Experience with *Health Canada*

It Started with a Letter

On March 31, 2000 we received a letter from Sheila Welock, Compliance Officer with the Therapeutic Products Program. The letter stated:

"… you are asked to immediately stop all sales and advertisement of these products.

"The continued sale and advertisement of products that are in violation of legislative requirements is a serious concern that can result in more stringent enforcement action. A written response to this letter, in which you confirm the discontinuation of all sales and advertisement of … is requested by April 17, 2000."

That was a shock! There was no invitation to work with the department to comply with regulations—only demands to shut down our Company.

Legal Help

We found a caring, warm-hearted lawyer, Shawn Buckley (referred to as Shawn from now on). He was recommended to us as he had successfully defended a natural health manufacturer who had been charged by Health Canada.

In describing our history to him, we explained: "We knew from day one that we would be sticking our necks out because we don't live in a country with health freedom. We consciously made the decision to do so, in order to help people. We do not believe in the system that our government advocates. We know that double-blind studies are what the government wants. We don't believe in double-blind studies. We believe each person must find their own path to health, and each path is different. That the cause of disease is multi-factorial and thus the answer for each person is also multi-factorial. Science wants to show one thing, one result."

We Alert Local Law Enforcement to Possibility of a Raid

As letters went back and forth between Shawn and Ms. Welock, we decided to talk with the local RCMP (law enforcement in Canada). Health Canada has raided natural health companies

as though the owners were dangerous criminals (as also happens in other countries) so we wanted our local law enforcement officers to have some knowledge of our situation. In the case of a raid, Health Canada confiscates records and product. After meeting with the officer in charge, we sent him the following letter:

"We want to thank you for meeting with us on May 15, 2000 regarding our situation with the Health Protection Branch (HPB). We appreciated the feedback you gave us on what role the RCMP would play in the event the HPB tries to do a search and seizure. We sincerely hope that this never happens, and that we are able to resolve our dispute with the branch in an honorable way." (The HPB became Health Canada.)

Listening to Spirit

After several letters back and forth between Shawn and Ms. Welock, on June 22, 2000 Lesley had second thoughts with regards to an earlier discussion on possible actions. She sent the following to Shawn:

"After talking with you regarding setting up a team of individuals to initiate action against Health Canada, I have had second thoughts. I have had some experiences, both physical and in the dream state, showing me that this action is not the way to go at this time. Life has taught me to listen to these experiences … as what is best for the whole always happens when I do."

Message from Three Countries

SOTA summed up events for Shawn on July 5, 2000:

"Last week we were hit with three government organizations' letters … the Advertising Standards Authority (ASA) in the UK, the Federal Trade Commission (FTC) in the U.S, and our own beloved HPB. So it put us into a little bit of a tizzy.

"Funny enough, the ASA didn't like us using testimonials in one of our ads. So we took out the testimonials and replaced them by telling people that the ASA, with person's name and contact information, had requested we take them out. They didn't like the fact that they were mentioned in our ad at all, and demanded that we immediately take all reference to them out of our ad.

"However, as always it has been a good exercise. Because we received three letters it made

us take a good look at every possible angle … and we now know we must stand and be who we are, because there ain't no way around it …"

Posting Government Letters for Public

SOTA launched a website about the politics of health and posted the letters from Therapeutic Products sent by Ms. Sheila Welock. She protested this public exposure of her name. On September 4, 2000 SOTA had a letter sent through Shawn responding directly to Ms. Welock:

> Unfortunately, due to our beliefs, we cannot comply with your request to remove your name from your letters. We understand your concern about having your name posted on the website, but we believe that we are all responsible for our actions in this world. And so, if you are uncomfortable with having your name attached to letters you have written, then perhaps you may want to look at the reason you feel uncomfortable.
>
> In our society today, it is very easy for individuals to hide behind the organizations they work for, to justify what they do as following or upholding the rules. When in fact what actually may be happening is that these individuals are taking away other's freedoms. Have you ever considered that many Canadians do not believe in what you and Health Canada are doing? Or if they knew wouldn't agree?
>
> We do not have any bitter or angry feelings towards you in the role you are playing … we just don't believe in what you are doing. We passionately believe in honesty, truth, freedom and responsibility. We believe the public has a right to know what individuals in government are doing … because it is individuals, like yourself, that make up the government. And so, the politics of health website has been born. All your letters and actions will be posted on this website—we will do our best to post everything in an unbiased way so as not to generate a lot of emotions from our customers and/or people who have similar beliefs as us.
>
> If you believe in what you do within Health Canada, you shouldn't have a problem with feedback from the people you serve (Canadian citizens). If you are uncomfortable with the idea of being contacted by Canadians who are interested in what you do, then you may want to look at whether or not you believe in what you do.

