IN THE MATTER OF A HEARING UNDER THE *HEALTH PROFESSIONS ACT*,
R.S.A. 2000, c. H-7

AND IN THE MATTER OF AN INVESTIGATION
INTO A COMPLAINT AGAINST
DR. BARRY LYCKA, A REGULATED MEMBER
OF THE COLLEGE OF PHYSICIANS AND SURGEONS OF ALBERTA

DECISION OF THE HEARING TRIBUNAL OF THE COLLEGE OF PHYSICIANS AND SURGEONS OF ALBERTA

I. INTRODUCTION

1. The Hearing Tribunal held a hearing into the conduct of Dr. Barry Lycka, a regulated member of the College of Physicians and Surgeons of Alberta ("the College") on October 29 and 30, 2018. The hearing was held at the offices of the College in Edmonton, Alberta.

2. In attendance at the hearing were:

   Members of the Hearing Tribunal:

   Dr. Don Yee, Chair
   Dr. John Pasternak, member
   Ms. Georgeann Wilkin, public member

   Also in attendance were:

   Mr. Craig Boyer, legal counsel for the Complaints Director
   Dr. Barry Lycka, investigated member
   Mr. James Heelan, Q.C., Mr. Matt Riskin and Ms. Natasha Birchall (Student-at-law), legal counsel for Dr. Lycka
   Ms. Julie Gagnon, independent legal counsel for the Hearing Tribunal

II. PRELIMINARY MATTERS

3. There were no objections to the composition of the Hearing Tribunal or the jurisdiction of the Hearing Tribunal to proceed with the hearing.

4. Following some preliminary remarks, Mr. Boyer raised the issue of having the hearing or portions of the hearing closed to the public pursuant to section 78 of the *Health Professions Act* (the "HPA"). Mr. Boyer advised the Hearing Tribunal that he had spoken with the complainant, whose preference it was that the hearing be closed, at least with respect to her evidence, on the basis that she was very nervous and had not expected to give her evidence in a public setting.

5. Mr. Heelan advised that he had no objection to closing the hearing but noted that he would be going through the medical records in detail with witnesses other than the complainant and if the confidential nature of the information in the medical records was of concern, then the entire hearing should be closed.

6. In response to a question from independent legal counsel for the Hearing Tribunal, Mr. Boyer confirmed that the College was requesting that the hearing be closed on the basis of the complainant's request and also on the basis that personal confidential medical information would be discussed in the hearing. As such, Mr. Boyer's position was that the Hearing Tribunal should consider closing the hearing, in part or for the entirety of the hearing.

7. The Hearing Tribunal adjourned the hearing to consider the submissions of the parties. Under section 78 of the HPA, a hearing is open to the public unless the Hearing Tribunal holds the hearing, or part of the hearing, in private. There are several grounds listed for

closing a hearing. In this case, the grounds presented to the Hearing Tribunal for consideration were that the presence of the public could compromise the ability of the complainant to testify and that not disclosing the complainant's personal or health information outweighed the desirability of having the hearing open to the public.

8. The Hearing Tribunal considered the submissions of the parties and the nature of the allegations. The Hearing Tribunal agreed that there is likely to be details of the complainant's personal and health information discussed in the hearing and that the majority of the hearing appeared to relate to the medical records and treatment received by the complainant. The Hearing Tribunal considered that the request was being made by the complainant and that both the Complaints Director and the investigated member did not object to the hearing being closed. Based on these factors, the Hearing Tribunal found that preserving the complainant's personal and health information outweighed the desirability of having the hearing open to the public.

9. The Hearing Tribunal notes that a decision of the Hearing Tribunal is still available to the public and, in order to preserve the confidentiality of the complainant's personal and health information, has referred to her by initials in this case.

III. ALLEGATION:

10. The Allegation in the Notice of Hearing is that:

    1. You did display a lack of skill or judgment in the provision of professional services to your patient, [redacted] particulars of which include one or more of the following:

        a. you did fail to have an informed consent discussion with your patient regarding the use of Dysport for the treatment of bruxism;

        b. you did fail to create a record of the informed consent of your patient, [redacted] before proceeding with the injection of Dysport for the treatment of bruxism on March 17, 2017;

        c. you did fail to discuss with your patient the option of proceeding with a lower dosage of Dysport for treatment of bruxism on March 17, 2017 as compared to your plan to use 60 units of Dysport on each side of her face for the treatment of bruxism;

    2. You did request your patient, [redacted] to sign a letter dated March 23, 2017 that provided for a refund of the monies paid by her to you for her Dysport injections on March 17, 2017 in exchange for her agreeing to not make a complaint to the College of Physicians and Surgeons of Alberta.

IV. EVIDENCE

11. The following documents were entered as Exhibits during the hearing:

Exhibit 1 – Exhibit Book containing

- Tab 1 Notice of Hearing dated September 12, 2018
- Tab 2 Complaint Reporting Form completed by [redacted] dated April 24, 2017
- Tab 3 Dr. Barry Lycka response letter dated July 18, 2017
- Tab 4 Dr. Barry Lycka patient chart for [redacted]
- Tab 5 Dr. Lycka's office day sheet for March 23, 2017
- Tab 6 Dr. Lisa Loeffelmann dental chart for [redacted]
- Tab 7 Emergency Department record for attendance by [redacted] on March 22, 2017
- Tab 8 Dr. Zaeem Siddiqi letter dated May 29, 2017 enclosing records for [redacted]
- Tab 9 Dr. Lycka letter date stamped October 17, 2017
- Tab 10 Dr. Mariusz Sapijaszko letter dated August 9, 2018
- Tab 11 Curriculum vitae for Dr. Mariusz Sapijaszko
- Tab 12 Patient information package about Botox, Dysport and Xeomin prepared by Dr. Barry Lycka's office
- Tab 13 Dr. B. Lycka Non-Hospital Surgical Facility policies on Informed Consent and Consent Requirements revised September 2008
- Tab 14 Dr. B. Lycka Non-Hospital Surgical Facility policies on Informed Consent and Consent Requirements revised December 2017
- Tab 15 Dr. B. Lycka Non-Hospital Surgical Facility policies on Informed Consent and Consent Requirements revised July 2018
- Tab 16 College of Physicians & Surgical of Alberta Standard of Practice regarding Informed Consent – revised June 2016
- Tab 17 College of Physicians and Surgeons of Alberta Standard of Practice regarding Informed Consent – revised January 2016
- Tab 18 College of Physicians and Surgeons of Alberta Standard of Practice regarding compliance with the Canadian Medical Association Code of Ethics – issued January 2010
- Tab 19 Canadian Medical Association Code of Ethics – revised 2004

Exhibit 2 – Agreed Statement of Facts
Exhibit 3 – Photographs dated 1/30/2017
Exhibit 4 – Photographs dated 3/15/2017
Exhibit 5 – Curriculum Vitae of Dr. Lycka
Exhibit 6 – Article entitled Overview of botulinum Toxins for Aesthetic Uses
Exhibit 7 – Breakdown of Injections of Neuromodulators
Exhibit 8 – Alberta Health Care billing information relating to March 17 and March 23, 2017 attendance of Ms. [redacted] with Dr. Lycka

12. The Complaints Director called Ms. [redacted] (the complainant) and Dr. Zaeem Siddiqi as witnesses. Dr. Barry Lycka, Ms. Tamaralyn McCalla, and Dr. Mariusz Sapijaszko gave evidence on behalf of Dr. Lycka.

13. A summary of the witness evidence is below.

[redacted]

14. [redacted] confirmed that she was the complainant and had prepared the complaint reporting form found in Exhibit 1, starting at page 4. She is 35 years old and works as an administrative assistant.

15. [redacted] indicated that she had been seeing Dr. Lycka for a number of years for cosmetic Botox in her forehead and around her eyes. During an appointment on February 1, 2017, she inquired about a facial (Hydrafacial) and microneedling. She also asked about having therapeutic injections done for her masseter muscles because she has bruxism and clenches her teeth. There was also a discussion with the nurse regarding microneedling and she was told this may not be the best option because she has anemia. She recalled meeting with Dr. Lycka in the consultation room. He agreed that her masseters were large and very strong. She indicated that Dr. Lycka was in with her for probably a few minutes that day. She did not recall the name of the nurse who she dealt with at this visit. She previously had her masseters successfully treated therapeutically with Xeomin by her family dentist Dr. Loeffelmann. She was told that Dr. Lycka also did Botox injections into the masseters and that it could be done at the same time as the Botox injections into her forehead and around her eyes. She then proceeded to have a facial done at that appointment.

16. Her next visit was on Friday, March 17, 2017 for a Hydrafacial and to get Dysport injections. She had the Hydrafacial done first. She then went into a different room to have the Dysport injections. The nurse took pictures of her face and Dr. Lycka came in and did injections for the crows' feet around her eyes and forehead. He was about to leave and [redacted] reminded him about her masseters. Dr. Lycka asked the nurse to get more medicine prepared, they prepared her jaw; he palpated the area and did the injections. She noted that the process was very quick. In contrast, [redacted] recalled that when her family dentist did the masseter injections, it took almost an hour where Dr. Loeffelmann landmarked on her face with crayon, took photos as she went and was situated on both sides of her as she did the injections. In comparison she did not recall Dr. Lycka taking any photos and there was just a quick palpation of the masseter area before the actual injections.

17. Following the March 17 appointment, [redacted] went to Calgary with her son for a weekend trip. While she was in Calgary, she started to have issues. She started salivating a lot and something in her face felt wrong. She felt she was losing some function in her face. She waited the weekend and called Dr. Lycka's office on Monday morning and spoke to a nurse there. She then went to the University of Alberta Hospital emergency room because the side of her neck was strained and the pain was going down into her arm. She was worried because she did not know what was happening and she did not hear back from Dr. Lycka's office right away. She was afraid she had botulism. She was examined at the ER and advised she should be careful with Botox injections.

18. She attended at Dr. Lycka's office on March 23, 2017 to see if he could tell her what happened. She did not know what had happened and whether it was going to be permanent. During this visit, she first spoke with the nurse in the room and then Dr. Lycka came in. She was trying to ask questions about what happened but he was not able to offer any type of satisfactory explanation. However, he indicated he would send her to a neurologist. She had also seen her family physician for these issues who referred her to a different

neurologist, Dr. Siddiqi. The neurologist Dr. Lycka referred her to was Dr. Brad Stewart. She asked Dr. Lycka if she could get her money back since this was a therapeutic treatment that did not work and she had already missed work to have the appointments. She did not ask for a refund for the injections into her forehead and around her eyes. [redacted] noted that Exhibit 1, page 8, is a copy of a letter she received after asking for her money back. She was instructed to go into a consult room and then the nurse brought the letter to her. She did not discuss the letter with Dr. Lycka. She never signed the letter and has not received a refund for the treatment costs.

19. Although she obtained a referral to a neurologist from Dr. Lycka, she ended up seeing Dr. Siddiqi, the neurologist she was referred to by her family doctor. Dr. Siddiqi initially sent her for some blood work which ruled out a genetic condition which can manifest after a Botox injection. She had another visit with Dr. Siddiqi and he did some nerve testing and indicated he was not of the belief that there was any permanent damage. She noted that by then the pain had resolved but she continued to have issues with clenching and feeling like the muscle still could not pull up as well as it used to.

20. [redacted] indicated that the whole experience has been very hard and a terrible thing to go through. It was even harder trying to ask questions and she felt like more of a problem than a patient. She did not feel her best interests were in mind throughout this experience.

21. In cross-examination, [redacted] confirmed that the first time she saw Dr. Lycka was on June 3, 2011 for Botox around the eyes. She completed a Patient History Form at that time (Exhibit 1, pages 12-13). She also had a consultation with members of Dr. Lycka's staff. She has a vague recollection of being asked questions in the Patient Profile and Consultation Form (Exhibit 1, page 14). The Patient Profile and Consultation Form notes under "patient teaching" that a pamphlet was given and discussed. [redacted] agreed that there must have been a discussion with Dr. Lycka's staff about what was involved with Botox. She recalls the pamphlet being a pamphlet on Botox. [redacted] was asked if the pamphlet she was given was the one in Exhibit 1, pages 121-125. She indicated that it looked different to her. She indicated she was given the pamphlet but did not recall whether she had read through the pamphlet at the time. [redacted] did not recall the specific contents of the pamphlet she was given but stated it had before and after pictures of people who had Botox injections. She did acknowledge that it likely contained information regarding the risks of Botox. She stated she is sure she would have read the pamphlet at the time.

