (2004), but that information is available, that's not a secret. Paragraph 66 refers to historically the records we have in our database, we talked at length about the database earlier. I think a colleague of mine confirmed for me yesterday that there are some in the order of twenty-two (2,200) to twenty-three hundred (2,300) drugs that have historically been released or are released through SAP.

Q. [844] Twenty-two (22)...?

A. Twenty-two (22)...

Q. [845] Hundred?

A. Yes, I'm referring to the second sentence:

"Historically records provided over two thousand (2,000) drugs."

And I'm saying I heard yesterday from a colleague, just as a, as an update, the number is somewhere between twenty-two (2,200) and twenty-three hundred (2,300), so two thousand two hundred (2,200) and two thousand three hundred (2,300), just to, just to provide greater clarity.

Q. [846] So total of fifteen (15) years is roughly two thousand (2,000) drugs product...

- A. Over two thousand (2,000)...
- Q. [847] ... it is over, okay?
- A. ... over two thousand (2,000).
- Q. [848] And for two thousand four (2004) only, there's about three hundred (300) of them; is that it?
- A. Hmm...
- Q. [849] That's your second sentence of 66.
- A. Yes, approximately, it would be approximate, yes.
- Q. [850] Yes, okay.
- A. Yes, I, what I said is that we could take an undertaking to get you the exact number, it's relatively easy...
- Q. [851] That's one of the undertakings, actually, that we have; right?
- A. I don't think so.
- Q. [852] Isn't that, it's not supplied yet? So, okay, undertaking, you give me the records that you refer to in paragraph 66.
- A. I'll give you, I'll give you the records which confirm the number of drugs, the number of unique drugs that were released in two thousand and four (2004).
- Q. [853] Okay, 66 also refers to some records:

"Two thousand (2,000) drug products...
fifteen (15) years."?

Would you have an undertaking to give me the
number of drugs per year, the entrance and the
exit?

Me CARMELA MAIORINO:

That's initial, yes...

Me JEAN-SYLVAIN PELLETIER:

That's at the beginning...

A. Yes, we did agree to that, yes.

Q. [854] ... okay, so that'll be covered partly in
the...

Me CARMELA MAIORINO:

Obviously, all these undertakings are under...

Me JEAN-SYLVAIN PELLETIER:

Reserve?

Me CARMELA MAIORINO:

... reserve of my objection, based on Rule 91,
and also some objections based on relevancy.

UNDERTAKING NO. 11: To provide the records
referred to in
paragraph 66 which
confirm the number of
unique drugs that were

released in 2004
(under reserve of
objection)

THE WITNESS:

A. Paragraph 66 was just an effort to give you a snapshot of the, of the scope, because it's within this section, of the operations of SAP in two thousand and four (2004), for context purposes.

Me JEAN-SYLVAIN PELLETIER:

Q. [855] We've mentioned before, and it's stated in your affidavit several times, that 714 entered the programme in nineteen eighty-nine (1989). At that time did, are you aware if Health Canada provided, or done a survey or some kind of research on the safety of the product...

Me CARMELA MAIORINO:

I'll have to object...

Me JEAN-SYLVAIN PELLETIER:

Q. [856] ... and on the efficiency of the product, did they do some kind of survey anyway?

Me CARMELA MAIORINO:

I'll have to object, based on the fact that Mr. Mackay was not there back in nineteen eighty-

nine (1989), his affidavit is here, he began...

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

So he wouldn't be answered, okay.

Me CARMELA MAIORINO:

... he began working there in nineteen ninety-two (1992).

Me JEAN-SYLVAIN PELLETIER:

Okay.

Q. [857] Seventy-four (74).

A. Seventy-four (74)?

Q. [858] Yes.

"Nevertheless, SAP does manage risk within the context of its review, in consideration of data supplied by a physician, or provided by a manufacturer."

"Data supplied by a physician," do you refer to the data that the physician should have supplied?

A. Yes, that's what I'm referring to, yes.

Q. [859] Okay. So you manage the risk with those reports, that, obviously, you didn't get much, and from the information provided by the manufacturer. Did you...

A. I'm sorry...

Q. [860] No, that's okay, when we talk about:

"Data supplied... or provided by a
manufacturer."

Do you have this data provided by the
manufacturer of 714-X, besides the, we looked at
the data this morning in...

A. Mm-hmm.

Q. [861] ... annex M, I believe, M as Mary...

A. Mm-hmm.

Q. [862] ... besides this data that comes from the
manufacturer, do you have other data that were
provided by the manufacturer?

A. Paragraph 74 refers to a general statement about
how we manage risk and information that may be
in our possession. With respect to information
that came from the manufacturer, we had the
information that was available to us, and that
was available for the Garber review, as we
described earlier, in Exhibit M.

Q. [863] Yes?

A. I'm not aware of any other substantial reports,
or reviews, or research that was conducted by
the manufacturer, that were submitted to us for
the purposes of SAP review.

- Q. [864] Did you request such information from the manufacturer at any time during fifteen (15) years?
- A. Laterally...
- Q. [865] Anytime?
- A. ... in December...
- Q. [866] Yes.
- A. ... in December two thousand and four (2004) a letter went out as part of our continuing review, and attempt to try to locate information that we may not have had in our possession. We requested that information from the manufacturer, that's a recent example.
- Q. [867] Did you get them, did you get something?
- A. We received a response to the letter, yes.
- Q. [868] Okay, that is provided in your...
- A. Yes.
- Q. [869] ... annex 2; I'm right?
- A. Yes, in my, in my amended affidavit, yes.
- Q. [870] Yes, in some, yes, some of the annexes.
- A. Yes.
- Q. [871] Annex is French, I think, appendix is English?
- Me CARMELA MAIORINO:
Exhibit.

