

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 8, 2005

NICOLE L'ABBÉ  
Official Court Reporter

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

CROSS-EXAMINATION ON AFFIDAVIT  
DEPOSITION OF Mr. IAN MACKAY

APPEARANCES:

Me MICHEL BÉLANGER,  
Me JEAN-SYLVAIN PELLETTIER,  
Counsels for Plaintiffs

Me CARMELA MAIORINO,  
Counsel for Defendants

February 8, 2005

NICOLE L'ABBÉ  
Official Court Reporter

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UNDERTAKING 15:	Provide a written definition of the word "efficacy". . . .	66
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LIST OF OBJECTIONS

Me CARMELA MAIORINO OBJECTS TO THE FOLLOWING  
QUESTIONS ASKED BY Me JEAN-SYLVAIN PELLETIER:

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Q.	[6] Okay. Paragraph 92 please, you mention that because the manufacturer didn't file a New Drug Submission or a Clinical Trial Application with Health Canada, Health Canada was not able or didn't have the opportunity to conduct a comprehensive regulatory review of the safety, efficacy and quality of the 714-X; could Health Canada have done this review even though the manufacturer wouldn't have filed the submission or New Drug Submission or a Clinical Trial Application? . . . . .	8
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Q.	[28] Why not? . . . . .	13
Q.	[77] What if after one year the therapy wasn't over? . . . . .	33
Q.	[78] Did you consider the fact, did you consider how many patients on the therapy would be, would have their therapy ended after one year? . . . . .	33
Q.	[80] Do you know how long it takes to a therapy to cure cancer? . . . . .	37
Q.	[81] How long does a therapy last for cancer? . . . . .	37
Q.	[82] Do you know how long it lasts, how long is a therapy to treat mastocytose, Mr. Mackay? . . . . .	38
Q.	[104] Mr. Mackay, is it possible to verify on this day, today, if there are any pending requests for the product, is it possible to verify that? . . . . .	50
Q.	[105] Mr. Mackay, is it possible that there were indeed pending requests but you were not aware of at the time you signed the affidavit? . . . . .	51
Q.	[106] For instance, Léopold Delisle, who's one of the applicant, is it possible that, at the time you signed the affidavit, he was in a situation where his request was pending? . . . . .	51
Q.	[226] After reading those files, do you believe that the 714 can help them to survive with their illness? . . . . .	104
Q.	[227] I'm not asking an opinion here, I'm just asking after reading these affidavits and the evidences submitted by those people: Laurent Légère, Dany Laforest and Daniel Grandmont, with obviously the main file of Léopold Delisle, my question was, after reading those documentations and affidavits, do you believe that the 714-X could be helpful to... for them to fight their illness, their cancer? . . . . .	104



1           IN THE YEAR TWO THOUSAND AND FIVE (2005), on  
2           this eighth (8th) day of February, personally  
3           came and appeared:

4

5           IAN MACKAY, born on October 22, 1964, domiciled  
6           and residing at 16, Ivy Crescent, Ottawa,  
7           Ontario, K1M 1Y2;

8

9           WHOM, after having been duly sworn, doth depose  
10          and say as follows:

11

12          CROSS-EXAMINED BY Me JEAN-SYLVAIN PELLETIER,  
13          Counsel for Plaintiffs:

14    Q.    [1] Mr. Mackay, okay, so you're at... the last  
15           time, we finished at Paragraph 88 of your  
16           affidavit, concerning your affidavit, I'm  
17           referring to the affidavit in the file number  
18           698-04, you follow me?

19    A.    Yes.

20    Q.    [2] And just to confirm that the first day that  
21           we had together was also regarding this number  
22           of affidavit, because I understand there are  
23           four of them, four affidavits, and most of the  
24           information in each affidavit is the same,  
25           except for a few paragraphs, I believe.

- 1 A. Yes, the most recent affidavit I filed did not  
2 contain all of the exhibits, so I think we're  
3 referring to, I'm sure we're referring to the  
4 same thing, there are a few paragraphs which  
5 differ from the original.
- 6 Q. [3] But we're talking here about the amended  
7 affidavit dated the thirteenth (13th) of  
8 January, two thousand five (2005), this is the  
9 one I'm speaking about.
- 10 A. Yes, I have, what I have in front of me was the  
11 original because there are appendices.
- 12 Q. [4] Fine, very fine.
- 13 A. But I have the January affidavit with me as  
14 well.
- 15 Q. [5] Okay. So in that affidavit, I was stating  
16 that the last time we were together, the last  
17 discussions or questions were about article 88,  
18 right?
- 19 A. Thank you, I'm at that state, I'm at that point,  
20 yes.
- 21 Q. [6] Okay. Paragraph 92 please, you mention that  
22 because the manufacturer didn't file a New Drug  
23 Submission or a Clinical Trial Application with  
24 Health Canada, Health Canada was not able or  
25 didn't have the opportunity to conduct a

1 comprehensive regulatory review of the safety,  
2 efficacy and quality of the 714-X; could Health  
3 Canada have done this review even though the  
4 manufacturer wouldn't have filed the submission  
5 or New Drug Submission or a Clinical Trial  
6 Application?

7 Me CARMELA MAIORINO:

8 I'll have to object, the question is  
9 hypothetical.

10

11 (OBJECTION N° 1)

12

13 Me JEAN-SYLVAIN PELLETIER:

14 Q. [7] The review that is stated in Paragraph 92,  
15 is this review dependent on the fact that the  
16 manufacturer did submit previously the New Drug  
17 Submission or Clinical Trial Application?

18 A. ... (no answer)

19 Q. [8] Do you understand my question?

20 A. I do, yes.

21 Q. [9] Okay, thank you.

22 A. Paragraph 92 refers to, in particular the latter  
23 part of the paragraph refers to regulatory  
24 review of the safety and efficacy and quality of  
25 714-X, and specifically, I am referring to a

1 formal drug submission that would either come as  
2 a Clinical Trial Application, as you say, or as  
3 a New Drug Submission, which is the standard way  
4 in which Health Canada receives information of  
5 other drugs pursuant to a request for marketing.

6 Q. [10] A general market drug?

7 A. Either a marketing application, as is the case  
8 for an NDS, or a Clinical Trial Application as  
9 is when the request is to conduct clinical  
10 research.

11 Q. [11] So what's the answer?

12 A. Regulatory review refers to of the formal  
13 process of reviewing an application, be it a  
14 Clinical Trial Application or a New Drug  
15 Submission.

16 Q. [12] I understand that, but is this review  
17 dependent on the fact that the manufacturer had  
18 to file a New Drug Submission or a Clinical  
19 Trial Application, that was the question?

20 A. I am specifically referring to a CTA and/or an  
21 NDS, which is an application which a  
22 manufacturer submits to Health Canada, yes.

23 Q. [13] Okay. This is the starting point for such a  
24 review, isn't it?

25

1 Me CARMELA MAIORINO:

2 The witness just answered, he just said yes.

3 Me JEAN-SYLVAIN PELLETIER:

4 Well, I'd like him to clarify this point.

5 A. Paragraph 92 specifically refers to New Drug  
6 Submissions or Clinical Trial Applications...

7 Q. [14] That's the...

8 A. ... those are applications which must be filed  
9 by a sponsor, be it a manufacturer or another  
10 form of sponsor, normally a manufacturer, and  
11 these are applications which are filed by a  
12 sponsor to Health Canada.

13 Q. [15] And that procedure is... has consequence on  
14 the review from Health Canada, in the second  
15 part of the paragraph, that's it?

16 A. What...

17 Q. [16] This is the only opening for Health Canada  
18 to proceed to that review?

19 A. I'm speaking here of a comprehensive regulatory  
20 review pursuant to applications filed by a  
21 sponsor. The comprehensive regulatory review is  
22 undertaken by Health Canada in response to an  
23 application, and seeks to comprehensively review  
24 the safety, and efficacy and quality of a drug  
25 pursuant to an application.

1 I think the key word is comprehensive.  
2 Health Canada conducts many reviews in many  
3 different ways, but I'm specifically referring  
4 here to a comprehensive review which ordinarily  
5 takes many, many months and requires the  
6 submission of many, many documents.  
7 Q. [17] I'd like you to go to Paragraph 96, please.  
8 We're referring to Exhibit 7 of the affidavit of  
9 Mr. Gaston Naessens. So if you can take a look  
10 at this document also?  
11 Me CARMELA MAIORINO:  
12 Exhibit 7?  
13 Me JEAN-SYLVAIN PELLETIER:  
14 Yes.  
15 Q. [18] And in Exhibit 7, there are numerous  
16 documents in that exhibit, and I'm referring  
17 specifically to... just a moment, I believe it's  
18 page 280, if your pages are...  
19 A. No.  
20 Q. [19] ... have numbers?  
21 Me CARMELA MAIORINO:  
22 Ours are not numbered.  
23 Me JEAN-SYLVAIN PELLETIER:  
24 Q. [20] Actually, it's the first page of this  
25 Exhibit 7.

- 1 Me CARMELA MAIORINO:  
2 The first page?  
3 Me JEAN-SYLVAIN PELLETIER:  
4 It starts by the title: Confidential.  
5 A. Yes.  
6 Q. [21] On the left, 1 of 35?  
7 A. Yes, I have that.  
8 Q. [22] And dated August twenty-second (22nd), two  
9 thousand (2000), right, you have that?  
10 A. Yes, I do have that.  
11 Q. [23] Now, in Paragraph 96, you refer to a bottom  
12 page note that you state:  
13 "Doctor Huang's position is that  
14 the tests are preliminary and  
15 that the results are too  
16 premature to support the  
17 conclusions drawn herein."  
18 Right?  
19 A. Uh-huh.  
20 Q. [24] Have you read this whole document, as a  
21 matter of fact?  
22 A. I'm familiar with the entire, I'm familiar with  
23 the entire document.  
24 Q. [25] You've gone through it?  
25 A. Yes.

1 Q. [26] You've gone through it. I specifically  
2 would like to look at the following reference at  
3 the bottom of this same page, after the  
4 reference that you speak, that finishes by the  
5 words:

6 "[...] conclusions drawn herein."

7 It's also said:

8 "Sponsor, Doctor Vanlastyni does  
9 not share Doctor Huang's view."

10 Do you know why Doctor Vanlastyni didn't share  
11 Doctor Huang's view?

12 A. No.

13 Q. [27] You don't know. Have you inquired about  
14 that?

15 A. No.

16 Q. [28] Why not?

17 A. ... (no answer).

18 Me CARMELA MAIORINO:

19 Objection, your question is irrelevant as to why  
20 he did not inquire.

21

22 (OBJECTION N° 2)

23

24 Me JEAN-SYLVAIN PELLETIER:

25 Okay.

1 Q. [29] Paragraph 104, please, you talk, in the  
2 middle of the paragraph, about minimal request  
3 standards; can you describe those minimal  
4 request standards?

5 Me CARMELA MAIORINO:  
6 Paragraph 104?

7 Me JEAN-SYLVAIN PELLETIER:  
8 104.

9 A. I'm referring here to requests that come to us,  
10 that are faxed to us and that are screened, we  
11 spoke about that last week about the screening  
12 process, and the minimal request standards that  
13 we apply are that all fields in the form are  
14 filled out with some form of answer. If there  
15 are deficiencies such as a question not  
16 answered, an address not given, a telephone  
17 number not given, the information about the  
18 patient not complete, and the various questions  
19 respecting the medical rationale on page 2 of  
20 the request form not answered completely, then  
21 that would not meet the minimal request  
22 standards to proceed to review.

23 Q. [30] In terms of medical... you said that there  
24 were requests about medical information in the  
25 form; this information, requested information,

1 is it stated somewhere what type of information  
2 is requested?

3 A. Question 2 of the Special Access Request form  
4 asks specific questions which allows the  
5 physician to document and to provide  
6 abbreviated, all be it abbreviated, but relevant  
7 questions that allow us to decide whether or not  
8 the obligations of the practitioner are met and  
9 whether or not the request meets the standard of  
10 an emergency and meets the standard that we  
11 apply for a review.

12 Q. [31] And concerning those standards, are they  
13 written somewhere?

14 A. We refer to those last week, and I think I gave  
15 you an undertaking to provide you with the kinds  
16 of criteria that we apply when exercising our  
17 discretion.

18 Q. [32] Yes, I recall that. Now, were you aware if  
19 those informations that you'll be providing  
20 eventually were known to physicians before they  
21 filled the requests?

22 A. The criteria that we apply are broad topics that  
23 we believe are relevant to our decision making,  
24 they are not secret per se...