22. [redacted] acknowledged that there had been some discussions with Dr. Lycka's staff regarding Botox but stated that they never specifically talked to her about her masseter muscles. She agreed there would have been a discussion, even if she was getting injections around the brow or her eyes that the material might move from one place to another.

23. [redacted] acknowledged signing the Botox Injection Informed Consent form (Exhibit 1, page 34) dated June 3, 2011. [redacted] confirmed her initials beside each of the paragraphs listed on the form, including acknowledging that: "Occasionally, slight swelling, and/or bruising may last for several days after the injection. Rarely, an adjacent muscle may be weakened for several weeks after an injection. I have been advised of the risks involved in such treatment, the expected benefits of such treatment, and alternative treatments, including no treatment at all." [redacted] stated she provided consent at this time with the understanding that

these potential complications applied to the injections she was getting into the forehead and around the eyes. [redacted] acknowledged that she understood when she got her masseters done that it was the same type of toxin being injected as that previously injected into her forehead.

24. [redacted] had another injection of Botox on June 7, 2012 and signed and initialed the Botox Injection Informed Consent form (Exhibit 1, pages 19 and 33).

25. [redacted] saw Dr. Lycka again on June 15, 2012 because only one of her eyebrows was moving when she lifted her forehead. Dr. Lycka did a touch up injection to try to correct this. She returned on June 21, 2012 as she was having an issue with a droopy eye. Her vision was also blurry and she was given eye drops. [redacted] stated that she understood that a droopy eye was a risk of getting Botox in her forehead. She knew this based on research she had done on the internet.

26. [redacted] returned to see Dr. Lycka in July 2014. The note in the patient chart indicates "patient in for NM injection around eyes. Patient unsure about forehead. Had droopy eye with last treatment. Dr. Lycka in to see patient. Suggest Dysport. Consent done prior." (Exhibit 1, page 21) At that point, there was a discussion with respect to moving from Botox to Dysport. [redacted] noted that all she could remember from that conversation was that it was being used more and that patients liked it better and it lasted a little bit longer. She signed and initialed a Dysport Injection Informed Consent form (Exhibit 1, page 35). She initialed the statement that: "Occasionally, slight swelling, and/or bruising may last for several days after the injections. Rarely, an adjacent muscle may be weakened for several weeks after an injection. I have been advised of the risks involved in such treatment, the expected benefits of such treatment and alternative treatments, including no treatment at all." [redacted] noted that the handwriting that states "hypertrophic masseters" on the Dysport Injection Informed Consent form (Exhibit 1, page 35) is not her writing. [redacted] did not recall any discussion of the risk that the injected substance could migrate.

27. The injection of Dysport went well and she had no issues or complications. She came back on August 6, 2015 for another Dysport injection (Exhibit 1, page 22). She had another Dysport injection and signed the Dysport Injection Informed Consent form again (Exhibit 1, page 35). She had no issues with the treatment on that occasion.

28. With respect to the injections done by her dentist, [redacted] agreed she likely discussed the risks involved but does not remember the details of the conversation. She saw her dentist in May 2016 where use of a neuromodulator for her masseters was discussed. She states the dentist probably discussed risks associated with the procedure and medication injected. She did not recall the dentist telling her the specific number of units of Xeomin that would be used but did confirm this was the first time she had Xeomin specifically. The dentist noted in the chart that the patient had previously had problems with Botox and experienced lid ptosis. [redacted] felt the dentist took a lot of time with the masseter injections because of her respect for all of the muscle groups and nerves in the region. She stated the dentist may have discussed the possibility of the injected material moving to different regions and immobilizing other mouth muscles. The procedure was done June 29, 2016.

29. [redacted] was asked about the statement on the Patient Profile and Consultation Form of February 1, 2017 noting that "procedure discussed with tech/nurse" and "pamphlet given" (Exhibit 1, page 18). [redacted] indicated she believed that related to the Hydrafacial. She did not recall a discussion about the risks of Dysport and denied that there was any discussion about the risks of treatment with Dysport into her masseters during that appointment. She also denied that a pamphlet was given to her about Dysport on February 1, 2017. [redacted] agreed that there was a discussion on February 1, 2017 about getting Dysport and that the Dysport injections occurred on March 17, 2017.

30. A photograph dated 1/30/2017 of [redacted] was entered as Exhibit 3. [redacted] indicated it was for the Hydrafacial procedure because she has no expression in the photo. She returned to Dr. Lycka's office March 17, 2017 and a second facial was performed along with the Dysport injections into her masseters. Photographs dated 3/15/2017 were entered as Exhibit 4. [redacted] stated the photo in Exhibit 3 she has no expression in it and feels this was to demonstrate the benefit of the Hydrafacial. She has expressions in the photos in Exhibit 4 (angry face, squinting, forehead) to demonstrate the effects of the Botox. [redacted] recalls at the time of the injection, Dr. Lycka palpated in the area of her masseters and then did the injection. She recalls it being a quick procedure. She confirmed that weekend she had issues and called Dr. Lycka's office the following Monday or Tuesday and indicated she was having trouble speaking properly and chewing. The following day she was evaluated in the ER and the day after that she saw Dr. Lycka. She was also evaluated by her family doctor the following week who referred her to see Dr. Siddiqi. She was evaluated by Dr. Siddiqi April 4, 2017. She also saw her dentist on March 23, 2017. The dentist's notes indicated [redacted] was having paralysis of the right cheek and neck muscles, right arm numbness, difficulty moving her tongue to the right and more pronounced paralysis of the right masseter, speech impediment and difficulty chewing.

31. [redacted] admitted to being scared, angry and upset when she went to Dr. Lycka's office on March 23, 2017. She did not know what was happening to her and if it was going to be permanent. She agreed that Dr. Lycka probably told her at that appointment that this was something she had been told about, that the toxin could move to other parts of the face. Mr. Heelan suggested to [redacted] that she was angry and shouting. [redacted] agreed that she was likely shouting when she was asking if this was permanent but denied shouting about getting her money back. She does not recall threatening to report Dr. Lycka to the College. Dr. Lycka left the room and she ended up dealing with some of the staff members. She was disappointed and upset by the form (Exhibit 1, page 8) she was being asked to sign. [redacted] indicated Dr. Lycka said it was likely a temporary thing but he wasn't sure.

32. In response to questions from the Hearing Tribunal regarding Exhibit 1, page 35, [redacted] noted that she does not believe the handwritten entry "hypertrophic masseters" would have been on the form in 2014 or 2015 when she signed the form because she did not know that Botox (or any other brands) could be used as treatment for the masseter muscles until 2016, when her dentist offered the treatment to her.

33. In response to questions from the Hearing Tribunal regarding Exhibit 1, page 18, [redacted] did not recall seeing this form. She was not required to sign it and does not believe it was shown to her. She recalls signing a consent form in 2016 to have masseter injections

performed by her dentist but not for the masseter injection done by Dr. Lycka. She indicated that the price list was told to her verbally.

Dr. Zaeem Siddiqi

34. Dr. Siddiqi was called to give evidence on behalf of the Complaints Director. He is a neurologist and practices at the University of Alberta Hospital. He specializes in peripheral muscular disease and has an area of interest in electromyography (studying nerves).

35. Dr. Siddiqi saw [redacted] on a referral from her general practitioner. The reason for referral was to rule out myastenia gravis. He assessed her within 3 or 4 days of receiving the referral as myasthenia gravis is a serious condition that requires emergency care. He initially sent her for some blood work for acetycholine receptor antibodies (diagnostic for myasthenia gravis) which was negative. He saw her again on May 23, 2017. He noted her weakness had significantly improved at that time by her own report. He recalls ruling out myasthenia gravis quite quickly after meeting her and taking a history of her recent botox injections and her associated physical exam findings. He also did some nerve conduction studies on her which were normal, which reinforced his diagnostic impression.

36. Dr. Siddiqi indicated he has much experience with botox injection side effects. He has seen patients end up in intensive care and develop myasthenia gravis after botox injections.

37. Dr. Siddiqi reviewed his letter (Exhibit 1, pages 97-98) and noted that within days of receiving an injection of botulinum toxin on March 17, 2017, [redacted] developed excessive weakness on her right sided facial muscles. She had drooping of the face, drooling of saliva, weakness of the right side of the tongue and weakness of cheek muscle resulting in difficulty chewing and talking. By the time he saw her the symptoms had plateaued and were improving. It was his opinion that the weakness of facial muscles was most probably an adverse effect of the toxin and would likely resolve spontaneously over the next several weeks.

38. Dr. Siddiqi indicated he administers botox injections but not for cosmetic reasons. He only administers neuromodulators for medical indications such as heavy facial spasm, dystonia, facial spasticity.

39. Dr. Siddiqi noted that in having informed consent discussions with a patient, a physician has to first advise the patient that botulinum toxin is not a curative treatment. It is a symptomatic treatment. It is important to set the right expectations for the patient. You are not curing the patient but making symptoms more manageable. You have to advise the patient that there are other treatment options such as medications. For bruxism, there are other treatments and you have to advise the patient of the risks of what may happen. You have to advise that there are injections and that the dosing is very variable and the dose may need to be adjusted in further treatments.

40. Dr. Siddiqi noted that the patient should be advised that they may be left with facial bruising, pain and swelling. Other side effects are dystonias which are common, in particular in women. There needs to be an upfront discussion with the patient about the mechanism of action and possible adverse effect of the toxin. It has to be explained that the purpose of the injection is actually to weaken the target muscles but at times the effect

can inadvertently be excessive. Additionally, the toxin can spread to nearby muscles, particularly with facial injections. The adverse effects are usually temporary. This discussion is very helpful and the patient is mentally prepared to accept the adverse effects, if they occur.

41. Dr. Siddiqi also noted that the toxin needs to be started at the minimal therapeutic dose. The patient should be informed about the conservative approach with gradual dose escalation. The patient should expect subtherapeutic effects after the first dose but the upside is avoidance of complications. The dose can be increased with subsequent injections. Dr. Siddiqi gave evidence about the units of Dysport and how these relate to both Botox and Xeomin. He explained Botox, Xeomin and Dysport are all botulinum toxin but in three different formulations and strengths. The original was Botox, then came Dysport in 2011 and then Xeomin became available in 2012.

42. Dr. Siddiqi advocates a conservative approach, especially with initial treatment in a new injection site. He explained most of the published evidence for neuromodulator dose efficacy comes from treatment of patients with severely affected muscles such as spasticity from strokes, Parkinson's, cerebral palsy and Huntington's disease.

43. Dr. Siddiqi explained facial injections of botox comes with the risk of downward spread or diffusion of the toxin due to gravity as the facial muscles lack deep fascia.

44. On cross-examination, Dr. Siddiqi confirmed that he has no dermatological training. He confirmed that injections into masseters is only a very small part of his practice. He admitted that he has less experience than a cosmetic dermatologist would with the use of botulinum toxin for cosmetic indications. However, he stated he could not say the same for use of botulinum toxin for medical indications. Dr. Siddiqi confirmed that he had never given a neuromodulator in a cosmetic setting for the treatment of wrinkles in the forehead and crows' feet around the eyes. He indicated the masseters can be affected by oromandibular dystonias and jaw clenching dystonia for which neuromodulator injections can be used but the dosing is different than for bruxism injections.

45. Dr. Siddiqi noted that one unit of Botox is equivalent to approximately 2.5-3 units of Dysport. He agreed that a conversion of 1-3 for Botox to Dysport units is acceptable. He also indicated one unit of Botox is equivalent to approximately one unit of Xeomin. He confirmed that there are no dosage guidelines and dose adjustments within the acceptable dose range is a matter of clinical judgement, taking into consideration factors such as size of muscle, severity of the clinical issue, previous patient exposure to the neuromodulator, previous responses to specific neuromodulator doses. Dr. Siddiqi indicated that in his opinion, 60 units of Dysport per side was a high dose. However, Dr. Siddiqi recognized that it is a reasonable dose.

