Testimony of
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Committee on Government Affairs
Subcommittee on Oversight of Government Management, Restructuring
and the District of Columbia

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Good morning. I am Bill Jeffery, National Coordinator of the Centre for Science in the Public Interest (CSPI) for Canada. CSPI is an independent health advocacy organization, focussing on nutrition and food safety, with offices in Ottawa, Canada and Washington, D.C. CSPI's Canadian advocacy efforts are supported by 125,000 subscribers to the Canadian edition of its *Nutrition Action Healthletter*. CSPI does not accept funding from either industry or government.

I am pleased to have the opportunity today to address the issue of how ephedra and other dietary supplements (or what we call in Canada "natural health products") should be regulated. I was specifically asked to address the following seven questions. I have provided complete answers to these questions in my prepared statement and I request that they be incorporated into the record.

1. Please discuss the reasons that Health Canada withdrew many ephedra-containing dietary supplements from the market.

Following two prior public advisories concerning health risks associated with unapproved products containing ephedra/ephedrine, Health Canada conducted a risk assessment and determined that, on the basis of at least 60 adverse reaction reports and one death in Canada (and similar international evidence), these products constituted a Class 1 health risk for some vulnerable population groups.[i] A Class 1 health risk is "a situation where there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death." Accordingly, Health Canada issued a voluntary recall of the offending products on January 8, 2002.

2. Did your organization support Health Canada's decision?

We support the recall of ephedra-containing products because the small benefit of taking ephedra to lose weight (about one or two additional pounds lost per month for up to four months) is not worth the risk of stroke, cerebral haemorrhage, heart attack, and death. Experts may quibble over individual reports of adverse reactions, but it is beyond dispute that ephedra triggered many serious complications and deaths in the United States and Canada.

3. Did many other consumer and health advocacy groups support Health Canada's decision?

At least nine organizations issued notices of Health Canada's voluntary recall on their web-sites, including the Canadian Medical Association, the Canadian Pharmacists Association, and the National Association of Pharmacy Regulatory Authorities.[ii] At least three other organizations publicly criticised Health Canada for not taking even stronger steps to prevent the sale of ephedra- containing products. They include the Canadian Health Coalition, the British Columbia Medical

Association, and the Vancouver-based St. Paul's Hospital Eating Disorders Program.

4. Please discuss the regulatory system in Canada that oversees dietary supplements.

Currently, the Canadian *Food and Drugs Act*[iii] and *Regulations* do not include a special regulatory category for herbal remedies. Accordingly, they are technically considered to be drugs and could be regulated as such.[iv] Vitamin and mineral supplements are explicitly regulated as drugs in Part D of the *Regulations*. Generally, drugs must be pre-approved for sale by the Minister of Health, assigned a Drug Identification Number (D.I.N.)[v] and must bear the D.I.N. on the label when sold to the public.[vi]

Until forthcoming natural health product regulations are in place, Health Canada is only taking regulatory actions against herbal remedies and other natural health products when they pose health risks or make claims about benefits in relation to 39 diseases and health conditions listed in "Schedule A" to the *Act*. The vast majority of natural health products currently on the market do not have health claims on labels.

The Federal Government pre-published proposed amendments to the *Food and Drug Regulations* on December 22, 2001 that, if approved, would establish a regulatory framework for licensing natural health products and production facilities. The proposed amendments would also set standards for Good Manufacturing Practices, quick mandatory adverse reaction reporting, and label disclosures. Under the proposed regulations, the Minister of Health would have the power to revoke product and site licenses and take other enforcement actions.[vii]

The *Food and Drugs Act* does not empower the Minister to issue mandatory recalls for drugs or natural health products.[viii] Health Canada's experience is that requests for recalls are almost universally respected making it virtually unnecessary to resort to more rigorous enforcement powers such as seizing products or obtaining injunctions against sale.[ix]

5. Has Health Canada taken other actions to safeguard Canadians from dangerous dietary supplements?

Health Canada issued a voluntary recall and stop-sale directive for products containing the herb Kava on August 21, 2002[x] after receiving reports of four cases of non-fatal liver toxicity in Canada. On June 19, 2002, a voluntary recall was issued concerning seven herbal supplements: Arthrin, Osporo, Poena, Neutralis, Oa Plus, Ra Spes and Hepastat found to contain undisclosed pharmaceutical drugs. Since November 1999, Health Canada issued at least 10 other voluntary recalls involving 31 natural health products[xi] and several other public advisories concerning products causing adverse interactions with prescription drugs and products that were seized or turned back at ports of entry.

6. Does the fact that these products are so widely available here in the United States pose a risk for Canadian consumers?

According to Health Canada, these types of products are frequently imported from the US for personal use, or to be sold clandestinely in fitness centres, truck stops (to improve wakefulness), and elsewhere. Canadian or American truck drivers obtaining this product during trips in the United States may pose highway traffic accident risks if they use the product while driving in Canada.