> Ms. Welock, your first two letters had a feeling of intimidation and the power of government behind them. We were very disappointed that you made no attempt to work with us, to help

us resolve this issue. We employ several Canadians, we take extra efforts to ensure we sell only to those knowledgeable on what we sell, we sincerely want to help others. You didn't take the time to find this out, instead you created a level of stress in our lives that we would have rather done without. We sincerely hope your letters in the future will be written in the spirit of cooperation.

Website Cleansed

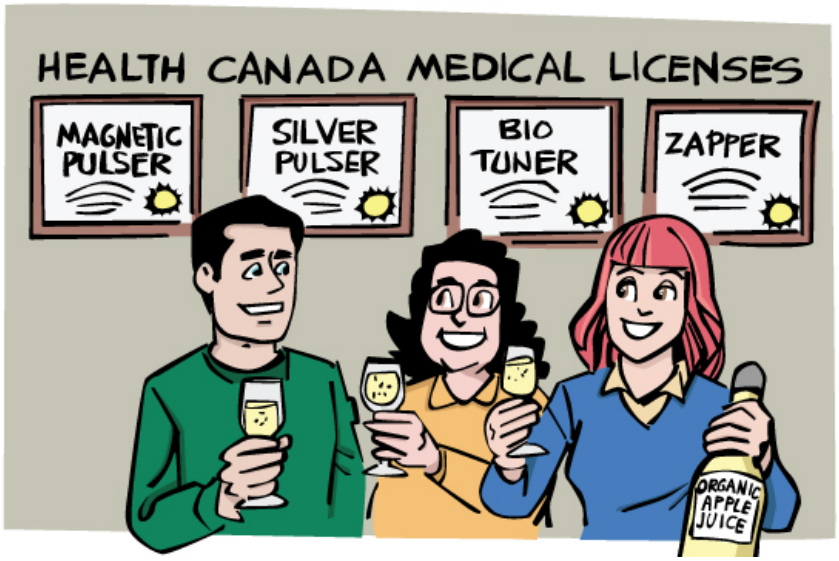
In July 2000, to meet regulator concerns, we revamped the SOTA website by deleting all references to names and publications. In addition the link to another website for more information was removed. In October 2000, we reviewed the website once again to remove any remaining offending information. When our current website was launched in 2007, it only provided information related to general health, well-being and relaxation.

SOTA Initiates Licensing Units with Health Canada

We designated Vicki (a former member of the SOTA team), who had experience working within government circles, to deal with all regulatory matters. Vicki corresponded and worked using the name NHM Research. [In 2005 NHM Research became an independent company owned by Vicki to assist companies, like ourselves, that run into problems with regulators.] In order to continue to provide the SOTA units, we decided it best to license the units. On January 19, 2001 Vicki sent the first letter to explore licensing.

Health Canada Licenses SOTA Units

To back up the licensing applications, Vicki collected a body of research based on the technology used for each unit. The result: May 2001 the Magnetic Pulser was licensed for pain. Licensing of The Silver Pulser, The Bio-Tuner and the Zapper as TENS units followed.