46. Dr. Siddiqi agreed that the starting doses for neuromodulator injections into the masseter are some of the highest for the facial region as this muscle is a relatively large facial muscle and it is anatomically deep. His starting dose is usually around 10-15 units of Botox, but he recognizes some colleagues will start at 20-25 units which is acceptable.

47. The neuromodulator doses used by the dentist for [redacted]s masseter were reviewed. She received 32 units of Xeomin into each masseter. Dr. Siddiqi felt this was at the high end

of dose. He stated he would not have used 60 units into each masseter as a repeat treatment as he felt that dose was too high even though the dose is within acceptable guidelines.

48. Dr. Siddiqi stated that a potential side effect of neuromodulator injection is excessive weakness of the target muscle to varying degrees and it does not always represent the result of a physician error.

49. Dr. Siddiqi confirmed that he had not reviewed the chart of Dr. Lycka and could not comment on whether Dr. Lycka had obtained informed consent. Dr. Siddiqi stated that informed consent means that you must tell the patient not only what the side effects are, but also what the patient is getting treatment for, what the other options are, that the patient has a choice, frequency of injections and what to expect with respect to potential benefits and side effects. The side effects that should be mentioned are swallowing and/or chewing issues, facial drooping, facial weakness, and drooling. Using the example of bruxism, he indicated there are medications and even surgical options of management in addition to botox injections. He indicated that when he first assessed [redacted] she seemed like she did not know that what was happening to her was potentially a side effect of her injections. He was not made aware that the patient developed a ptosis from a previous injection. He confirmed that by his second clinic visit with [redacted] her symptoms were resolving and that from there he expected a complete recovery.

50. In response to questions on redirect, Dr. Siddiqi indicated that in his opinion, receiving 120 units of Dysport in the forehead and around the eyes, which is going to gravitate down, plus another 120 units in both masseters is a huge amount. He indicated he has never given that amount of toxin. He indicated he has never given injections of neuromodulator in the forehead and around the eyes for cosmesis.

51. In response to questions from the Hearing Tribunal, Dr. Siddiqi noted that toxicity or side effects are directly proportionate to the dose used. The higher the dose, the higher the significance. In Dr. Siddiqi's opinion, where there is a higher dose used, you have an increased risk of having side effects and you should tell the patient that there is a higher chance of side effects. While he has not done injections for cosmetic reasons, he indicated he has injected the same muscles targeted for cosmetic reasons for medical conditions such as the corrugator and procerus muscles. He explained the facial muscles are unique in that there is little to no redundancy in their function so that weakening one has more noticeable effects compared to if you weaken a muscle in a different body area. He explained that the lack of deep fascia around the facial muscles allows fluid such as blood and injected neuromodulator to accumulate. He recalled a case of a patient who ended up in the intensive care unit after receiving a botox injection in the head and neck region and losing control of the swallowing and chewing muscles and going into respiratory failure. He re-emphasized the closer botox injections are done to the face and neck the more chance of significant side effects, mostly through local diffusion of the neuromodulator.

<u>Dr. Barry Lycka</u>

52. Dr. Barry Lycka is a dermatologist. He graduated in 1989 and has been practicing independently since 1994. His practice is a combined practice of medical dermatology, surgical dermatology and cosmetic dermatology. Dr. Lycka noted that Botox, Dysport and

Xeomin are all types of neuromodulators available in Canada. Botox and Xeomin have 1 standard unit whereas Dysport is generally 3 units for every 1 unit of Botox or Xeomin. All three agents have the same end result of blocking a nerve signal at the motor endplate.

53. Dr. Lycka outlined his informed consent process. He first asks the individual what it is they wish to achieve, what their goals are and what they would like to have happen. He asks if they have ever had a material like this before and whether they have ever had any side effects. He asks if they have ever had any cosmetic procedures, because this indicates they will have a fairly good understanding of what is going on. He tells them exactly what Botox is and how it works. He advises the individual that it is meant to paralyze a muscle for a certain period of time and that it is a temporary paralysis that will last according to the muscle but that it varies in every person. He notes that part of the informed consent procedure is to advise the patient about the risks, benefits, and alternatives of the procedure, including the alternative of not having any procedure done.

54. Dr. Lycka noted that the informed consent process is a fairly involved process and occurs at several levels. He explains to the patient the risks, benefits and alternatives to neuromodulators like Botox and his nurse will go into a great deal of material on it so a person understands the full implications of Botox and what it does. During the process, the individual is given a pamphlet and the pamphlet is reviewed with the patient. He indicated a nurse in the clinic will go over the written material with the patient. He said that he personally explains to the patient the realities of what the injections can and cannot achieve. He outlines the potential risks of the injection and stated the most common risk is swelling and bleeding at the injection site. Infections rarely happen. He warns patients 3 to 4 days after the injection they may notice excessive weakness of a muscle and it may manifest as an unexpected facial expression like a raised eyebrow, depending on what area was injected.

55. Dr. Lycka noted that he started out using Botox but has switched to Dysport. He indicated he was one of the earlier practitioners who injected the masseters. He attended many continuing medical education events for Botox use when he started offering it to patients. The benefits of Dysport are that it works more quickly, lasts a little bit longer and also has a more natural look. He indicated that his practice with respect to neuromuscular injections currently is approximately 80% Dysport and 20% Xeomin or Botox.

56. Dr. Lycka reviewed his Patient History form (Exhibit 1, pages 12-13) and the Patient Profile and Consultation form (Exhibit 1, pages 14-15). Dr. Lycka noted that the picture on Exhibit 1, page 15 is used when they are talking to the patient to note where the procedure will be done. Dr. Lycka noted that for the heading “patient teaching”, a pamphlet is given to the patient and a discussion of the high points of the pamphlet occurs with the nurse, in the event the patient does not read the pamphlet. Dr. Lycka confirmed that the pamphlet in Exhibit 1, pages 121-125 is the pamphlet that is referenced in the Patient Profile for [redacted]

57. Dr. Lycka reviewed the procedure notes starting at Exhibit 1, page 19. These are done on the date of the procedure and on the same date, consent forms and pictures are also done. The patient will sign the form and initial various boxes indicating they have read the form and pictures will be taken and a signed consent form for the pictures is done as well.

58. Dr. Lycka noted that the patient first came in on June 3, 2011 for Botox. She returned on June 7, 2012 and the informed consent discussion would have occurred again. On June 15, 2012 he saw the patient as she was complaining that only her right eyebrow moved when she lifted her forehead. He reminded her that this was an expected complication and he had talked to her about it. He administered a very low dosage of Botox as a touch-up procedure. She came back a week later with complications of a droopy eyelid and some blurring of the vision on that side. This was treated and she came back one week later and was doing pretty well. She was happy with the results. She returned on July 19, 2014 and Dr. Lycka suggested Dysport to her based on what the medical literature was showing. The informed consent process was followed during that appointment as well, including and explanation of the procedure, potential side effects and opportunity for the patient to ask questions. She returned on August 6, 2015 for a Dysport injection. The photographs and consent forms were done for this appointment as well.

59. An overview article of botulinum toxins for aesthetic uses (Exhibit 6) was referenced in discussion of the amount of neuromodulator used for injecting [redacted]s masseters. This article indicated that due to the relative large size of the masseter muscles, an appropriate starting range of neuromodulator would be 30-35 units of Botox or 90-105 units of Dysport. Dr. Lycka confirmed he used 20 units of Botox into each masseter for [redacted] (60 units of Dysport) which he felt was a fairly low conservative dose. Dr. Lycka indicated that in his experience of injecting neuromodulators in the face region, the only time he has ever seen gravitational diffusion is when the area of the upper eyelid is injected. He has seen diffusion from the masseter to other parts of the lower face, but does not find neuromodulators diffuse from the upper face to lower face.

60. With respect to the handwritten entry of "hypertrophic masseters" made on the Dysport Injection Informed Consent form (Exhibit 1, page 35), Dr. Lycka noted that he has a habit of writing on any piece of paper that he has available at the time as an aid memoir. He wrote the note down that she had mentioned she had large masseters and it was mainly meant for him, in the future, to talk to her about it and let her know that they will attend to it at another point in time.

61. He saw the patient again on February 1, 2017. A new Patient Profile and Consultation form was done (Exhibit 1, pages 17-18). Dr. Lycka noted that where a patient wants a new procedure done, he thinks it is important to start things over again. The document indicates that [redacted] had Xeomin injected into her masseters previously which lasted one month. She was in to talk about Hydrafacial treatments and about her bruxism and hypertrophic muscles. The picture at Exhibit 1, page 18 shows the areas where Dysport would be injected. They also talked to [redacted] about microneedling and PRP but the patient was not a good candidate for that given her anemia. Under "patient teaching" it indicates "procedure discussed" and "pamphlet given". Dr. Lycka noted that one of his nurses would have gone over the pamphlet given to [redacted] to make sure that she understands the risks and benefits of injecting this new area. This would have been the pamphlet at Exhibit 1, page 121. He explained that the Hydrafacial treatment is done by clinic staff and not him.

62. There is a note at Exhibit 1, page 30 which is a dictated chart note for February 1, 2017, indicating: "Patient was seen for cosmetic consultation for facial options. Dysport, Microneedling, PRP and Hydrafacial discussed. The risks, benefits, expectations and

pricing have been discussed with the patient. She seems to understand this well." Dr. Lycka believes that he was the one to discuss these with her and that he was the one who dictated this clinic note. He confirmed that this discussion would have included a talk about potential risks and benefits, expectations and pricing. He confirmed that [redacted] had a Hydrafacial treatment done on February 1, 2017 and would return in a week for the Dysport.

63. Dr. Lycka also provided evidence regarding the chart entry at Exhibit 1, page 23 and the stamp: "Patient seen and treatment reviewed" which is initialed by Dr. Lycka. He indicated he stamps the chart entries at the end of the day confirming that he went through the entire procedure with the patient.

64. Exhibit 3 was presented as a photo of [redacted] Dr. Lycka indicated the date on the photo is incorrect (1/30/2017) which was due to a glitch in the office computer. He indicated the photo was taken February 1, 2017.

65. Dr. Lycka noted that for the March 17, 2017 appointment (Exhibit 1, page 24), the whole process would have been repeated with respect to the consent forms and pictures. He noted that there is no signed consent form for this date in the record which he finds peculiar. He noted that his usual routine is for a consent form to be there. The consent form has to be present before he will do the procedure on a patient. He looks at the consent form before he does that. He does not know why it is not in the chart or in the record as his usual routine is to review everything before he provides any treatment. Dr. Lycka noted that there were 240 units of Dysport used for the entire face on March 17, including 60 in the glabella, 30 in each area around the eyes. [redacted] also had a Hydrafacial done on March 17, 2017. A chart summarizing the different injections Dr. Lycka performed on [redacted] was entered as Exhibit 7.

66. Dr. Lycka recalled that [redacted] had called the clinic staff, worried about some side effects she was having. His immediate response when she called the office was to get her in as soon as possible. She came in two days later on March 23, 2017. She complained of weakness in her lower face and pain in her neck. She complained of pain in her right arm. There was numbness to the cheek area. She was having problems chewing and swallowing and he became concerned. The arm and neck problems were unusual in his view. The whole constellation of symptoms [redacted] had did not make sense to him and did not seem to be just a localized reaction to Botox.

67. He reminded [redacted] that they had discussed the possibility of weakness that could happen in the surrounding muscles, which is usually temporary, from the material moving outside of the injection area. He does not remember exactly how the issue came up, but [redacted] said she wanted her money returned for the injections to her masseter muscles. He indicated it was not the time and place to discuss the returning of money. He wanted to make sure that she was doing well from a medical point of view and wanted to get her in to see a neurologist. He told her that they would talk about money at a later time.

68. Dr. Lycka stated that March 23 was a surgical day for him. He was busy with other patients. He left [redacted] with his staff and she was seen by his charge nurse, Wendy. [redacted] demanded her money back and became quite belligerent. Wendy discussed this with Tammy who came to the door of the surgical suite and asked Dr. Lycka what she could do. He told Tammy

that he would be glad to give her a refund but that he needed a release. He asked Tammy to check any guidelines that exist with the College and refer to them and to use a boilerplate for an existing release if there was one. He indicated he did not have time to deal with it, as he was busy with a patient. He did not see the form of release in Exhibit 1, page 8 before it was given to [redacted]

69. Dr. Lycka indicated that Tammy told him about the release afterward and he became very angry with her. He did not think it was appropriate for a person not to be able to complain to the regulatory body and he stated that he tore a strip off Tammy. He indicated that he did not do anything else about the release.

