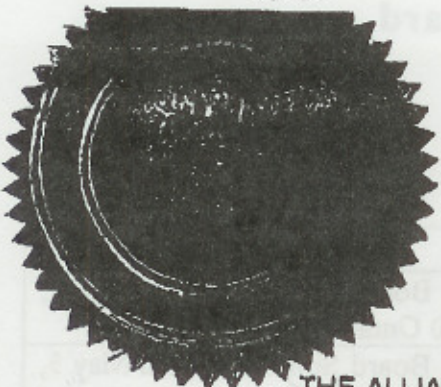


COURT No.
No. DE LA COUR

T-1198-04



Action

FEDERAL COURT

BETWEEN:

THE ALLIANCE OF NATURAL HEALTH SUPPLIERS INC.
AND
FREEDOM OF CHOICE IN HEALTH CARE INC.

Plaintiffs

- and -

HER MAJESTY THE QUEEN IN THE RIGHT OF CANADA and
the MINISTER OF HEALTH OF CANADA

Defendants

STATEMENT OF CLAIM

TO THE DEFENDANTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Plaintiffs. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or a solicitor acting for you are required to prepare a statement of defence in Form 171B prescribed by the *Federal Court Rules, 1998*, serve it on the plaintiff's solicitor or, where the plaintiff does not have a solicitor, serve it on the plaintiff, and file it, with proof of service, at a local office of this Court, WITHIN 30 DAYS after this statement of claim is served on you, if you are served within Canada.

If you are served in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period for serving and filing your statement of defence is sixty days.

Copies of the *Federal Court Rules, 1998*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-922-4238) or at any local office.

IF YOU FAIL TO DEFEND THIS PROCEEDING, judgment may be given against you in your absence and without further notice to you.

Dated this 22nd day of June, 2004.

Issued by: _____ (Registry Officer)

Address of local office: PO Box 10065, 701 West Georgia Street, Vancouver, B.C. V7Y 1B6.

TO: Her Majesty the Queen in the Right of Canada
c/o The Attorney General of Canada
Deputy General of Canada's Office
284 Wellington Street
Ottawa, Ontario
K1A 0H8

TO: The Minister of Health
Tunney's Pastur
Ottawa, Ontario
K1A 0K9

CLAIM

1. The Plaintiffs claim:

- (a) a declaration that the definition of "drug" found in section 2 of the *Food and Drug Act*, RSC 1985 c. F-27, is overly broad so as to take the application of the Act beyond the jurisdiction of Parliament set out in s. 91 of the *Constitution Act, 1867*. Following a declaration that the definition of "drug" is overly broad, the Plaintiffs will be seeking to have the definition read down to exclude substances such as food and dietary supplements/natural health products that do not pose a health risk and consequently do not engage Parliament's jurisdiction under s. 91 of the *Constitution Act, 1867*;
- (b) a declaration that the definition of "drug" found in section 2 of the *Food and Drug Act*, RSC 1985 c. F-27, does not include substances such as food and dietary supplements/natural health products that do not pose a health risk and consequently do not engage Parliament's jurisdiction to regulate in the area of health under the *Constitution Act, 1867*;
- (c) a declaration that the definition of "drug" found in section 2 of the *Food and Drug Act*, RSC 1985 c. F-27, does not include food and dietary supplements/natural health products on the basis that Parliament never intended the definition of "drug" to apply to such substances;
- (d) a declaration that the *Natural Health Products Regulations*, SOR/2003-196 enacted pursuant to subsection 30(1) of the *Food and Drugs Act*, RSC 1985 c. F-27, are ultra vires the Parliament of Canada and as such are contrary to sections 91 and 92 of the *Constitution Act*,

1867;

- (e) a declaration that the *Natural Health Products Regulations*, SOR/2003-196 enacted pursuant to subsection 30(1) of the *Food and Drugs Act*, RSC 1985 c. F-27, are ultra vires the Governor General in Council;
- (f) a declaration that the definition of "drug" found in section 2 of the *Food and Drug Act*, RSC 1985 c. F-27, is overly broad and should be declared void for vagueness and/or for a violation of section 7 of the *Canadian Charter of Rights and Freedoms*;
- (g) an order striking down subsections 3(1) and 3(2) of the *Food and Drugs Act*, R.S.C. 1985, c. F-27 as unconstitutional for violating the Plaintiffs' rights to freedom of expression as guaranteed by subsection 2(b) of the *Canadian Charter of Rights and Freedoms*;
- (h) an order striking down subsections 3(1) and 3(2) of the *Food and Drugs Act*, R.S.C. 1985, c. F-27 as unconstitutional for violating s. 7 of the *Canadian Charter of Rights and Freedoms* in that the effect of the subsections is to deny Canadians personal choice in the area of personal health and medical care;
- (i) costs on a solicitor and client basis, and
- (j) such further relief as to this Honourable Court may seem just.

