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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 as 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



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