70. On cross-examination, Dr. Lycka was asked about his response to the College dated July 18, 2018 (Exhibit 1, pages 9-10). In that letter, he states: "When she came to the office for her follow up appointment I explained that occasionally weakness occurs in the surrounding areas and I showed her on the consent where she had acknowledged this." Dr. Lycka indicated that this is referring to a consent form that he cannot find in his records. He does not know why the form is not there but states that he did an informed consent process that day.

71. Dr. Lycka was asked about his comment that the note on Exhibit 1, page 35 of "hypertrophic masseter" is an aid memoir that he states he wrote on August 6, 2015. He was challenged on how it can be an aid memoir when it is not in the treatment note, patient record or dictation note made by him. He stated [redacted] had indicated interest on August 6, 2015 in having injections into her masseters at some point and Dr. Lycka made note of it to remind himself to discuss this with her at a later date. He explained that the designation of a procedure as 'cosmetic' implies it is not covered by Alberta Health Care.

72. Dr. Lycka acknowledged that he did not specify the Dysport dose used on [redacted] in his written referral to Dr. Stewart the neurologist but stated it was detailed to Dr. Stewart in a phone discussion with him about the case.

73. Dr. Lycka indicated that he did not consider calling or writing a letter to [redacted] after March 23 to discuss the release she had been given. He indicated the patient left the office very angry and he did not think it was appropriate to contact her. Dr. Lycka stated that he understands one of the roles of the College is to deal with complaints and ensure that members of the College are acting in accordance with the Standards of Practice and Code of Ethics but that he is not responsible for the actions of his staff. He stated he felt that there was something wrong with the Release presented to [redacted] and that it should not have been given to her. Dr. Lycka stated he understands that patients do have a right to complain to the College about regulated members. He stated his understanding that to ask a patient to not complain to the College is an attempt to undermine one of the roles of the College.

74. Dr. Lycka stated the patient profile portion of a patient chart is updated every time a patient returns to clinic for another procedure. He indicated patients are asked if there are any changes to their medical record since their last visit with them. He was challenged as to how patients could remember every last question on the patient profile in the chart. He indicated he relies on his staff to distribute the correct pamphlet material to patients according to what procedure they are having, whether it be a Hydrafacial or neuromodulator injection.

75. Dr. Lycka re-iterated the dates on the photos in Exhibits 3 and 4 were incorrect but was not sure of the source of the error as he does not directly oversee every detail in his clinic.

76. Dr. Lycka stated when [redacted] came to clinic on March 17, several procedures were planned including injections into the forehead, around her eyes and into the masseters. He was asked about whether there was a discussion with [redacted] about the cumulative effect of the neuromodulators given to her on March 17. Dr. Lycka indicated he did not believe the cumulative effect from the eyes is essential to the effect on the masseters. He agreed that there is no record on the patient chart of any discussion with the patient about the cumulative effect of neuromodulators.

77. In response to questions from the Hearing Tribunal, Dr. Lycka was asked about his letter of response to the College (Exhibit 1, pages 9-10) where he states: "She requested her money back and I requested her to sign a release before receiving it. I did this without the benefit of legal counsel. It is now my understanding that a release which purports to stop a Complaint to the College is inappropriate but I was unaware of this at the time and I am very sorry that this happened. This will not happen again." Dr. Lycka was asked about the discrepancy between this statement and his comment that the letter was done without his knowledge. Dr. Lycka noted that the letter was written without him talking to his staff. When he talked to Tammy, his office manager, she reminded him of exactly what had happened. Dr. Lycka had forgotten that he tore a strip off Tammy with respect to this when he wrote his letter to the College. Dr. Lycka noted that following this event, he talked to his staff about what should be done in these situations and developed a template.

78. Dr. Lycka was asked about why some consent forms have more than one signature and date on them and he indicated that it is at the discretion of staff whether to use the same consent form or a new one. With respect to stating that he was not responsible for the actions of his staff, Dr. Lycka indicated that in this particular situation, he could not control their behavior. The staff member acted while he was involved in a surgery, dealing with an urgent surgical complication. The patient was requesting her money back and demanding it in such a way that the staff member felt she had to take action. He indicated that he did instruct his staff to get a boilerplate consent form and consult any guidelines available from the College in this respect. He indicated that it is rare for him to get requests for refunds from patients and that he does not have a standard release form for such a situation.

<u>Tamaralyn McCalla</u>

79. Ms. McCalla is the Nursing and Reception Manager at Dr. Lycka's clinic and has worked for Dr. Lycka since November 2010. She oversees all of the nurses, nursing assistants and reception staff. She stated that there is a Procedure Manual for the clinic for both nursing and reception. The manual is updated annually. There is a procedure for informed consent (Exhibit 1, page 126). There are other procedures at Exhibit 1, pages 132 and 138 which are updated procedures. Nursing staff are trained on these procedures.

80. Ms. McCalla reviewed the forms in Exhibit 1. With respect to the Patient History form, this is created when the patient first comes into the clinic. Patients are asked each time if there are any changes to address, doctor, new allergies. If reception does not ask, the nurse

will ask if there are updated medications. With respect to the Patient Profile and Consultation form, this is typically filled out when a patient comes in for a cosmetic consultation. Patients are given a new one every time they come in for a different procedure. In addition, the patient is always given all information pertaining to the procedure, including a pamphlet on the procedure. The Informed Consent form (Exhibit 1, page 35) is filled out every time a patient has a procedure. The patient can sign a form more than once or a new form, it depends on the nurse. She confirmed the signature at the bottom of Exhibit 1, page 18, (the clinic's Patient Profile and Consultation form for [redacted] is that of a nursing assistant who is not employed at the clinic presently (K. Lafferty). She explained that patients are given pamphlets related to every cosmetic procedure they have done and given a chance to ask any questions. Dr. Lycka and a nurse usually go through the pamphlet material with the patient. She confirmed patients would receive new pamphlets even if they had undergone the procedure before and Dr. Lycka prefers the patient have a chance to take the pamphlets home to review before a procedure is actually done.

81. Ms. McCalla confirmed the consent form on Exhibit 1, page 35 as the current form used at the clinic for Dysport procedures. She stated patients have this filled out every single time they have a Dysport procedure.

82. The notes from [redacted]s chart on Exhibit 1, page 23 was reviewed. The signature for the February 1, 2017 chart entry is that of the nursing assistant, K. Lafferty. The second entry for the Hydrafacial is of the laser technician who performs the procedure. Dr. Lycka is not involved with the Hydrafacials. She indicated that photos are taken prior to every procedure with the patient's written consent. If there are no photos done, no procedure is done and the consent to photograph is done prior to every set of photos. She explained that they used to take Polaroids, then used a digital camera but have transitioned to Rx Photo as of about February 2017. She indicated one of the glitches with Rx Photo when they first started using it was the software incorrectly dated photos one day earlier. This problem was resolved quickly.

83. The chart entry for March 17, 2017 (Exhibit 1, page 24) was authored by Tina David who was a laser technician at the clinic at the time. The informed consent discussion for the Hydrafacial would have been with the technician and the informed consent discussion for the Dysport would have been with the registered nurse. Generally, the nurse goes through the informed consent with the patient and when Dr. Lycka comes into the room, he checks the photo consent and the informed consent and asks the patient if there are any questions or concerns before they proceed. With respect to the March 17, 2017 procedures, she indicated that she would expect that a discussion would have occurred on the day of the procedure even though a discussion also had occurred on February 1, 2017.

84. With respect to the stamp at the bottom of the page which states: "Patient seen and treatment reviewed", Ms. McCalla noted that is Dr. Lycka's stamp. He goes through the charts at the end of the day and makes sure that everything is there and that the charting is correct. He then stamps the chart entry.

85. Ms. McCalla explained that patients are given an after-hours phone number to call if problems arise. The calls go to her and she is available 24 hours a day, 7 days a week. If

she gets a call, she will take the information from the patient and then contact Dr. Lycka to relay the information. Dr. Lycka then speaks with the patient. She will document on the chart the details of the call. If Dr. Lycka is not available, she will send the patient to the Emergency Room. After the March 17 procedures, she never received an after-hours call from [redacted]. She did take a call from [redacted] during working hours which she documented in the chart (Exhibit 1, page 25). She recalls [redacted] being a little bit upset but does not remember other details of the call. She would have taken the chart to the nursing station and the patient would have been called back. The chart note indicates that Jennifer Graham, a nursing assistant called [redacted] back.

86. Ms. McCalla gave evidence of the appointment with [redacted] on March 23, 2017. Jennifer Graham made the intake note. Dr. Lycka did examine the patient with Wendy Sorochan, the clinic's senior nurse, present in the room. Dr. Lycka then had to address a bleeding complication with one of his surgical patients. Ms. McCalla understood that Dr. Lycka was referring [redacted] to a neurologist. [redacted] was being walked out of the room and Ms. McCalla described [redacted] as having a meltdown in the hallway. She was stating loudly that she wanted her money back or that she would go to the College. Ms. McCalla went out to see what was going on as she could hear this from her office. Ms. McCalla got [redacted] into a room and went to talk to Dr. Lycka. She explained to Dr. Lycka that [redacted] was upset and was asking for a refund. Dr. Lycka said to write a release letter, to use a boiler template, and he said to follow the guidelines of the College and just get her out of the clinic. Dr. Lycka could not leave his surgical patient. Ms. McCalla tried to find guidelines. She did not know what a boiler template was. She typed a letter stating backwards what [redacted] had said to her. She did not have Dr. Lycka check the letter. She gave it to the nurse and asked her to give it to the patient. She confirmed the letter she wrote is on Exhibit 1, page 8. She said [redacted] took the letter and left. She confirmed [redacted] did not sign the letter.

87. After the patient had left, Ms. McCalla told Dr. Lycka what had happened and he asked for a copy of the letter. Ms. McCalla stated that at that time "all hell broke loose". Dr. Lycka was very mad and told her she could not write things like that. She noted that Dr. Lycka sometimes flies off the handle, they will have a meeting about the issue, put different policies in place and then just move on.

88. She recalls [redacted] being very agitated in the clinic on March 23 and remembers thinking that [redacted] "might have been on something" as she was agitated, loud and angry. She admitted in cross-examination that she had not considered [redacted] may have been scared due to the extent of her complications and her uncertainty about how permanent they were.

89. In cross-examination, Ms. McCalla confirmed that there were no notes for the March 17, 2017 visit made by the registered nurse, Wendy Sorochan. She would have expected to see notes from Ms. Sorochan about the discussion of consent for Dysport. Wendy did enter chart notes from the March 23 visit. With respect to Exhibit 1, page 18, under "Patient Teaching" the word "nurse" is crossed out and "tech" is written above it. Ms. McCalla responded by saying that the policy is to give a pamphlet for any procedure that the patient has. She confirmed the laser technician Jennifer Graham is not a nurse or licensed practical nurse. She re-iterated that for every procedure a patient undergoes they will receive an accompanying information pamphlet, including the interaction between Wendy and [redacted] in clinic on March 17. However there are no clinic notes to document this interaction.

90. In response to questions from the Hearing Tribunal with respect to Exhibit 1, page 24, Ms. McCalla believes that Wendy Sorochan, the nurse, made the markings on the diagram, as the handwriting is not Tina David's, the technician. She noted 3 registered nurses witnessed [redacted]s signature on Exhibit 1, pages 34 and 35, Wendy Sorochan, Jenna Kolesar and Natalia Kutcher. It was also noted by a Hearing Tribunal member that there was no consent form in the record for the treatment received on June 15, 2012. Ms. McCalla could not explain the absence of a consent form in this instance. She confirmed that even though the June 15, 2012 procedure was a small touch-up there should have been a consent form. In response to a question about staffing, Ms. McCalla noted that there are usually four registered nurses working and sometimes five on Tuesdays. There are two nursing assistants and two laser technicians. Ms. McCalla noted that they had a bad couple of years with lots of staff turnover. She verified that the laser tech gets consent for Hydrafacials and an RN or LPN gets consent for neuromodulator injections. When the patient is in the room ready for the procedure(s), Dr. Lycka comes in and verifies all of the documentation, answers any patient questions and then performs the procedure. She confirmed that the RN's are the ones obtaining consent for medical procedures in the clinic and they are given extra training to be able to explain other management options.

