COLLEGE OF
NATUROPATHIC PHYSICIANS
OF BRITISH COLUMBIA

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Public Notification

Dr. Allan Strauss, ND

Date of action: October 2015

Description of action taken:

The Inquiry Committee of the College of Naturopathic Physicians of British Columbia (the "College") has entered into a Consent Order with Dr. Allan Strauss, ("the Registrant"), license # 524, under sections 33(6) and 36(1)(b), (c), and (d) of the *Health Professions Act,* RSBC 1996, c 183 (the "*Act*"), on the following terms:

1) The Registrant admitted and undertook not to repeat the conduct of:

    a. failing to meet the standard of care in his treatment of patients, including by
        i. administering counterfeit medical devices and/or substances to patients; and
        ii. failing to exercise reasonable care and diligence in notifying patients who might be adversely affected by treatment with a non-sterile, counterfeit, injectible product labelled "Juvederm"(the "Product"); and
    b. teaching a course and/or practicing in a treatment modality outside of his scope of practice.

2) The Registrant consented to the suspension of his practice of naturopathic medicine and undertakes not to engage in the practice of naturopathic medicine for a period of seven (7) days from October 18 to October 25, 2015.

3) The Registrant consented and undertook to pay a fine of $10,000 to the College within thirty (30) days of the date of the Consent Order.

4) The Registrant consented to be reprimanded for having purchased and injected counterfeit products into patients, and having failed to exercise appropriate diligence in notifying those patients.

5) The Registrant consented and undertook to satisfactorily complete a six (6) week correspondence course in ethics for naturopathic doctors, such course to be approved in advance in writing by the Registrar of the College, within six (6) calendar months of the Consent Order.

6) The Registrant consented and undertook to write an open letter to the profession which summarizes his experience with purchasing and administering a counterfeit product, and warning the profession about the risks of purchasing and using unlicensed medical products.

7) The Registrant consented and undertook to send a monthly patient notification progress report to the College which will include an update on the Registrant's efforts to contact patients who received the counterfeit Product, including any additional patients who may have received the counterfeit Product from shipments not yet accounted for.

8) The Registrant consented and undertook to provide a monthly list to the College containing the contact information of each patient he provided services to that month for a period of twelve (12) months following the date of the Consent Order.

9) The Registrant consented to random spot audits by an Inspector appointed by the Inquiry Committee at any time during the two (2) year period following the date of the Consent Order, to review his clinical records for the purpose of ensuring that his practice remains consistent with the standards of practice for naturopathic doctors in British Columbia. The frequency and timing of the audits is at the sole discretion of the Inquiry Committee.

10) The Registrant consented and undertook that his future practice of naturopathic medicine and professional conduct will be above reproach.

Reasons for action taken:

The College received a written complaint filed by the Health Products and Food Branch Inspectorate of Health Canada alleging that the Registrant had imported and used the non-sterile, counterfeit, injectable Product in his practice. The complaint was forwarded to the Inquiry Committee, which commenced an investigation into the complaint.

As a result of its investigation, the Inquiry Committee observed that:

1) there were inconsistencies in the Registrant's records regarding the number of shipments and number of syringes of the Product he had received;
2) there were inconsistencies as to how much the Registrant had paid for the Product and the amount of taxes he paid based upon the value of the Product;

3) the Registrant's clinical records did not include records of him seeking informed consent from his patients for the treatment; and

4) the Registrant had not contacted all patients who had received the Product, nor had he taken any steps to identify or notify patients who may have been affected by any additional shipments of the Product.

Dr. Strauss admitted to and expressed an understanding of his misconduct and provided an assurance that he would not repeat the conduct in the future. However, the Committee was concerned that Dr. Strauss' conduct fell well below the standard of a naturopathic physician, and that he had not been diligent in his efforts to notify his patients.