Me JEAN-SYLVAIN PELLETIER:

Exhibit, thank you.

Q. [872] Beside this request of two thousand four (2004), did you ever request from the manufacturer any data on the 714-X?

A. Did I? Yes, I...

Q. [873] To your knowledge, since you're aware, since you are involved in the programme SAP.

A. Yes, I...

Q. [874] To your knowledge, was the manufacturer ever contacted to, for him to supply, upon your request, information on the product?

A. I did not request that information, the only thing that could be, the information I described earlier, that is reports, etc., etc. We did have contacts with the manufacturer, and we had, a specific letter went to the manufacturer back in, on or about two thousand (2000), respecting the issue of product going directly to patients' homes, there was correspondence, and we asked them at the time for an undertaking, but there was correspondence...

Q. [875] But that's what we discussed this morning?

A. Right, but it did not include, and it was, it was correspondence between the regulator and

between the company, but it was not requesting information per se, that would relate to what I'm describing in 74.

Q. [876] Would this information be pertinent for your management of the 714?

Me CARMELA MAIORINO:

Which information are you...

Me JEAN-SYLVAIN PELLETIER:

Information from the manufacturer.

A. Well, as I said, we had, we had in our possession information, and information was readily available.

Q. [877] But would any new information from the manufacturer be pertinent and of interest for you to manage the product?

Me CARMELA MAIORINO:

I'll have to object, I mean, that's hypothetical once again. Would any information, what information are we talking about, and...

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Q. [878] Are you interested in receiving all type of information regarding 714 product from the manufacturer, if any?

A. I think I go back to, you know, what I spoke

about earlier at length, and that the obligation is primarily and first and foremost on the part of the physician to supply us with information, and there's occasion when we have access to information, for various reasons, and once that information is in our possession, clearly, we can't ignore that information, and so, but we don't generally seek information from any manufacturer on a regular basis, unless there is a reason to do so, unless there's a trigger of some sort, and we spoke about triggers earlier.

Q. [879] Seventy-four (74)...

A. Yes?

Q. [880] ... you talk at the page 20:

"This framework takes into consideration what is known about the risk and the benefits of a product."

A. Mm-hmm.

Q. [881] This, just to clarify, this applies to SAP; right?

A. I'm specifically talking about SAP and, in broad terms, managing risk, that's correct.

(SHORT RECESS)

(UPON RESUMING)

Me JEAN-SYLVAIN PELLETIER:

Q. [882] Seventy-six (76)...

A. Mm-hmm.

Q. [883] ... refers to a review by the Senior Medical Advisor Bureau. I believe this review is deposited as evidence; am I right, and if so...

A. This is the so-called Garber review.

Me ANDRÉ LESPÉRANCE:

M.

Me JEAN-SYLVAIN PELLETIER:

Q. [884] That's annex M; right?

A. Yes.

Q. [885] Seventy-seven (77), first paragraph:

"SAP also seeks advice from medical, scientific and other experts within the Health Products and Food Branch as is necessary."

A. Mm-hmm.

Q. [886] Besides all the consultation you've had in the last years that we discussed already, were there other advice that you sought regarding 714-X?

Me CARMELA MAIORINO:

What was your question exactly?

Me JEAN-SYLVAIN PELLETIER:

Q. [887] Besides the other reviews and studies that we've discussed already in this hearing, are there any other advices that you sought that we haven't discussed?

A. The Garber review clearly represents the final review, if you will, of, and constitutes the final advice which ultimately allowed us to support the decision that was announced on January the nineteenth (19th). Leading up to that decision, and between July, when I attest that we...

Q. [888] July of...?

A. July two thousand and three (2003), excuse me. I describe that review in paragraph...

Q. [889] We discussed earlier, okay.

A. Yes, we discussed it spanning that seven (7) month time frame. There were a number of people that we consulted within that time frame. Dr. Garber's was the final review, if you will, but there were a number of people we consulted. I described some of those earlier to you, some are clearly in the management stream, Dr. Gillespie, being the director of the Senior Medical Advisor, actually being the Senior Medical

Advisor, and Dr. Robert Peterson, who is the Director General of the Therapeutic Products Directorate, were two (2) key people that I turn to on a whole range of things, and with respect to 714-X, turned to them for advice throughout that time frame. However, paragraph 77 has to do with, really, specifically, how it is and where it is that we might seek advice from, so I'm providing the context there, that we have access to...

Q. [890] I understood that, yes.

A. ... a wide variety of experts.

Q. [891] Eight-two (82), please, page 22.

A. Yes.

Q. [892] You say:

"SAP conducted a complete review of its drug and authorization records to determine the extent of authorization for all products."

When was that done?

A. I think it's important to go back to paragraph 81, that the audit process was implemented in two thousand and one (2001), and the review was completed between two thousand and one (2001), and, in fact, is an ongoing review, and so that

process started in two thousand and one (2001), and a review happened subsequent to that. I don't have a specific recollection of the exact month, but this was a process that we put in motion, stemming from a management report I developed in two thousand (2000), which then was implemented in two thousand and one (2001), and, in fact, is an ongoing effort within the program.

