



45 (6) 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))

50 SECTION 3. DEFINITIONS.

In this Act—

- 55 (1) For the purposes of this Act the term “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 as referenced by the Food and Drug Administration in Regulations.gov Docket
FDA-2017-D-6580.

60 SECTION 4. PROHIBITED ACTS.

- (1) The Food and Drug Administration shall not apply a Risk/Benefit Analysis to the regulation
of any Homeopathic Remedy.
- 65 (2) No Homeopathic Remedy shall be deemed a “new drug” under the Food, Drugs and
Cosmetics Act, but shall be deemed a Homeopathic Remedy available without prescription.
- (3) No person in the United States shall be deprived of access to any 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.

70 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
75 relief.
- (2) The United States District Courts are empowered to issue preliminary, temporary or
permanent injunctive Orders protecting access to 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
80 acting under color of law, without a showing of other irreparable harm.

SECTION 6. EFFECTIVE DATE.

- (1) This Act is effective immediately.