Health Canada Questions Licenses

On October 26, 2001, the Director of the Medical Devices Bureau, Beth Peterson wrote a letter questioning the applications for the licensed units and implying clinical trials using the SOTA units were necessary. After several phone calls, Vicki determined additional background information was all that was necessary. On November 30, 2001 she wrote to Don Boyer, Manager of the Licensing Service Division who became her main contact in the Therapeutic Products Division of the Medical Devices Bureau. There seemed to be a spirit of cooperation and a refreshing lack of bias in dealing with Don. Vicki sent necessary data in a timely manner and gave an open and honest summary of our position to Don:

> In response, I am pleased to submit the attached information supporting the TENS indications for use. Thank you for extending the deadline for two weeks until December 7th, as you can see, we did not need that entire extra period. …
>
> SOTA Instruments has exceptional, well-trained, customer service staff. Individuals who attempt to buy an instrument who appear to be buying with a general lack of knowledge as to what it is they are purchasing, are actively dissuaded from purchasing by the customer service representative. It is just as important for SOTA's present and future endeavors for the public to be well-informed, as it is for Health Canada to ensure reasonable public safety.
>
> While we recognize the authority of the TPD [Therapeutic Products Division] to investigate medical device problems when necessary, it usually concentrates its efforts and resources on serious problems where there is potential for injury. In the case of the TENS units, there is no known potential for injury except that in rare cases there have been rashes and slight burning at the electrodes site. Historically, any kind of electrotherapy with the exception of electric shock therapy, has been recognized as having no adverse side effects, and in particular, the SOTA instruments have been sold for the past five years internationally with no reported unusual adverse effects or instrument safety concerns.
>
> Although SOTA stands behind the indications as they have been presented to Health Canada, SOTA does not hide the fact that their broader vision is shared by prominent researchers in the field, and at some point, when enough research has been gathered for the regulatory authorities, SOTA would like to move away from the TENS standing indication for use in pain.

SOTA Corresponds with the Minister of Health

On February 25, 2002 SOTA asked Vicki to correspond with the Minister of Health outlining the need for changes. In a 3-page letter, in addition to emphasizing the long history of safe use of electrotherapy units, a system using a disclaimer to accommodate devices that serve

the natural health market was suggested. A disclaimer such as:

"This experimental product has not been evaluated by Health Canada for safety and effectiveness. Any educational material accompanying this product is theoretical only. It is not intended to treat or cure any condition or disease. Use only as directed, and consult a medical practitioner for treatment of any condition or disease."

The letter concluded with:

"This issue is urgent for manufacturers to continue operating. These manufacturers produce jobs and contribute to the economies of their localities. We are asking for your assistance and support in making minor and justified changes to the current regulations."

Health Canada Notifies of Intent to Suspend Licenses

A letter dated June 24, 2002 from Roland Rotter, Director of the Medical Devices Bureau stating: "The purpose of this letter is to inform you that it is our intention to suspend these medical device licenses on July 8, 2002 … the Medical Devices Bureau has concluded that insufficient evidence has been provided to establish that these devices are safe and effective for the following indications:

1. May increase ATP production in tissue.
2. May increase microcirculation.
3. May disable or neutralize electrically sensitive pathogens."

The application for pain was not questioned but the letter ignored this fact. Regulators chose to threaten suspension rather than suggest the licenses be modified with use for pain only.

Bias within Health Canada

It seemed to SOTA that the bias within the department was coming to the fore. We had also learned that Terry Polevoy, Canada's version of the US-based Quackbusters, had been corresponding by e-mail with at least one regulator within Health Canada … questioning our licenses. Tim Bolen, who has been successfully helping to defend natural health companies in the US, informed us he discovered that health regulators seemed to depend on Quackbusters for their information about natural health!

After phone calls and letters, on July 25, 2002 Vicki sent another letter on behalf of SOTA. " … we propose to your department that SOTA drop the novel indications for use from the license and labeling. There has been no criticism by your department to the standard TENS indication, of 'symptomatic relief of acute and chronic intractable pain.' Therefore we respectfully request that this remain the only indication until such time as SOTA's study is completed and more evidence for other indications is obtained."

Vicki included copies of letters from Revelstoke community organizations as well as community awards that SOTA had received. The letter concluded: "For your interest, I have attached letters of support attesting to their reputation and important contribution to this small community."

Nature of Complaint

SOTA was also attempting to discover the nature of the complaint that had alerted Health Canada to our products. We informed Health Canada that if there was a valid complaint, it was important we know so we could rectify the problem. Health Canada's response to this was: "This information is confidential and unfortunately it cannot be released by the Medical Devices Bureau." We would later learn there was no complaint against SOTA.