Q. [893] The audit process came out with specific document?

A. The audit process?

Q. [894] Yes, did...

A. We have a, we have a standard operating procedure which describes a process that we undertake with respect to the activities described.

Q. [895] But you say that the audit process was implemented in two thousand one (2001)...

A. Correct.

Q. [896] ... to monitor all drugs, etc.

A. Correct.

Q. [897] This audition, did it come, is the result of that process confirmed in a document of some kind?

- A. Yes, it's, I refer to this in 82, this would have been the review of drugs...
- Q. [898] Do we have this document in the evidence?
- A. No, I don't believe I have...
- Q. [899] I would appreciate it if you could supply.
- A. We can provide an undertaking too, it's straightforward.
- Q. [900] That it already exists, understand?
- A. Yes, straightforward, yes.
- Me CARMELA MAIORINO:
So, just for clarification, you're seeking the plea document which attests to the auditing process?
- Me JEAN-SYLVAIN PELLETIER:
Yes, dealing with paragraph 81...
- A. No, no, no, no, it was, I understood that it was 82. The audit process is a procedure...
- Q. [901] Okay, so there's no document attached to audit process as such?
- A. No, let me, let me...
- Q. [902] No, it's only in 82 there's a document; right?
- A. Let me clarify: there is an audit process, there's a standard operating procedure whereby we describe the audit process.

Q. [903] Mm-hmm.

Me CARMELA MAIORINO:

Mm-hmm.

THE WITNESS:

A. Eighty-two (82) describes a product of that
process...

Me JEAN-SYLVAIN PELLETIER:

Q. [904] The review?

Me CARMELA MAIORINO:

Right.

THE WITNESS:

A. ... which was a review of the drug...

Me JEAN-SYLVAIN PELLETIER:

Q. [905] Okay, so...

A. ... which we have the document.

Q. [906] Okay, so the undertaking, to your
understanding...

A. Is 82.

Q. [907] ... from 82, okay, so...

A. So we'll provide you, for instance, with a
review of the drug and authorizations record to
determine the extent of authorization...

Q. [908] Okay.

A. ... as it was at the time.

Q. [909] Okay.

- A. Furthermore, which then, as my affidavit describes, at the end of the review each product was assigned a relative priority number...
- Q. [910] So 714 will be listed there?
- A. I'd have to go back to the document, I believe, I believe it is...
- Q. [911] Okay, but, anyway, if you don't remember we'll see in the document itself.
- A. Yes, I'd have to go back to be absolutely sure...
- Q. [912] Okay, okay.
- A. ... but that's my recollection at this point.

UNDERTAKING NO. 12: To provide copy of the review of the drug and authorizations records to determine extent of authorization as it was at the time, re: Paragraph 82

Me JEAN-SYLVAIN PELLETIER:

- Q. [913] Paragraph 87...
- A. Eighty-seven (87), yes.
- Q. [914] ... you refer to:

"714-X is promoted by the manufacturer
and patient advocates."

Who's that, what is that, if it's a "it,"
patient advocates?

A. Through the year there have been, through the
years there have been news reports, I described
those earlier to you, and that on occasion
patients have found themselves in the news,
promoting the product, or describing the
product, or attesting to the product, and those
have ended up in the public domain...

Q. [915] Do you keep track of that?

A. I described earlier that there were some
documents that I was aware of back in and around
the time of nineteen... back when the product
went on the programme...

Q. [916] Nineteen ninety (1990)?

A. Yes, where there was, where there was high
interest in the press, and there, I think there
were some, my understanding is that there were
some, there were some patients and other figures
who were not, who were not the company, and who
were not physicians, who were talking about the
product, promoting the product, describing the
product.

Q. [917] Okay, so when you say "patient advocates," it refers to a general term, generic term, actually, it doesn't refer to...

A. To me.

Q. [918] ... to some specific people?

A. Oh, no, no, no, no, in English I'm referring to someone who is, who is either, who are patients who are advocating the use of the, of the drug. No, it's not a lawyer or anyone representing them.

Q. [919] Eighty-eight (88), you say:

"Its use is recommended in the context of an unorthodox biologic theory."

A. Mm-hmm.

Q. [920] This is Gaston Naessens' theory; right?

A. Yes, I just, absolutely.

Q. [921] Why do you say it's unorthodox?

A. I think this is a word that I've used and that others have used to describe the nature of his theories that do not appear to comply with a general understanding of disease states, and disease progression, and treatment.

Q. [922] Who came with this word "unorthodox," is it you or someone else in the...

A. I've certainly used it in this, and, but I've

seen it in, I've seen it or a synonym of it in other, in other areas as well, in other commentaries on the product.

Q. [923] Will you be able to trace back those...

A. Yes, I'll look to see if I can find something...

Q. [924] ... comments, if it's not in the evidence already?

A. Yes, I think...

Q. [925] What are you referring to?

A. Oh, I'm just trying to find something first, and I, but I may not be, I may not be in the right spot, so I don't want to refer you to an area that... I may have to take an undertaking to inquire as to how others have described 714-X... describe the theory, excuse me.

Q. [926] Yes?

UNDERTAKING NO. 13: To advise how others
 have described the
 theory, re: Paragraph
 88: "Unorthodox
 biologic theory"

Me JEAN-SYLVAIN PELLETIER:

Q. [927] Do you recall Mr. Naessens' answer to that

presentation of paragraph 88, as specifying that his theory was unorthodox, do you remember his, some answer on that?