25 Q. [33] Are they known?

1     A.     ... they are not published, but we believe this  
2           is within our discretion to, the practitioner,  
3           we go back to the situations where we have a  
4           practitioner who is describing an emergency and  
5           we have ways for them to describe that  
6           emergency, and we have, they have certain  
7           obligations to provide us with information  
8           respecting that emergency and respecting the  
9           use, safety and efficacy of the drug; and that  
10          minimal criteria is well laid out in our  
11          published information as to the kinds of  
12          information that we require from the  
13          practitioner, that's what the regulations speak  
14          to: the information that's required by the  
15          physician to complete an application to the  
16          program.

17                 The criteria and the discretion we apply is  
18                 discretion and, as I had mentioned when we met  
19                 last, discretion means that we bring our mind to  
20                 each and every request; and so, we have to take  
21                 a look at the information contained in that  
22                 request.

23                 Our experience, and the documents which we  
24                 have agreed to provide to you, will provide you  
25                 the context of the various factors that we

1 consider are very relevant to our decision  
2 making, and I think that will be helpful to you  
3 when we disclose them to you.

4 Q. [34] Am I wrong if I understand that those  
5 factors are stated in your Web site?

6 A. Some of them are in general terms. Naturally, an  
7 internal document describing how we apply  
8 discretion in an exact form is not something  
9 that we publish, that's something that we  
10 consider part of the authority that we have to  
11 apply discretion.

12 So, we have general overarching themes  
13 which we keep in mind when we apply discretion.  
14 But ultimately, we bring our mind to each and  
15 every request, and that presents a challenge to  
16 us, and I describe that at length elsewhere in  
17 my affidavit, where you operate a program, where  
18 you have thousands of requests every year,  
19 having to look at each one separately, but at  
20 the same time applying consistent criteria so as  
21 to make consistent decision making and support a  
22 credible process.

23 Q. [35] Did those criteria change between nineteen  
24 eighty-nine (1989) and two thousand (2000)?

25

1 Me CARMELA MAIORINO:

2 I believe that that question was asked during  
3 the last time.

4 Me JEAN-SYLVAIN PELLETIER:

5 Not quite, not specifically.

6 Me CARMELA MAIORINO:

7 Well, one of the criteria evolved...

8 Me JEAN-SYLVAIN PELLETIER:

9 Anyway, if he can answer quickly, it would be  
10 done.

11 A. All regulatory standards have evolved since  
12 nineteen eighty-nine (1989), and the special  
13 access program is... would not be different.

14 Q. [36] I'm talking about 714 specifically, right,  
15 all the questions relating to 714, I'm talking  
16 about the criteria for 714-X?

17 A. The standards that we apply to 714-X have  
18 evolved in the same way that they've evolved for  
19 other products that have been on the program,  
20 and the program in general, within the context  
21 of regulation, evolving both nationally and  
22 internationally, yes. And you would expect that.

23 The regulator is constantly informing  
24 himself of better ways to do things and more  
25 consistent ways of doing things, more harmonized

1           ways of doing things, which create a system  
2           whereby the safety of the product is paramount  
3           in its use in clinical trials, in the  
4           marketplace and to the extent possible through  
5           the special access program.

6    Q.    [37] Paragraph 106, please. Just one question,  
7           we're going back to 104, I'm sorry.

8    A.    Yes.

9    Q.    [38] The last lines of 104, you state that:

10                               "Despite these efforts, the SAP  
11                               continued to receive requests for  
12                               714-X with little or no  
13                               supporting data."

14           Are you aware, can you tell me what is this  
15           little data that you refer to, is it part of the  
16           evidence, as a matter of fact, that you recall?

17   A.    I'm not, I don't have an exhibit that relates to  
18           104, I'm basically talking here about the fax-  
19           back procedure which was something that was  
20           initiated, you recall that this paragraph is  
21           within a section called: The Impact of Recent  
22           Initiatives within the SAP on the Availability  
23           of 714-X. So there were a number of program that  
24           changes within the program, which, if you will,  
25           business improvement within the program, which

1 identified deficiencies with a number of drugs,  
2 and 714-X was one of those drugs. 714-X was not  
3 the only drug that fell out of that review.

4 When you seek to better your business  
5 processes, you will find out what's going right  
6 and what's going wrong, and what might be in-  
7 between. In this case, the changes in business  
8 showed that the requests that were coming in and  
9 the new standards that were being gradually  
10 ramped up over the course of years were showing  
11 that 714-X fell out of the general, the general  
12 acceptability, if you will, of requests that  
13 were coming in.

14 So when I refer to little, I'm speaking  
15 about what we've spoken a lot about, in that the  
16 evidence, going back to the basic requirements  
17 within the regulations, that the practitioner is  
18 obligated to provide us with information to  
19 support the use of the drug in an emergency  
20 context, and what we were finding was 714-X and  
21 other drugs was that physicians were not doing  
22 that, and that raised the obvious question: why  
23 were they not doing it, were they not able, was  
24 information available to them in order to meet  
25 their obligations, and if there was information,

1           was that information credible enough to meet the  
2           standards that we would normally apply to an SAP  
3           request?

4   Q.    [39] About efficacy and about...?

5   A.    About the use, safety and efficacy of the drug,  
6           which is what the obligation of the physician  
7           is.

8   Q.    [40] But do you keep track of those data even  
9           though they're little, do you keep them in a  
10          separate file, do you keep them listed  
11          somewhere?

12  A.    I think we spoke about this at length when we  
13          met last week.

14  Q.    [41] It was part of the undertakings?

15  A.    Part of the undertakings.

16  Q.    [42] Okay. So 106.

17  A.    Yes.

18  Q.    [43] We're talking about OCCAM, O-C-C-A-M.

19  A.    Yes.

20  Q.    [44] You know this organization?

21  A.    I am familiar with the acronym and the  
22          organization, yes.

23  Q.    [45] You're stating, you're talking about a  
24          review, the OCCAM review.

25  A.    Yes.

1 Q. [46] Is this documented, is this a paperwork, is  
2 this a...?  
3 A. Yes, I'm referring here to the OCCAM review  
4 which was basically the best-case series review.  
5 Q. [47] The five best-case series?  
6 R. Pardon me?  
7 Q. [48] The five best-case series?  
8 A. I can't recall the exact number off the bat, but  
9 it was entitled A Best-Case Series Review.  
10 Q. [49] Is this document deposited as evidence?  
11 A. Yes, it is.  
12 Q. [50] Can you refer me to the annex, to the  
13 exhibit?  
14 A. I'm referring to Exhibit O of my affidavit.  
15 Me MICHEL BÉLANGER:  
16 Q. [51] Which one, I think there is two Os, there  
17 was one in your first affidavit, if it's not my  
18 mistake?  
19 A. I wasn't aware that we had a...  
20 Me MICHEL BÉLANGER:  
21 Is it possible, Maître Maiorino?  
22 Me CARMELA MAIORINO:  
23 We added a document in Exhibit O as en liasse,  
24 in the second affidavit.  
25

1 Me MICHEL BÉLANGER:

2 So, there's two Os, there was one...

3 Me CARMELA MAIORINO:

4 So, there's O en liasse, the first part of O is  
5 in the first affidavit.

6 Me MICHEL BÉLANGER:

7 Oh, yes, it was...

8 Me CARMELA MAIORINO:

9 And the second part of O is in the second  
10 affidavit, because...

11 Me MICHEL BÉLANGER:

12 Okay, so you've added some documents...

13 A. To the exhibit.

14 Me MICHEL BÉLANGER:

15 Okay, in the same exhibit, the first O was a...

16 Me CARMELA MAIORINO:

17 Yes, we just did that for organizational  
18 purposes, because they flow together, the two  
19 documents flow together.

20 Me MICHEL BÉLANGER:

21 Okay.

22 Me CARMELA MAIORINO:

23 O en liasse in Exhibit, in the second affidavit  
24 filed in January is the follow-up of the OCCAM  
25 review, so that's why we deemed it appropriate

1 to put them together.

2 Me MICHEL BÉLANGER:

3 Okay.

4 Me JEAN-SYLVAIN PELLETIER:

5 Q. [52] Mr. Mackay, are you referring to a document  
6 of two pages dated July twenty-second (22nd) of  
7 two thousand three (2003)?

8 A. I am.

9 Q. [53] This is it?

10 A. Yes.

11 Q. [54] And the first paragraph starts:  
12 "The National Cancer Institute is  
13 committed in finding a [...]"

14 A. Yes.

15 Q. [55] Yes, so we're talking about the same  
16 document?

17 A. Yes.

18 Q. [56] And the page 2 has only one small paragraph  
19 of five lines.

20 A. Yes.

21 Q. [57] Okay. So this is the document that is  
22 referred to in Paragraph 106, correct?

23 A. In 106, I refer to the OCCAM review and I'm  
24 referring to this, yes.

25 Q. [58] Okay. And at the end of Paragraph 106, you

1 state:

2 "[...] the information submitted  
3 by physicians and credibility of  
4 scientific evidence available to  
5 support the use, safety and  
6 efficacy of the drug in humans."

7 Right, this relates also to SAP, am I right?

8 A. I'm referring to... I'm referring to Health  
9 Canada there, but basically, we're talking about  
10 the context of information that is submitted by  
11 physicians as part of an SAP application, and  
12 I'm referring specifically to the evidence which  
13 physicians had used or used to support the use,  
14 safety and efficacy of drugs in an SAP context,  
15 yes.

16 Q. [59] And the second line of the same paragraph,  
17 you speak about:

18 "[...] the new knowledge of the  
19 OCCAM review."

20 A. Yes.

21 Q. [60] In the page that we've identified as Annex  
22 O, can you identify such new knowledge?

23 A. When I speak of new knowledge was that I was not  
24 previously aware of the OCCAM undertaking the  
25 best-case series review.

1 Q. [61] So it's general knowledge, it's not  
2 specific knowledge?

3 A. It was knowledge that the review was taking  
4 place at all.

5 Q. [62] So was there any new knowledge for you in  
6 that OCCAM document?

7 Me CARMELA MAIORINO:

8 He just answered the question.

9 Me JEAN-SYLVAIN PELLETIER:

10 No, he answered that the document was new to  
11 him, but I'm talking about inside the document  
12 specifically.

13 A. The entire document was new to me.

14 Q. [63] I know, but was the information in that  
15 document new also? That's my question.

16 A. ... (no answer).

17 Q. [64] Do you understand my question?

18 A. I do.

19 Q. [65] Thank you.

20 A. As I look at the document now, I see there are a  
21 number of different kinds of information in  
22 there, and I maintain the document was new to  
23 me. I was aware that there was such a thing as  
24 the best-case series review, I was aware of that  
25 as a program that OCCAM undertakes. The

1 information... so in general terms, I think this  
2 clearly elaborated on the way in which they  
3 undertake that review, which was new to me.

4 The information in the fourth paragraph was  
5 new to me in general terms; however, clearly, I  
6 was aware that 714-X was a compound manufactured  
7 and distributed by CERBE, and so, there are some  
8 sentences within that paragraph that are  
9 familiar to me and that would not be new.

10 The last paragraph, Paragraph 5, in general  
11 terms is familiar to me; these are attestations  
12 that are contained elsewhere, such as the  
13 manufacturer's claim that the ingredient, the  
14 main ingredient in 714-X is camphor, that it's  
15 not approved by the US Food and Drug  
16 Administration. So, there are facts in there  
17 that certainly I'm familiar with, but the entire  
18 document as a whole, I was not familiar with.

19 Q. [66] Paragraph 107, just a clarification, the  
20 second sentence, you say:

21 "Notwithstanding our growing  
22 understanding of what little data  
23 existed on the drug [...]"

24 We're still always talking about 714-X, right?

25 A. Paragraph 7 refers to...

1 Q. [67] 107.

2 A. Sorry, 107, yes?

3 Q. [68] Yes, did I say 7?

4 A. No, I may have misspoken.

5 Q. [69] My mistake, my mistake.

6 A. Paragraph 107 refers to 714-X requests...

7 Q. [70] Okay.

8 A. ... and when I speak of the phrase, most

9 requests, I am referring to most requests for

10 714-X, yes.

11 Q. [71] Paragraph 109, at the end of the paragraph,

12 you state:

13 "After considering the

14 information from the OCCAM, we

15 began to reconsider the release

16 of the product through SAP."

17 Why did you begin to reconsider then such

18 release?

19 A. I think that Paragraph 109 is in the context of

20 a series of paragraphs which talks about the

21 evolution of our knowledge and the understanding

22 that we had an issue that we felt obligated to

23 solve. The issue began sometime before this, and

24 I think I refer to this when we last spoke about

25 the audit, I spoke about the audit process that

1 we put in place a couple of years before that,  
2 wherein we undertook to try to insure that the  
3 drugs that were going to their program were, and  
4 the requests that were being received were in-  
5 keeping with the regulations that we  
6 administered. And so, when I refer to  
7 considering the release of product, I'm really  
8 talking about this in the context of the  
9 evolution of our knowledge and an evolving story  
10 that we were working on.