Support of Elected Members of Parliament

We realized it was important to inform our local Member of Parliament (MP), Jim Abbott, about the political issues we faced. On one of his visits to Revelstoke, we arranged a meeting to show a video clip of G. Edward Griffin succinctly explaining the situation that the Natural Health industry faced with governments and briefly explained our products and situation. We established a relationship that we called on a few weeks later.

Video Clip

It was also helpful and comforting to have the support of James Lunney, another Member of Parliament. Prior to his election, Dr. Lunney was a practicing chiropractor and had used the SOTA units. He supported us by helping to educate Jim Abbott and other Members of Parliament about our company and our products.

The Appeal Process

Regulators became more aggressive about revoking our licenses, so we decided to formally appeal. We were informed of the appeal process. First it would be necessary to fly across the country to Ottawa, the seat of federal government. Rather than present our case to an impartial person or group, we would only meet with the regulator who made the decision to suspend our licenses. We would be allowed to present our case. We would not be allowed to ask questions or expect any discussion. We were not willing to participate in what we perceived as a biased and no-win situation.

Regulators then threatened to immediately revoke our licenses and halt the sale of our units. It was at this point we appealed to Jim Abbott, our MP, for help. His office made one phone call to the Medical Devices Bureau. One phone call from the office of an elected representative of we, the people, brought about an immediate change. Communication lines suddenly opened in a spirit of cooperation. Dr. Rotter called as though there had been no great problem and to assure us we could work something out.

Minister of Health Refuses to Meet

On September 13, 2002 the Minister of Health finally responded to the letter sent more than 6 months ago. Health Canada had no intention of reviewing their regulations. The Minister suggested that our units pose a health hazard as individuals who are sick may choose to use them instead of conventional, and by inference, 'proven' medical procedures. Vicki responded asking for an explanation:

"You say in your letter that the choice to use a natural health bio-resonance device for a particular disease can pose a direct health hazard to the user. Since the devices in question are historically proven safe, and there are no conventional devices that could be used, please explain the direct health hazard."

On March 10, 2003, Lesley and Russ wrote a letter to the Minister outlining the case for natural health and explaining the difference between the two models for health—the Medical Health Model and the Natural Health Model. They requested a meeting to talk personally with the Minister. After two follow-up letters asking for a response, on June 10, 2003 the Minister responded, "Unfortunately, prior commitments prevent me from meeting with you at this time."

Letter to Members of Parliament

After discovering that Terry Polevoy had been sending information about SOTA to Members of Parliament, on January 30, 2003 SOTA sent a letter to the same list. The 2-page letter included the following:

"It is unfortunate that the rules outlined by Health Canada make it illegal to provide and share information like customer feedback. We feel this is a gross abuse of freedom of information. Consumers and the general public deserve to have free access to truthful and balanced information. …

"History shows that any person or company working to bring new ideas and possibilities to the forefront typically face great resistance by regulators and others whose beliefs are threatened. Polevoy and many working within Health Canada would have you believe that these companies are quacks preying on the sick. The truth is quite the opposite. They are individuals with great compassion, high ethics, and a desire to help others. …

"We believe the future of health care is in electro-medicine. Canada should be embracing this exciting research; not suppressing it because of fear and ignorance."

After Move to Penticton, Local Member of Parliament Contacted

On March 2, 2003 our local Member of Parliament, Stockwell Day, responded to an invitation to visit the office for a brief outline of our difficulties with Health Canada. As with our former Member of Parliament, we showed a video clip of G. Edward Griffin succinctly outlining the issues commonly referred to as the politics of health. We wanted our elected representative to be informed should we need to call on his office for help. Thankfully, we have not needed to do so.

Health Canada Suspends TENS Licensing

On March 3, 2003 the Director General of the Therapeutic Products Directorate wrote informing SOTA the licenses for the Silver Pulser, the Bio Tuner and the Zapper were suspended due to a labeling concern.