A. In his, in his response in May, you mean?

Me CARMELA MAIORINO:

I'd like to, just for clarification...

Me JEAN-SYLVAIN PELLETIER:

In the, in the procedures you actually deposit schedule S, as Sam, the letter, actually, Mr. Brian Gillespie, December eight (8), two thousand four (2004), letter...

A. Oh...

Q. [928] ... from Dr xxxxxxxxxxxxxxxx, that you deposit, and also the letter from Brian Gillespie...

A. Yes, yes.

Q. [929] ... and then you have...

A. Yes.

Q. [930] ... Mr. Naessens'...

A. Yes.

Q. [931] ... answer, his letter of December ninth (9th), two thousand four (2004); right?

A. In fact...

Q. [932] It's listed, yes, indeed, in page 62, this is my, maybe you don't have the same...

Me MICHEL BÉLANGER:

Non, non...

(OFF THE RECORD DISCUSSION)

Me JEAN-SYLVAIN PELLETIER:

Well, it seems to be, it seems to be...

Me CARMELA MAIORINO:

Mais, on a, we have the document, yes, but
not...

Me JEAN-SYLVAIN PELLETIER:

But not the page...

Me CARMELA MAIORINO:

... the page numbering that must appear to have.

THE WITNESS:

A. I don't have the page numbering, you have a page
number.

Me JEAN-SYLVAIN PELLETIER:

Q. [933] Okay, but, anyway, you have that letter...

Me CARMELA MAIORINO:

Yes.

Me JEAN-SYLVAIN PELLETIER:

Q. [934] ... you have that before you...

A. I believe we're talking about the same thing.

Q. [935] ... the letter is...

Me CARMELA MAIORINO:

The letter is December ninth (9th)...

Me JEAN-SYLVAIN PELLETIER:

Q. [936] ... addressed to Brian Gillespie...

A. Yes, I'm familiar with the one.

Q. [937] ... and the date is December ninth (9th),
okay.

A. Correct.

Q. [938] He refers, Mr. Naessens refers, in his
title:

"Votre lettre du 1er décembre deux
mille quatre (2004)."

Okay, that is appearing a few pages before.

A. Yes. Mr. Naessens, in page 3 of his
documents...

A. Mm-hmm.

Q. [939] ... speaks specifically, in the middle of
the page roughly...

A. Mm-hmm.

Q. [940] ... when he says, starts the paragraph by:

"D'une part, nous comprenons
difficilement que les mots « 714X »,
traitement, prévention..."

Are you, do you understand those words, Mr....

A. I think I could, yes, we had a translation of
this, but I'm also...

Q. [941] You remember...

- A. ... but I think I can remember the general...
- Q. [942] ... the rough idea?
- A. ... if I have something I'll ask for a
authoritative translation.
- Q. [943] Okay, he carries on, he says:
"Ce sont des concepts différents. Il
y a une grande distinction à faire
entre la théorie somatidienne..."
- A. Mm-hmm.
- Q. [944] And then paragraph, the...
- A. In parentheses, yes.
- Q. [945] Yes:
"... (que j'ai déposée à l'Académie
des Sciences de Paris, en 1961..."
Do you check, did you check for that --
actually, l'Académie des Sciences, do you know
what that is?
- A. No, other than I assume it's an establishment of
higher learning in Paris.
- Q. [946] Okay, and in nineteen sixty... so did you
check for this validation of his theory in
nineteen sixty-one (1961) by l'Académie des
Sciences?
- A. No.
- Q. [947] You didn't check that. The, you didn't,

you didn't ask Mr. Naessens neither for those validation?

A. No.

Q. [948] No. Mr. Naessens carries on:

"... et qui a été validée en 2003 par l'Université de Montréal)..."

To your perspective, does Université de Montréal a credible institution, and credible scientific institution?

Me CARMELA MAIORINO:

I'll have to object to this, to this question.

Me JEAN-SYLVAIN PELLETIER:

Mm-hmm.

Q. [949] Okay, what is the reputation of Université de Montréal as a scientific institution?

Me CARMELA MAIORINO:

I'll have to object to that question as well...

Me JEAN-SYLVAIN PELLETIER:

Well...

Me CARMELA MAIORINO:

... what's the relevancy of it?

Me JEAN-SYLVAIN PELLETIER:

Well, it's written here, Université de Montréal,

I want to...

Me CARMELA MAIORINO:

So?

Me JEAN-SYLVAIN PELLETIER:

... it's Mr. Naessens' term, so I'm asking him
the question on that.

Me CARMELA MAIORINO:

I object...

Me JEAN-SYLVAIN PELLETIER:

Why?

Me CARMELA MAIORINO:

... I maintain my objection, I don't see the
relevancy as to what is the reputation of
University of Montreal...

Me JEAN-SYLVAIN PELLETIER:

Because, because...

Me CARMELA MAIORINO:

... irrespective of whether it's referred to...

Me JEAN-SYLVAIN PELLETIER:

... because there's a wording here by Mr.

Naessens, he said:

"... et qui a été validée en 2003 par
l'Université de Montréal..."

I mean, this is quite pertinent.

Me CARMELA MAIORINO:

Just because it's referred to in Mr. Naessens'

letter does not make it relevant to the crux of the case.

Me JEAN-SYLVAIN PELLETIER:

Well, I'm asking the question to the witness.

Q. [950] What is the reputation of Université de Montréal as a scientific institution?

Me CARMELA MAIORINO:

I object to the question as is.

