United States District Court for the District of Columbia

Holistic Candlers and
Consumers Association
58 Plotts Road
Newton, NJ 07860

Natural Solutions Foundation
58 Plotts Road
Newton, NJ 07860

Foundation for Health Choice
777-K Schwab Road
Hatfield, PA 19440

Harmony Cone
3318 Hwy 5 #410
Douglasville, GA 30135

King Cone Intl
2751 Plaza Del Amo
Torrance, CA 90503

C and H Ranch, LLC
9108 W. Single Tree Lane
Payson, AZ 85541

Betty Lee
dba Betty Lees Candles
10630 East FM 1518 N
Schertz, TX 78154

Becks Natural
2557 Herrondale W.
Henry, TN 38231

Farist Enterprises
506 Wards Creek Dr.
Dahlonega, GA 30533

Case: 1:10-cv-00582
Assigned To : Leon, Richard J.
Assign. Date : 4/12/2010
Description: Admn Agency Review

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Home Remedy Solutions
10630 E. Fm 1518 N,
Schertz, TX 78154

Regalabs, Inc.
5060 Sugar Pike Road
Canton, GA 30115

Wholistic Health Solutions
103 Panama Road
Oak Ridge, TN 37830

Gladys Moreno
1106 S. Sycamore Circle
Payson, AZ 85541

Denese M. Traynor
3411 Preston Pointe Way
Cumming, GA 30041

John and Jane Doe

Plaintiffs,

vs.

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993,

Kathleen Sebelius,
in her official capacity as Secretary of Health and Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201

U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

and

Margaret A. Hamburg, MD,
in her official capacity as
Commissioner of Food and Drugs 10903
New Hampshire Ave Silver Spring, MD
20993
Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I. INTRODUCTION

1. This action involves a case or controversy in which the Court is empowered to declare the lawfulness, or lack thereof, of certain official actions of the named Defendants and to grant injunctive and other relief.

2. Plaintiffs in this action, as more fully set forth below, are several nongovernmental organizations and private associations that advocate natural alternatives to government-licensed health care (herein, the NGOs), various natural product manufacturers, distributors, practitioners and consumers who are all members of the NGOs.

3. This Civil Action seeks to challenge the recent actions of Defendants which effectively outlaw the manufacture and use of Holistic Candles (sometimes also referred to as "Ear Candles") as unapproved Medical Devices under the Safe Medical Devices Act, as amended, 21 U.S.C. 321.

Plaintiff asserts and claims that the Holistic Candle is a generic product that is exempt from defendant FDA's device regulation requirements.

4. This Court is not being asked to merely interpose its august authority between the Plaintiffs and Federal Executive authority, but to fashion appropriate remedies that will advance natural and personal health care options in the United States and reduce adverse events. Plaintiffs

seek a Declaratory Judgment and a Permanent Injunction protecting important judiciable interests of the Plaintiffs and all Americans.

5. Plaintiffs seek, in part, Remedies fashioned under the logic of *Thompson v. Western States Medical Center* ,535 U.S. 357 (2002). This First Amendment case concerns a clause in the Food, Drug and Cosmetics Act that allowed pharmacists to "compound" medications for specific prescriptions without safety testing, but forbade pharmacists from advertising the specific compounds they make. The Supreme Court held that the statutory restriction was unconstitutional, stating,

> "We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information. ...Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown."

6. Thus, one of the Remedies Plaintiffs seek is that proper Disclosure and Disclaimers be given with regard to Holistic Candles, to save them from being considered Medical Devices. Plaintiffs contend, (1) Holistic Candles are not Medical Devices under 21 U.S.C. 321; (2) in the alternative, if Holistic Candles are Medical Devices then they are exempt from registration as Class I Devices and (3) in the alternative, if Holistic Candles are not exempt Class I Devices, they are Grandfathered as having been in use prior to 1974. A Brief History of Holistic or Ear Candling is attached hereto as Exhibit A.

7. Plaintiffs further seek a mandate from this Court that the Defendants shall cease to claim that Holistic Candles are unapproved Medical Devices. Plaintiffs allege there is no

significant scientific agreement that they are used for Medical Treatment. To the contrary, Holistic Candles are traditionally used for holistic relaxation and comfort.