Exhibit 8

91. Exhibit 8 was entered with the consent of both parties as Alberta Health Care Billing information relating to March 17 and March 23, 2017 attendance of [redacted] with Dr. Lycka. Mr. Heelan explained there were 2 billings made to Alberta Health for [redacted] from those visits, one from March 17 and one from March 23. Neither billing is for the masseter injections. The billings relate to a question of hyperpigmentation. However neither of the billings should have been submitted. Dr. Lycka was not aware of the billings as he has a separate billing department.

Dr. Mariusz Sapijaszko

92. Dr. Sapijaszko is a dermatologist. He graduated from the University of British Columbia Dermatology Program in 1999, when he moved to Edmonton and started practicing dermatology. He has done a Fellowship at the University of California San Francisco in skin cancer surgery and cosmetic procedures. His practice includes prevention, detection and treatment of skin cancers as well as cosmetic and other procedures. His practice involves the use of all three neuromodulators also referred to as botulinum toxins (Botox, Dysport and Xeomin) and his practice involves the use of neuromodulators in the masseters. He estimates his practice is about 50% cancer surgery and 50% cosmetics. He is a Clinical Professor at the University of Alberta and was the Vice President of the Canadian Dermatology Association until June 2018. He is a Member of the Facility Accreditation Committee of the College.

93. Dr. Sapijaszko prepared a letter in this matter which is at Exhibit 1, pages 107-109. In preparing his letter, he reviewed the letter of complaint, the two replies by Dr. Lycka and Dr. Lycka's chart. It is Dr. Sapijaszko's opinion that Dr. Lycka did not fail to obtain informed consent for the Dysport injections into the masseters. He based that opinion on the fact that when it comes to patient consent, it is not in isolation, it takes into account prior treatments including treatments with the three botulinum toxin products. [redacted] was

familiar with all three products from undergoing prior treatments with Dr. Lycka and other health care practitioners. She had interactions and instructions with non-medical staff and with Dr. Lycka. She had treatments in the past with botulinum toxin for her masseters.

94. Dr. Sapijaszko discussed the team approach in a clinic to informed consent and noted that overall, he is responsible for making sure that the information is provided accurately and all the questions the patients have are answered. He is responsible for teaching his staff to counsel the patient to be familiar with the treatment and alternative treatments, including side effects, potential benefits and risks, contraindications and so on.

95. Dr. Sapijaszko noted that the picture at Exhibit 1, page 18, indicates to him that the proposed Dysport injections would be in the masseters, in the area around the eyes and forehead region. Dr. Sapijaszko indicated that he based his understanding of the matter in part on the note at Exhibit 1, page 30, which he stated was a fairly standard way of charting. He noted it was not unusual to have the consent documented in advance of an actual procedure, as you want the patient to have time to digest the information, go over the pamphlets prior to treatment and then, generally speaking, review the consent closer to the actual treatment. With respect to Exhibit 1, page 24, Dr. Sapijaszko noted that while he is not certain of everyone's different office procedures, there are standard operating procedures triggered by checklists, and in this case, a stamp, which reflected standard operating procedures to him.

96. With respect to the neuromodulator dosages received by [redacted] between June 2011 and August 2015, Dr. Sapijaszko noted that the dosages were not unusual in the practice of dermatology. In his view the dosages were on the low range of the dose spectrum and reflected a conservative approach. Specifically, with respect to the masseters, in Dr. Sapijaszko's opinion the dosage used was in the low range. He noted that he was not concerned with the use of Dysport in the masseters, eye area and forehead at the same time for a total of 240 units of Dysport on March 17 and noted that he routinely would inject more than that. He noted the forehead, crow's feet and masseter doses used on March 17, 2017 were all conservative. He indicated that in general Xeomin and Botox are equivalent in dosing and 3 units of Dysport is equivalent to 1 unit of Xeomin. He noted that the dose equivalent of Xeomin injected by [redacted]s dentist was higher than Dr. Lycka's dose but he was not concerned with the Xeomin dose used by the dentist.

97. With respect to comments made by Dr. Siddiqi in his letter at Exhibit 1, page 98, Dr. Sapijaszko noted that in dermatology, if it comes to neuromodulators, dermatologists try not to be subtherapeutic. He would give a therapeutic dose versus an inadequate dose. He indicated that there is at least a theoretical concern that multiple injections closely spaced apart may lead to development of antibodies. Dr. Sapijaszko also noted that there is no concern from his perspective with respect to a botulinum draining down the face and creating problems. He noted that botulinum toxin type A molecules can diffuse from the original site, and that is programmed into the treatment locations. If they spread, it is negligible. Dr. Sapijaszko noted that generally, his informed consent discussion with a patient does not involve a discussion about dosage. He noted that the only time dosage is discussed is when it comes to cost, so that a patient can budget. He noted that a patient may indicate how much they are willing to spend and then he will determine how that translates for the dosage in terms of sticking to the patient's budget.

98. In cross-examination, Dr. Sapijaszko confirmed that he considered the Standards of Practice of the College in preparing his letter although he did not have the actual Standards of Practice in front of him. He confirmed that he did not see any indication in Dr. Lycka's charts about a discussion of reasonable alternative treatments available. He noted that in his practice, he will tell patients that no treatment is an option and sometimes talk about the fact that surgery is a treatment. There are not really any other alternative treatments. Dr. Sapijaszko stated that he did not have a chance to examine the patient but that it is reasonable to assume that her symptoms were related to the Dysport injections. He agreed that an increase in the dosage of neuromodulators could increase the risk of complications. He also agreed with Dr. Siddiqi's assessment that [redacted] was experiencing symptoms due to her Dysport injections.

99. Dr. Sapijaszko noted that his opinion on informed consent was based on the assumption that the patient did get information about Dysport on February 1, 2017. The patient had received Dysport a year and a half previously and Dr. Sapijaszko noted that his practice would be to ensure the informed consent process is repeated for the patient. His opinion was based on a review of the record and the complaint by the patient but he assumed that the patient was incorrect in her recollections of the informed consent process. With respect to the release given to [redacted] Dr. Sapijaszko noted that this would not be a document that his office would ask a patient to sign.

100. Dr. Sapijaszko reviewed his clinic procedure for a treatment visit. He estimates it is a short visit, between 2-4 minutes.

101. Dr. Sapijaszko indicated that he felt that teeth clenching due to bruxism may represent a medical as opposed to cosmetic indication for neuromodulator injection into the masseters as there are medical reasons to stop teeth clenching and grinding.

102. In response to questions from the Hearing Tribunal, Dr. Sapijaszko indicated that where Botox is being provided to a new area, prior consent would not be adequate. He noted that you would indicate that you are injecting a different area but generally the same types of side effects and risks might apply. If you are talking about different muscles, Dr. Sapijaszko noted that those are injection-specific with respect to consent and that for a new muscle to be injected he would point out specifically what could happen if the specific muscle injected became too weak due to the injection. He indicated that the consent process of botulinum injection involves talking about muscle weakness, bruising, a bit of pain. Regardless of whether you are using Botox, Dysport or Xeomin, the same muscle weakness is part of consent. He noted it would be very unusual for airway muscles to be affected by a masseter injection and he does not counsel patients that they may have difficulty breathing or swallowing. Dr. Sapijaszko noted that he found it very unusual that [redacted] had had difficulty swallowing. He noted that he has administered Botox and Dysport in much larger quantities in the masseters and has never had a patient complaining of difficulty swallowing or decreased sensation.

103. Dr. Sapijaszko explained that 3 sets of factors generally contribute to treatment side effects from neuromodulators: individual patient circumstances such as pre-existing illnesses, dose and location.

104. Dr. Sapijaszko was asked whether his consent process for neuromodulator injections would change if the patient has had one sided ptosis from a previous neuromodulator injection. Dr. Sapijaszko noted that it may change slightly the injection pattern, however, it would not affect the counselling he would do for injections in other areas. Dr. Sapijaszko was asked if he delegates the consent process in his office. He noted they have information on their website, they use cosmetic consultants, he uses a written consent form and asks the patient to initial each statement after having read it. He also comes in and sees the patient before the consent is signed to ensure there is a good indication for the treatment. When he leaves, further discussion happens, the patient is taken into a different room, and at that point the consent is signed. He allows his technicians to obtain written consent.

105. Dr. Sapijaszko was asked to verify if a neuromodulator injection into the masseters for bruxism is a medical or cosmetic intervention. He stated the clinical situation is somewhere between cosmetic and medical. He did confirm however that injections for medical reasons are covered by Alberta Health while cosmetic injections are not. He verified he took the February 1, 2017 chart note indicating [redacted] was seen for a cosmetic consultation for facial options as documentation of a consent discussion for the masseter injections performed March 17, 2017.

106. On re-direct, Dr. Sapijaszko stated that in the community, dentists, nurses, physicians and nurse practitioners all administer botox injections. He was not sure if nurses who administer botox do so under the supervision of a physician or not. The ER record for [redacted] from March 22, 2017 was reviewed (Exhibit 1, page 95). It was pointed out that a note was made that there was no aspiration noted and the discharge diagnosis was neck strain. The physical assessment from Dr. Siddiqi's consult with [redacted] was reviewed and no mention is made of any issue with swallowing.

V. SUBMISSIONS BY THE PARTIES

Submissions on behalf of the Complaints Director

107. Mr. Boyer indicated the roles of the Hearing Tribunal was to make findings, to determine the standard against which the findings are judged and to apply those findings against those standards. He noted that the Standards of Practice dealing with informed consent are Exhibit 1, starting at pages 144 and 146. The Code of Ethics and is at Exhibit 1, page 149 and section 46 applies to the second allegation in this case which states each member would recognize that the self-regulation of the profession is a privilege. Mr. Boyer submitted that section 46 applies to a request made by or on behalf of a member that a patient agree not to complain in exchange for money payment. He stated section 46 applies in this instance because the College's primary duty is protection of the public and ensuring that the Code of Ethics and Standards of Practice are applied and enforced by members of the profession.

108. Mr. Boyer noted that Dr. Sapijaszko's opinion was only an interpretation of the Standards of Practice, which relates to the issue the Hearing Tribunal must ultimately determine, but he did not actually review the applicable College standard in providing his opinion. Mr. Boyer indicated Dr. Sapijaszko's opinion may provide some context, but ultimately the written College Standards of Practice is what the Hearing Tribunal should interpret and apply to the facts of the case.

109. Mr. Boyer noted that the Hearing Tribunal will need to make determinations regarding credibility of the witnesses. With respect to the evidence of Dr. Lycka, Mr. Boyer noted that in his response to the College, Dr. Lycka noted that "I showed her on the consent where she had acknowledged this." Dr. Lycka notes he is enclosing pertinent portions of his chart, but no consent form for the treatment to the masseter muscles is enclosed (for either February 1, 2017 or March 17, 2017). Further, while Dr. Lycka stated that he wrote the words "hypertrophic masseters" on Exhibit 1, page 35 as an aid memoir at the time, [redacted]

indicated that she was not even aware that neuromodulator injections into the masseters were a possible treatment for bruxism until 2016 when she saw her dentist. [redacted]'s dental chart has no reference to teeth clenching or grinding before 2016.

110. Dr. Lycka has a very busy practice, he sees many patients and he relies on his staff. This is consistent with the evidence of [redacted] who described the appointment on March 17, 2017. She noted that Dr. Lycka was about to leave the room when she reminded him about the masseter injections. Dr. Lycka quickly did the injections on the masseters at that point. The chart indicates a February 1, 2017 consultation for cosmetic procedures. Dr. Lycka testified that he does not consider treatment of bruxism as a medical treatment but a cosmetic procedure instead. However Dr. Sapijaszko testified it is not wholly cosmetic. Mr. Boyer noted that [redacted]s evidence should be preferred over the evidence of Dr. Lycka.