11 After, there's no question that when a  
12 respected agency, if you will, even colleagues  
13 in an international sense pronounce judgement in  
14 one way or the other, respecting the use, safety  
15 and efficacy of drug, that that is something  
16 that we pay attention to.

17 It's common for regulators, and I mentioned  
18 this when we last spoke as well, to gather  
19 information and to consider information, that  
20 important statements that have been made by  
21 other regulators and other respected agencies,  
22 there's no question that after we became aware  
23 of the results of their review, or at least the  
24 direction that they were going, this was not  
25 their final announcement, but it was a

1 communication that we have with them, that it  
2 would have been untenable for us not to proceed  
3 forthwith with a more comprehensive review and  
4 reconsideration of the facts and the  
5 circumstance in Canada. That's not to say that  
6 we were... that we were guided alone by this  
7 fact, but this was an important factor in our  
8 decision making, and the decision making to  
9 proceed with a review and ultimately a  
10 reconsideration of the requests that were being  
11 released to the program.

12 When a respected agency such as OCCAM makes  
13 a statement to say that there's insufficient  
14 evidence to support government sponsored  
15 research...

16 Q. [72] That's the American, the American  
17 Government?

18 Me CARMELA MAIORINO:

19 Can you please let him finish his answer?

20 Me JEAN-SYLVAIN PELLETIER:

21 I'm asking a precision.

22 Me CARMELA MAIORINO:

23 Well, he's in...

24 THE WITNESS:

25 A. What I'm saying is that when a respected agency

1           says there is insufficient evidence to support  
2           government sponsored research, we are a  
3           government organization as well, and so, that  
4           kind of conclusion rings true with us. That's  
5           not to say that we are guided alone by that, we  
6           are, we make separate decisions, but we are a  
7           force guided by evidence and available  
8           information that will help us make a better  
9           decision and a credible decision within the  
10          Canadian context.

11                 This is very common within the regulatory  
12           environment, and indeed, the comprehensive  
13           regulatory environment we have now would not be  
14           what it is if it wasn't for that kind of  
15           cooperation and information sharing.

16                 I should also add that this is very common  
17           within the context of the scientific community,  
18           wherein the scientific community rarely has  
19           international boundaries, and that information  
20           available in one country as published is then  
21           available to others for consideration, for  
22           debate and for further reflection.

23    Q.    [73] Paragraph 115, please.

24    A.    Excuse me, 115?

25    Q.    [74] 113, 1-1-3.

1 A. 113, yes.

2 Q. [75] At the end, you state:

3 "The merits of continuing to  
4 authorize SAP requests for  
5 patient currently being treated  
6 with 714-X for the period of one  
7 year was also considered."

8 Why was it considered, why this consideration?

9 A. Paragraph 113 refers to the analysis of options  
10 that we were considering, ultimately respecting  
11 the availability of 714-X through the special  
12 access program. Naturally, when regulators are  
13 confronted with new information and when we seek  
14 to make a decision about that new information,  
15 we have to develop options as to how we may  
16 proceed. Options such as curtailing access  
17 altogether on a given date...

18 Q. [76] Stick to the question, please.

19 A. ... curtailing access to the product altogether  
20 was one option, continuing access was another,  
21 and an in-between option is what I'm talking  
22 about here, whereby we would limit access in  
23 general, but for patients who are currently on  
24 therapy, we considered allowing them an  
25 opportunity to complete their therapy, and that

1 was an option that was debated.

2 So I'm specifically referring to patients  
3 who are currently on the product and the  
4 consideration that we gave to allow them to  
5 complete their therapy for a reasonable period  
6 of time.

7 Q. [77] What if after one year the therapy wasn't  
8 over?

9 Me CARMELA MAIORINO:

10 Objection, the question is hypothetical.

11

12 (OBJECTION N° 3)

13

14 Me JEAN-SYLVAIN PELLETIER:

15 Q. [78] Did you consider the fact, did you consider  
16 how many patients on the therapy would be, would  
17 have their therapy ended after one year?

18 Me CARMELA MAIORINO:

19 Objection, how is that relevant?

20 Me JEAN-SYLVAIN PELLETIER:

21 Well, it's a one-year period, I'm allowed to ask  
22 questions on that period.

23 Me CARMELA MAIORINO:

24 How is the relevancy as to the remaining number  
25 of patients pertinent to the case?

1 Me JEAN-SYLVAIN PELLETIER:

2 Well, this is what the paragraph talks about, he  
3 just mentioned that... he states, the  
4 consideration to leave this period open for past  
5 patients using the drug 714-X was for them to  
6 terminate or to complete their therapy; and the  
7 question is: Did you inquire on how many  
8 patients would have their therapy ended after  
9 one year?

10 Me CARMELA MAIORINO:

11 Objection, under reserve.

12

13 (OBJECTION N°4)

14

15 THE WITNESS:

16 A. We did not know how many patients would be,  
17 would continue therapy after that year, within  
18 that year period, or after... or who may want to  
19 continue after that year period, we had no idea  
20 of the numbers at the time. We knew that the  
21 total number of people who were currently on the  
22 product at the time was relatively small, but we  
23 had no idea as to how many would continue, how  
24 many physicians would continue to make requests  
25 to us within that year period.

1 Me JEAN-SYLVAIN PELLETIER:

2 Q. [79] So am I understanding your answer stating  
3 that it could have been, instead of one year, it  
4 could have been three years?

5 A. The period we discussed was a period of a year,  
6 and some of the discussions that went into that  
7 was what was a reasonable period of time for  
8 people to look at alternatives, a reasonable  
9 period of time to seek advice from medical  
10 specialists, it's not necessarily easy to get in  
11 to see a specialist these days, so we wanted to  
12 leave a reasonable period of time for patients  
13 to meet with their physicians, discuss other  
14 treatment options and other ways to manage their  
15 disease, and, ultimately, I don't think we  
16 considered an extended period of time because  
17 there is no evidence that we were familiar with  
18 at the time and, subsequently, that would  
19 support a long-term or chronic use of 714-X, and  
20 this was part of the evolving knowledge that we  
21 had that there was little information and,  
22 certainly, little information to support long-  
23 term use.

24 Drugs are always recommended for a period  
25 of time, be it for a headache, you take two

1 pills in the morning and your headache goes  
2 away, and you don't need to take anymore pills  
3 for the rest of the day; other drugs are  
4 indicated for longer periods of time, take a  
5 drug for a month or two months, and some drugs  
6 are recommended for use in a long-term context;  
7 some people, for instance, insulin people are on  
8 insulin for an extended period of time.

9 In each of those scenarios, the physician,  
10 in making a decision, would always turn to  
11 information and evidence to support either the  
12 short-term or long-term use, and without data to  
13 support the long-term use, it would be unusual  
14 for a physician to request access to something  
15 where there is no evidence to support, and I  
16 bring this back to the regulations, ultimately,  
17 the physician is required to provide us with  
18 information supporting the use, and the extended  
19 use of that over a long period of time is  
20 something that we brought into consideration.

21 So, those are the facts that we considered  
22 for debating the year period. We thought it was  
23 a reasonable period of time to allow people to  
24 consider other options, to gain access to  
25 specialists if that was necessary for

1           reconsideration of other treatment of periods,  
2           and that, ultimately, there was no evidence to  
3           support the use of this forever.

4    Q.    [80] Do you know how long it takes to a therapy  
5           to cure cancer?

6           Me CARMELA MAIORINO:

7           Objection, how is that relevant?

8           Me JEAN-SYLVAIN PELLETIER:

9           He mentioned cancer in his standards, I'm  
10          allowed to ask questions on that, we're talking  
11          about delays to cure.

12

13          (OBJECTION N° 5)

14

15    Q.    [81] How long does a therapy last for cancer?

16          Me CARMELA MAIORINO:

17          Completely, I object, I don't see the relevancy  
18          at all as to the knowledge of Mr. Mackay's...

19          Me JEAN-SYLVAIN PELLETIER:

20          Well, under objection then?

21          Me CARMELA MAIORINO:

22          No, I object.

23          Me JEAN-SYLVAIN PELLETIER:

24          That will be debated before the judge, I insist  
25          on that question.

1 Me CARMELA MAIORINO:

2 Yes.

3

4 (OBJECTION N° 6)

5

6 Me JEAN-SYLVAIN PELLETIER:

7 Q. [82] Do you know how long it lasts, how long is  
8 a therapy to treat mastocytose, Mr. Mackay?

9 Me CARMELA MAIORINO:

10 Objection, under the same grounds.

11 Me JEAN-SYLVAIN PELLETIER:

12 It will be asked before the judge.

13

14 (OBJECTION N° 7)

15

16 Q. [83] Paragraph 115, please. You state that:

17 "On or about December 20th, 2003,  
18 all requests for special access  
19 to 714-X were held [...]"

20 Why was it held?

21 A. I described when we spoke last about the period  
22 of time between July and January, as an evolving  
23 story with respect to the review that we  
24 undertook for 714-X in the context of its use  
25 and availability through the special access

1 program. That evolving story, as we performed  
2 our due diligence, was coming to a close on or  
3 about December twentieth (20th).

4 I spoke last week about the development of  
5 a communication which we were going to send to  
6 physicians who had requested access to the  
7 product and who had pending requests, and while  
8 there were some requests that were authorized  
9 and dealt with in that period of time, there  
10 was, without question, a trend towards a closer  
11 and closer scrutiny as the review and the  
12 options that we had available to us neared  
13 completion, and I describe in this paragraph  
14 that the scientific review, undertaken by Doctor  
15 Garber, referred to in the previous paragraph,  
16 was the final step in that process beginning in  
17 July and ultimately announced in January. They  
18 were held because we were about to announce the  
19 results of that and the impact of that review on  
20 the subsequent processing of requests.

21 We spoke last week, or I spoke last week  
22 about the fact that this response would  
23 ultimately describe the review that we undertook  
24 and would be a response to requests that at the  
25 time were outstanding, and it would provide

1 guidance to others, who had gained access to it  
2 in the past, as to what the new standards were  
3 going to be for review in light of this new  
4 information, and the review that we had  
5 undertaken.

6 Q. [84] Paragraph 115 speaks about, the third line:

7 "[...] prepared to render  
8 decisions [...]"

9 When was that decision rendered in fact?

10 A. Well...

11 Q. [85] Are we talking about the January two  
12 thousand four (2004) decision?

13 A. Yes. We spoke about that last week, talking  
14 about the January nineteenth (19th), dated  
15 January nineteenth (19th), a letter was  
16 essentially a response to outstanding requests  
17 and, as I described, ultimately was guidance to  
18 physicians who would be considered future  
19 applicants.

20 In other words, what I'm describing here on  
21 January twentieth (20th) is really the cut-off  
22 point, is that, as a regulator, it's always a  
23 balancing access to when you make a decision,  
24 and with growing understanding of an issue. This  
25 is something which regulators around the world

1 do every day, and it's a judgement call as to  
2 when your comfort level is... when you're no  
3 longer comfortable in light of the new  
4 information available, and it stands to reason,  
5 as you are completing the scientific review, and  
6 that the evidence that we had before us was  
7 clearly going to impact, we no longer had  
8 comfort with processing requests at that time.  
9 Knowing that we were going to be able to respond  
10 shortly, we then held requests on or about that  
11 date.

12 Q. [86] Paragraph 137, page 35.

13 A. Yes.

14 Q. [87] No, 134, page 35.

15 A. Oh, I'm sorry, Paragraph 134, page 35, I have it  
16 in front of me, yes.

17 Q. [88] Okay. The first sentence says:

18 "Special consideration would be  
19 given to both pending and future  
20 requests for repeat patients."

21 Can you explain to me that sentence, please?

22 Why a special consideration?

23 A. We spoke about this a few moments ago, talking  
24 about the one-year period, and essentially, the  
25 option that was debated and that we spoke about

1 a few moments ago, this was, this explains what  
2 in fact we did. So that one-year period was  
3 essentially a special consideration that we were  
4 giving to patients who had previously used the  
5 drug and who perhaps wanted to, in consultation  
6 with their physician, would want to continue and  
7 complete their therapy.

8 Q. [89] Paragraph 136, please. A question back to  
9 134, I'm sorry.

10 A. Yes.

11 Q. [90] Was the information the same, the  
12 information requested to physicians, was it the  
13 same information requested for past patients as  
14 compared to future patients?

