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CODEX
WORLD TRADE ORGANIZATION
WORLD HEALTH ORGANIZATION
& THE REGULATION OF HERBAL MEDICINES & NEUTRACEUTICALS

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The regulation of herbal medicines, both here in Canada and abroad, has reached a critical juncture. No longer are they viewed as just a relic of the past, or simply dietary supplements; they are now on the radar of the world stage… and the image is disturbing.

In Canada, The Natural Health Products Directorate (NHPD) is now in charge of the manufacture and sale of vitamins, minerals and herbs; their new regulations came into force on January 1 2004. While some larger players in the industry are in agreement with this new regulatory model, others – small & medium sized manufacturers, practitioners and the public see the extreme costs and onerous regulations as an unabashed attempt by bigger interests in taking over this market. Currently, there are many companies that have downsized their product line, and given up bringing new products to the market, as they realize the onerous costs associated with compliance.

A number have quietly closed their doors, having seen the writing on the wall.

That the GMP's, Standards of Evidence, etc in this regulatory approach are from the 'drug' model, can be clearly be seen upon a full examination of the original documents. The requirements of this regulatory model violate the spirit and written recommendations of the '98 'REPORT' et al (House of Commons Standing Committee on Health).

Because of this, a private member's bill: BILL C420 was brought to Parliament by Dr James Lunney MP, in 2003. It passed first and second reading, but was then lost when Parliament was prorogued before the last election. It was brought back last year, and passed first reading in November, 2004, with a successful 2nd reading this past March 9th. Now, referred to the Standing Committee on Health before a 3rd and final reading possibly this Fall, a number of MP's and industry stakeholders are requesting amendments to refine the original Bill, in an effort to make it more palatable. Should there ultimately be some sort of consensus in this matter, it could well pass into law late this year, and thus provide the public and practitioner with greater access to these products.

The continued viability of this scenario is, however, subject to a number of initiatives currently on the world stage, specifically those that *seek to disable national sovereignty, as a requisite for international trade.* An appreciation of the complexity and interwoven nature of current and proposed regulations - both nationally and inter-nationally is thus critical and necessary to see the larger picture.

Let me *attempt* to explain…

The CODEX ALIMENTARIUS owes its beginnings to the FOOD & AGRICULTURAL ORGANIZATION (FAO) of the WORLD HEALTH ORGANIZATION (WHO). Initial efforts on this began back in the 1960's. Over the years, it slowly percolated and chugged along in the dreary chambers of sub-committees until it began more formal meetings in 1997. On June 10th, 2002, the European Union (EU) published Directive 2002/46/EC, which proposed to deal with food supplements in Europe and its member states.

This Directive is profoundly disturbing insofar as the standards it sets:

1) would allow for the formation of a 'positive' list: if vitamins and minerals are not on this list, they would be banned from sale across the EU.;

2) in order to be registered on this list, dossiers would have to be compiled that are extremely expensive. Many would find that impossible with the net effect of eliminating over 5000 products currently on the market.

These were the thoughts of David Hinde, Legal Director of The Alliance for Natural Health (ANH) that has launched a legal challenge to CODEX in the European Court of Justice. A decision will be rendered in early June of this year.

This is not the only area that they wish to regulate;

in the opening preamble ("Whereas…" # 7 & 8) vitamins and minerals are referred to:
#7 " as a first stage.."
#8: " specific rules concerning *nutrients other than vitamins and minerals or other substances with a nutritional or physiological effect*….should be laid down at a later stage.."

Further on, they advise: "… until such specific Community rules are adopted…national rules concerning nutrients (et al).. may be applicable" .

I don't know about you, but I smell herbs and other therapeutic agents; I also see the attempt at 'drug' type regulations now, (ie. NHPD regulations) in a new light. And to add, for sake of clarity and timelines, #8 referred to in the Preamble above, has to be undertaken no later than July, 2007; similar regulations would follow for herbs, neutraceuticals, etc. For those who have been told that compliance is voluntary, CODEX voted last year to remove the section on voluntary compliance, stating that it was outdated.

