Dear [Redacted]

Re: Your request for access to information under Part II of the Access to Information and Protection of Privacy Act (the Act) [Our File #: HCS 002 2013]

On January 16, 2013 the Department of Health and Community Services (Department) received your request for access to the following records/information:

"Correspondence, in any and all formats, including paper & electronic, between the Department of Health & Community Services and Avalon Laser Health RE: Thermography. Date Range of request is Nov. 1, 2012 to the present."

On January 28, 2013 the Department sent you a notification that the records you requested may have contained information that, if disclosed, might affect the business interests of Avalon Laser Health. The Department advised you at that time that a decision regarding your request would be made within 30 days of January 28, 2013.

The Department received a response from Avalon Laser Health regarding the foregoing on February 15, 2013. On February 22, 2013, the Department sent you a notification that the initial 30-day time period for responding to your request had been extended for an additional 30 days in accordance with sections 16(1)(c) and (d) of the Act. We advised at that time that we expected to respond to your request by March 16, 2013. On March 22, 2013 the Department sent you a notification that we had considered representations made by Avalon Laser Health regarding the disclosure of the records you requested. We advised at that time that we were required under section 29(3) of the Act to notify Avalon Laser Health of the Department’s decision regarding disclosure of the records. At that time, we also notified you that Avalon Laser Health had 20 days from the date of the Department’s notification to ask the Office of the Information and Privacy Commissioner for a review of the Department’s decision under section 43(2) of the Act. Avalon Laser Health was notified on March 22, 2013. We advised you that, during that period, the Department could not release the requested records to you.
The Department has reviewed your request in the context of the Act. The Department is able to provide you with partial access to the information that you have requested. Portions of the attached documents have been severed as they are non-responsive to your request or in accordance with:

1. Section 20(1)(a) of the Act whereby the head of a public body may refuse to disclose to an applicant information that would reveal advice, proposals, recommendations, analyses or policy options developed by or for a public body or minister;

2. Section 27(1)(b) of the Act whereby the head of a public body shall refuse to disclose to an applicant information that would reveal commercial, financial, labour relations, scientific or technical information of a third party, that is supplied, implicitly or explicitly, in confidence and is treated consistently as confidential information by the third part;

3. Section 27(1)(c)(i) of the Act whereby the head of a public body shall refuse to disclose to an applicant information that would reveal commercial, financial, labour relations, scientific or technical information the disclosure of which could reasonably be expected to harm the competitive position of a third party or interfere with the negotiating position of the third party;

4. Section 27(1)(c)(iii) of the Act whereby the head of a public body shall refuse to disclose to an applicant information that would reveal commercial, financial, labour relations, scientific or technical information the disclosure of which could reasonably be expected to result in significant financial loss or gain to any person or organization; and,

5. Section 30(1) of the Act whereby the head of a public body shall refuse to disclose personal information to an applicant where the disclosure would be an unreasonable invasion of a third party's personal privacy.

Please note that pages 4-7 have been fully redacted under sections 20(1)(a), 27(1)(b), 27(1)(c)(i) and 27(1)(c)(iii) of the Act. As well, it is our understanding that you are already in possession of the letter addressed to [REDACTED] dated December 12th, 2012, found at page 33 of the attached documents; as such, no redactions have been applied to that document.

Section 43 of the Act provides that you may ask the Information and Privacy Commissioner to review this refusal of access or you may appeal the refusal to the Supreme Court Trial Division. A request to the Commissioner shall be made in writing within 60 days of the date of this letter or within a longer period that may be allowed by the Information and Privacy Commissioner.

The address and contact information of the Information and Privacy Commissioner is as follows:

Office of the Information and Privacy Commissioner
2nd Floor, 34 Pippy Place
P. O. Box 13004, Stn. A
St. John’s, NL A1B 3V8

Telephone: (709) 729-6309
Facsimile: (709) 729-6500
Email: oipc@gov.nl.ca
In the event that you choose to appeal to the Trial Division, you must do so within 30 days of the date of this letter. Section 60 of the Act sets out the process to be followed when filing such an appeal.

If you have any further questions, please feel free to contact Ms. Rachelle Cutler, ATIPP Coordinator at 729-7776 or via e-mail at RachelleCutler@gov.nl.ca.