15 A. ... (no answer).

16 Q. [91] Do you understand my question?

17 A. ... (no answer).

18 Me CARMELA MAIORINO:

19 I think the problem is that it's just asking it  
20 in a very general fashion, and the witness has  
21 explained that...

22 Me JEAN-SYLVAIN PELLETIER:

23 No, I'm...

24 Me CARMELA MAIORINO:

25 ... the requests are on an analyzed basis...

1 Me JEAN-SYLVAIN PELLETIER:

2 No, okay.

3 Q. [92] In terms of your discretionary power in  
4 application of the regulation, do you request  
5 the same information for... I'm speaking about  
6 the period of... from January two thousand four  
7 (2004), was your discretion applied the same,  
8 with the same criteria and the same basis for  
9 past patients compared to future patients?

10 Me CARMELA MAIORINO:

11 As for repeat patients or new patients?

12 Me JEAN-SYLVAIN PELLETIER:

13 Q. [93] Repeat patients meaning past patients, and  
14 new patients, new applicants.

15 A. I think I'm confused with respect to the use of  
16 past, pending, et cetera. Perhaps I'll try to  
17 explain what I'm describing in Paragraph 134.  
18 I'm referring, in the first sentence, to pending  
19 and future requests.

20 Q. [94] Pending meaning past, right?

21 A. Pending meaning that were, that had not yet been  
22 decided upon, such as those which were held  
23 after December twentieth (20th) until such time  
24 as the letter was issued.

25 So, what I'm basically talking about here

1 is ultimately I'm talking about pending and  
2 future requests for repeat patients, I'm not  
3 referring to new patients here. And I think I  
4 described in here that with the letter that we  
5 sent out to give direction to physicians who  
6 would be applying for access for repeat  
7 patients.

8 So all of them would be dealing, they'd all  
9 be dealt with in the future, if you will. I'm  
10 talking about the future after January  
11 nineteenth (19th), applications that would come  
12 to us; so when I speak of future, I'm referring  
13 to requests that would come to us after the  
14 letter and the instructions we gave to  
15 physicians for repeat patients.

16 Q. [95] But regarding your discretion in appliance  
17 of the regulation, did you apply your discretion  
18 exactly the same way for pending requests than  
19 for future requests?

20 Me CARMELA MAIORINO:

21 For repeat patients?

22 Me JEAN-SYLVAIN PELLETIER:

23 Q. [96] For repeat patients, yes.

24 A. Yes.

25 Q. [97] Exactly the same?

1 A. I'm speaking about, we set out criteria in the  
2 letter of January nineteenth (19th) that would  
3 allow physicians to apply for future access for  
4 repeat patients for the period of one year, and  
5 in that letter, we laid out basically what we  
6 would be looking for, and I refer, in the letter  
7 that I think you're going to... in the paragraph  
8 that you're going to speak about with respect to  
9 the adverse events, and we gave specific  
10 direction to physicians that one of the things  
11 that we were going to require in the  
12 consideration of repeat patients was a statement  
13 to the effect that whether or not the patient  
14 had experienced any adverse effects on the drug  
15 at any point in time in the past. So that was a  
16 specific criteria, if you will, which we  
17 transparently described to physicians that we  
18 would bring into consideration.

19 Q. [98] Paragraph 136, please. I'll let you read it  
20 and I have only one question regarding the end  
21 of the paragraph.

22 A. Yes, I'm familiar.

23 Q. [99] At the end you state:

24 "This approach considered that  
25 the level of risk incurred

1                                   differed for new patients  
2                                   compared with repeat patients."

3    A.    Yes.

4    Q.    [100] Can you explain to me that?

5    A.    Basically talking about that information that we  
6           would have available to us respecting the  
7           adverse event profile for an individual patient  
8           was something that we were willing to consider,  
9           and so, if a patient had not experienced adverse  
10          effects, that we were within this one-year  
11          period, we would be willing to consider requests  
12          because we didn't have any specific information  
13          in our possession, and the physician did not  
14          report anything to us that would indicate that  
15          the patient had some adverse experience.

16                 Had a patient experienced adverse  
17                 experience, had some adverse effect to the drug,  
18                 then we'd be dealing with a different scenario,  
19                 and we, ultimately, in our letter of January  
20                 nineteenth (19th), did not, we had to be careful  
21                 in wording this while we had to give direction  
22                 to physicians, we also could not fetter our  
23                 discretion by saying what we were going to do  
24                 and not going to do, and basically talked about  
25                 the information that we had available to us and

1           that we would consider, and the January letter,  
2           the January nineteenth (19th) letter, we  
3           believed sort of gave direction, gave specific  
4           direction and guidance to physicians and, at the  
5           same time, allowed us to ultimately make a  
6           discretionary decision on requests that would  
7           come to us subsequently.

8           So when I speak about level of risk, we're  
9           talking about the level of risk at the  
10          individual level, and that for that period of  
11          one year, we were willing to consider the  
12          individual, the information we had available to  
13          us with respect to that individual,  
14          notwithstanding the larger context that we did  
15          not believe that the information that was  
16          available supported continued widespread access  
17          to this drug through the special access program.

18          And I think it's very important to note  
19          that this is all in the context of a special  
20          access program being an exception to the rule;  
21          special access program is not a way in which  
22          drugs are developed. Drugs are developed and  
23          information, and credible information is  
24          obtained through other means, and we were  
25          basically trying to describe the decision that

1 we made that we were willing to apply factors of  
2 individual risk and not broad, either community  
3 or population based risk, to those individuals  
4 for that one period, that one-year period.

5 Q. [101] Paragraph 137, please, at the very end,  
6 you state:

7 "As of this date, there are no  
8 pending requests for special  
9 access to 714-X."

10 Did you state this and sign your affidavit after  
11 checking indeed in your file or not?

12 A. Well, we don't have files per se, operationally.  
13 Operationally, requests come to us on a daily  
14 basis, and I spoke about this at length earlier,  
15 and I described this at length in my affidavit.  
16 To my knowledge, at the time that we had, that I  
17 had filed the affidavit, there were no pending  
18 requests for 714-X, but at the moment I signed  
19 the affidavit, the next minute, a request could  
20 have come across my desk. I just don't know the  
21 details of it, but this is the normal operations  
22 that would happen in SAP, we receive things on a  
23 given day, most are processed within that period  
24 of time - we spoke about that earlier - some are  
25 taken out for various reasons - I described

1           those earlier, and we had a discussion about  
2           those last week.

3                     And at the time, I had, to my knowledge, I  
4           had no outstanding request for 714-X. They would  
5           not be in a file, they would not be in a filing  
6           cabinet, these would be all requests or  
7           something that are in constant motion within the  
8           office.

9    Q.    [102] How could you have stated that there are  
10           no pending requests if you have no way to check  
11           this statement?

12   A.    I'm saying that the way in which we operate is  
13           that requests are either on my desk or they're  
14           not on my desk, on any given day.

15   Q.    [103] You mean all requests go through your  
16           desk?

17   A.    All requests that are screened come to my desk  
18           twice a day. If you want to know, they arrive at  
19           my desk at or about eleven o'clock (11:00), and  
20           at or about three o'clock (15:00), and my staff,  
21           if I'm not at my desk, my staff track me down  
22           because those requests are dealt with twice  
23           daily. So nothing is inserted into a file where  
24           it would go missing, if you will. If it was  
25           withdrawn from the normal course, I would know

1 about it.

2 Q. [104] Mr. Mackay, is it possible to verify on  
3 this day, today, if there are any pending  
4 requests for the product, is it possible to  
5 verify that?

6 Me CARMELA MAIORINO:

7 I'd like to know the relevancy as to, are there  
8 any pending requests today?

9 Me JEAN-SYLVAIN PELLETIER:

10 Well, I'd like to have an update. On the date of  
11 his affidavit, he states that there are no  
12 pending requests...

13 Me CARMELA MAIORINO:

14 Uh-huh.

15 Me JEAN-SYLVAIN PELLETIER:

16 ... and I'd like to see what would be the  
17 situation today, if he's available to verify  
18 that.

19 Me CARMELA MAIORINO:

20 I will have to object because we have four  
21 judicial reviews at bar, and the question is:  
22 did those four particular applications, ask if  
23 these requests were dealt with. So whether there  
24 are other pending requests today, I mean, I  
25 think it's just a fishing expedition, and this

1 is not an examination on discovery, it is not  
2 the...

3

4 (OBJECTION N° 8)

5

6 Me JEAN-SYLVAIN PELLETIER:

7 Q. [105] Mr. Mackay, is it possible that there were  
8 indeed pending requests but you were not aware  
9 of at the time you signed the affidavit?

10 A. ... (no answer).

11 Q. [106] For instance, Léopold Delisle, who's one  
12 of the applicant, is it possible that, at the  
13 time you signed the affidavit, he was in a  
14 situation where his request was pending?

15 A. ... (no answer).

16 Me CARMELA MAIORINO:

17 I'll have to object as well, this is  
18 hypothetical whether there is a possibility that  
19 there was a pending request.

20

21 (OBJECTION N° 9)

22

23 Me JEAN-SYLVAIN PELLETIER:

24 So, your client didn't answer, I believe.

25

1 Me CARMELA MAIORINO:

2 I'll object under reserve.

3 Me JEAN-SYLVAIN PELLETIER:

4 Under reserve.

5 Q. [107] Go ahead, Mr. Mackay.

6 A. Sorry, there was a time line there, could you  
7 repeat the question?

8 Me CARMELA MAIORINO:

9 Is it possible that there were pending requests  
10 the day the affidavit was signed?

11 Me JEAN-SYLVAIN PELLETIER:

12 Q. [108] Specifically in the case of Léopold, in  
13 particular in the case of Léopold Delisle, for  
14 example, in his case?

15 A. My statement stands in that, at the time that I  
16 signed this, I, to the best of my knowledge, I  
17 had no outstanding requests on my desk, and if  
18 we're talking about far-fetched possibilities  
19 that wouldn't fall within my responsibility, if  
20 someone had faxed something to us and there was  
21 a fax transmission error or, et cetera, perhaps  
22 someone believes there is something pending, but  
23 to my knowledge, and I'd have to know the name  
24 of the physician, but because there were no  
25 requests pending to my knowledge.

1                   If there was one or two, if I had stated  
2                   that, then I would have to go back to check to  
3                   see whether or not a doctor's name matched the  
4                   patient you described, but I'm basically saying  
5                   that as of this date, there were no requests  
6                   pending on my desk, and within my office. It's  
7                   really important to note though that, as I said,  
8                   the office is a dynamic place, it's a relatively  
9                   small office which is good and...

10    Q.    [109] I understood that, you stated it several  
11           times.

12    A.    Right. So, so administrative things can happen,  
13           but I wouldn't... I'm basically saying that I  
14           would not be aware of those, there was no  
15           pending requests for 714-X on that day.

16                   Usually, in the normal course of events,  
17                   when a physician has a request pending, and if  
18                   for some reason, they've not heard from us,  
19                   quite often, a physician or a physician's office  
20                   will call the office to say: "Do you have this  
21                   request, are you processing it, is there a  
22                   problem with it?" and that would alert us to do  
23                   a double check of our desks, and that happens  
24                   every day, and both my staff and I are  
25                   frequently sort of checking through our in-boxes

1 to insure that either we received something, we  
2 didn't receive something, and processing it or  
3 describing to the caller what the status of the  
4 request is.

5 But to the best of my knowledge, and on the  
6 date I signed that letter, there were no pending  
7 requests for 714-X on my desk for any physician,  
8 and therefore, the specific example you request,  
9 it's a moot point, because there was nothing on  
10 my desk.

11 Q. [110] Paragraph 139.

12 A. Yes.

13 Q. [111] It indicates that Léopold Delisle, you  
14 refer to Léopold Delisle's affidavit.

15 A. Yes.

16 Q. [112] And you mention that:

17 "Health Canada officials met with  
18 Léopold Delisle to discuss his  
19 physician's pending special  
20 access request for 714-X."

21 Do you recall what was the date of the request?

22 A. No.

23 Q. [113] Do you recall, in that context, if his  
24 physician made one or two requests?

25 A. My paragraph is referring to our request, but

1 I'm referring back to monsieur Delisle's  
2 affidavit.

3 Q. [114] Is it possible that there is a little  
4 error in the date, the fourth line, December  
5 eighteenth (18th), two thousand three (2003)  
6 rather than two thousand four (2004)?

7 A. ... (no answer).

8 Q. [115] Paragraph 139, you state that Mr.  
9 Boudreau... "I'm also aware..." at Paragraph  
10 139.

11 A. Yes, that must be an error in... I'm just double  
12 checking, because the years are running  
13 together.

14 Q. [116] Yes, yes.

15 A. But it must be, yes, it should say two thousand  
16 and three (2003). Yes, I have just confirmed  
17 that Exhibit Q, in looking at Exhibit Q, I can  
18 confirm that we are talking about December two  
19 thousand and three (2003).

