ENSURE PARLIAMENT'S INTENTION IN BILL C-17 IS FOLLOWED

An Act to Amend the Food and Drugs Act

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Whereas in their report "Natural Health Products A New Vision" the Standing Committee on Health recommended that the Food and Drugs Act be amended to include the definition of Natural Health Product;

And whereas when *Vanessa's Law* was passed adding new measures into the *Food and Drugs Act* Parliament was clear that the new measures were not intended to apply to natural health products, Parliament including in the preamble to *Vanessa's Law*:

> "And whereas new measures are required to further protect Canadians from the risks related to drugs and medical devices, *other than natural health products*;"

And whereas Parliament's intention in *Vanessa's Law* to exempt natural health products from the new measures can be undermined by repealing the *Natural Health Products Regulations* and such a regulatory change can occur without the consent of Parliament;

And whereas Health Canada has published a plan to regulate natural health products under the same set of regulations as chemical non-prescription drugs, which would involve repealing the *Natural Health Product Regulations*;

And whereas Canadians want Parliament to have to authorize significant changes to the regulation of natural health products, such as the imposition of the *Vanessa's Law* measures;

And whereas if the definition of natural health product is added to the *Food and Drugs Act* Parliament's intention in *Vanessa's Law* would be safeguarded as would the desire of Canadians to have Parliament authorize significant changes to the regulation of natural health products.

Now, therefore, Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

FOOD AND DRUGS ACT

1. Section 2 of the *Food and Drugs Act* is amended by adding the following:

natural health product means any of the following that is manufactured, sold or represented as a ***drug*** for human beings:

(a) a plant or plant material, an alga, a bacterium, a fungus, or a non-human animal material;
(b) an extract or isolate of a substance described in paragraph (a), the primary molecular structure of which is identical to that which it had prior to its extraction or isolation;
(c) any of the following vitamins: biotin; folate; niacin; pantothenic acid; riboflavin; thiamine; vitamin A; vitamin B6; vitamin B12; vitamin C; vitamin D; vitamin E; vitamin K1; vitamin K2;
(d) an amino acid;
(e) an essential fatty acid;

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(f) a synthetic duplicate of a substance described in paragraphs (b) to (e);

(g) a mineral;
(h) a probiotic;
(i) any product whose medicinal ingredients consist entirely of things referred to in any of the paragraphs (a) to (h);
(j) a homeopathic medicine, or
(k) a traditional medicine.

However, a natural health product does not include:

(1) a substance set out in Schedule I, any combination of substances that includes a substance set out in Schedule I, or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule I, or

(2) a substance or combination of substances or a traditional medicine if its sale, under the *Food and Drugs Regulations*, is required to be pursuant to a prescription;

2. The definition "therapeutic product" in section 2 of the Act is replaced by the following:

therapeutic product means a drug or device or any combination of drugs and devices, but does not include a ***natural health product***;

3. The Act is amended by adding the following after Schedule H:

Schedule I

1. A substance set out in Schedule C to the Act.

2. A substance set out in Schedule D to the Act, except for the following:

   (a) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and

   (b) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy.

3. A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*.

4. A substance that is administered by puncturing the dermis.

5. An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic.

6. Cannabis as defined in subsection 2(1) of the *Cannabis Act*, except for a derivative or a product made from a derivative that is exempt from the application of the *Cannabis Act* under the *Industrial Hemp Regulations* and that does not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoid.

7. Anything referred to in Schedule 2 to the *Cannabis Act* that contains more than 10 µg/g THC, an isolated or concentrated phytocannabinoid or a

synthetic duplicate of that phytocannabinoid.

EXPLANATORY NOTES

The intention of this Bill is to move the existing definition of natural health product as found in the *Natural Health Product Regulations* into the *Food and Drugs Act* so that Parliament's intention in *Vanessa's Law* (S.C. 2014, c. 24) is not undermined by regulatory changes. The intention is not to change the definition of natural health product.

The definition of natural health product as found in the *Natural Health Product Regulations* is governed by four parts. They are:

(1) the definition of natural health product found in s. 1 of the Regulations;
(2) Schedule 1 of the Regulations;
(3) Schedule 2 of the Regulations, and
(4) subsection 2(2) of the Regulations.

To make the definition of natural health product understandable in a stand-alone definition, items (1), (2) and (4) were combined into a single definition. Item 3 was changed to Schedule I of the Act.

Because the proposed definition incorporates the word "drug" which is defined in the Act, it was not necessary to include parts (a) to (c) of the definition of natural health product as found in the *Natural Health Product Regulations*.

As written this Bill will not affect what currently is a natural health product.

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