Me JEAN-SYLVAIN PELLETIER:

I, really, I don't understand the objection here. You object because...?

Me CARMELA MAIORINO:

I don't understand the relevancy as to Mr. Mackay's understanding of, or knowledge of the reputation of University of Montreal. If you kindly would like to explain to me the relevancy of that question, I'll allow Mr. Mackay to answer it.

Me JEAN-SYLVAIN PELLETIER:

Well, because all the way your witness, in his affidavit and his testimony, specifies that research had to be made through...

Me MICHEL BÉLANGER:

Recognized.

Me JEAN-SYLVAIN PELLETIER:

... yes, recognized institutions, and so on;
right? He states National Cancer Institute and
other, and other institutions like this one, so
I'm asking the question, very pertinently, about
Université de Montréal, what's the reputation of
Université de Montréal as a scientific
institution.

Me CARMELA MAIORINO:

I maintain my objection...

Me JEAN-SYLVAIN PELLETIER:

Well, unless he answer...

Me CARMELA MAIORINO:

... under advisement.

Me JEAN-SYLVAIN PELLETIER:

... unless he answers under reserve.

Me CARMELA MAIORINO:

Under reserve, sorry.

Me JEAN-SYLVAIN PELLETIER:

Q. [951] Mister, please?

Me ANDRÉ LESPÉRANCE:

Sorry, this is an objection under reserve.

Me CARMELA MAIORINO:

Under reserve.

THE WITNESS:

A. So I have...

Me JEAN-SYLVAIN PELLETIER:

Go ahead.

THE WITNESS:

A. I have no specific knowledge of...

Me JEAN-SYLVAIN PELLETIER:

Q. [952] Of Université de Montréal's reputation as a scientific institution; not at all, okay. Did you try to inquire about this validation of Université de Montréal, of the "théorie somatidienne" of Mr. Naessens?

A. No.

Q. [953] You didn't?

A. No, this letter came to us in December, so...

Q. [954] Yes, but still, you had the occasion to read it...

A. Mm-hmm.

Q. [955] ... before you prepare your affidavit, and before you signed it; right?

A. Correct.

Q. [956] So. Do you know a researcher by the name of xxxxxxxxxxxxxxxxxxxxxxx, does that sound familiar to you?

A. No.

Q. [957] Do you know:

"Département de Pathologie et de
Biologie Cellulaire, Faculté de
Médecine, Université de Montréal."?

Me CARMELA MAIORINO:

I'll have to object, I don't see the relevancy
as to where you're going.

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Bien, well, I'm relating directly to your own
evidence, this is your own evidence that I'm
asking questions on, details.

Me CARMELA MAIORINO:

The question you're asking right now pertaining
to the...

Me JEAN-SYLVAIN PELLETIER:

Université de Montréal.

Me CARMELA MAIORINO:

... fellow you just mentioned, I...

Me JEAN-SYLVAIN PELLETIER:

Université de Montréal, this is your evidence.

Me CARMELA MAIORINO:

This is...

Me JEAN-SYLVAIN PELLETIER:

Q. [958] You deposit the letter addressed by Brian

Gillespie to Mr. Naessens on December first (1st), two thousand four (2004). Would you mind to have that letter before you, please?

A. December the first (1st), I believe.

Me CARMELA MAIORINO:

Letter from Dr. Gillespie to... okay.

THE WITNESS:

A. Okay.

Me JEAN-SYLVAIN PELLETIER:

Okay?

Me CARMELA MAIORINO:

Mm-hmm.

THE WITNESS:

A. This is Exhibit R?

Me JEAN-SYLVAIN PELLETIER:

Q. [959] Within Exhibit R, yes, actually, probably the last page of Exhibit R.

A. Yes.

Me CARMELA MAIORINO:

The first page.

Me JEAN-SYLVAIN PELLETIER:

Q. [960] First page or last page?

A. No, I believe it's the second or third last page.

Me CARMELA MAIORINO:

Oh, to Mr. Naessens', okay, yes.

Me JEAN-SYLVAIN PELLETIER:

Yes.

A. English and French.

Q. [961] So Brian Gillespie, just refer me again
who is that person related to you?

A. I described earlier in my testimony that Dr.
Gillespie is the director of the Senior Medical
Advisor Bureau.

Q. [962] So he's your...?

A. Boss.

Q. [963] Your boss, thank you for the word. So
your boss is asking, on December first (1st),
two thousand four (2004), to Mr. Naessens, in
French, if I, if I may read it.

Me MICHEL BÉLANGER:

There's an English version, eh, if you want.

THE WITNESS:

A. En anglais.

Me JEAN-SYLVAIN PELLETIER:

Huh?

Me MICHEL BÉLANGER:

There's an English version just before...

Me JEAN-SYLVAIN PELLETIER:

Oh, there's an English version, okay, okay:

"I am specifically writing...

Second paragraph:

"I am specifically writing to you today to determine whether you are aware or in possession of any credible scientific information that would support the use, safety and efficacy of 714-X and the treatment, prevention or diagnosis of any form of cancer."

And he carries on at the end of this paragraph, last two (2) lines:

"Whether a programme of formal drug development for 714-X, which would include both nonclinical studies and clinical trials, has been proposed or initiated."

This is what he asks Mr. Naessens...

A. Correct.

Q. [964] ... on December first (1st), two thousand four (2004). Mr. Naessens's answer, and he asked specifically, actually, at the last paragraph of the translation:

"If you have such information, please

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advise our office as soon as possible
before December ten (10) of two
thousand four (2004)."