The Committee determined, under section 33(6)(c) of the *Act*, that this would be an appropriate case in which to seek a consent order under section 36(1) of the *Act* with comprehensive terms to address the Registrant's failure to meet the standards of practice of the profession because:

1) the Registrant had admitted to, and expressed an understanding of, the seriousness of the conduct at issue;
2) the Registrant was willing to take rehabilitative and remedial action, including a reprimand, temporary suspension and a fine, additional education in professional ethics, and agree to supervision by the College in his further efforts to notify patients injected with the Product; and
3) adequate steps could be taken to monitor the Registrant's practice, as well as to assess his ongoing ethical and professional development.

Salveo Enterprises Ltd.

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To: Naturopathic Profession and Public
Re: Importation and Safety Concerns for Medical Devices

As Naturopathic doctors, we must adhere to regulations for public safety. This letter addresses what happened to me and how to prevent it from happening to you.

I purchased a substance and imported it to Canada with the use of a brokerage firm, paid taxes to the border and duties as one should. The substance was counterfeit Juvederm, which we did not know. Health Canada knew, because they checked the batch and lot numbers. The counterfeit Juvederm was seized at the Canadian Border Services. Health Canada was notified an they inspected my office immediately. Health Canada first thought that I was smuggling medical devices into Canada, but after showing them my brokerage paperwork and taxes/duties paid, no criminal action was taken against me or my company. Health Canada proceeded with multiple batch testing of the syringes and gave me a consent order to immediately have the products destroyed.

The counterfeit Juvederm failed sterility testing. Once Health Canada and I had this information, all patients who were treated with this product were contacted VIA letter and multiple telephone calls. Health Canada felt that this recall was sufficient for public and public safety.

In the letter sent to the patients I had to address what it is that happened, what to pay attention to, and how to correct the issue if it happened. I had to contact 100% of the patients who were injected with this product before Health Canada finished the inspection. The waiting process ensued for response from each patient.

After Health Canada was finished with the investigation, they notified the CNPBC. I agreed to a consent order with the CNPBC because of my administration of a counterfeit product. I had to issue another patient list, and contact every patient on that list. This was for treatments directly affecting patients 2.5 years earlier. I also had to pay a fine of $10,000, not practice for a week and be subject to random spot audits.

What can I say from my personal experience in this? Know exactly where and what you are buying because you are responsible for its effects in patients. Check batch and lot numbers on your medical devices to make sure it matches what Health Canada has on its database.

Some of the possible risks and harms of injecting counterfeit Juvederm are:

- Poor sterility
- Infection (local or systemic)
- Tissue rejection
- May be composed of other ingredients
- Granuloma
- Disfigurement (physical)
- Emotional discontentment

I can imagine the emotional impact of this was the worst experience for my patients, and all those involved:

- Patients not being able to trust me being their doctor, receiving a letter or call by my office telling them I have given and injected them with counterfeit Juvederm
- Patients feeling scared for their health, safety and appearance
- Patients feeling like they have been scammed by myself, the doctor they trust
- Patients given the impression that as their doctor, I do not care about their health, just after money. Which is not the case.

The risks attributed to public health and safety from using unregulated counterfeit product:

- Uncertainty (Public and Patients)
- Confusion
- Doubts about the real drug
- Patients pay for services with little to no value (feeling taken advantage of)
- Lacks trustworthiness in doctor and profession

I recommend that we protect our patients by doing the following:

1. Ensure that what you intend to import is Health Canada approved. The CNPBC does not regulate medical devices. Health Canada does.
2. Find a reputable HC-Licensed supplier.
3. Make sure all documentation clearly states what and how much you purchase.
4. Pay your commercial taxes and importation fees.
5. Check Health Canada laws. As doctors we are not allowed to import medical devices without a license. I did not know this.
6. Health Canada has everything you imported on record. Double check their records.
7. Dermal fillers all have a batch lot and serial number on the box. Phone Health Canada and the manufacturer to confirm batch lot.

Dr. Allan Strauss

September 13 2016