111. Mr. Boyer indicated Dr. Lycka has such a busy practice there are signs that details get missed. He did not include the photographs of [redacted] when he submitted what he described as pertinent portions of her chart to the College in response to the complaint. Billings were mistakenly made to Alberta Health in relation to the cosmetic procedures done on [redacted] Despite a clinic protocol where patients are to receive a pamphlet for every procedure they undergo, [redacted] testified she did not receive the relevant Dysport pamphlet prior to her procedure on March 17, 2017. A nurse would have routinely done and documented the initial consent discussion for the Dysport masseter injection on [redacted] but there is no chart documentation of this. There is no documentation in the referral to Dr. Stewart of the Dysport dose used and Dr. Lycka testified he relayed the dose to Dr. Stewart over the phone. Both Drs. Siddiqi and Sapijaszko testified there are treatment options available for bruxism including a mouthguard, medications and potentially surgery, but there is no documentation that these or any other options were presented to [redacted] Mr. Boyer indicated there is a pattern of a busy practice. However the Standard of Practice is that the medical record should clearly show the details of the treatment and care of a patient. If it is not documented, then it should be assumed that it did not happen.

112. Mr. Boyer noted that there was also a disagreement on the pamphlets that were given to [redacted] and noted there is also a missing consent for treatment on June 15, 2012. Mr. Boyer also reviewed the evidence provided by Dr. Siddiqi and Dr. Sapijaszko who had differing opinions on what was an appropriate dosing approach to Dysport. He suggested that Dr. Sapijaszko did not provide wholly objective testimony and opinion as he made a number of assumptions in favor of Dr. Lycka and at times did not give any weight to [redacted]s perspective of the events.

113. Mr. Boyer submitted that the evidence was more than sufficient on a balance of probabilities to prove both allegations and that the Hearing Tribunal should make a finding of unprofessional conduct on both charges. There is no record of informed consent on [redacted]s chart. Despite the business of his practice, Mr. Boyer submitted the responsibility still rests with Dr. Lycka with respect to his staff presenting the Release letter to [redacted] He submitted [redacted]s version of events is the version that is most consistent and best fits.

Submissions on behalf of Dr. Lycka

114. Mr. Heelan noted that the burden of proof rests on the Complaints Director to prove the allegations on a balance of probabilities. Mr. Heelan noted the case was about two issues. The first issue relates to informed consent and whether there was informed consent, whether it was documented and whether there needed to be a discussion about the increased dosage of Dysport. The second issue relates to whether Dr. Lycka is guilty of unprofessional conduct in the circumstances of this case which led to the letter being presented to [redacted]

115. Mr. Heelan cautioned the Hearing Tribunal regarding matters that arose in the hearing but that are not related to the two issues before the Hearing Tribunal. Mr. Heelan took the position that the charges were not proven on a balance of probabilities.

116. Mr. Heelan reviewed the evidence given by [redacted] that she had received a pamphlet, read and signed the consent forms in June 2011, June 2012, July 2014 and August 2015. She signed a consent form regarding the use of Dysport. She acknowledged reading and signing on two occasions the forms which noted the risks associated with the treatment, including swelling, bruising and that an adjacent muscle may be weakened and that alternatives for treatment had been discussed. She had had a droopy eye from a previous treatment and had informed consent discussions with her dentist about injections in the masseters.

117. Mr. Heelan indicated that Dr. Sapijaszko testified that surgery is not really done any more for bruxism and that medications are not used for bruxism. Therefore the only realistic options available are neuromodulator injections, a mouthguard (which was not satisfactory for [redacted] or nothing.

118. Mr. Heelan reviewed the chart note dictated by Dr. Lycka (Exhibit 1, page 30), which he noted was shorthand for doctors noting that informed consent had been obtained. He noted that the documentation of informed consent in Exhibit 1, page 30 was clear, convincing and compelling. Mr. Heelan noted that both Dr. Lycka and Ms. McCalla confirmed the pamphlet found in Exhibit 1 would have been the one given to [redacted]

119. Mr. Heelan stated that it is unfortunate that there was no consent form signed for that day, but that the lack of a consent form is not evidence of a breach of the Informed Consent Standard of Practice. He stated that it is good practice to obtain informed consent on February 1, 2017, weeks before the treatment date as it allows the patient to think about it. Mr. Heelan reviewed the Informed Consent Standard of Practice at Exhibit 1, page 144. Mr. Heelan noted that there was no evidence that the dosage of Dysport should have been discussed with [redacted] He also noted the evidence of Dr. Sapijaszko that the dosage given was conservative. He pointed out that [redacted] did acknowledge that Dysport was discussed on February 1. He pointed out the large staff in Dr. Lycka's clinic and established protocols

for informed consent would have ensured that [redacted] provided informed consent for the masseter injections. He submitted that [redacted] herself knew a great deal about Dysport and its potential side effects from her internet research and previous injection experiences which included some side effects such as ptosis. He argued that [redacted] had a thorough understanding of the risks of Dysport prior to her masseter injections and thus had informed consent.

120. With respect to Allegation 2, Mr. Heelan noted that Dr. Lycka agrees the letter is unfortunate and regrettable. Mr. Heelan noted that there was no active action by Dr. Lycka to put the letter in front of [redacted] Dr. Lycka told his staff to prepare a boilerplate letter and to review guidelines of the College, but no guidelines exist. Mr. Heelan acknowledged that there is no doubt that Dr. Lycka is the captain of the ship but noted that his conduct does not amount to unprofessional conduct in relation to the release. Mr. Heelan also noted that Dr. Lycka's failure to contact [redacted] after the release was given to her does not constitute unprofessional conduct. Her complaint was made to the College shortly after March 23, 2017 and there was nothing for Dr. Lycka to follow up on with [redacted] after the release was given to her or after her complaint was made.

VI. DECISION OF THE HEARING TRIBUNAL ON THE ALLEGATIONS

121. The Hearing Tribunal has reviewed and considered the evidence and the submissions of the parties. The Hearing Tribunal finds Allegations 1 (a) and (b) proven and that the conduct constitutes unprofessional conduct. The Hearing Tribunal finds that Allegation 1(c) is not proven. The Hearing Tribunal finds that Allegation 2 is proven and that the conduct constitutes unprofessional conduct. The Hearing Tribunal's findings and reasons are set out below.

VII. FINDINGS AND REASONS

Allegation 1

122. Allegation 1 is that Dr. Lycka displayed a lack of skill or judgment in the provision of professional services to his patient, [redacted] particulars of which include one or more of the following:

    a. he did fail to have an informed consent discussion with his patient regarding the use of Dysport for the treatment of bruxism;
    b. he did fail to create a record of the informed consent of his patient, [redacted] before proceeding with the injection of Dysport for the treatment of bruxism on March 17, 2017;
    c. he did fail to discuss with his patient the option of proceeding with a lower dosage of Dysport for treatment of bruxism on March 17, 2017 as compared to his plan to use 60 units of Dysport on each side of her face for the treatment of bruxism.

123. The Hearing Tribunal has carefully reviewed and considered the evidence, including the testimony of the witnesses and the exhibits presented and the submissions of the parties.

124. The Hearing Tribunal heard testimony that the consent process does not occur in isolation and that it is a continuum that takes into account previous similar procedures performed

and previous experiences with a type of therapeutic agent. In this instance, [redacted] had undergone previous Botox and Dysport injections with Dr. Lycka in her forehead and eye area. She had also undergone previous injections into her masseters but performed by a different practitioner (her dentist) with a different neuromodulator (Xeomin). The Hearing Tribunal finds that regulated members cannot assume appropriate informed consent is obtained based only on previous similar interventions with the same practitioner for different anatomic areas or the same intervention but with a different practitioner.

125. In addition, the Hearing Tribunal finds that informed consent can be an ongoing process, but that it must occur in a relatively close timeframe to the date of treatment. The consent obtained in 2011, 2012 and 2015 would not meet the requirements of informed consent for a procedure in March 2017. As such, the Hearing Tribunal focused on the appointments of February 1 and March 17, 2017 in considering the evidence.

126. [redacted] gave evidence that she had received Botox and Dysport injections from Dr. Lycka previously around her eyes and forehead area. [redacted]s evidence is that on February 1, 2017, she inquired about injections to her masseter muscles in addition to the eye area and forehead. She had previously had Xeomin injections in the masseter muscles with her dentist. Dr. Lycka spent a few minutes with her at that clinic visit, and in their discussion, he agreed that her masseter muscles were large and very strong. [redacted] does not recall seeing the document at Exhibit 1, page 18, although she recalls the price list being told to her verbally. She did not recall being given the pamphlet at Exhibit 1, pages 121–125, but rather recalled a pamphlet that had before and after treatment photos. [redacted] does not recall a discussion about the risks of Dysport in the masseter muscles on February 1 or March 17, 2017. She next attended at Dr. Lycka's clinic on March 17, 2017 for a Hydrafacial and Dysport injections. [redacted]s evidence was that on March 17, Dr. Lycka did the injections in the eye area and forehead but she needed to remind him about the injections to the masseters.

127. In considering the evidence of [redacted] the Hearing Tribunal found her evidence consistent during questioning and consistent with her written complaint (Exhibit 1, page 6). Although there were some things she did not remember from earlier appointments, the Hearing Tribunal found that this may happen with the passage of time. The Hearing Tribunal found [redacted] to be a credible witness and accepted her evidence with respect to the events during the appointments of February 1 and March 17, 2017.

128. With respect to the evidence of Ms. McCalla, the Hearing Tribunal accepted her evidence that the clinic cosmetic technician has discussions with the patient regarding Hydrafacials, but that it is the nurse who will discuss neuromodulator injections with the patient. Dr. Lycka and Ms. McCalla gave evidence about the informed consent process in the office, including that a nurse will give the patient a relevant pamphlet at each appointment where a neuromodulator will be injected and that there is a discussion about the pamphlet with the patient. Neither Dr. Lycka nor Ms. McCalla were in the room when the technician or nurse discussed the process with [redacted] on February 1 or March 17, 2017.

129. The Hearing Tribunal also reviewed the documents relevant to February 1 and March 17, 2017. In particular, the Hearing Tribunal reviewed the Patient Profile and Consultation of February 1, 2017 (Exhibit 1, pages 17 and 18), the handwritten chart entries (Exhibit 1, pages 23 and 24), and the dictated Chart Note from Dr. Lycka (Exhibit 1, page 30).

130. The Hearing Tribunal notes that Exhibit 1, page 18 notes that "procedure discussed" and "pamphlet given". However, for "procedure discussed", the word "nurse" is crossed out and the word "tech" written over top. The Hearing Tribunal accepted evidence that a cosmetic technician in Dr. Lycka's clinic would discuss the Hydrafacial, but that a nurse would discuss the neuromodulator injections. In reviewing this document, the Hearing Tribunal finds that there is no indication that a nurse also discussed a procedure with [redacted] or that a second pamphlet was given.

131. In addition, the handwritten chart entry (Exhibit 1, page 23) makes no mention of a discussion regarding risks and benefits of treatment or alternatives to the treatment with respect to the Dysport injections. The notes mention the Hydrafacial treatment that [redacted] was receiving on February 1, 2017 along with the fact that she will come back for Dysport. There is no indication in the handwritten notes that there was an informed consent discussion regarding Dysport generally, and no discussion regarding an injection in a new muscle, the masseter.

132. There is similarly no indication of an informed consent discussion in the handwritten note for March 17, 2017 (Exhibit 1, page 24). The Hearing Tribunal notes that the handwritten notes on other occasions do make note of consent being done (Exhibit 1, pages 19, 21 and 22). The lack of notes regarding consent on February 1 and March 17, 2017 are consistent with the evidence of [redacted]

133. Dr. Lycka's chart note for February 1, 2017 (Exhibit 1, page 30) indicates: "Patient was seen for cosmetic consultation for facial options. Dysport, Microneedling, PRP and Hydrafacial discussed. The risks, benefits, expectations and pricing have been discussed with the patient. She seems to understand this well." Dr. Lycka takes the position that this note is itself proof of informed consent.

134. The Hearing Tribunal recognizes that the Standard of Practice does not require every single verbatim detail of a consent discussion to be documented but in this instance there are no direct references at all in [redacted]s chart of Dysport injections into the masseters. Dr. Lycka's dictated chart note on Exhibit 1, page 30 does document a consent discussion that took place at the February 1 clinic visit, but the Dysport injections into the masseters was a procedure he had never done on [redacted] The Hearing Tribunal heard expert testimony that the language of this chart note was fairly standard shorthand for the type of practice Dr. Lycka has. The Hearing Tribunal accepted this type of shorthand note would be sufficient documentation of a new consent for a repeat of a procedure performed in the past by the same practitioner but felt that in this instance, a consent discussion note should have specifically indicated that there was an additional new procedure in a new anatomic site that Dr. Lycka had never injected before for the patient. The Hearing Tribunal finds that this Chart note is not in itself sufficient evidence of informed consent for the injections to the masseter muscles with Dysport done on March 17, 2017.