Sincerely,

Bruce Cooper
Deputy Minister

/rc
Encl.
Via Courier

Ms. Clare Barry
Avalon Laser Health
#306-12 Gleneyre St.
Wedgewood Medical Centre
St John’s, NL
A1A 2M7

Dear Ms. Barry:

It has been brought to my attention that your facility offers thermography, which is described on your website as a medical diagnostic screening test.

You should be aware that under the Diagnostic and Public Health Laboratories Regulations, a person is prohibited from establishing or operating a facility in Newfoundland and Labrador, for the purpose of providing diagnostic services, unless that person has the written permission of the Minister of Health and Community Services. The regulations are available online at http://assembly.nl.ca/Legislation/sr/regulations/rc960789.htm.

Given that you do not have written permission to operate you must immediately cease the provision of thermography services. I have directed my officials to commence an investigation of this situation immediately.

Your anticipated co-operation is appreciated. Please contact my Deputy Minister, Bruce Cooper, at 729-3125 immediately to arrange a meeting to discuss the services you are providing in your facility.

Sincerely,

SUSAN SULLIVAN
Minister
Dear Ms. Barry,

I am writing further to correspondence from the Honourable Minister Susan Sullivan and our phone discussion on Tuesday, November 27th, 2012. Thank-you for your prompt compliance with our request for the suspension of the further use of thermography in assessing breast health and your concurrence to meet on Monday, December 3rd to discuss this matter with Departmental officials.

As discussed, I have prepared the following questions which I would ask that you consider in advance of our meeting on Monday:

- Who uses the thermography machine at Avalon Laser Health?
- Does the user require special training/qualifications to use the machine?
- How many thermography machines do you have?
- Are there different types of thermography machines?
- Who certifies and maintains the machine?
- Who would do repairs on the machine?
- How does thermography work? What is the benefit of thermal imaging?
- What is the purpose of thermography? (i.e to diagnose illness?)
- Are there non-diagnostic purposes for this particular machine?
- Are there risks associated with the use of this machine?
- Are there clinical indicators as to who receives thermography?
- In what frequency do clients receive thermography? Do they receive it multiple times? For what purpose?
- Do clients sign a consent when they receive thermography?
- Who reads the image?
- Is that person licensed in Newfoundland and Labrador?
- How are findings communicated to the client?
- Who communicates with the client?
- Do you share findings with health care professionals?
• Do you make referrals, on behalf of clients, to health care professionals?

• Is there any further follow up with the client? What is the nature of the follow-up? When do you follow up with the client?

• Do you operate in accordance with the requirements of the *Personal Health Information Act*?

• Has Avalon Laser Health had any consultations with the College of Physicians and Surgeons and/or the Association of Registered Nurses of NL regarding the use of thermography?

• How many clients have received thermography at Avalon Laser Health as a breast screening or other diagnostic tool?

• Do you have any plans to contact those people?

• Does Avalon Laser Health have other diagnostic equipment that it uses? What? For what purpose?

I look forward to seeing you on Monday.

Sincerely Yours,

Bruce Cooper, Deputy Minister
Department of Health and Community Services
Your Questions

Who uses the thermography machine at Avalon Laser Health?

Does the user require special training/qualifications to use the machine?

How many thermography machines do you have?

Are there different types of thermography machines?

Who certifies and maintains the machine?  
Who would do repairs on the machine?

How does thermography work? What is the benefit of thermal imaging?
27(1)(b), 27(1)(c)(i), 27(1)(c)(iii)

What is the purpose of thermography? (i.e to diagnose illness?)

27(1)(b), 27(1)(c)(i), 27(1)(c)(iii)

Are there non-diagnostic purposes for this particular machine?

Are there risks associated with the use of this machine?

27(1)(b), 27(1)(c)(i), 27(1)(c)(iii)

Are there clinical indicators as to who receives thermography?

In what frequency do clients receive thermography? Do they receive it multiple times? For what purpose?

27(1)(b), 27(1)(c)(i), 27(1)(c)(iii)

Do clients sign consent when they receive thermography?

Who reads the image?

27(1)(b), 27(1)(c)(i), 27(1)(c)(iii)
Is that person licensed in Newfoundland and Labrador?

How are findings communicated to the client?

Who communicates with the client?

Do you share findings with health care professionals?

Do you make referrals, on behalf of clients, to health care professionals?

Is there any further follow up with the client? What is the nature of the follow-up? When do you follow up with the client?
Do you operate in accordance with the requirements of the Personal Health Information Act?

