115TH CONGRESS
2nd SESSION
HR. _____

IN THE HOUSE OF REPRESENTATIVES
OF THE UNITED STATES

[Date]

[Sponsors] introduced the following bill; which was referred to the Committee on _____, for a period to be subsequently determined by the Speaker of the House, for consideration of such provisions as fall within the jurisdiction of the committee concerned.

A BILL

To ensure the continued availability of traditional and newly developed natural remedies.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ‘‘Natural Remedies Access Act of 2018’’ or the “NRAA Act.”

SECTION 2. CONGRESSIONAL FINDINGS

The Congress of the United States finds:

(1) Congress has previously provided for the continued access of Americans to Dietary Supplements through the Dietary Supplement Health and Education Act of 1994 (DSHEA), 108 Stat. 4325, to Medical Foods through the Orphan Drug Act of 2005, and to Homeopathic Remedies, by including the Homeopathic Pharmacopeia of the United States (HPUS) in the statutes of the United States, Pub. L. No. 75-717, 52 Stat. 1040 (1938), codified as amended at 21 U.S.C. §§ 301-392 (1994).
(2) The existing regulatory structures as provided in the Food and Drug Administration’s DSHEA GMPs, 21 CFR Part 111, and regarding Homeopathy, CPG sec. 400.400, are adequate to protect the public interest.
(3) Recent actions by the Food and Drug Administration, to apply a “Risk/Benefit” analysis to the further development of Natural Remedies, including Homeopathic Remedies, have been criticized as inappropriate and unnecessary by users of Natural Remedies and Homeopathy and by persons trained in Natural Health Methods, including Homeopathy or certified, licensed or permitted by law to provide natural remedy or homeopathic advice.
(4) Due to the principles of biological individuality the application of a “Risk/Benefit” analysis is scientifically inappropriate.

(5) Due to the nature of Homeopathic Remedies (which are dynamic and not of material substance), homeopathic remedies are inherently safe when pure and formulated according to the principles of the HPUS.

(6) Due to the nature of Natural Remedies which are DSHEA Dietary Supplements such Natural Remedies are deemed safe when used as directed.

(7) Natural and Homeopathic Remedies ought to be readily available to Americans for self-health and on at least as effective a basis as Medical Foods are available under the Orphan Drug Act of 2005 which provides for the recommendation of Medical Foods "based on recognized scientific principles ... established by medical evaluation...." Section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3))

(8) When the original States formed the Federal Union they adopted the Common Law of England as it existed on July 4, 1776. That law included the Herbalists Charter of Henry VIII, United Kingdom Statutes at Large, 34&35 Henry VIII. C8, A Bill that Persons, being no common Surgeons, may minister Medicines, notwithstanding the Statute, which provided that purveyors of Natural Remedies were to be free from "suit, vexation, trouble, penalty or loss of their goods..." as a perpetual Charter of Rights. This Charter remains the Common Law in the United States.

SECTION 3. DEFINITIONS.

In this Act—

(1) For the purposes of this Act the terms -

(a) "Natural Remedy/Remedies" means any Dietary Supplement under DSHEA or Medical Food under the Orphan Drug Act intended as a natural therapeutic agent which may be of benefit, based on recognized scientific principles, established by nutritional evaluation.

(b) "Homeopathic Remedy/Remedies" means any dilute or nano remedy listed in the HPUS or formulated according to the principles of the HPUS, based on recognized scientific principles, established by homeopathic evaluation.

(2) The term "Risk/Benefit Analysis" means the application of the principles of Risk/Benefit Analysis, for example, as referenced by the Food and Drug Administration in Regulations.gov Docket FDA-2017-D-6580.

SECTION 4. PROHIBITED ACTS.

(1) The Food and Drug Administration shall not apply a Risk/Benefit Analysis to the regulation of any Natural or Homeopathic Remedy.

(2) No Natural or Homeopathic Remedy shall be deemed a "new drug" under the Food, Drugs and Cosmetics Act, but shall be deemed a Natural or Homeopathic Remedy available without prescription.

(3) No person in the United States shall be deprived of access to any Natural or Homeopathic Remedy by action of any agent or agency of the United States or of any State, or by any

person acting under color of law.

SECTION 5. CAUSE OF ACTION.

(1) Any person aggrieved by any violation of this Act may sue in any United States District Court in the District where the person resides or in the District where any defendant resides or is located for redress of grievances, including damages, punitive damages and injunctive relief.

(2) The United States District Courts are empowered to issue preliminary, temporary or permanent injunctive Orders protecting access to Natural or Homeopathic Remedies whenever it shall appear by the preponderance of the evidence that such access has been restricted or is at immanent risk of restriction by any governmental department, agency or agent, or person acting under color of law, without a showing of other irreparable harm.

SECTION 6. EFFECTIVE DATE.

(1) This Act is effective immediately.