135. The Hearing Tribunal heard an argument that the masseters were marked off on the Patient Profile and Consultation form from the February 1, 2017 clinic visit (Exhibit 1, page 18) and that this indicates a discussion of the masseter injections was undertaken at that visit. However the Hearing Tribunal felt that marking a diagram is not sufficient documentation of a proper informed consent discussion as it only suggests a therapeutic intention.

136. There are no written records to confirm that an informed consent discussion took place on March 17, 2017. The Hearing Tribunal finds that on February 1, 2017, there was a limited discussion regarding injections to the masseters but that such discussion was not sufficient to meet the requirements of informed consent. The "Patient Profile and Consultation" form from [redacted]s February 1, 2017 visit to Dr. Lycka does not indicate any adequate discussion about neuromodulator injections into the masseters. In the "Patient Teaching" section, it is indicated that the procedure was discussed and pamphlet information was provided but "nurse" is crossed out and replaced with "tech". This would indicate that the Hydrafacial procedure was discussed but not neuromodulator injections, according to the testimony accepted from Ms. McCalla regarding the delegation of duties within the clinic with respect to which clinic staff does the discussion with a patient depending on the procedure being considered. This point is also consistent with [redacted]s testimony that she has no recollection of any discussion regarding the risks of neuromodulator injections into her masseters having been held that day.

137. The Hearing Tribunal finds that it is not sufficient that [redacted] had prior knowledge regarding injections with neuromodulators, or that she had a prior ptosis, or prior injection in the masseters with her dentist. Where a new site is being injected, a physician is responsible to ensure a new informed consent process is completed. Similarly where a significant period of time has passed since the last injection, the physician cannot rely on the prior informed consent process as being valid and applicable to the current clinical scenario.

138. With respect to the handwritten note "hypertrophic masseters" on the Dysport Injection Informed Consent form signed on July 2014 and August 6, 2015, Dr. Lycka noted that he made this entry as an aid memoir at the August 2015 appointment to remind him to discuss masseter injections at a later date. [redacted] denied that the note was there when she signed the form in July 2014 or August 2015. [redacted]s evidence was that she was not aware that neuromodulators could be used for bruxism until 2016. The Hearing Tribunal prefers the evidence of [redacted] on this point and felt Dr. Lycka's testimony to this point undermined his credibility. The Hearing Tribunal finds that in 2014 or 2015, there was no discussion of the masseters and that this note did not exist on the form when [redacted] signed the document. There is no evidence that [redacted] saw this document again on February 1 or March 17, 2017. As such, the Hearing Tribunal rejects the suggestion that the handwritten note "hypertrophic masseters" on Exhibit 1, page 30 is an indication of an informed consent discussion occurring on February 1 or March 17, 2017.

139. The Hearing Tribunal accepts that Dr. Lycka has a busy practice and delegates certain duties to his staff. However, the responsibility to ensure informed consent remains with him. It is possible for a physician to use a team approach to consent and to obtain informed consent in advance of a procedure, so long as that informed consent is confirmed at the time of the procedure. As such, Dr. Lycka could have obtained informed consent on February 1, 2017 and confirmed it on March 17, 2017. His practice is to obtain a signed

consent on the date of the procedure. In this case, the Hearing Tribunal is left with the absence of a signed consent form, or notes from the nurse regarding any consent being obtained on February 1 or March 17, 2017. The Hearing Tribunal must weigh the conflicting evidence of [redacted] and Dr. Lycka. As noted above, the Hearing Tribunal accepts the evidence of [redacted] and finds that it is consistent with the documents at Exhibit 1, pages 18, 23 and 24.

140. The Hearing Tribunal heard evidence that Dr. Lycka's clinic has well-documented protocols and procedures including a protocol of obtaining informed consent. Specific allied health professionals will perform and document the consent discussion with a patient depending on the type of procedure being considered. Dr. Lycka confirms proper documentation at the end of each day with a signed stamp on the chart. Consent is obtained not only for procedures but also for pre-procedural photos taken of the patient. Relevant informational pamphlets are given to the patient every time they have a procedure done even if they had had it done in the past. At the time of the procedure, Dr. Lycka reviews the chart to ensure all proper consent for the specific procedure is documented before proceeding. The Hearing Tribunal accepted these clinic policies and procedures as being thorough and appropriate. However somehow for the masseter injections performed on [redacted] on March 17, 2017, the normal consent process in Dr. Lycka's clinic broke down resulting in inadequate documentation of a proper consent discussion and what the Hearing Tribunal finds was inadequate consent discussion for the specific procedure. The testimony the Hearing Tribunal accepted from [redacted] also indicated that at the March 17, 2017 clinic interaction, [redacted] had to remind Dr. Lycka to perform the masseter injections as he was exiting the procedure room and that he seemed unaware that he was to perform the masseter injections.

141. The Informed Consent Standard of Practice, at Exhibit 1, page 144 provides that the patient must receive a proper explanation that includes but is not limited to:

a. Diagnosis reached;

b. Advised interventions and treatments;

c. Exact nature and anticipated benefits of the proposed examination, assessment, treatment or procedure;

d. Common risks and significant risks;

e. Reasonable alternative treatments available, and the associated common risks and significant risks; and

f. Natural history of the condition and the consequences of forgoing treatment.

142. In this case, a diagnosis was reached, regarding the masseters and [redacted] was expecting treatment. However, the Hearing Tribunal finds that [redacted] was not advised of the exact nature and anticipated benefits of the proposed treatment or the common risks and significant risks. There is no evidence that Dr. Lycka discussed alternatives to treatment, such as continuing with her dentist, a nightguard or the option to do nothing. The area for injection was new, as it related to Dr. Lycka. It involved different muscles with its own

unique anatomy. Dr. Lycka was required to ensure he obtained informed consent from [redacted] as it relates to this unique clinical scenario.

143. While a pamphlet can form part of the informed consent process, it does not replace the discussion that must occur with the patient. Alone, a pamphlet does not demonstrate that a patient understands the various components necessary to obtain informed consent.

144. The Hearing Tribunal finds that Allegation 1(a) is proven and that such conduct is a breach of the Standard of Practice for Informed Consent.

145. With respect to Allegation 1(b), there is no documented evidence of informed consent for the Dysport injections on March 17, 2017. The Standard of Practice for Patient Record Content (Exhibit 1, page 146) provides that the physician "must ensure the patient record contains information pertaining to the consent process".

146. The usual practice in many clinics and in Dr. Lycka's practice is to have the patient sign a Consent Form. Such consent form is not present here for the treatment administered on March 17, 2017. In addition, in reviewing the records for February 1 and March 17, as reviewed above, no other documented information exists except the dictated Chart Note for February 1, 2017 (Exhibit 1, page 30) that an informed consent discussion took place.

147. For the reasons noted above, the Hearing Tribunal finds that, in reviewing the entire circumstances of the case, the February 1, 2017 Chart Note dictated by Dr. Lycka is not sufficient evidence of informed consent for the masseter injections he performed on [redacted] and as such, does not constitute a record of the informed consent of [redacted] before proceeding with the injection of Dysport for the treatment of bruxism on March 17, 2017.

148. The Hearing Tribunal finds that Allegation 1(b) is proven.

149. With respect to Allegation 1(c), the Hearing Tribunal finds that this allegation is not proven. The evidence is that Dr. Lycka did not discuss the dose with [redacted] However, the evidence did not establish an obligation on Dr. Lycka to discuss with [redacted] the dosage to be used or the option of proceeding with a lower dosage of Dysport for treatment of bruxism on March 17, 2017.

150. The Hearing Tribunal finds that the dose used was not excessive or outside of the accepted dose range used for this muscle and that the dose amount is not generally part of the informed consent discussion. In reaching this conclusion, the Hearing Tribunal considered the Article entered into evidence as Exhibit 6, the testimony of Dr. Sapijaszko, the fact that the dentist provided a similar or higher dose, and the concept that the dosage used is part of clinical judgment so long as it is within an appropriate range. The Hearing Tribunal accepts that Dr. Lycka is a long-time professional who is very experienced in the use of neuromodulator injections for cosmetic indications and appropriately exercised his professional judgment in this case. There was no obligation on Dr. Lycka to discuss the option of proceeding with a lower dosage of Dysport for treatment of bruxism on March 17, 2017 and as such, there is no finding on Allegation 1(c).

151. The Hearing Tribunal finds that the conduct with respect to Allegation 1(a) and (b) constitutes unprofessional conduct. The HPA defines unprofessional conduct to include a

breach of the Standards of Practice. The Hearing Tribunal finds that the failure to obtain and document informed consent breaches the Informed Consent Standard of Practice and the Patient Record Content Standard of Practice.

152. Informed consent is a core principle in the practice of medicine. Physicians must recognize and respect the patient's right to make informed decisions regarding their health and treatments or procedures to be performed.

153. Having a busy practice or a process whereby part of the consent discussion is delegated to members of the team are not acceptable excuses for lack of an informed consent discussion or documentation. The physician retains ultimate responsibility to ensure the informed consent process is adequately obtained and appropriately documented. The Hearing Tribunal does recognize and accept that it cannot be expected that a physician document every last detail of the informed consent process for every single intervention discussed with every one of their patients, but in this case, the documentation of the informed consent process for the March 17, 2017 masseter injections was non-existent. Further, the Hearing Tribunal accepted the evidence from [redacted] that there was insufficient discussions between her and Dr. Lycka and his qualified staff to consider [redacted] to have been fully informed of this intervention.

154. The Hearing Tribunal recognizes that there is a distinction between "cosmetic" versus "medical" interventions in Dr. Lycka's practice for the purposes of billing and delegation of clinical discussions and duties to various staff members in the clinic. However, where Dr. Lycka is the practitioner performing invasive procedures on patients, the responsibility to obtain and properly document informed consent for said procedures ultimately rests with him. If a fulsome consent discussion were undertaken for the masseter injections it may not have changed [redacted]s decision to proceed with the procedure or the eventuality of her experiencing treatment-related side effects but it may have changed her experience and interpretation of the side effects when they occurred. The Hearing Tribunal feels that it ultimately falls on Dr. Lycka to ensure proper execution and documentation of the informed consent process for every procedure he performs as it is part of the fiduciary duty a physician has to a patient to ensure safe and competent care and a complete and accurate medical record of care.

Allegation 2

155. Allegation 2 is that Dr. Lycka did request his patient, [redacted] to sign a letter dated March 23, 2017 that provided for a refund of the monies paid for her Dysport injections into her masseters on March 17, 2017 in exchange for her agreeing to not make a complaint to the College of Physicians and Surgeons of Alberta.

156. There is no dispute that the letter at Exhibit 1, page 8 was presented to the patient. The Hearing Tribunal considered the response letter of Dr. Lycka to the College dated July 18, 2017 (Exhibit 1, pages 9 and 10) in which Dr. Lycka states: "She requested her money back and I requested her to sign a release before receiving it. I did this without the benefit of legal counsel. It is now my understanding that a release which purports to stop a Complaint to the College is inappropriate but I was unaware of this at the time and I am very sorry that this happened."

157. However, at the hearing, Dr. Lycka took the position that he had no knowledge of the letter. The Hearing Tribunal felt this discrepancy in Dr. Lycka's explanation surrounding the details of the letter negatively impacted Dr. Lycka's credibility. The Hearing Tribunal accepts Dr. Lycka's statement as set out in his letter to the College of July 18, 2017. The letter was written closer in time to the date of the events. The Hearing Tribunal finds that it is more likely than not that Dr. Lycka knew what was in the letter before it was presented to [redacted]

158. Whether or not Dr. Lycka had knowledge of the letter, he is responsible for the correspondence from his office. The letter of March 23, 2017 is trying to compel [redacted] not to complain to the College. Dr. Lycka can delegate certain responsibilities to his staff, but he remains responsible for the actions of his staff to the extent that they involve his ethical duties.