Most likely because of the following…

Now, having come this far (I hope you're still with me..) you might make the reasonable assumption that this only applies to the EU.

Here's where it gets interesting…

The original rationale of this Directive was to facilitate better trade amongst the member states in the EU. The problem is that many of these countries, and the EU, are also members of the WTO… to which Canada and the USA are signatories. All member countries (signatories) must comply with WTO regulations that stipulate:

"The WTO Agreement is a treaty – the international equivalent of a contract. It is self-evident that in an exercise of their sovereignty, and in pursuit of their own respective national interests, the Members of the WTO have made a bargain. In exchange for the benefits they expect to derive as Members of the WTO, they have agreed to exercise their sovereignty according to the commitments they have made in the WTO Agreement."

The above is quoted from the WTO website. With reference to the last sentence: ".. they have agreed to exercise their sovereignty according to commitments they have made in the WTO agreement". This clearly implies that national sovereignty takes 2nd place to international agreements such as the WTO.

So… as much as on a national level, it makes sense to push for BILL C 420, as it is the lesser of two evils, especially in its *amended form,* unless the industry can figure out a way to negate this WTO agreement, or to stop CODEX, these products will be subject to very onerous 'drug' regulations – either through NHPD regulations, through CODEX, and even through World Health Organization (WHO) proposed standards.

The WHO has also stepped up to bat on this issue; in fact, they were there all along, quietly in the background.

In their January 2004 declaration:

"GUIDELINES ON… PROPER USE OF TRADITIONAL, COMPLEMENTARY & ALTERNATIVE MEDICINE" they state:

1) Preface:

".. a number of reports have revealed examples of incorrect use…including incidents of overdose, unknowing use of suspect or counterfeit herbal medicines, and unintentional injuries caused by unqualified practitioners"

Commendable, for sure, until you get a closer look at what is being proposed. In their 109 page document, they offer suggestions for the regulation of all CAM products, all the practitioners, all the various disciplines (including 'spiritual' matters) and regulatory control of what is given out in the media, including internet.

The premise, given at the beginning, is:

" it is *extremely important* to create the correct and appropriate use of Complementary Medicines.."
(italics mine)

As admirable as this may be, it also allows for 'extreme' regulations such as seen in CODEX, or existing regulations in Germany, France and Australia. Why the need for extensive control – not only of the products, but the practitioner and even the information given out by any means whatsoever ?

Why do they also cite false evidence regarding Ephedra, Kava Kava and Gingko: when the Ephedra-related deaths were specific to its synthetic analog ephedrine; when the wrong parts of Kava, (and even an inappropriate menstruum) were used in preparing Kava extracts; and Gingko's only deficit was its use before surgery when it thinned the blood ?

Perhaps it had something to do with the WHO's assistant Director-General for health technologies and pharmaceuticals, Dr Vladimir Lephakin who said: ".. it is not rue that traditional medicines are good for everybody, every time, in big quantities.." and that: "there are a lot of examples of people who not only suffer, but die because of drug-interaction or non-proper use of traditional medicine"

Sounds reasonable on the surface; perhaps the issue is to define what is meant by 'big quantities', and actually provide hard facts about just who has died and from what substance(s). In the larger picture, and in context of understanding the large scale demographic shift away from drugs, to that of dietary supplements, it starts to make sense that any number of regulatory agencies are crying out for regulatory control. Ostensibly, this is under the rubric of concern for public safety; however, it allows for the exercise of greater control via regulations that are punitive and extreme in nature.

A number of years ago, the Centre for Disease Control (CDC) released a chart showing the number of deaths, in descending order of: 1) drugs; 2) foods; 3) dietary supplements. The number of deaths attributed to pharmaceutical drugs is huge: the bare <u>minimum</u> number cited is 100,000 per year, with more added to include iatrogenic causes. Food came next, ie e. coli from bad beef, etc. Dietary supplements, on the other hand, have negligible rates.