SOTA responded immediately with a 2-page letter. In addition to noting their bias, and making another attempt to educate them about natural health, the letter also stated:

> Your department attempted to suspend our licenses last September. An MP intervened on our behalf, and Dr. Roland Rotter called our regulatory correspondent to inform her that we misunderstood the intent of your letters. He informed us that your department wanted to work with us to resolve any issues. …
>
> You took several months to get back to us and it was a surprising reply. … We do not accept the suspension of our license number 30096. NHM Research will be investigating what looks like mainly labeling concerns and will address these issues with you.
>
> In summary, these are the points we would like answered by your department. We would appreciate a response within four weeks.
>
> 1) We would like to receive a legal letter signed by either Dr. Robert G. Peterson or signed by Kevin Doyle. If from Kevin Doyle, we ask that his position within Health Canada be stated. (The person who wrote the letter was Kevin Doyle. He had not identified his position within Health Canada and the letter had merely been initialed on his behalf.)
>
> 2) We would like to know the reason that your department keeps sending us letters suspending our licenses. Why are you so intent on getting rid of us? The reasons given for the suspension do not warrant this kind of treatment.

3) We would like to know the solutions so we can be in alignment with Health Canada regulations as per the letter of March 3, 2002. It seems your department is not forthcoming with assistance. You know your regulations far better than we do, and we know there are solutions … it takes both parties cooperating and working together to come up with them.

We did not receive an answer to this letter.

Licensing Reinstated

The SOTA licensing was reinstated except for the Bio Tuner. Ongoing correspondence questioned the labeling information for the Bio Tuner. On principle, SOTA pursued reinstatement of the Bio Tuner license. On October 17, 2003 Vicki received an e-mail from Nancy Shadeed: "You will be receiving a medical device license next week. It is in the final stages of processing."

Freedom of Information Request Received

If requested by the company, the Canadian government is obligated to provide a Freedom of Information package when a company is under investigation. For a fee, photocopies of correspondence among government regulators are provided. SOTA applied for a Freedom of Information package.

Many months later, when copies of the correspondence arrived, we discovered that

regulator bias was alive and well from the start of the investigation into SOTA. Many areas of the correspondence had been blanked out but samples of the bias were still intact. For example, on July 14, 2000 a memo from, Philip Neufeld, a senior officer with Health Canada, was sent to 19 people in Health Canada stating: "SOTA Instruments sells a quack electromedical device without a license."

Freedom of Information Package Reveals Nature of Complaint

A letter dated back in November 1999 to Health Canada from Industry Canada, Commissioner of Competition indicated a complaint about a Zapper. The information had nothing to do with SOTA but rather included literature from another company with claims about the Zapper. Information from the Quackbusters was also included as educational material about the Zapper.

On November 28, 2003 Vicki sent the following on behalf of SOTA:

"Just to clarify Don—SOTA does not believe they have been treated unfairly by you personally. However, if you had read the FOI package that SOTA received, it is clear others in Health Canada are building up SOTA to be something they are not. It is unfair for Mr. Neufeld to continually accuse SOTA of being 'quacks.' Further, all this started by a complaint from Terry Polevoy about ANOTHER COMPANY that made claims and that company's advertising is in our FOI package. Interesting. As the FOI package progressed, it was interesting to see how the fervor about SOTA was building—and for what? SOTA hasn't done anything wrong. It is incredible to me how much time and energy that HC is spending on a company that has been in business for eight years WITH NO CONSUMER COMPLAINTS."

Throughout the regulator correspondence, the Zapper was mostly the focus of their concern.

Complaint Against Health Canada with Regards to Freedom of Information Package

SOTA currently has an unresolved complaint filed with the Canadian government. Large sections of the correspondence among regulators in the FOI package were blanked-out. There is no explanation as to why these comments have been blanked-out and we feel these comments are important—they could provide us with more insights into the bias and unfair treatment by government employees.

In May 2006, in response to our complaint, we received a few more pages of correspondence. Currently, we still do not know what was written in most of the blanked-out sections.

Government Requirements

When we started making the SOTA units available, we also provided information to help educate those who purchased. We felt providing information was important to anyone who wanted to purchase the units. Government regulations soon created a challenge, as the

information that can be supplied with health products is limited.