8. The Defendants are bound by the Data Quality Act to produce and disseminate only truthful information to the people of the United States. They have woefully failed in that duty and are thereby harming these Plaintiffs. The Court should therefore act with judicious restraint to fashion a permanent injunction that requires only truthful and not misleading public health care advice and information from these Defendants regarding Holistic Candling. The impact of the Defendants' actions, based on these Defendants' unlawful categorization of Holistic Candles as "Medical Devices" puts these Plaintiffs at imminent risk of loss of income or other valuable rights.

II. STATEMENT OF THE CASE

9. The Complaint in this matter involves the February 2010 Warning Letters issued by the Defendant Food and Drug Administration (herein, FDA) to fifteen ear candle companies (herein the Mandated Companies) ordering them to cease and desist from distributing ear candles as they have been determined to be unapproved Medical Devices. In discussions thereafter with the Mandated Companies agents of the FDA indicated that, contrary to the holding in *Pearson v. Shalala,* 164 F.3d 650 (D.C. Cir. 1999), *rehearing denied* 172 F.3d 72 (1999), there is no Disclaimer or Disclosure that the Mandated Companies could make that would save ear candles from being banned.

III. JURISDICTION AND RIPENESS

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1361 (mandamus). The relief requested is authorized pursuant to 28

U.S.C. § 1651 (all writs act); 28 U.S.C. § 2201 (declaratory relief); and 28 U.S.C. § 2202 (further relief). Plaintiffs have a right to bring this action pursuant to the Administrative Procedures Act because the Defendants, including the FDA, have engaged in final agency actions that "are contrary to law" (in the language of the Administrative Procedures Act - APA) presenting actual controversies for which these Plaintiffs are entitled to relief. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) because this is a civil action in which at least one of the Defendants is an officer of the United States that resides in this judicial district or an agency of the United States that resides in this judicial district.

11. This matter is ripe for adjudication as the fifteen-day period that the Mandated Companies were given has expired without extension.

IV. STANDING

12. The Plaintiffs are all nongovernmental organizations and individual United States citizens who are members or supporters of the organizations and who are manufacturers, distributors, consumers or other users of Holistic Candles. The specific harm which the individual Plaintiffs will suffer as a result of the FDA actions complained of herein are set forth in this Complaint.

13. Plaintiffs therefore have standing to challenge the defendant's determination that ear candles are unapproved medical devices.

14. These Plaintiffs stand in imminent peril of risk of health or life, loss of liberty, property, livelihood or licensure, or other public. Thus, they have been harmed by the acts of the Defendants.

V. PARTIES

15. Plaintiffs in this action are several nongovernmental organizations and private associations that advocate natural alternatives to government-licensed health care (herein, the NGOs), various natural product manufacturers (the Mandated Companies), distributors, practitioners and consumers who are all members of the NGOs.

(a) Holistic Candlers and Consumers Association by Ralph Fucetola JD, 58 Plotts Road, Newton, NJ 07860, its trustee in formation, is an unincorporated private association of holistic candle manufacturers, distributors, practitioners and consumers.

(b) Natural Solutions Foundation by Ralph Fucetola JD, 58 Plotts Road, Newton, NJ 07860, its trustee, is a Nevada nonprofit corporation duly recognized as an exempt nongovernmental organization which educates the public and decision makers regarding natural approaches to health; the Foundation provides Holistic Candles to its private associates through its web site.

(c) Foundation for Health Choice is a non-profit corporation working to advance the rights of patients and their families to choice, information, safety, and redress in healthcare.

(d) The holistic candle manufacturers and distributors listed as parties plaintiff are all enterprises which have, in some cases prior to 1974, manufactured or distributed holistic candles, with varying claims, and all have received warning letters from the FDA during February, 2010.

(e) Plaintiff Denese M. Traynor is individual consumer of holistic candles.

(f) J. Doe, representing all other consumers who wish to continue to use Holistic Candles.

16. The Defendants are all either Departments, Agencies or Officials of the United States Government: United States Food and Drug Administration [10903 New Hampshire Ave. Silver Spring, MD 20993], Kathleen Sebelius, Secretary of Health and Human Services [200 Independence Avenue, S.W. Washington, D.C. 20201], Department of Health and Human

Services [200 Independence Avenue, S.W. Washington, D.C. 20201], Margaret A. Hamburg, MD, Commissioner of the Food and Drug Administration [10903 New Hampshire Ave. Silver Spring, MD 20993.