20 Me CARMELA MAIORINO:

21 Exhibit Q to...?

22 THE WITNESS:

23 Exhibit Q to my, the original affidavit, yes.

24 Me JEAN-SYLVAIN PELLETIER:

25 Q. [117] And it was authorized on the same date,

1 right, there's two dates on that document, I  
2 recall, if I recall well?

3 A. It's a bit blurry, but in my affidavit, I'm sure  
4 I double checked with our computer records, but  
5 it looks like the stamped authorization on the  
6 bottom right-hand corner, it says December  
7 eighteenth (18th), two thousand and three  
8 (2003).

9 Q. [118] Thank you. Paragraph 147, in the middle of  
10 the paragraph, you say:

11 "[...] the review undertaken by  
12 Health Canada in December 2003  
13 [...]"

14 A. Sorry, Paragraph 147?

15 Q. [119] 141, in the middle of the paragraph.

16 A. Yes.

17 Q. [120]

18 "[...] the review undertaken by  
19 Health Canada in December 2003  
20 and whether they were involved  
21 with or aware of any effort to  
22 initiate [...]"

23 Who is they, just to clarify my understanding?

24 A. I'm referring here to a letter that was sent to  
25 physicians, so I'm referring...

1 Q. [121] So, they, refers to physicians?

2 A. Yes.

3 Q. [122] Okay. And you mention further:

4 "[...] they were involved with or  
5 aware of any effort to initiate a  
6 programme of formal drug  
7 development."

8 Why did you ask that?

9 A. This respects a letter that we sent to  
10 physicians in December of two thousand and four  
11 (2004), wherein in anticipation of the end of  
12 the year period that we've spoken about now, we  
13 were trying our best to insure that our  
14 understanding of the drug and the status of the  
15 drug had not changed; this was part of our due  
16 diligence to see whether or not any activity had  
17 been undertaken in the last year or so, that  
18 would, that would... that these physicians may  
19 have been aware of or involved with, that would  
20 be, that would constitute a drug development  
21 program.

22 So basically, physicians and physicians  
23 with experience products are often the  
24 individuals that manufacturers turn to when  
25 they're looking at conducting clinical trials;

1 clinical trials ultimately have to be conducted  
2 by a physician, and so, it was reasonable to  
3 assume that if there was going to be any  
4 activity to initiate clinical trials, that some  
5 of the physicians with whom, who had gained  
6 access to the product over the last year, and  
7 then perhaps over the last number of years,  
8 would have been the physicians that the cut  
9 manufacturer turned to.

10 Q. [123] Yes.

11 A. So we wanted to, as part of our due diligence,  
12 to see, you know, are we missing something here,  
13 is there information that may be out there that  
14 we're not familiar with, and that may have  
15 changed over the last years, significantly? And  
16 we just basically asked the question, open and  
17 honestly, to say: listen, are you ware of  
18 anything that would allow us to get an  
19 understanding of whether this, the drug and  
20 development of the drug had moved anywhere in  
21 the intervening year?

22 Q. [124] Would it have changed something in your  
23 position if indeed such effort would have been  
24 initiated?

25 A. There's no question if there was a clinical

1 trial that was operating, if there was a new  
2 drug submission, if there was either of those,  
3 those would be absolutely significant events,  
4 and would signal that the process of drug  
5 development was under way or perhaps even in an  
6 advanced stage. Those are the ways in which, and  
7 that could have happened in Canada and it could  
8 have happened in another regulatory jurisdiction  
9 that would have similar standards to Canada.

10 Q. [125] With the same product, we're talking  
11 about?

12 A. With the same product, yes.

13 Q. [126] Okay.

14 A. We're basically talking about both... basically,  
15 what we're looking for is making sure that we  
16 weren't missing anything. If we were making a  
17 final decision and we had a final decision  
18 making in January, we wanted to be sure that we  
19 weren't missing something significant, and a  
20 clinical trial application efforts to convene an  
21 expert advisory committee of experts in Canada,  
22 or elsewhere, to start to put together a trial,  
23 to initiate the kinds of preclinical studies or  
24 non-clinical studies, be it lab studies and/or  
25 in vitro studies, anything of that sort would

1           have allowed us to bring that into  
2           consideration.

3                     It's not to say that we would necessarily  
4           sway or sway the balance one way or the other,  
5           but we were looking for something. If we found  
6           something small, that would be one thing; if we  
7           found something large, that would be another.  
8           Everything in drug regulation is degree, and I  
9           spoke earlier, and I speak in my affidavit about  
10          drug development being an ongoing process where  
11          you start small and information, gained in one  
12          study, provides evidence and support for future  
13          studies.

14                    And so what we were looking for was any  
15          significant movement in that area that these  
16          physicians may have been involved with that  
17          would have allowed us to understand that drug  
18          development had been initiated or that there was  
19          serious consideration being given to launching  
20          trials in the very near future. The reason why  
21          we were looking for that information is that  
22          there was a trial that was under way in the  
23          United States, for instance, if there was a  
24          trial that was under way in a western European  
25          country, for instance, then we would presume

1           that that regulatory jurisdiction would have  
2           given authorization to that trial.

3           Generally speaking, when a regulatory, when  
4           a regulator gives authorization, that would be  
5           done in an evidence base way, so they would take  
6           a look at the available information, the  
7           appropriate studies that would need to be done  
8           before moving it into formal clinical trials,  
9           and that would be a signal to us that there's  
10          been movement on the file, movement on drug  
11          development, which means there would be  
12          information available respecting the use, safety  
13          and efficacy of that product, which then could  
14          be used to support an SAP application. But I do  
15          underscore the fact that drug development is a  
16          graduated process where you have to start small  
17          and move larger, and information that's gathered  
18          at one level supports additional information.

19          Having said all that, SAP is still not the  
20          way in which drugs are developed. We spoke about  
21          that last week when we talked about anecdotal  
22          information, and that, you know, the goal for  
23          everyone here is to try to bring some order to,  
24          and bring some light on to whether or not this  
25          product has some use in one or more cancers, and

1 the only way to do that, the way to do that is  
2 not through SAP.

3 SAP can never, you can never gather  
4 information in any credible way that would allow  
5 you to pronounce judgement on the use, safety  
6 and efficacy of the product, the quality of the  
7 product; that can only be done through clinical  
8 trial. So the effort here was a way to smoke  
9 out, if you will, any information that we were  
10 not already privy to.

11 I should also note that the normal way in  
12 which information... the normal way in which  
13 information such as this would be, would come to  
14 us, would be its availability through the  
15 medical literature where studies, be it  
16 preclinical studies or clinical studies would be  
17 published and scrutinized by the scientific  
18 community before being available to the wider  
19 international community for consideration.

20 Q. [127] Paragraph 146, please, the Exhibit F, a  
21 letter from Doctor Pardee.

22 A. Yes.

23 Q. [128] Is this person known to you, Doctor  
24 Pardee?

25

1 Me CARMELA MAIORINO:  
2 Just give us a minute to...  
3 Me JEAN-SYLVAIN PELLETIER:  
4 Get to the document?  
5 Me CARMELA MAIORINO:  
6 Yes.  
7 THE WITNESS:  
8 A. I'm aware of this person in name only as it  
9 relates to the document that I'm familiar with;  
10 I don't know this person personally.  
11 Me JEAN-SYLVAIN PELLETIER:  
12 Q. [129] Is it in your documentation, Exhibit S,  
13 that's part of your affidavit?  
14 A. Yes, it's the last page of Exhibit S I believe.  
15 Q. [130] Okay, okay.  
16 Me CARMELA MAIORINO:  
17 Yes, it's the last page of Exhibit S.  
18 A. Yes.  
19 Me JEAN-SYLVAIN PELLETIER:  
20 Q. [131] So you have this document dated August  
21 nine (9), nineteen ninety-nine (1999), you have  
22 this letter before you?  
23 A. I do.  
24 Q. [132] Does Dana Farber Cancer Institute tell you  
25 something?

- 1 A. ... (no answer).
- 2 Q. [133] I'm sorry, did you answer, did you  
3 understand my question?
- 4 A. Sorry, I'm not answering, doesn't it tell me  
5 something?
- 6 Q. [134] Well, do you know Dana Farber Cancer  
7 Institute?
- 8 A. I'm familiar...
- 9 Q. [135] In Boston, Massachusetts.
- 10 A. ... I'm familiar with the institute as a major  
11 cancer institute in the United States, yes.
- 12 Q. [136] A major cancer institute, okay. I  
13 understand that you've gone through this whole  
14 letter before writing your affidavit, right?
- 15 A. I have, yes.
- 16 Q. [137] Do you find any evidence in that letter  
17 from Doctor Pardee and Doctor Huang that  
18 supports the 714-X product in terms of efficacy?
- 19 A. No.
- 20 Q. [138] Not at all, with respect to efficacy?
- 21 A. No.
- 22 Q. [139] I would like to pinpoint Paragraphs 1, 2,  
23 3, 4, actually, maybe Paragraph 3, which seems  
24 to be separate.
- 25 A. Uh-huh.

1 Q. [140] There's a sentence that says:

2 "For the first time, our data  
3 [...]"

4 At the end of the line, you have that?

5 A. One more time, just a second. Yes.

6 Q. [141]

7 "For the first time, our data  
8 provides scientific evidence  
9 supporting that 714-X is an  
10 immune stimulus."

11 A. Yes.

12 Q. [142] Doesn't that tell you something or some  
13 clues about the efficacy of the product?

14 A. No.

15 Q. [143] Not at all?

16 A. No.

17 Q. [144] Why not?

18 A. My reading of this is that this paragraph in  
19 this letter is describing in vitro work, so this  
20 is work that's done in test tubes. Work that is  
21 done in test tubes is not efficacy data.  
22 Efficacy data refers to how well it works in a  
23 human being to treat, or to diagnose, or to  
24 prevent an individual disease. Efficacy has a  
25 specific, we can have an undertaking if you

1 want, we can get you a...

2 Q. [145] I would like that indeed.

3 A. ... a definition of efficacy.

4 Q. [146] I would like to have that, please.

5

6 UNDERTAKING 15: Provide a written  
7 definition of the word  
8 "efficacy".

9

10 A. Basically, these paragraphs are describing  
11 the... are trying to characterize the properties  
12 of the compound they tested, and it's... these  
13 are standard ways in which you expose, you take  
14 a compound and try to figure out how it works,  
15 the so-called mechanism of action, and the  
16 author of this letter, and I describe in my  
17 affidavit, says in their own words, they're  
18 trying to characterize the compound. So this  
19 study that is performed is part of an effort to  
20 try to characterize the constituency of the  
21 compound, and are proposing how that product  
22 might work upon cells, that's essentially what  
23 they're saying.

24 Q. [147] A little further in the same paragraph,  
25 there's a paragraph at the end that starts by



1                                   year period. 714-X is thought to  
2                                   elevate the immune response and  
3                                   has some role in killing tumor  
4                                   cells. Our data provides evidence  
5                                   to support this theory."

6                   Same question, do you see, in those sentences,  
7                   presentation, some evidence, some clue to  
8                   support the efficacy of the product 714-X?

9       A.       When you talk about supporting, you know, the  
10               words here I think are very clear, the author is  
11               talking about - First of all, the first part of  
12               the sentence is a claim, someone's claiming  
13               this.

14       Q.       [151] Yes.

15       A.       Claims are a dime a dozen. Ultimately, a claim  
16               has to be proven, and that's the point of the  
17               regulatory system, is to verify claims.

18       Q.       [152] Right.

19       A.       And so, there are a lot of drug companies  
20               developing a lot of drugs with a lot of  
21               claims...

22       Q.       [153] Right.

23       A.       ... and not all make it. There's a rough  
24               scenario where every thousand compounds that are  
25               ever tested in a world as potential drugs, one

1 or two get through; and so there's always, in  
2 terms of a pyramid, you start with many  
3 compounds and you rarely, you would never, for  
4 every thousand that are started, one or two end  
5 up as drugs on the market.

6 So basically, the first part of this is  
7 someone is making a claim, I don't know who is  
8 claiming, it's a dramatic claim, but it's  
9 nevertheless a claim, and the author is  
10 describing it as nothing other than that.

11 Q. [154] But what about the end of the sentence?

12 A. The end of the sentence is basically talking  
13 about the claims as well, the word they use is:  
14 "thought to elevate immune response".

15 Q. [155] And what about the last... I'm sorry:

16 "Our data provides evidence to  
17 support this theory."