He was asking for a certain day, but, anyway.
Mr. Naessens did, indeed, answer, and my point
is the following: I show you here a document
that's titled:

"Projet Somatides - Rapport du
travail effectué du quinze août
(15) au quinze (15) novembre
mille neuf cent trois (2003),
xxxxxxxxxxxxxxxxxx, Département de
Pathologie et de Biologie
Cellulaire Faculté de Médecine
Université de Montréal,
Montréal."

Have you ever seen this document before?

A. No.

Q. [965] Never? Would you mind to go to page 2,
please -- page, no, page 1, I'm sorry, not page
2, but page 1. Okay, he states roughly:

"Gaston Naessens, homme de science
travaillant au Québec depuis plusieurs
années, a émis une théorie portant sur
des éléments cellulaires que l'on

retrouverait dans toutes les cellules;
la théorie somatidienne."

Right?

A. I'm not sure that I could have...

Q. [966] Do you understand the French?

A. ... fully grasped that in English, but...

Q. [967] It talks about la théorie somatidienne...

A. I understand that, yes.

Q. [968] ... I'm referring to Gaston Naessens as being the author of this theory. I would ask you to go to page 12, please, and eventually it may be appropriate, indeed, to get a translation. "Conclusion," if you may look at paragraph 3:

A. Yes.

Q. [969] ...

"Ces particules sont des éléments
acceptés par la communauté
scientifique. Elles ont été
rapportées par un très grand nombre de
groupes scientifiques et on s'accorde
à leur attribuer des rôles
physiologiques importants."

And a little above it's stated, the paragraph
above, above the word "conclusion":

"Pour cela les investigations devraient être encouragés afin d'établir leurs caractéristiques et leur pertinence biologique in vivo. Quelle que soit la nature des phénomènes faisant intervenir les microparticules en tant que marqueurs ou participants, il est primordial de poursuivre leurs études."

And I refer to paragraph, last paragraph of page 11...

A. I'm sorry, I have to say that I'm not agreeing to the comprehension of that in...

Q. [970] Because of the wording in French?

A. Yes, I mean, it's technical information, and...

Me CARMELA MAIORINO:

And beyond that I really have to object to any line of questioning with respect to this document. Mr. Naessens did not file this document with his letter sent to Dr. Gillespie, and...

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Yes, but.. okay.

Me CARMELA MAIORINO:

... and I don't see how it is relevant in terms of determining whether the data that physicians submitted to the SAP with their SAP requests in the four (4) judicial review applications at bar, how this is relevant.

Me JEAN-SYLVAIN PELLETIER:

Okay, first of all, this simply completes your client's testimony, and completes your own evidence that you have deposited, the letter of Gaston Naessens was deposited by you, and his letter specifically refers to the validation in two thousand three (2003) by Université de Montréal of le théorie somatidienne, which...

Me CARMELA MAIORINO:

Which he did not include with is letter.

Me JEAN-SYLVAIN PELLETIER:

... which, yes, but it completes your own evidence, first of all; second of all, this document is certainly pertinent in the fact that we are discussing, in particular, paragraph number 88 of the affidavit of the witness, which he states is:

"An unorthodox biological theory."

So this is the comment regarding this notion of

unorthodox theory, referring to this document specifically.

Me CARMELA MAIORINO:

Your line of questioning tends to call for an answer from an expert in medicine, and this is not the case. I believe Mr. Mackay's statement in paragraph eighty...

Me JEAN-SYLVAIN PELLETIER:

Eight (8).

Me CARMELA MAIORINO:

... eight (88) is in terms of his understanding as unit head of the SAP programme, and not as an expert physician.

Me JEAN-SYLVAIN PELLETIER:

Right, you're right, but actually my point is not to discuss medical issue in terms of expertise on one side or the other, my point is simply to specify that he already knew that Mr. Naessens had a confirmation from Université de Montréal in two thousand three (2003) of his theory, and that this document only confirms the...

Me CARMELA MAIORINO:

He knew as of December two thousand four (2004).

Me JEAN-SYLVAIN PELLETIER:

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... the saying, the saying of Mr. Naessens.

Yes, but before he wrote the affidavit, so this information...

Me CARMELA MAIORINO:

He knew as of December, or maybe you should ask him when he had knowledge of the letter received on December ninth (9th) from Mr. Naessens.

Me JEAN-SYLVAIN PELLETIER:

I think it's not really pertinent...

Me CARMELA MAIORINO:

Absolutely.

Me JEAN-SYLVAIN PELLETIER:

... since he has deposited this letter in conjunction with his affidavit.

Me CARMELA MAIORINO:

So then we...

Me JEAN-SYLVAIN PELLETIER:

Obviously it's linked.

Me CARMELA MAIORINO:

... he knew, he knew as of the date then of the signature of the affidavit.

Me JEAN-SYLVAIN PELLETIER:

Or before, definitely.

Me CARMELA MAIORINO:

So you should ask him when, if he knew before.

Me JEAN-SYLVAIN PELLETIER:

Well, actually, if I look at the Senior Medical Advisor stamp, it's state reception on December the fourteenth (14th), two thousand five (2005) -- two thousand four (2004). So I take for granted that this document was available in the department of Mr....

Me CARMELA MAIORINO:

But maybe we should ask Mr. Mackay when he had knowledge of the...