The grounds for the Plaintiffs' claims are:

1. the definition of "drug" found in s. 2 of the *Food and Drug Act*, RSC 1985 c. F-27 (the "Act"), is so broad as to include "any

substance or mixture of substances" for which health claims are made regardless of whether the substances can be reasonably expected to pose a health risk to Canadians. For example, substances such as water, fruit and vegetables are "drugs" under the Act if health claims are made despite the fact that they cannot reasonably be expected to pose health risks to Canadians if regulated as "food" under the Act;

2. insofar as the overly broad definition of "drug" in the Act extends to substances that cannot reasonably be expected to pose any health risk to Canadians, it does not fall within Parliament's criminal law power. The applicant does not take issue with Parliament's jurisdiction to regulate substances such as foods to protect against adulteration and to enforce standards of purity to protect against harm as is done for "foods" under the Act;
3. insofar as the overly broad definition of "drug" in the Act extends to substances that cannot reasonably be expected to pose a health risk to Canadians, it does not fall within Parliament's emergency power under the head of peace order and good government;
4. because the definition of "drug" is overly broad so as to engage the Act in areas beyond Parliament's jurisdiction, the definition should be read down to exclude substances such as food and dietary supplements/natural health products that do not pose a health risk and consequently do not engage Parliament's jurisdiction to regulate in the area of health;
5. the Parliamentary debates surrounding the Act make it clear that Parliament never intended the definition of "drug" to apply to substances such as food and dietary supplements/natural health products;
6. the Minister of Health's historic enforcement of the Act makes it

clear that Parliament never intended the definition of "drug" to apply to substances such as food and dietary supplements/natural health products;

7. the *Natural Health Products Regulations*, SOR/2003-196 purport to regulate natural health products. The overwhelming majority of Natural Health Products as defined by the Regulations pose no or only a de minimis health risk to Canadians;
8. Parliament has the jurisdiction to regulate any product that has a potential health risk. Parliament cannot extend this jurisdiction to products which pose no or only a de minimis health risk. The *Natural Health Products Regulations*, SOR/2003-196 are ultra vires the jurisdiction of Parliament;
9. the *Natural Health Products Regulations*, SOR/2003-196 impose product licence, site licence, manufacturing, storing and labelling requirements for natural health products. Parliament has not given or delegated legislative authority under the provisions of the Act to create regulations that propound a scheme for imposing these requirements on natural health products;
10. the definition of "natural health product" in the *Natural Health Products Regulations*, SOR/2003-196 is ultra vires the Governor General in Council;
11. the *Natural Health Products Regulations*, SOR/2003-196 are ultra vires the Governor General in Council in that they purport to apply to a subset of drug that goes beyond the definition of "drug" as found in the Act;
12. the definition of "drug" in the Act does not differentiate between pharmaceutical formulations and natural health products, and as such has the potential to obstruct Canadians', including

- the Plaintiffs', access to foods and dietary supplements/natural health products that have beneficial health effects;
13. the definition of "drug" found at section 2 of the Act is overly broad and should be declared void for vagueness and a violation of section 7 of the *Canadian Charter of Rights and Freedoms* (the "Charter");
 14. this vagueness has created the situation where the regulatory body, Health Canada, has demonstrated confusion as to whether natural health products are "drugs" under the Act;
 15. this vagueness has created the situation where Canadians do not know which natural health products will be treated by Health Canada as "drugs" at any given time;
 16. this vagueness and the overly broad nature of the definition of "drug" has created the situation that when Health Canada decides to treat a natural health product as a drug because of Schedule "A" health claims, a conviction under s. 3 of the Act will automatically follow;
 17. the violation of s. 7 of the Charter cannot be saved under section 1 of the Charter;
 18. subsection 3(1) of the Act prohibits all advertising to the general public of any treatment, preventative or cure for any condition listed in Schedule A of the Act;
 19. subsection 3(2) of the Act prohibits all selling of foods or drugs where there is any representation by label or advertisement to the general public that the food or drug is a treatment, preventative or cure for any conditions listed in Schedule A of the Act;
 20. the purpose of subsections 3(1) and 3(2) is to limit freedom of

- expression;
21. the effect of subsections 3(1) and 3(2) is to limit freedom of expression;
 22. the violation of freedom of expression caused by subsections 3(1) and 3(2) cannot be saved under s. 1 of the Charter;
 23. one of the purposes behind subsections 3(1) and 3(2) of the Act is to ensure that Canadians seek "proper" medical treatment for the conditions listed in Schedule A. "Proper" medical treatment means treatment by a medical doctor;
 24. "proper" medical treatment is not without risks. One of the leading causes of death in Canada, if not the leading cause of death, is "proper" medical treatment;
 25. there are numerous dietary supplements/natural health products that are effective in the safe treatment, mitigation or prevention of the conditions listed in Schedule A of the Act;
 26. the right to make personal choices in the area of personal health and medical care is a right guaranteed by s. 7 of the Charter;
 27. Canadians cannot choose to take dietary supplements/natural health products for conditions listed in Schedule A, because subsections 3(1) and 3(2) prohibit the advertising necessary to educate Canadians about the products;
 28. the absence of choice caused by subsections 3(1) and 3(2) forces Canadians to assume the risk of "proper" medical treatment;
 29. this violation of s. 7 and the harm it causes cannot be justified under s. 1 of the Charter;
 30. the Plaintiffs rely on sections 1, 2 and 7 of the *Canadian Charter of Rights and Freedoms*, sections 2, 3 and 17 of the

Federal Court Act, RSC 1985 c. F-7, and rules 61, 62, 63, and 64 of the *Federal Court Rules*, 1998.

The Plaintiffs propose that this action be tried at 701 West Georgia Street in Vancouver, British Columbia.

Dated this 21st day of June, 2004.

Shawn P. Buckley
Counsel for the Plaintiffs

Buckley & Company
201 - 444 St. Paul Street
Kamloops, B.C.
V2C 2J6
Phone: (250) 372-1404
Fax: (250) 374-5800

Court File No.

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STATEMENT OF CLAIM

Buckley & Company

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File: 20 0027 000