18 What are your comments on that?

19 A. Well, they're describing, the theory they're  
20 describing is the previous sentence, that it has  
21 some role in killing tumor cells, that's the  
22 theory, and they're saying that their data  
23 provides support to that theory. But ultimately,  
24 the data that they have is in vitro data, again,  
25 once a character... an information that tries to

1 characterize the product, and while they're free  
2 to make the claim and to describe their data in  
3 the way they choose, it would have - and I refer  
4 in my affidavit that normally, theory and data  
5 to support theory are subjected to scrutiny.

6 And if I read this letter correctly, this  
7 was a letter by the two signatories at the  
8 bottom, basically asking a colleague or perhaps  
9 a manager within the Dana Farber Cancer  
10 Institute, permission to publish this, which  
11 would be the normal way in which scientists who  
12 have conducted experiments and conducted  
13 research would announce their findings to the  
14 world, if you will, through the publication of  
15 this scientific evidence.

16 Q. [156] Paragraph 150, please: "To date..." you  
17 state:

18 "To date, no adverse events have  
19 been reported with the use of  
20 714-X since January 2004 in  
21 patients who have gained [...] et  
22 cetera."

23 Do you have any report of adverse effect before  
24 January two thousand four (2004)?

25 A. I think we spoke about that last week.

1 Q. [157] Do you recall briefly your answer?

2 A. Well...

3 Q. [158] Those were undertakings? No, it wasn't.

4 Me CARMELA MAIORINO:

5 I'd have to check.

6 Me JEAN-SYLVAIN PELLETIER:

7 Yes, me neither.

8 Me CARMELA MAIORINO:

9 But there was a line of questioning...

10 Me JEAN-SYLVAIN PELLETIER:

11 Q. [159] So can you briefly answer anyway?

12 Me CARMELA MAIORINO:

13 There was a line of questioning nevertheless on  
14 the address of this...

15 Me JEAN-SYLVAIN PELLETIER:

16 Yes.

17 Q. [160] Can you briefly answer anyway?

18 A. I think I spoke in general terms about the fact  
19 that... I know we had a long discussion about  
20 the fact that physicians in general are not  
21 great at reporting adverse events, and that also  
22 applies to the special access program. I was not  
23 aware of any, I don't think I had any specific  
24 recollection of receiving an adverse event  
25 report in the normal way in which they come to

1 us, yes.

2 Q. [161] I recall last week we spoke a lot about  
3 that indeed.

4 A. Yes.

5 Q. [162] 150 at the end, you state:

6 "SAP will continue to consider  
7 requests from physicians treating  
8 repeat patients for continued  
9 access to the drug until such  
10 time as the courts render a  
11 decision or the matter is  
12 otherwise settled."

13 Why to apply such criteria?

14 A. This was a decision that we undertook with  
15 consultation and debate, and that we realized  
16 that the matters that are before the court  
17 within this judicial review are asking important  
18 questions, and that while we reserve the right  
19 at any time to make the final decision, and for  
20 instance, if there was evidence of adverse  
21 events to come forward in the interim, we would  
22 certainly exercise our discretion appropriately  
23 with that new information.

24 But basically, we are still in the position  
25 with respect to the information available to

1 support requests, we're not confident and we  
2 know that ultimately there's going to be a  
3 decision relatively soon, and but in the  
4 meantime, if there was reason for making a final  
5 decision, we can, but that the matters before  
6 the court are important, and that we felt that  
7 it was appropriate to delay the final  
8 implementation of our review for a short period  
9 of time.

10 Q. [163] At the end of this paragraph, you state:

11 "Practitioners will be notified  
12 of this position."

13 Were they indeed notified?

14 A. They are about to be.

15 Q. [164] So they're not notified today?

16 A. They are not notified as today, we've had a  
17 number of other pressing issues within the  
18 program, we endeavoured to try to get it out  
19 last week, but there were circumstances within  
20 the office that didn't allow us to be, to allow  
21 us to finish that, the letter is complete and we  
22 expect to go to translation before the end of  
23 this week, and we'll be, we expect, our aim is  
24 to try to get it out next Monday.

25 Q. [165] And how many practitioners will be

1           advised, do you know?

2    A.    I believe the list is the same list, it is the  
3           same list as we used for the December letter,  
4           and I think there will be thirteen (13) or  
5           fourteen (14), or no more than fifteen (15)  
6           letters going out, I'd have to double check.

7    Q.    [166] And regarding this list, what is this  
8           list, I mean, this is the list from all  
9           practitioners who applied for 714-X in the last  
10          year, the last two years?

11   A.    Yes, yes, we're basically talking about  
12          physicians that currently have patients within  
13          their practice on 714-X. So it's a targeted  
14          communication to those physicians who have  
15          patients on the product and who could very well  
16          have questions about continued access at this  
17          time. There's no need to broadcast that further,  
18          we're talking about a targeted communication to  
19          those who have to know.

20   Q.    [167] Paragraph 169.

21   A.    169?

22   Q.    [168] Yes, page 44. The response that refers to  
23          January twenty-third (23rd), two thousand four  
24          (2004) is the general response I understand?

25   A.    Yes, I should clarify. I think, when we spoke

1 last week, or when I spoke last week, I  
2 described that in the original affidavit, we  
3 were using the January twenty-third (23rd),  
4 because it took three or four days for us to fax  
5 the letters to all the physicians, so at that  
6 time, we gave the outside date that a physician  
7 would have received. The actual letter was dated  
8 January the nineteenth (19th), but we wanted to  
9 make sure that we provided the outside date at  
10 which a physician may have received that letter.

11 There were a number of reasons why, the fax  
12 machines weren't working or people weren't  
13 answering, et cetera, and there were a couple  
14 of, I believe one or two physicians who did not  
15 have faxes and we mailed them out. So that was  
16 the last date at which we attempted to try to  
17 distribute the letter to physicians.

18 Q. [169] Paragraph 173, please. I understand that  
19 this paragraph can be separated in two parts,  
20 the first part is your statement and the other  
21 one is the justification, am I right?

22 A. That's a good description of how I've set it up,  
23 yes.

24 Q. [170] Okay. Now, if we... does the paragraph  
25 make sense without the justification, just the

1 first part:

2 "There is no evidence to support  
3 that any deterioration of the  
4 physical state of patients could  
5 be linked to being denied access  
6 to 714-X [...]"

7 To your perspective, does this only paragraph  
8 make sense by itself?

9 A. I think I stand behind the paragraph as a single  
10 sentence. I'm describing that, again to our  
11 knowledge, the effort that we undertook to try  
12 to gather as much information as we could, and  
13 the ultimate conclusion that there's not a lot  
14 of information out there to support the use,  
15 safety and efficacy, so it would be very  
16 difficult for a physician to provide us, and in  
17 fact, the physicians have not provided us with  
18 any credible evidence that would support, to  
19 support that scenario; and that the reason why  
20 that is in an evidence based decision making  
21 environment is that if there isn't any  
22 information available to the physician on the  
23 use, safety and efficacy of that drug, that good  
24 data, then no one is in a position to say that  
25 something cured or may have ameliorated the

1 symptoms of the disease, just as I described.

2 Q. [171] So if I understand your answer, you didn't  
3 inquire at all with the physicians requesting  
4 the SAP, the 714 under the SAP, to verify if any  
5 deterioration of their patients' state would be  
6 linked to the denied access of 714?

7 A. Basically, in Paragraph 173, I'm referring to  
8 evidence, and I'm referring to the basic  
9 information and obligation of the physician to  
10 provide us with information respecting the use,  
11 safety and efficacy that would support the  
12 emergency use of the drug to treat, and the  
13 answer to your specific question is that the  
14 physician had opportunity to provide us with  
15 information about individual patients, as all  
16 physicians do, making application to us in the  
17 so-called page 2 of the application form, and  
18 there are occasions - we talked about this last  
19 week - when we go back looking for information,  
20 but ultimately, the obligation of the physician  
21 is to provide us with information data  
22 respecting the use, safety and efficacy, and I  
23 spoke on many times about the fact that we, our  
24 standard, if you will, is that, that evidence be  
25 credible evidence, that isn't gained in the

1 normal way in which a physician seek that  
2 information such as the availability of  
3 information in the medical literature, clinical  
4 studies that are otherwise reported, product  
5 monographs that are available from other  
6 jurisdictions, investigators brochures which  
7 summarize the extent of the knowledge of a drug  
8 that's used in clinical trial.

9 So Paragraph 173 is referring to, in a  
10 broad sense, the evidence that's required, the  
11 evidence that the physician has an obligation to  
12 report to us respecting the use, safety and  
13 efficacy of the drug they're requesting.

14 And because we had drawn a conclusion, I  
15 think, after a considerable review, that if  
16 there is no evidence to support the use, safety  
17 and efficacy of it, then it would be very  
18 difficult for a physician using this, because  
19 there's absence of that information, they would  
20 not be able to draw an evidence based conclusion  
21 of that.

22 Q. [172] 174, please, you state:

23 "If the application for judicial  
24 review is allowed and Health  
25 Canada is forced to provide

1 continued access to the product  
2 for any patient [...]"

3 Do you mean for any patient under the SAP or any  
4 patient at large?

5 A. I'm referring specifically to the judicial  
6 review wherein SAP, the decision making  
7 respecting SAP is being called into question.

8 Q. [173] Okay.

9 A. So I am referring here to access to 714-X for  
10 patients through SAP, yes.

11 Q. [174] And then you carry on, you say:

12 "[...] there is risk that such  
13 access could be interpreted as an  
14 endorsement of the use, safety  
15 and efficacy of the drug."

16 Can you give me an example of risk that you  
17 state here?

18 A. Yes, that's a good question.

19 Q. [175] Yes, it is.

20 A. I think that this is part of the... one of the  
21 problems that we identified, and if you look  
22 at... if you look at, for instance, Exhibit O of  
23 my original affidavit, the document that we  
24 spoke about earlier that described the OCCAM  
25 best-case series review, the very last paragraph

1           talked about, the very last, the second last  
2           sentence, it says...

3    Q.    [176] Just a moment, let me take it out.

4    A.    Oh, I'm sorry.

5    Q.    [177] O is the OCCAM document, right?

6    A.    Yes.

7    Q.    [178] Okay, so where were you?

8    A.    I'm talking about the second last sentence on  
9           that first page.

10   Q.    [179] Okay, "Although the CBS, the BCS"?

11   A.    I'm sorry, no, the last paragraph.

12   Q.    [180] Yes.

13   A.    The second last sentence of the last paragraph.

14   Q.    [181] Uh-huh.

15   A.    It says:

16                                    "It is legally available in  
17                                    Canada[...]?"

18   Q.    [182]

19                                    "[...] on compassionate ground"?

20   A.    Right. That's of course their words. One of the  
21           problem that we had, and it...

22   Q.    [183] Why do you say it's their words?

23   A.    It's their document.

24   Q.    [184] Yes, where is: "[...] about compassionate  
25           grounds."?

1 A. I'm saying there, the sentence is their  
2 sentence.

3 Q. [185] Yes, okay.

4 A. And what I'm trying to describe, in answer to  
5 your question, is that one of the things that we  
6 identified was that its availability through the  
7 special access program, for as long as it was  
8 available, did unwittingly end, lend an error of  
9 credibility to the drug.

10 When a major regulator provides access to a  
11 product, then in the same way, I described that  
12 we look at other decisions from other regulatory  
13 agencies as significant, they, in their  
14 description, they talk about this being legally  
15 available in Canada. It's true at one level, but  
16 it's also not true at another level.

17 And so, the risk that we would take is  
18 that, I'm describing in this paragraph, is the  
19 risk that its continued availability through the  
20 program would lend the regulators credibility to  
21 it, which is not the case. We take great pains  
22 in the information that we distribute about SAP  
23 to say that notwithstanding the fact that this  
24 product is not approved, and notwithstanding the  
25 fact that the information available about the

1 drug may not be voluminous, we're willing to  
2 allow access to it on an emergency basis. This  
3 is the standard lines that we publish on the Web  
4 site, in the CPS and other areas which describe  
5 that the purpose of SAP, in meeting emergency  
6 needs, is just that, and that it's not an  
7 endorsement of the use of it.

8 Others have, through the years, taken the  
9 fact that the product was available through SAP  
10 as an endorsement to some degree; it's their own  
11 decision, and despite the efforts that we have  
12 taken to say that we're not endorsing this  
13 product one way or the other, because an  
14 endorsement of the product would only happen in  
15 the context of a clinical trial application and  
16 a positive new drug submission review. So...