159. Dr. Lycka's conduct in this regard undermines the ability of the College to self-regulate. A regulated member cannot compel a patient to give up the right to complain to a regulatory body. The Hearing Tribunal finds that the conduct is a breach of the Code of Ethics. The Code of Ethics provides at section 46: "Recognize that the self-regulation of the profession is a privilege and that each physician has a continuing responsibility to merit this privilege and to support its institutions".

160. The Release breaches the recognition of self-regulation by attempting to thwart a patient's right to complain. It strikes at the heart of the concept of self-regulation. Such actions would serve to release a regulated member from acting within the ethical bounds of his/ her profession and completely disrupt the fiduciary duty a regulated member has to his patients. This undermining of the ability of a regulatory body to self-regulate potentially would enable a regulated member to act only to serve themselves.

VIII. CONCLUSION

161. As a result of the Hearing Tribunal's findings of unprofessional conduct against Dr. Lycka, the Hearing Tribunal will need to determine what, if any, orders it will make pursuant to section 82 of the HPA.

162. The Hearing Tribunal will receive submissions on penalty from the parties. The Hearing Tribunal requests that the parties discuss the timing and method of providing submissions on penalty to the Hearing Tribunal. If the parties are unable to agree on a proposed procedure and timing, the Hearing Tribunal will make further directions on this point.

Signed on behalf of the Hearing Tribunal by the Chair this 17th day of January, 2019.

Dr. Don Yee

IN THE MATTER OF A HEARING UNDER THE *HEALTH PROFESSIONS ACT*,
R.S.A. 2000, c. H-7

AND IN THE MATTER OF AN INVESTIGATION
INTO A COMPLAINT AGAINST
DR. BARRY LYCKA, A REGULATED MEMBER
OF THE COLLEGE OF PHYSICIANS AND SURGEONS OF ALBERTA

DECISION OF THE HEARING TRIBUNAL OF THE COLLEGE OF PHYSICIANS AND SURGEONS OF ALBERTA ON SANCTION

I. INTRODUCTION

1. The Hearing Tribunal held a conference call to consider the matter of sanction in the hearing involving Dr. Barry Lycka, a regulated member of the College of Physicians and Surgeons of Alberta ("the College") on February 25, 2020.

2. In attendance were:

Members of the Hearing Tribunal:

Dr. Don Yee, Chair
Dr. John Pasternak, member
Ms. Georgeann Wilkin, public member

Also in attendance was:

Ms. Julie Gagnon, independent legal counsel for the Hearing Tribunal

II. BACKGROUND

3. The hearing on the allegations was held on October 29 and 30, 2018. The Hearing Tribunal issued its decision on January 17, 2019. The Hearing Tribunal found Dr. Lycka guilty of unprofessional conduct on allegations 1(a) and (b) and 2, which stated:

> 1. You did display a lack of skill or judgment in the provision of professional services to your patient, [redacted] particulars of which include one or more of the following:
>   (a) you did fail to have an informed consent discussion with your patient regarding the use of Dysport for the treatment of bruxism;
>   (b) you did fail to create a record of the informed consent of your patient, [redacted] before proceeding with the injection of Dysport for the treatment of bruxism on March 17, 2017;
> 2. You did request your patient, [redacted] to sign a letter dated March 23, 2017 that provided for a refund of the monies paid by her to you for her Dysport injections on March 17, 2017 in exchange for her agreeing to not make a complaint to the College of Physicians and Surgeons of Alberta.

4. The Hearing Tribunal dismissed allegation 1(c), which stated:

> 1. You did display a lack of skill or judgment in the provision of professional services to your patient, [redacted] particulars of which include one or more of the following:
>   (c) you did fail to discuss with your patient the option of proceeding with a lower dosage of Dysport for treatment of bruxism on March 17, 2017 as compared to your plan to use 60 units of Dysport on each side of her face for the treatment of bruxism;

III. DOCUMENTS PROVIDED TO THE HEARING TRIBUNAL

5. With respect to sanction, the parties agreed to proceed by way of a joint submission on sanction and written submissions.

6. the following documents were provided to the Hearing Tribunal by agreement of the parties:

   a. Joint Submissions Agreement dated January 29, 2020, signed by Mr. Heelan, counsel for Dr. Lycka and Mr. Boyer, counsel for the Complaints Director;

   b. Sanction Exhibit Book containing:

      Exhibit 9: Summary of Relevant Complaints and Discipline Findings against Dr. Lycka;
      Exhibit 10: Findings of Investigating Committee and Order of Council – June 2000
      Exhibit 11: Findings of Investigating Committee and Order of Council – November 2000
      Exhibit 12: Undertaking signed by Dr. Lycka on July 15, 2005; and

   c. Brief of Law regarding Joint Submissions.

7. Counsel for the Complaints Director provided an email dated January 31, 2020 setting out the position of the Complaints Director on costs of the investigation and hearing. The following were provided:

   a. Summary of CPSA decisions where full costs ordered;
   b. *Dr. Adams*, 2013 CanLii 14723;
   c. *Dr. Barr*, 2019 CanLii 73594;
   d. *Dr. Sendziak*, 2012 CanLii 9798;
   e. *Dr. Makis*, 2018 CanLii 12723;
   f. *Dr. Goldstruck*, 2011 CanLii 21685;
   g. *Dr. Metcalfe*, 2015 CanLii 103208.

8. Counsel for Dr. Lycka provided written submissions dated February 13, 2020, enclosing the following:

   a. *Pankiw* v. *Chriopractors' Assn (Saskatchewan*), 2009 SKQB 268;
   b. *Jaswal* v. *Newfoundland (Medical Board*), 42 Admin LR (2d) 233, 1996 CarswellNfld;
   c. *Visconti* v. *College of Physicians and Surgeons (Alberta*), 2010 ABCA 250;
   d. *Milne (Re)*, 2017 CanLii 47675 (BC CPS);
   e. *Wachtler (Re*), 2009 CanLii 32656 (AB CPSDC);
   f. *Jusli (Re)*, 2013 CanLii 51859 (AB CPSDC).

IV. SUBMISSIONS BY THE PARTIES

Joint Submission Agreement

9. The parties jointly submit that the following sanction is appropriate:

   a. Dr. Lycka shall receive a reprimand;

   b. In the event that Dr. Lycka were found by the Physician Health and Monitoring Program of the College to be sufficiently fit to return to practice, that he shall then be required to serve a suspension of his practice permit for a period of two months to start on a date determined by the Complaints Director; and

   c. Dr. Lycka shall pay costs of the investigation and the hearing as determined by the Hearing Tribunal and then paid by a date set by the Complaints Director.

10. The Joint Submission Agreement notes that Dr. Lycka has a history of prior complaints and discipline findings against him that are relevant to determination of sanction in this matter (and which are described in Exhibits 9 to 12).

11. Dr. Lycka has currently withdrawn from practice.

12. The Brief of Law regarding Joint Submissions outlines that deference should be given to a joint recommendation on sanction and that the Hearing Tribunal should not reject a Joint submission unless it is unfit or unreasonable. As noted by the Court in *Pankiw* v. *Chiropractors' Assn (Saskatchewan)*, 2009 SKQB 268, at para. 34:

> Joint submissions are to be encouraged, not ignored. If joint submissions are ignored, plea bargains such as occurred here will be much less likely to occur. Lengthy discipline hearings and increased costs to be borne initially by members of the profession and perhaps ultimately by the public they serve will result. Joint submissions are in the public interest and should be followed by administrative tribunals in the same fashion as is done by the Courts unless it can be clearly demonstrated they are unfit, unreasonable or contrary to the public interest

Submissions on behalf of the Complaints Director on Costs

13. With respect to costs, counsel for the Complaints Director notes that Dr. Lycka has previously been ordered by the Council in June 2000 to pay full costs of the investigation and hearing. The following are also noted: the prior discipline history of Dr. Lycka; the gravity of the findings of the Hearing Tribunal (failure to obtain informed consent and asking the patient to agree to not make a complaint to the College); Dr. Lycka is a senior and well-experienced physician; and he has been found guilty of serious unprofessional conduct.

14. Counsel for the Complaints Director takes the position that Dr. Lycka should be responsible for the full costs of the proceedings and provides decisions in support of the position that full costs should be ordered in this case.

Submissions on behalf of Dr. Lycka on Costs

15. Counsel for Dr. Lycka takes the position that it is appropriate that Dr. Lycka be required to pay 2/3 of the costs of the investigation and hearing. Counsel for Dr. Lycka submits that allegations 1(a) and (b) were essentially one allegation involving informed consent and that therefore Dr. Lycka was successful in having one out of three charges dismissed. Given that one of the three contested allegations was dismissed, payment of 2/3 of the cost of the investigation and hearing is reasonable.

16. Counsel for Dr. Lycka notes that considerable time was spent at the hearing on the dosage issue (the allegation that was dismissed) which included expert evidence. He notes that this approach has been followed by Council in prior cases. Further, it is noted that Dr. Lycka was cooperative throughout the entirety of the investigation and hearing process as demonstrated by his willingness to resolve the matter on sanction consensually. Given that the College was not successful in proving 1/3 of the allegations against Dr. Lycka, it is fair that Dr. Lycka not be asked to pay for this proportion of the associated costs.

V. DECISION OF THE HEARING TRIBUNAL ON SANCTION

17. The Hearing Tribunal has carefully considered the joint submissions, exhibits and written submissions of the parties. The Hearing Tribunal finds that the joint submission is reasonable and protects the public interest. The Hearing Tribunal accepts the joint recommended sanction. The Hearing Tribunal orders Dr. Lycka to pay 85% of the costs of the investigation and hearing.

VI. FINDINGS AND REASONS

18. The Hearing Tribunal considered the joint submission of the parties. A reprimand is a serious sanction and is appropriate in this case. A two month suspension is also warranted. While Dr. Lycka is not currently practicing, should he return to practice, it is appropriate that a two month suspension be served. The suspension is appropriate given Dr. Lycka's prior discipline history. Dr. Lycka is an experienced member of the profession. He is expected to understand the requirements of obtaining informed consent. In addition, he is expected to understand that it is not appropriate to attempt to get a patient to agree not to complain to the College.

19. The Hearing Tribunal considered the factors in *Jaswal* v. *Newfoundland (Medical Board).* These include the nature and gravity of the proven allegations, the age and experience of the offending physician, the previous character of the physician and in particular the presence or absence of any prior complaints or convictions, the impact on the offended patient, the number of times the offence was proven to have occurred, the role of the physician in acknowledging what had occurred, whether the physician has already suffered other serious financial or other penalties, and the presence or absence of any mitigating circumstances. The proposed sanction is appropriate having consideration to the factors.

20. In addition, the proposed sanction will also serve the need to promote specific and general deterrence, the need to maintain the public's confidence in the integrity of the medical professional, and is within the range of sentences in other similar cases. Having regard to the factors in *Jaswal* and the deference to be given to a joint submission on sanction, the Hearing Tribunal finds that joint recommended sanction is reasonable.

21. The Hearing Tribunal considered the issue of costs. It is reasonable and appropriate for Dr. Lycka to bear a portion of the costs of the investigation and hearing in this case. The Complaints Director was successful in proving 3 out of 4 allegations put forward in the hearing. The Hearing Tribunal finds that the allegations that were proven were the more serious allegations in this matter. The Hearing Tribunal does recognize that a portion of time of the hearing was spent on providing evidence for allegation 1(c) which was dismissed. This is recognized in the costs order of 85%. Further, although Dr. Lycka did cooperate in the sanction phase, time and expense was required to prove the allegations in the hearing.

22. The Hearing Tribunal finds that 85% of costs is appropriate in this case.

VII. ORDER OF THE HEARING TRIBUNAL

23. The Hearing Tribunal orders as follows:

    a. Dr. Lycka shall receive a reprimand;

    b. In the event that Dr. Lycka is found by the Physician Health and Monitoring Program of the College to be sufficiently fit to return to practice, he shall serve a suspension of his practice permit for a period of two months, to start on a date determined by the Complaints Director; and

    c. Dr. Lycka shall pay 85% of the costs of the investigation and the hearing, to be paid by a date set by the Complaints Director.

Signed on behalf of the Hearing Tribunal by the Chair this 28 day of February, 2020.

Dated: February 28, 2020

Dr. Don Yee