Government regulations require that products be deemed both safe and effective. SOTA accepts the importance of safety and the need to ensure safety. We question government requirements for effectiveness for two reasons:

1) Effectiveness is subjective. Studies can be misleading. Even though studies are supposed to be scientific or conducted by the scientific method, results are often biased in favor of the company funding the study. Consumers can be told that studies prove effectiveness. If the research is examined more closely, it may be found that the drug or product was only marginally more effective than the placebo effect. The study proved effectiveness—but we are not told the degree of effectiveness.

The requirement to prove effectiveness came into existence with the rise of the pharmaceutical industry. With prescription drugs, there are often harmful side-effects or safety issues. When deciding whether to license the drug, government regulators must weigh safety and the extent of harm from the side-effects along with effectiveness.

We question this procedure being applied to products that are shown to be safe and without side-effects. We are each unique, our bodies react differently—especially to gentler, natural products or therapies. Perhaps freedom to choose could be respected for products that are safe.

2) Cost is prohibitive. Expensive research must be conducted for each benefit claimed. This procedure is necessary for the pharmaceutical industry as most drugs have highly specific applications that override the body's natural processes. By contrast, safe natural products usually work to boost the body's natural ability to heal. In addition there is the safety issue with drugs. Should cumbersome and costly restrictions be applied to health products that do not have safety risks? Does this not add to the problem of making our medical system unaffordable?

SOTA Products Classed as Consumer Products

On March 10, 2003 Health Canada gave SOTA an alternative to medical device licenses. Vicki responded to the conversation with a letter:

"You said simply that as long as there are no medical claims made, that SOTA Instruments can still sell consumer products that are health oriented. This is obviously welcome but very surprising to myself and SOTA Instruments.

"After leaving the phone for a moment to confirm, you also said, that along with the claim of relaxation, SOTA can also use the term 'well-being."

On May 6, 2003 a formal letter from Roland Rotter stated, "As was discussed during our telephone conversation, the Medical Devices Bureau would not consider SOTA Instruments products to fall within the definition of a 'device' provided that the claims for these products were limited to relaxation and well-being. Should the term 'health' be utilized in the labeling or advertising of these products, the Bureau would consider the products to meet either paragraph (a) or (b) of the definition, and compliance with the Medical Devices Regulations would be required."

In response on May 27, 2003, SOTA objected to the limitation on the word 'health.' Vicki wrote:

"As an example, I'd like to point you to the Health Canada Medical Devices Bureau Surveillance Division, Philip Neufeld's MDMC Issue Paper on Static Magnet Medical Devices dated March 15, 2001. It states under recommended regulatory action: 'promoting a sense of well-being and general good health–fall outside the scope of medical claims.' …

"I'd like to also point out the common and non-controversial usage of the word 'health' by 'health' clubs, 'health' spas, and 'health' food stores, among others."

We did not feel the regulators had a case to limit our use of the word 'health' when it is in such common use as these examples indicated.

At this point, we did not know which way to go—consumer product or medical licenses. For that reason, we continued to work with regulators to reinstate our licenses.

To License or Not To License?

In order to renew the licenses, SOTA was now required to meet new regulations—the International Standards of Operation (ISO) procedures. SOTA had a staff member dedicated to ensuring our manufacturing and office procedures would meet ISO regulations. After considerable time and effort to investigate the regulations and then many months of preparation, we were confident the necessary procedures were in place. We had not, however, paid the fees to complete the ISO certification process. On October 29, 2003, SOTA

sent license renewal forms for the three licenses held. Rather than pursue costly ISO certification, Vicki informed government regulators, "SOTA has committed to remaining ISO ready and will conduct its own internal annual audits to ensure ISO quality of customer service."

March 12, 2004 a letter from Dr. Roland Rotter stated that as a result of not being ISO certified, "… these licenses are cancelled …"

A Decision Made

After reviewing correspondence with regulators, we reviewed our options and decided to accept the offer to be classed as Consumer Products for general health, well-being and relaxation.

April 2, 2004 Vicki responded:

"This is to inform you that SOTA Instruments has not sold medical devices for several months. Upon your notification several months ago advising them that their units could be sold as consumer products, they chose this route. …

"On behalf of SOTA Instruments and their customers, I wish to thank you and your staff for your cooperation and assistance."