17 Q. [186] Yes?

18 A. So basically, when I speak about the risk here,  
19 we're basically talking about trying to make it  
20 very clear to all concerned that continued  
21 access to it, in the absence of evidence, would  
22 be inappropriate, and that, that would confuse  
23 matters for all concerned.

24 The issue here ultimately is the issue of  
25 whether or not there's evidence to support the

1 use of this drug, and our conclusion, and others  
2 have concluded in their own way that there's  
3 nothing to support the use of this at this time,  
4 and that in order to verify theories and verify  
5 claims, establish whether or not 714-X is safe  
6 and efficacious and of high quality for use in  
7 humans, it ought to go through the kinds of  
8 steps that all other drugs go through: through a  
9 credible process of drug development.

10 So the risk here that I'm speaking about is  
11 the risk that its continued availability through  
12 SAP would misrepresent the facts, and we would  
13 want to make sure that, as a regulator, that  
14 people understood exactly where we stand, and  
15 that's the reason why we issued the letter we  
16 did in January, to make it very clear what the  
17 level of evidence was from our perspective, and  
18 that this was not out of step with other  
19 conclusions that had been drawn and that have  
20 been available in the public domain for a number  
21 of years.

22 The most obvious other one that we  
23 described is the OCCAM review and the  
24 information that was available to us in  
25 September, that was ultimately provided, that

1           was ultimately posted on their Web site in the  
2           summer of two thousand and four (2004).

3       Q.    [187] Wasn't that risk present at the same  
4           level, with the same consideration in nineteen  
5           ninety-five (1995), for instance, six years  
6           after the SAP authorized the usage of 714?

7       A.    Yes, and I described earlier that Health Canada,  
8           as a regulator, within the context of evolving  
9           regulatory standards throughout the world, has,  
10          does a better job now than it has ever done, and  
11          this is the result of general, the evolution of  
12          drug regulation experiences that have happened  
13          throughout the world, and that the system that  
14          we have now is more comprehensive than it was in  
15          the late eighties ('80s), is more comprehensive  
16          than it is... than it was in the middle of the  
17          nineties ('90s), and I don't think that's a  
18          surprise or a secret.

19       Q.    [188] So I understand from your answer that the  
20           risks that you're stating here in 174 are not  
21           the risks for the patients, they are risks for  
22           regulators?

23       A.    No, I think I mentioned, I've used the phrase  
24           all concerned, and I think there are...

25       Q.    [189] Are the patients risky in that context?

1 A. Yes, if there was a misinterpretation as to the  
2 availability of information or the endorsement  
3 of a product, that could translate into patient  
4 risk, a physician could look at that information  
5 and say: oh, Health Canada provides access, then  
6 they say, it must be okay. Physicians rely on  
7 the regulators for informed decisions, as do  
8 other regulators.

9 So I used the phrase all concerned, I think  
10 that there are a number of important  
11 stakeholders, patients are one, physicians are  
12 others, other health care providers,  
13 researchers, regulators, there are a number of  
14 stakeholders that we would want to make it clear  
15 that exactly the status of the product, exactly  
16 the information that we had available to us, and  
17 our considered opinion of the credibility and  
18 extent of that information.

19 Q. [190] Mr. Mackay, isn't it the case for all  
20 products on SAP anyway?

21 A. Yes, it is, and we make that statement in our  
22 publicly available information that none of the  
23 products that we provide access to, we endorse  
24 the safety of.

25 However, the level of evidence that is

1 provided, ultimately, this comes back to the  
2 information that physicians provide to us,  
3 ultimately, the information that physicians  
4 provide to us, as part of their regulatory  
5 obligation, is, you know, can vary, and part of  
6 the effort of the audit that we spoke about last  
7 week was to try to determine, in a credible way,  
8 in an objective way, to make sure that the  
9 information that was coming in to us, from  
10 physicians, was information that was credible  
11 information, and by and large, with the possible  
12 couple of exceptions, I describe in my affidavit  
13 714-X and DHEA, the information that physicians  
14 have available to them either through the  
15 medical literature, through conferences and  
16 other scientific symposia, would constitute  
17 credible information and, in some cases,  
18 constitute voluminous information to support the  
19 use, safety and efficacy of a drug, which, as I  
20 continue to say, is their obligation under the  
21 regulations to support an SAP request, to  
22 support the emergency use of a product.

23 Q. [191] 177, please, you state:

24 "Health Canada is not aware of  
25 any plans on the part of the

1 manufacturer to pursue formal  
2 drug development and to formally  
3 generate data to support or  
4 refuse the claims made about the  
5 drug's action, safety and  
6 efficacy."

7 If the manufacturer had indeed plans to pursue  
8 such formal drug development, would it have  
9 affected your decision of January, two thousand  
10 four (2004)?

11 Me CARMELA MAIORINO:

12 I'll have to object, it's hypothetical.

13 Me JEAN-SYLVAIN PELLETIER:

14 Okay, I'll phrase it otherwise.

15 Q. [192] How important is the development from the  
16 manufacturer to pursue formal drug development  
17 in the fact that the manufacturer did not pursue  
18 formal drug development in your decision of  
19 January, two thousand four (2004)?

20 Me CARMELA MAIORINO:

21 I think Mr. Mackay has repeatedly addressed that  
22 issue throughout his whole deposition in the  
23 past two days as the importance of formal drug  
24 development.

25

1 Me JEAN-SYLVAIN PELLETIER:

2 I talk about specifically the manufacturer, Mr.  
3 Naessens or CERBE who is the manufacturer.

4 Q. [193] If CERBE did indeed start the process to  
5 pursue formal drug development, how would it  
6 affect your decision of January, two thousand  
7 four (2004)?

8 Me CARMELA MAIORINO:

9 You're still back at a hypothetical question. I  
10 mean, you can ask him whether he's aware as to  
11 if... as to whether there are any formal drug  
12 development...

13 Me JEAN-SYLVAIN PELLETIER:

14 I'll skip it, I'll skip it, that's fine.

15 Q. [194] 178, please. The second line:

16 "The SAP does have lower  
17 thresholds for data and  
18 evidence."

19 Can you give me detail on that, the lower  
20 thresholds, how much lower?

21 A. I described earlier that any time you're dealing  
22 with evidence within drug development, you're  
23 talking about a range of evidence from product  
24 that begins life in a test tube or through a  
25 serendipitous discovery through to a drug being

1 on the market for thirty (30) years.

2 I'm describing here that, clearly, that a  
3 product that's going through SAP does not have,  
4 probably, and would not be expected to have the  
5 level of evidence required to support a  
6 marketing application.

7 I describe in my affidavit, and I can  
8 describe for you now, that in order for a drug  
9 to gain access to the market, to be available at  
10 corner drugstores, you know, literally, a truck  
11 backs up to the back of our building and empties  
12 a truckload of information, which then a team of  
13 scientists reviews for months and, in some  
14 cases, years, which is the, you know, the full-  
15 fledged process of drug review.

16 Clearly, given that it's an emergency  
17 application, an emergency provision within the  
18 SAP, if a truck, if a physician backed the truck  
19 up to our office and unloaded the information  
20 supporting the use, safety and efficacy, we  
21 would not be able to make a timely decision, and  
22 so, I'm describing here that out of necessity,  
23 we impose a lower threshold compared with that,  
24 which is required for either a clinical trial  
25 application or a new drug submission.

1 Q. [195] Who decides on the level of lowness, you  
2 talk about lower threshold?

3 A. Yes.

4 Q. [196] Who decides on that notion of lower, you  
5 are?

6 A. That's part of our discretion, I mean, the  
7 evidence, the information that's filed by a  
8 practitioner ultimately comes to us and we make  
9 that judgement within the discretion that we are  
10 given within C.08.010 and C.08.011... excuse  
11 me...

12 Q. [197] Anyway.

13 A. ... regulations.

14 Q. [198] Okay.

15 A. And I describe in the second part of that  
16 paragraph that we exercise our discretion with  
17 respect to the amount of evidence required, but  
18 zero is not acceptable. And so, there had been  
19 times, and we are challenged, not infrequently,  
20 to provide access to something, for instance,  
21 that is in phase 1 of clinical research, in  
22 other words, after the product has been in  
23 humans, say ten (10) or twenty (20) humans, in a  
24 formal study, those are difficult decisions for  
25 us normally.

1           In general, we provide access to products -  
2           and I spoke to this, I think, at length in the  
3           affidavit - that are somewhere in drug  
4           development, either in phase 1, phase 2, phase 3  
5           trials somewhere in the world, where we can gain  
6           access to credible information through the  
7           public's literature or other avenues.

8           We have within, I'm describing here the  
9           discretion, that you don't need to back up a  
10          truck, but you need to send us something, and  
11          what you send us has to be credible information  
12          to support the emergency use of that product  
13          within the context of the physician's request.

14    Q.    [199] You're talking here about the... in the  
15          context of the SAP still?

16    A.    Of course, yes. For instance, you know, a good  
17          example of this would be, just to provide some  
18          clarity for you, you know, when SARS hit Canada  
19          a couple of years ago now, there was a great  
20          flurry of activity as to how we were going to  
21          manage this disease that we didn't... we didn't  
22          even know whether it was a viral disease, a  
23          bacterial disease, and physicians turned to SAP  
24          to gain access to products that were not  
25          approved, as a way of, as an option, and so, but



1                                   accordance with the highest  
2                                   possible standards for patient  
3                                   protection and clinical  
4                                   research."

5    A.    Uh-huh.

6    Q.    [201] This clearly refers to market, open market  
7           product, right?

8    A.    No.

9    Q.    [202] It doesn't refer to SAP, does it?

10   A.    I'm referring to:

11                               "[...] that evidence being  
12                               gathered and reviewed in  
13                               accordance with the highest  
14                               possible standards for patient  
15                               protection and clinical  
16                               research."

17           I'm talking about evidence that would be  
18           gathered prior to a product being approved for  
19           marketing. So we're talking about clinical  
20           research happening within the context of drug  
21           development, which is the first part of the  
22           paragraph.

23   Q.    [203] Okay. But that paragraph doesn't apply to  
24           SAP products, SAP drugs?

25   A.    Well, yes, it does. Basically, we're talking

1           about that the information that physicians would  
2           submit to us would normally come from, and by  
3           and large, always comes from information...  
4           comes from evidence that, and data that is  
5           gathered as part of formal clinical research.

6    Q.    [204] So this paragraph would indeed apply to  
7           SAP?

8    A.    What I'm saying is that the evidence that's  
9           gathered as part of clinical research, which has  
10          high standards for scientific credibility and  
11          patient protection and ethical standards, et  
12          cetera, is normally the evidence that physicians  
13          submit to us to meet their obligation in  
14          providing us information respecting the use,  
15          safety and efficacy of a product.

16   Q.    [205] For SAP, right?

17   A.    Yes.

18   Q.    [206] Okay. Paragraph 193, please.

19   A.    193.

20   Q.    [207] Why do you use the word regrettably?

21   A.    I use the word regrettably to describe the  
22          situation that I think we all, all concerned:  
23          physicians, patients, regulators and other  
24          agencies we've described, would want  
25          information.

1                   As regulators and as agencies, you know,  
2                   our aim is not to suppress information; our aim  
3                   is to say, if someone wants...

4

5                   (OFF THE RECORD DISCUSSION)

6

7       A.       The aim here is that I think we all would want  
8                   to be in a different position that we are now.

9       Q.       [208] Why?

10      A.       Because I think that we would all be well-  
11                   served, physicians and patients, if we had  
12                   information to support the use of this product.  
13                   The regulator would be in a better position to  
14                   apply the high standards of drug development  
15                   that are universally applied around the world,  
16                   and if we had this information, we'd be in a  
17                   position to make a better evidence based  
18                   decision about whether or not this product has  
19                   any merit, either at the individual level or at  
20                   the population based level.

21                   So, I'm using the word honestly in that I  
22                   think we'd all be in a better position.  
23                   Certainly, the review of the affidavits that I  
24                   had, and I speak to this particular paragraph,  
25                   is that there would appear to be that some sense

1 of being singled out, and what we're saying, as  
2 a regulator who must undertake its activities in  
3 an objective way, is that we didn't want to be  
4 in this situation that we were in, we didn't  
5 want to necessarily make the decisions that we  
6 did, but we were in a position where we had to.

7 As a regulator, we have a certain... we  
8 have, we are in a position of leadership, and  
9 that leadership has to be credible and, at  
10 times, making difficult decisions on difficult  
11 matters, but where we have the authority as we  
12 do, we undertake that leadership as carefully as  
13 we can. What I'm describing by regrettable is  
14 that I think we all would be better served if we  
15 were in a different position than we are now.