Perhaps to illustrate the intent to capture (novel forms of) herbal medicine, consider the following:

Under the heading of 'Glossary' (WHO Guidelines et al) wherein they define conventional medicine, complementary medicine, herbs and herbal products, is the reference to finished herbal products:

".. however, finished products or mixture products, to which *chemically defined <u>active substances</u>* have been added, including synthetic compounds and/or isolated constituents from herbal materials, are *<u>not considered to be herbals</u>*" (page xiv)
(all italics/underline mine)

Where does this leave a lot of NHP's on the market today, that are a combination of herbs, vitamins, neutraceuticals, etc ?

I would hazard a guess that they will be removed to a drug category, given for example, the regulatory drift of Schedule F (NHPD regs) here in Canada. It is worth emphasizing this little known mechanism that will allow authorities to remove any substance: 1) with a narrow margin of safety (keep in mind here the work of Dr Bruce Ames 'Ranking Possible Carcinogens') ; 2) any substance that, although found effective, is deemed unsuitable for self-medication.

Remember… this is coming down from WHO, that was the instigator of CODEX, and that through WTO, requires all signatory countries to comply with these and other regulations. This is the main reason why Canada has promulgated these new regulations.

I hope by now, in spite of the above, you are not feeling the situation is hopeless. I am simply wanting everyone to understand what exactly we are faced with. The issue is much bigger than the new NHP reg's;

it is much bigger than BILL C420, but from a tactical point of view, in the short term, we must push for (an amended) BILL C420. It will give us some breathing room, while we organize on the international level.

I would again encourage as many as possible to support the ANH challenge; this was heard on January 25/05. The Attorney General of the European Court of Justice will give his report in early April; and the ECJ will render their decision in June. IF the decision is unfavorable, CODEX starts in earnest August of this year in Europe, and will likely lead to similar regulations for herbal products by 2007(Europe) with eventual compliance here in north America.

There are a number of actions underway in the USA, in Africa, New Zealand, etc. Ron Law, an activist from New Zealand is promoting the idea of the need for "robust evidence based risk analysis", that is, no product should be taken off the market anywhere, unless there is real hard evidence of potential for harm. His approach mirrors what is being argued (legally) elsewhere, and is in keeping with the principle of common law: innocent until proven guilty.

Many years ago (1984), I saved an article from the GLOBE & MAIL about a decision handed down from the Supreme Court of Canada., about a case of trafficking in marijuana. The appellant was forced to continually prove his innocence from the lower courts on up. At the Supreme Court, his conviction was overturned because the action of the Crown had offended the common law principle of innocent until proven guilty. It became known as 'reverse onus', and aptly describes the situation we find ourselves in today.

In 2002, I had occasion to discuss this situation with Dr Sheilagh Martin, a very seasoned lawyer with CODE HUNTER in Calgary. This firm is ranked as one of the top constitutional law firms in Canada.
After discussing other constitutional arguments ('forced expression' contrary to freedom of expression in the Charter, et al), she felt that the case had merit.

There has been a profound sea-change in regulation – both here in Canada, as well as in Europe (under CODEX). This fundamental principle of common law has been cast aside, in favor of hype, fraudulent science, and regulatory *fiat*. It is being challenged on this basis (and others) by ANH, and can provide a solid foundation upon which to launch a legal action.

I don't know about anyone else, but having been involved in various provincial/federal lobby efforts since 1984, invariably it comes down to the government ultimately doing what they wanted to do in the first place. Any comparison between the original 53 recommendations accepted by former Health Minister Allan Rock, and what we are faced with today, would confirm that statement.

For those who still feel that dialog is the best approach, I would suggest remembering the tact of President Roosevelt in the 1940's: walk softly but carry a big stick. We need a big stick, and we need it now.

The usefulness of dialog is pretty well at an end.