COUNT ONE

17. On or about February 22, 2010, several of the Mandated Companies received a letter from the FDA dated on or about February 17, 2010 announcing the FDA's determination that ear candles are, per se, unapproved Medical Devices and cannot be sold in the United States and in the several States. The FDA determination was made without the prior petition of Citizens and without an FDA Request for Comments. The letter requested a reply within 15 days setting forth what the Mandated Companies would do to conform to the FDA determination.

18. Plaintiffs deny the contention of the FDA that the holistic relaxation and comfort products, sometimes known as "ear candles" (herein, the "Holistic Candles") are "medical devices." A device is defined via 21 U.S.C. § 321:

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

19. Holistic Candles are not medical devices. Properly made Holistic Candles are a natural holistic modality are used for and intended to be used for relaxation, comfort, reduction of stress and for the natural furtherance of the well-being of the user. The relaxation process, from the viewpoint of any alternative health modality, is for the fostering of and the support for the human body's own propensity to spontaneously seek natural homeostasis, via relaxed and stress-reducing circumstances, catalysts, or environments.

20. Such traditional and intended use, usually in a family or private association context, does not "treat or cure" any condition of illness, and does not specifically affect any body function. Alternative modalities simply allow the body to do what the human body does naturally, and that is to find a proper and necessary balance between the integrated components of the mind-body-spirit. This, in essence, is what homeostasis is.

21. As such, homeostasis is the natural human biologic/physiologic/emotional balancing activity that is necessary for optimum health (and life), as we know and understand it. This natural human process can also be assisted by a variety of non-medical, environmental,

alternative, or holistic modalities. Thus, human homeostasis is the natural tendency to seek and obtain a stable equilibrium between interdependent elements. Such modalities that relax the body to allow it to achieve homeostasis are not "the treatment of disease" but, rather, they create relaxation that allows the body to achieve metabolic equilibrium actively that is maintained by several complex biological mechanisms that operate via the autonomic nervous system to offset disrupting changes.

22. Holistic therapies foster the user's sense of comfort and well-being and focuses upon health promotion, balance, comfort, and the ability to draw upon one's own healing capacities (i.e.: homeostasis). Consequently, many of the alternative modalities and holistic systems have been in existence and use throughout human history, and are an integral part of cultures, customs and traditions. The beneficial claims are permitted Traditional Use claims.

23. The use and effectiveness of such therapy have been well established and legitimized by using or integrating holistic methodology and techniques in modern practices. Additionally, natural healing, as we know it, does not equate to effecting a "curing," rather it creates relaxation that allows the body to reach homeostasis which on some occasions might allow the body to "heal" or rebalance some aspect of itself.

24. But, presuming that Holistic Candles may be medical devices, they would be nothing but generic "Class I Devices." An ear candle "(I) is not represented to be and is not used to support or sustain human life and the product is not used for the purpose of preventing other impairments or risks to human health. Plaintiff's products (II) do not present a potential unreasonable risk of illness or injury." See § 360c(a)(1)(A).

25. There have been, at most, three FDA adverse events reported in recent decades that specifically involve the use of ear candles.

26. Under 21 U.S.C. § 379a, FDCA presumes jurisdiction for any actions taken by FDA: "In any action to enforce the requirements of this chapter respecting a device, food, drug, or cosmetic[,] the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist." The exercise of FDA regulatory power under this statutory provision is unconstitutional because the regulatory power belongs to the several States and to the people respectively as secured by the 10th Amendment to the U.S. Constitution. This principle was expressed very early during the days of the creation of this country by Federalist No. 45:

> "The powers delegated by the proposed Constitution to the Federal Government, are few and defined. Those which are to remain in the State Governments are numerous and indefinite. The former will be exercised principally on external objects, as war, peace, negotiation and foreign commerce; with which last the power of taxation will for the most part be connected. The powers reserved to the several States will extend to all the objects, which, in the ordinary course of affairs, concern the lives, liberties and properties of the people; and the internal order, improvement, and prosperity of the State."

27. To enforce certain portions of the FDCA, the FDA must use procedures and take actions that ultimately lead to federal courts. Defendants have threatened to commence an action to seize and confiscate Plaintiff's property, to restrain Plaintiffs from marketing, promoting and distributing ear candle products, and to obtain pecuniary penalties against Plaintiffs. Defendants knew or should have known that 21 U.S.C. § 379a, enforced without appropriate procedures, is an unconstitutional exercise of power.