7. Are there other actions that your organization would like to see Health Canada take to better safeguard Canadians with respect to dietary supplements?

CSPI and the editor of the Canadian Medical Association Journal have voiced the concern that Health Canada is excessively reliant on guidance from the natural health products industry in developing the new regulatory program. CSPI believes that Health Canada should instead rely on a panel of experts with no conflicts of interest. Furthermore, the proposed natural health product regulations do not assure a publicly transparent system of review for product safety and efficacy. We believe that active ingredients of such products are, by definition, not subject to proprietary confidentiality (patent or otherwise) and, accordingly, their safety and efficacy is best reviewed through a fully transparent process of safety and efficacy review, prior to approval. Lastly, while voluntary recalls are typically heeded, including mandatory recall authority in the *Act*, for drugs and natural health products, would reinforce the capacity of Health Canada to protect the public health in an administratively efficient manner.

I would like to thank the Committee for the opportunity to testify and will be happy to answer any questions.

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ENDNOTES

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[i] Such groups include persons with pre-existing conditions such as hypertension, diabetes, heart disease, etc.

[ii] Others include: the Ontario College of Pharmacists, the Ordes de pharmaciens du Québec, and the Calgary Health Region. At least three Canadian amateur sport organizations posted web-site notices of the recall prepared by the Canadian Centre for Ethics in Sport. (See: Judo Canada at http://www.judocanada.org/results/022202.html, Cross Country [Skiing] Canada at http://canada.x-c.com/coaching/technical/advisorynote.htm , Federation of Canadian Archers at http://www.fca.ca/weeklys/2002/8feb02.html.) See also, notices posted by the following consumer magazines: Energy Magazine at http://www.energymagazine.com/news/?news_id=2 and Natural Life Magazine at http://www.life.ca/nl/84/ephedra.html . Seven pharmaceutical and herbal manufacturers and retailers issued public statements either supporting the Health Canada recall (e.g., Beohringer Ingelheim Canada (BIC), S & H Health Foods in Kitchener, Ontario) or stressing that their products do not contain enough ephedra/ephedrine to be captured by the recall (e.g., including Pfizer Canada, BIC, Herbal Success Inc., McNeil Consumer Healthcare in relation to Tylenol); see, Canada News Wire news releases for January 10-11, 2001 at http://keyword.newswire.ca/cgi-bin/keyword.cgi?BIN=ME&QUERY=ephedrine. In addition, the following retail stores publicly stated that their products did not include items encompassed by the recall: Hy and Zel's retail store in Cambridge Ontario, and Nathuleal retail store in Kitchener, Ontario.

[iii] See, generally, the *Food and Drugs Act,* R.S.C. 1985, c. F-27.

[iv] Drug is defined in section 2 of the *Food and Drugs Act*, R.S.C. 1985, c. F-27 as:

> " includes any substance or mixture of substances manufactured, sold or represented for use in
> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals,
> (b) restoring, correcting or modifying organic functions in human beings or animals, or
> (c) disinfection in premises in which food is manufactured, prepared or kept;"

[v] Section C.01.014 of the *Food and Drug Regulations*, C.R.C., c. 870 states:

"Assignment and Cancellation of Drug Identification Numbers

C.01.014. (1) No manufacturer shall sell a drug in dosage form unless a drug identification number has been assigned for that drug and the assignment of the number has not been cancelled pursuant to section C.01.014.6." [The *Regulations* then prescribe the application procedure.]

[vi] Section C.01.005 of the *Food and Drug Regulations*, C.R.C., c. 870 states the following:

> C.01.005. (1) The principal display panel of both the inner label and outer label of a drug sold in dosage form shall show in a clear and legible manner the drug identification number assigned by the Director for that drug pursuant to subsection C.01.014.2(1), preceded by the words "Drug Identification Number" or "Drogue : identification numérique" or both, or the letters "DIN".

[vii] See the proposed natural health products regulations in: *The Canada Gazette, Part I*, Vol. 135, No. 51 (December. 22, 2001) pp. 4912-4971 at: http://www.canada.gc.ca/gazette/hompar1-2_e.html.

[viii] In contrast, section 19 of the *Canadian Food Inspection Agency Act* authorizes the Minister of Agriculture and Agri-Food to issue mandatory recalls for foods. See: *Canadian Food Inspection Agency Act*, R.S.1997, c. 6.

[ix] Approved drugs posing health risks may be subject to mandatory stop-sale orders pursuant to subsection C.01.013(3) of the *Food and Drug Regulations*, C.R.C., c. 870.

[x] See: http://www.hc-sc.gc.ca/english/protection/warnings/2002/2002_56e.htm.

[xi] See, for instance, http://www.hc-sc.gc.ca/english/protection/warnings/2002.htm and http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/adviss_tpd_bgtd_e.html and http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/publicat/adrv12n4_e.html#6.