Me JEAN-SYLVAIN PELLETIER:

Well, okay.

Q. [971] Mr. Mackay, when have you had knowledge of this letter, since you have used this letter in your own affidavit... if you can, if you can remember?

A. Yes, the stamp reflects the date of its receipt in our, by our clerks...

Q. [972] Yes.

A. ... and where it's tracked. Generally speaking, I see things like this one (1) or two (2) days after, depending on whether there's a weekend.

Q. [973] Okay, so the sixteenth (16th), roughly, of December?

A. I was certainly, I was certainly aware of the

letter before the Christmas break, and, because we were working on...

Q. [974] So I think this document is definitely very pertinent to complete the evidence that you have already submitted, and complete the testimony of the witness.

Me CARMELA MAIORINO:

I still fail to see.

Me JEAN-SYLVAIN PELLETIER:

And relevant to the paragraph 88 of his affidavit, that says this is unorthodox theory. And also, also, that this document is actually a, I'd say a follow-up on the request of Mr. Gillespie, who is the boss of the witness.

Me CARMELA MAIORINO:

But Mr. Naessens had the opportunity to respond and it was not included in his reply.

Me JEAN-SYLVAIN PELLETIER:

Doesn't change the pertinence of the document, since the request of Mr. Gillespie was done before the affidavit, so I think it's very pertinent in the context of the debate today, since you have already deposited the letter of Mr. Gillespie requesting all types of information, so here's one of the answers. I

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think it's absolutely pertinent.

Me CARMELA MAIORINO:

What is your question?

Me JEAN-SYLVAIN PELLETIER:

It's not a question.

Me CARMELA MAIORINO:

Okay.

Me JEAN-SYLVAIN PELLETIER:

My questions were asked already, the witness answered, and the point is simply to deposit this document as evidence, regarding the...

Me CARMELA MAIORINO:

Oh, you're seeking to file this into evidence...

Me JEAN-SYLVAIN PELLETIER:

Absolutely.

Me CARMELA MAIORINO:

... for the judicial review application?

Me JEAN-SYLVAIN PELLETIER:

Sure, sure.

Me CARMELA MAIORINO:

I object, I object. Any evidence...

Me JEAN-SYLVAIN PELLETIER:

The client...

Me CARMELA MAIORINO:

... any evidence that had to be filed, had to be

filed with the affidavits that were filed, so I maintain my objection, it'll be argued before the Court.

(OBJECTION)

Me JEAN-SYLVAIN PELLETIER:

Okay, it'll be argued.

Me CARMELA MAIORINO:

The document is dated two thousand three (2003)?

Me JEAN-SYLVAIN PELLETIER:

This document, yes.

Me CARMELA MAIORINO:

So the applicants had access to this document as of two thousand three (2003)?

Me JEAN-SYLVAIN PELLETIER:

Not the applicant, we're talking about the fabricant, this comes from the fabricant.

Me CARMELA MAIORINO:

The manufacturer filed an affidavit...

Me JEAN-SYLVAIN PELLETIER:

Yes.

Me CARMELA MAIORINO:

... in two thousand four (2004).

Me JEAN-SYLVAIN PELLETIER:

Yes.

Me CARMELA MAIORINO:

He could have filed that...

Me JEAN-SYLVAIN PELLETIER:

He, yes.

Me CARMELA MAIORINO:

... the manufacturer filed evidence in support
of his...

Me JEAN-SYLVAIN PELLETIER:

Yes, but that's, that's not...

Me CARMELA MAIORINO:

... of his, of his...

Me JEAN-SYLVAIN PELLETIER:

... the applicant, that's the witness.

Me CARMELA MAIORINO:

But the manufacturer did file an affidavit with
evidence in support of his affidavit...

Me JEAN-SYLVAIN PELLETIER:

Yes, but the manufacturer is not a party, the
manufacturer is not the applicant.

Me CARMELA MAIORINO:

Yes, but, I agree, but the manufacturer did file
an affidavit in support of this judicial review
application.

Me JEAN-SYLVAIN PELLETIER:

What tells you that the applicant didn't have

access to this document before?

Me CARMELA MAIORINO:

The manufacturer had access to it, the
manufacturer had access to the document, the
manufacturer...

Me JEAN-SYLVAIN PELLETIER:

Possibly.

Me CARMELA MAIORINO:

... filed an affidavit...

Me JEAN-SYLVAIN PELLETIER:

Yes?

Me CARMELA MAIORINO:

... and had the opportunity to file it...

Me JEAN-SYLVAIN PELLETIER:

Yes?

Me CARMELA MAIORINO:

... with his affidavit.

Me JEAN-SYLVAIN PELLETIER:

Yes?

Me CARMELA MAIORINO:

So all this to say is we'll argue the objection
before the Court.

Me JEAN-SYLVAIN PELLETIER:

Okay. Actually, I think you should be pleased,
in a sense, to receive such a documentation

since Mr. Gillespie himself asked for that.

Me CARMELA MAIORINO:

This is not a question of whether we're pleased or not, it's a question of whether it can be admitted into evidence in support of the JR application, so I don't think we should argue that.

Me JEAN-SYLVAIN PELLETIER:

But beyond, beyond the legal procedure, I think it certainly goes in the will of Mr. Gillespie to receive as much as possible information regarding 714-X.

Me CARMELA MAIORINO:

There's correspondence between Dr. Gillespie and Mr. Naessens with respect to exchange of information.