16 Q. [209] To your knowledge, did the product 714-X  
17 under SAP save lives of Canadians?

18 Me CARMELA MAIORINO:

19 I'll have to object to that. How is that...

20 Me JEAN-SYLVAIN PELLETIER:

21 I think it's pretty pertinent.

22 Me CARMELA MAIORINO:

23 If it saved lives?

24 Me JEAN-SYLVAIN PELLETIER:

25 Yes, if it saved lives, to his knowledge.

1 Q. [210] Do you know if the product ever saved  
2 lives of Canadians?  
3 Me CARMELA MAIORINO:  
4 You're asking Mr. Mackay...  
5 Me JEAN-SYLVAIN PELLETIER:  
6 Q. [211] Under the SAP.  
7 Me CARMELA MAIORINO:  
8 ... to pronounce himself as to whether...  
9 Me JEAN-SYLVAIN PELLETIER:  
10 Yes, if he knows, if he knows, yes.  
11 Me CARMELA MAIORINO:  
12 I think, logically...  
13 Me JEAN-SYLVAIN PELLETIER:  
14 As the regulator.  
15 Me CARMELA MAIORINO:  
16 ... you can infer that...  
17 Me JEAN-SYLVAIN PELLETIER:  
18 Sorry?  
19 Me CARMELA MAIORINO:  
20 I think, logically, that the whole tenure of his  
21 affidavit is in the sense that there is no  
22 evidence as to the efficacy of that drug.  
23 Me JEAN-SYLVAIN PELLETIER:  
24 I'm not talking about efficacy, I'm talking  
25 about saving lives.

1 Me CARMELA MAIORINO:

2 Well, if it saved lives, it would have been...

3 Me JEAN-SYLVAIN PELLETIER:

4 This is not your answer, I'm sorry, he has to  
5 answer, not you, so...

6 A. When we talk about knowledge about saving lives,  
7 as a regulator, I have no knowledge that 714-X  
8 saved lives. There are attestations, we spoke  
9 about those last week, but the knowledge that we  
10 normally require to answer that question, we  
11 talked about it earlier, about the gradation of  
12 knowledge, there are claims, there are  
13 suppositions, there are wishes and there are  
14 wants, but the evidence and knowledge that is  
15 required to pronounce something as being a cure  
16 or to save a life, is that truckload I spoke  
17 about.

18 Q. [212] Looking at your curriculum vitae,  
19 Mr. Mackay, that we discussed last week, that is  
20 Annex A.

21 A. Yes.

22 Q. [213] Tell me, is there a link between  
23 compassion and the SAP?

24 Me CARMELA MAIORINO:

25 The witness already answered that question in

1 detail.

2 Me JEAN-SYLVAIN PELLETIER:

3 Not quite.

4 Me CARMELA MAIORINO:

5 We were at length with that.

6 Me JEAN-SYLVAIN PELLETIER:

7 No, no, not specifically that question.

8 Me CARMELA MAIORINO:

9 The question being?

10 Me JEAN-SYLVAIN PELLETIER:

11 Q. [214] Being, is there a link between compassion  
12 and SAP?

13 Me CARMELA MAIORINO:

14 He precisely responded to the link between the  
15 concept of compassion and SAP last week.

16 Me JEAN-SYLVAIN PELLETIER:

17 Okay. So I'll refer to that answer then.

18 Q. [215] Mr. Mackay, do you recall in April,  
19 nineteen ninety-nine (1999) writing an article  
20 on Special Access Program, Partners in  
21 Compassion, do you recall that?

22 A. In April of nineteen ninety-nine (1999)?

23 Q. [216] Yes, before the Drug Information  
24 Association.

25 A. Yes, it was not an article.

1 Q. [217] What was it?

2 A. It was an exhibit as part of a larger, a larger  
3 conference sponsored by the Drug Information  
4 Association to talk about and to explain the  
5 various regulatory functions that Health Canada  
6 undertook, undertakes.

7 Me CARMELA MAIORINO:

8 Is this document, Maître Pelletier, referring  
9 to... referred to in Mr. Mackay's CV?

10 Me JEAN-SYLVAIN PELLETIER:

11 Yes, exactly.

12 Me CARMELA MAIORINO:

13 Where?

14 Me JEAN-SYLVAIN PELLETIER:

15 Actually, his CV is not paged, but in this  
16 impressive CV, it's part of the chapter:  
17 Publications, Reports and Presentations.

18 Me CARMELA MAIORINO:

19 Okay.

20 Me JEAN-SYLVAIN PELLETIER:

21 Q. [218] Do you have that reference before you?

22 A. I do, yes, I do, yes.

23 Q. [219] Okay. So can you briefly describe this  
24 exhibit?

25 A. I describe...

1 Q. [220] About SAP and compassion.

2 A. Right. This was not, this was a presentation,  
3 basically, as you may know it, at conferences  
4 where you have fifty (50) booths or so, when  
5 people attend these they will walk by and  
6 interact with people manning or talking to  
7 particular issues, and so, this was a... I  
8 recall specifically that we had a PowerPoint  
9 presentation that was on a screen that was  
10 revolving constantly, and so people who attended  
11 the conference could walk by and ask questions  
12 about, particularly about SAP, and we would  
13 engage in discussions on any questions they had  
14 or any issues they had about the functions that  
15 we perform.

16 Q. [221] What about this Special Access Program,  
17 Partners in Compassion, that was the title of  
18 the booth?

19 A. Yes, it was, yes.

20 Q. [222] So there was a big board showing those  
21 words?

22 A. I don't know how big it was, but it was  
23 certainly part of the presentation.

24 Q. [223] Okay. And how were you relating SAP to  
25 compassion then?

1 A. When I spoke last week about the... when you  
2 asked specific questions about the word  
3 compassion, I did say that it was a word that  
4 was used in the past, and nineteen ninety-nine  
5 (1999) was the past. It's not something that we  
6 use now because of the confusion we felt it  
7 creates, in that, I think I described last week  
8 that compassion can mean different things to  
9 different people, and it was not something  
10 that... It was, I think back in the nineties  
11 ('90s), it was an effort to sort of, in a  
12 general way, describe some of the activities  
13 that SAP undertook, and so, it was used in the  
14 ways in which organizations try to explain  
15 themselves for public consumption, and  
16 sometimes, those are good and sometimes, they're  
17 bad, and sometimes, they last a long while, and  
18 sometimes, you run into problems with people  
19 understanding exactly what you mean.

20 And so, we acknowledged that the word  
21 compassion can mean different things to  
22 different people; it does not specifically  
23 relate to our mandated authority in the Food and  
24 Drugs Act and Regulations, and we thought  
25 latterly best to eliminate it from our public

1 documents, if you will.

2 And it wasn't something that we used and  
3 walked around with and talked about on a daily  
4 basis. We were simply trying to describe that,  
5 in the effort of getting drugs, authorizing  
6 requests for drugs for emergency purposes, that  
7 some would understand that to be the various  
8 partners, that is physicians and manufacturers  
9 and the Government, responding to individual  
10 needs.

11 There's no question that we respond to  
12 individual needs, because the requests that come  
13 to us are individuals, and so, it was a way of  
14 describing that, but it is not in any of the  
15 public documents we use now, and its use in  
16 nineteen ninety-nine (1999) reflected that sort  
17 of approach at the time, but has since been  
18 eliminated from our public documents.

19 Q. [224] Mr. Mackay, you, I believe you read,  
20 you've gone through all the four, three other  
21 files actually, there are four files before us  
22 that we're discussing, you've been through those  
23 affidavits and evidences supportive of the  
24 affidavits, did you?

25 A. For the... I think there was... yes.

1 Q. [225] The other people, the other applicants,  
2 you've gone through those documents?

3 A. Yes.

4 Q. [226] After reading those files, do you believe  
5 that the 714 can help them to survive with their  
6 illness?

7 Me CARMELA MAIORINO:

8 I'll have to object, Mr. Mackay is not a  
9 physician.

10

11 (OBJECTION N° 10)

12

13 Me JEAN-SYLVAIN PELLETIER:

14 Q. [227] I'm not asking an opinion here, I'm just  
15 asking after reading these affidavits and the  
16 evidences submitted by those people: Laurent  
17 Légère, Dany Laforest and Daniel Grandmont, with  
18 obviously the main file of Léopold Delisle, my  
19 question was, after reading those documentations  
20 and affidavits, do you believe that the 714-X  
21 could be helpful to... for them to fight their  
22 illness, their cancer?

23 Me CARMELA MAIORINO:

24 I will maintain my objection, your question  
25 clearly begs the opinion of an expert that has

1 expertise in that field.

2 Me JEAN-SYLVAIN PELLETIER:

3 So he will not testify as an expert obviously.

4 Me CARMELA MAIORINO:

5 Your question is, does he believe, that calls

6 for an expertise and Mr. Mackay is not

7 testifying...

8 Me JEAN-SYLVAIN PELLETIER:

9 It's an opinion.

10 Me CARMELA MAIORINO:

11 An opinion calls, can only be rendered by an

12 expert, and Mr. Mackay is testifying today in

13 his capacity as manager of the SAP.

14

15 (OBJECTION N° 11)

16

17 Me JEAN-SYLVAIN PELLETIER:

18 Q. [228] Well, Mr. Mackay, as the manager of SAP,

19 do you know if SAP indeed saved lives of

20 Canadians, if the 714-X available through SAP

21 saved lives of Canadians, do you know that?

22 A. No, I have no knowledge of that. I am aware of

23 attestations that are part of the affidavits

24 we've been speaking about, attestations and

25 knowledge, and I keep coming back to what I

1 understand as knowledge in my capacity, and the  
2 knowledge that is required to be submitted,  
3 evidence that's required to be submitted to us,  
4 you know, pronouncing that a drug cures or helps  
5 someone, helps mitigate the effects of a disease  
6 is a large pronouncement, and again, the  
7 evidence that would support that, I come back to  
8 the truckload, you know, if we're talking about  
9 making a large pronouncement about a drug being  
10 efficacious, being safe, being of high quality,  
11 that can only be determined after a  
12 comprehensive review of a truckload of  
13 information.

14 I should say, I'm not trying to be funny,  
15 just for the record, I'm not trying to be funny  
16 with the truckload, I'm just trying to describe  
17 the volume of information in reality that comes  
18 to us that allows us to make those decisions.  
19 And I should say that even with a truckload of  
20 information, not all drugs get approved.

21 So even after extensive research and  
22 extensive clinical trials, there are drugs that  
23 are turned down at the last moment, after phase  
24 1, 2, 3, research, thousands of patients exposed  
25 to it, and so the evidence that's required is

1 very large.

2 Not to mention that there are circumstances  
3 that are contained in these affidavits that I  
4 was familiar with, wherein patients have been  
5 receiving a number of different therapies, and  
6 in those circumstances, it's extraordinarily  
7 difficult without applying an appropriate  
8 methodology to determine the extent to which any  
9 of the interventions may have contributed to  
10 someone getting better or managing the disease  
11 better, and that's a big challenge for everyone,  
12 it's a big challenge for physicians to be able  
13 to tease out exactly whether if someone was on  
14 chemotherapy and on 714-X at the same time, it's  
15 virtually impossible to do, it is impossible to  
16 do it at the individual level.

17 The only way in which you can determine,  
18 that is through a credible scientific process  
19 which brings and allows you the opportunity to  
20 control for certain factors within scientific  
21 methodology, and that's the challenge of  
22 clinical trials, to be able to, when you're  
23 applying, when you're applying standards such as  
24 a drug versus a placebo, that's the whole effort  
25 in trying to determine whether or not you have,

1           if you have fifty (50) people who are given  
2           placebo, fifty (50) people who are given the  
3           drug, and you determine how well they responded  
4           to the drug, how long they were able to stay  
5           alive; that's the only way you can pronounce and  
6           make a decision about whether or not a drug is  
7           better than placebo or better than nothing. If  
8           someone is receiving two things at the same  
9           time, it's incredibly difficult, if not  
10          impossible to determine what effect one had  
11          against a given disease process.

12    Q.    [229] This is all for the moment.

13                    I will reserve other questions eventually,  
14                    depending on the position of the judge and  
15                    depending on also the reception of the  
16                    undertakings.

17                    So, no more questions, actually based on  
18                    the undertakings. So maybe we'll have a chance  
19                    to meet again at another time.

20                    THE WITNESS:

21                    Sure.

22

23                    AND FURTHER DEPONENT SAITH NOT

24

25

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1                   I, the undersigned, NICOLE L'ABBÉ, Official  
2                   Court Reporter, do hereby certify under my oath  
3                   of office that the foregoing pages are and  
4                   contain the exact transcription of the testimony  
5                   and pleadings herein, taken by means of  
6                   stenomask and according to the law.

7

8                   AND I HAVE SIGNED:

9

10

11

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