Has Avalon Laser Health had any consultations with the College of Physicians and Surgeons and/or the Association of Registered Nurses of NL regarding the use of thermography?

How many clients have received thermography at Avalon Laser Health as a breast screening or other diagnostic tool?

Do you have any plans to contact those people?

Does Avalon Laser Health have other diagnostic equipment that it uses? What? For what purpose?
27(1)(b), 27(1)(c)(i), 27(1)(c)(iii)
ATTACHMENT 1
Confidential Questionnaire

Breast

Name_________________________ Birth Date_________________________ Today’s Date_________________________
Address_________________________ City_________________________ State_________________________ Zip_________________________
Phone Number Home_________________________ Cellular_________________________ Work_________________________
E-Mail Address_________________________
Referring Physician_________________________

Is there a specific reason or concern for this exam?

Yes No

1. Have you recently had any of these breast symptoms?

   Pain/Tenderness
   Lumps
   Change in breast size
   Areas of skin thickening or dimpling
   Excretions of the nipple

   RT   LT
   ○     ○
   ○     ○
   ○     ○
   ○     ○
   ○     ○

2. Are any of the above symptoms cycle related?

   ○     ○

3. Are you still having your periods?
   If yes, date of last period_________________________

   ○     ○

4. Have you had a surgical hysterectomy?
   If yes, date_________________________
   Reason for hysterectomy?
   ○ Excess bleeding ○ Endometriosis ○ Fibroid cysts ○ Cancer ○ Other

   ○     ○

5. Has anyone in your family ever been treated for breast cancer?
   If yes, ○ Mother ○ Grandmother ○ Sister ○ Daughter

   ○     ○

6. Have you ever been diagnosed with breast cancer?
   If yes, date_________________________
   Cancer type ○ Local ○ Metastatic ○ Lymph node involvement
   ○ Inner ○ Outer ○ Nipple
   ○ Inner ○ Outer ○ Nipple
   Treatment ○ Surgery ○ Chemo ○ Radiation ○ None
   ○     ○

7. Have you ever been diagnosed with any other breast disease?
   If yes, ○ Cysts/fibrocystic ○ Mastitis/inflammatory breast disease

   ○     ○

8. Have you had any cosmetic breast surgery or implants?
   If yes, date_________________________
   Experience ○ Problems ○ No problems

   ○     ○

Revised 2/8/08
9. Have you ever had any biopsies or any other surgeries to your breasts?
   
   If yes, date______________________

   Left breast  ○ Inner  ○ Outer  ○ Nipple
   Right breast ○ Inner  ○ Outer  ○ Nipple
   Results      ○ Negative ○ Positive ○ Calcifications

10. Have you ever taken contraceptive pills for more than one year?
    If yes,  ○ Currently  ○ Less than 5 years  ○ More than 5 years

11. Have you had pharmaceutical hormone replacement therapy (HRT)?
    If yes,  ○ Currently  ○ Less than 5 years  ○ More than 5 years

12. Do you have an annual physical examination by a doctor?

13. Do you perform a monthly breast self exam?

14. Have you ever smoked?

15. Have you ever been diagnosed with diabetes?

16. Date of your last mammogram_______________ Were you re-called?__________

17. How many mammograms have you had in total?__________

18. Your age at your first mammogram?__________

19. Number of full term pregnancies?__________

20. Your age at birth of your first child?__________

21. Age when you started your period?__________

Do you have any special concerns or are there any details related to the information above?

Procedure: You will be imaged with a state of the art infrared imaging camera in comfortable and controlled surroundings. Your thermal imaging baseline reports will provide information about current and future conditions only and does not diagnose breast disease. Thermal imaging should be correlated with other medical investigative methods to better direct definitive testing for diagnosis and treatment. It does not replace any other breast examination.

Patient Disclosure: I understand that the report generated from my images is intended for use by a trained health care provider to assist in evaluation and treatment. I further understand that the report is not intended to be used by myself for self-evaluation or self-diagnosis. I understand that the report will not tell me whether, I have any illness, diseases, or other conditions, but will be an analysis of the images with respect only to the thermographic findings discussed in the report.

By signing below, I certify that I have read and understand the statement above and consent to the examination.