Me JEAN-SYLVAIN PELLETIER:

Yes.

Me CARMELA MAIORINO:

They'll pursue that avenue when it's deemed appropriate.

Me JEAN-SYLVAIN PELLETIER:

Okay, so that'll be debated before the judge.

Q. [975] Mr. Mackay, are you aware of, because this letter from Mr. Naessens was addressed to Mr.

Gillespie, and received in your department December fourteenth (14th), are you aware of any follow-up made by Mr. Gillespie regarding this letter of Mr. Naessens, example: Mr. Gillespie requesting further documentation, calling Mr. Naessens to discuss the letter, matters like that, are you aware of something like that?

A. Dr. Gillespie has not, has not contacted Monsieur Naessens, nor has he responded, this, the letter of Dr., Dr. Gillespie's letter of December the first (1st) was a request looking for specific information and, as you know, we received four (4) responses, including Mr. Naessens' response...

Q. [976] The three (3) positions that support...

A. Three (3) positions, plus the response...

Q. [977] ... the product, yes.

A. ... we're talking about here, and that information, in its entirety, has been received, and considered by Dr. Gillespie, myself, and others, as we, as we considered the final part of the review leading towards the year time frame described earlier, and my affidavit talks about our decision at that point. So the...
yes.

Q. [978] Mr. Mackay, just a few questions roughly, quickly. Are you aware of some research, or studies, or documentation from a certain Mr. Bechamp? Maybe you can look at page 10 of the document we have discussed.

A. My affidavit?

Q. [979] No, page 10 of the last document that we submitted.

A. Page 10?

Q. [980] Yes, 10, in the middle there are names underlined. Bechamp, is that name familiar to you? Page 10.

A. In the context of?

Q. [981] No, in the context of Mr. Naessens' theory.

Me CARMELA MAIORINO:

I'm objecting under reserve.

Me JEAN-SYLVAIN PELLETIER:

Okay.

Q. [982] Same for Rife, does that name sound familiar...

A. No.

Q. [983] ... in Mr. Naessens... okay. Enderlein, Enderlein neither?

A. No, it's not familiar to me at all.

Q. [984] And different attributions of those
particle called "Ascit," the line below,
"Ascit," "Ascit," or something like, does that,
have you ever seen those terms?

A. Can you provide me a translation, I may...

Q. [985] A-S-C-I-T.

A. ... I may recognize the translation in
English...

Q. [986] Yes.

A. ... but I don't recognize that as a French...

Q. [987] Well, to me it's Chinese, those words,
"Ascit," I don't know how...

A. Chinese?

Q. [988] No, no, I'm teasing.

A. Oh, I'm sorry, I'm sorry.

Q. [989] It's a little late...

A. Sorry.

Q. [990] ... I'm a little more permitted.

A. Sorry, I wasn't looking at you, I didn't get it
was a joke, I'm sorry.

Me CARMELA MAIORINO:

Are you at the second paragraph?

Me JEAN-SYLVAIN PELLETIER:

Yes, no, no, no, the line under the names that
we looked.

Me CARMELA MAIORINO:

"Ascit," okay.

Me JEAN-SYLVAIN PELLETIER:

- Q. [991] Okay, "Ascit, Chondrit," does that sound familiar, have you ever seen those words before?
- A. These, I certainly would want a full authoritative English translation before I could attest to...
- Q. [992] But I don't think it's translation of any kind, as I'm mentioning, I think it could be used in French or English anyway. "Mycrozomas," have you ever seen those, this word before, no, "Mycrozomas"?
- A. Sometimes there are subtle difference in spelling between English and French words, and they're important, so...
- Q. [993] I understand, but answer to the best of your knowledge.
- A. I would really want a full translation, an authoritative translation on such technical terms before, before advising. The word looks familiar, but I want to provide you with the best possible answer, and I would have to have an authoritative translation on it.
- Q. [994] Okay, so...

A. They are technical terms, there's no question.

Me CARMELA MAIORINO:

And, once again, I object to any question...

Me JEAN-SYLVAIN PELLETIER:

Q. [995] How you do that, it's undertaking, under,
yes, if...

Me CARMELA MAIORINO:

... under reserve...

Me JEAN-SYLVAIN PELLETIER:

... if the document is, okay...

Me CARMELA MAIORINO:

... because this document is not filed into
evidence...

Me JEAN-SYLVAIN PELLETIER:

... undertaking, under reserve, page 10, okay?

UNDERTAKING NO. 14: To advise if the names
"Bechamp, Rife,
Enderlein, Ascit,
Chondrit, Mycrozomas,
Bessis," in page 10
are familiar, and what
they refer to (under
reserve of objection)

Me JEAN-SYLVAIN PELLETIER:

Q. [996] The name a few lines below, "Bessis," B-E-S-S-I-S, does this name...

A. This refers to a surname?

Q. [997] I believe it's a family name.

A. Okay.

Q. [998] Dose that sound familiar to you?

A. I'm not familiar with it at all.

Q. [999] You've never seen that before. That's all.

AND FURTHER DEPONENT SAITH NOT

CERTIFICATE

I, the undersigned, EVA WARSZAWSKI, Official Court Reporter being duly authorized to practice in English, using the method of stenomask in the district of Montreal, hereby certify under my oath/affirmation of office the foregoing to be a true and faithful transcript of evidence, the whole in accordance with the law on this 1st day of February, 2005;

And I have signed:

EVA WARSZAWSKI

Official Court Reporter