Patient Signature____________________________________ Today’s Date__________

Revised 2/8/08
ATTACHMENT 2

There are thousands of Thermography Clinics in at least 24 countries of the world, including

Australia
Canada,
Caribbean,
Cyprus,
Denmark,
El Salvador,
France,
Germany,
Greece,
India,
Japan,
the Netherlands,
New Zealand,
Oman,
Philippines
Romania,
South Africa,
Spain,
Sweden,
Trinidad & Tobago,
Turkey,
UK, and
the United States.
Potential copyright material

If you wish to obtain a copy please contact the ATIPP Office at (709) 729-7072 or atippoffice@gov.nl.ca.
Power, Colleen (HCS)

From: Lindahl, Lisa
Sent: Monday, December 17, 2012 10:28 AM
To: Power, Colleen (HCS)
Subject: TRIM: Fw: Fwd: Questions re: Thermography Practice
Attachments: non-responsive

Department of Health & Community Services
Executive Council
Government of Newfoundland and Labrador
P.O.Box 8700
St.John's, NL
Canada
A1B 4J6

From: Sullivan, Susan
Sent: Monday, December 17, 2012 10:27 AM
To: Lindahl, Lisa
Subject: Fw: Fwd: Questions re: Thermography Practice

Please make sure someone responds to this asap. Tks
Susan Sullivan, MHA
District of Grand Falls-Windsor-Buchans
Minister of Health and Community Services

From: Clare Barry [mailto:livewithoutpain@gmail.com]
Sent: Monday, December 17, 2012 10:24 AM
To: Sullivan, Susan
Subject: Fw: Questions re: Thermography Practice

Honourable Minister of Health, Susan Sullivan,

Hon. Ms Sullivan,

On November 27th, the Department of Health issued a Cease and Desist in reference to the thermography services offered at Avalon Laser Health Clinic.

Thermography is offered in dozens of clinics in Canada and in at least twenty-four countries in the United States. It was approved by the US Food and Drug Administration in 1982. Over 800 peer reviewed studies have demonstrated its role in providing additional information about breast health. Thermography is an important service and provides useful, additional information about women’s health.
Sincerely,

Clare Barry

On Thu, Nov 29, 2012 at 4:55 PM, Cooper, Bruce <brucecooper@gov.nl.ca> wrote:

Dear Ms. Barry,
I am writing further to correspondence from the Honourable Minister Susan Sullivan and our phone discussion on Tuesday, November 27th, 2012. Thank-you for your prompt compliance with our request for the suspension of the further use of thermography in assessing breast health and your concurrence to meet on Monday, December 3rd to discuss this matter with Departmental officials.

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• Do you have any plans to contact those people?
Does Avalon Laser Health have other diagnostic equipment that it uses? What? For what purpose?

I look forward to seeing you on Monday.

Sincerely Yours,

Bruce Cooper, Deputy Minister

Department of Health and Community Services

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Clare Barry
Avalon Laser Health - live without pain
Suite 306, 12 Gleneyre Street
Wedgewood Medical Centre
St John's, NL
A1A 2M7

Telephone: 709-753-0155
Fax: 709-753-0154

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Clare Barry
Avalon Laser Health - live without pain
Suite 306, 12 Gleneyre Street
Wedgewood Medical Centre
St John's, NL
A1A 2M7

Telephone: 709-753-0155
Fax: 709-753-0154
Pages 33-67 have been removed due to personal information.
Dear Ms. Sullivan,

Thank you for your response. Avalon Laser Health Clinic

We look forward to hearing from you in the New Year.

Regards,

Clare

On Thu, Dec 20, 2012 at 11:39 AM, Sullivan, Susan wrote:

Ms. Clare Barry
HYPERLINK "mailto:livewithoutpain@gmail.com"livewithoutpain@gmail.com

Dear Ms. Barry:

I am writing in response to your e-mail of December 17, 2012, while I acknowledge your concerns about the accuracy of information conveyed in a recent CBC investigative report, I would like to make it clear that this report does not form the basis of government's concerns regarding the use of thermography in breast cancer screening. The Department of Health and Community Services is responsible for ensuring that all medical and diagnostic services in this province are offered in accordance with established legislative and regulatory provisions.

Sincerely,

SUSAN SULLIVAN
Minister

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Clare Barry
Avalon Laser Health - live without pain
Suite 306, 12 Gleneyre Street
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Telephone:  709-753-0155
Fax:  709-753-0154