28. Furthermore, federal law prohibits a federal agency from acting outside the jurisdiction delegated to it. See 5 U.S.C. §558. Defendants knew or should have known that they were acting outside of the agency's jurisdiction were committing and threatening to commit ultra vires acts against the Plaintiffs.

29. By statute, the regulatory jurisdiction of the FDA extends to two distinct areas. Pursuant to 21 U.S.C. §331(g), the FDA can regulate and control the "manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded." Via 21 U.S.C. § 331(a), (b), (c), and (d), the FDA has jurisdiction over the following:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.
(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 355, or 360bbb-3 of this title.

Plaintiffs products do not fall within the scope and purview of a device under the relevant laws of the United States and the products were not adulterated, misbranded or mislabeled.

30. Thus those parts of the FDCA that concern the manufacture of "devices" only relate to the manufacturing of devices in U.S. territories, which is within the scope of 21 U.S.C. §331(g). Defendants knew or should have known that the FDA cannot constitutionally or statutorily regulate the manufacture of devices within the jurisdiction of any particular State of the Union.

31. In its letters, FDA capriciously contends that the Mandated Companies have distributed adulterated devices by making ear candles available for purchase. The specific

criteria for what constitutes an adulterated device are set forth in 21 U.S.C. § 351.

32. In its letters, the FDA also contends that the Mandated Companies have distributed misbranded devices by making ear candles available for purchase. The statutory criteria for misbranded devices are set forth in 21 U.S.C. § 352. Plaintiffs did not misbrand products and FDA had no adverse events reports or other substantive evidence that Plaintiffs had and intended to manufacture or distributed misbranded products.

33. Holistic Candles are not misbranded and consequently not violative of § 352.

34. As noted above, some of the alleged requirements imposed by FDA upon Plaintiffs products, and as set forth in § 352 (o) are unconstitutional.

35. 21 U.S.C. § 352 (o) imposes requirements based on § 360 that mandate registration of manufacturers in any State. Defendants knew or reasonably should have known that Congress was not vested with power to regulate production within any of the several States of the Union and that the assertion of regulatory powers by the FDA against Plaintiffs was unconstitutional.

36. Defendants knew or should have known that the statutory definition of "device" was so vague and ambiguous that it would allow FDA to exercise arbitrary powers against Plaintiffs that were intended to completely and permanently take away and destroy the livelihood of Plaintiffs, and prohibit each of the Plaintiffs from using, enjoying and disposing of their property in a lawful manner.

37. 21 U.S.C. § 352 (o) also imposes requirements based on § 360(j), which adopts the requirements of §§ 351, 352, 360, and 360i. Section 360i requires reports of certain incidences pursuant to regulations adopted by the Secretary which, via subparagraph (a)(1)(B)(i), "shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor

regulations)". However. the reporting requirement regulations that appear in 21 C.F.R. Part 803 have not been assigned and do not display OMB control numbers as required by 44 U.S.C. §§ 3501, et. seq. For the consequences of the failure of a regulation that is an "information collection request" but does not display an OMB control number.

38. 21 U.S.C. § 352 (o) also imposes requirements based on § 360(k), which provides that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement — (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Defendants knew or reasonably should have known that the same said statute is in contravention to the separation of powers mandated by the Constitution for the United States of America, Amendment 10.

39. 21 U.S.C. § 352 (o) also imposes requirements based on § 360e, which concerns premarket approvals.

Defendants knew or should have known that Plaintiffs products were not subject to and were immune from FDA premarket approval requirements.

40. Defendants contend and administratively allege that the Mandated Companies have violated the FDCA because of claims made about ear candles and demands that Plaintiffs remove any reference to their product on their Internet web sites.

Defendants knew or should have known that their demand made upon Plaintiffs to remove any reference to their product on their Internet web sites was in violation of Plaintiff's right to free

speech as secured and protected by the Constitution for the United States of America, Amendment 1.

41. Wherefore the Mandated Companies and the distributors, practitioners and consumers who depend upon Plaintiffs for relevant information, manufacturing, distribution and proper and safe use of Holistic Candles, are not in violation of the FDCA and ought to be free from arbitrary and capricious interference by the named Defendants and FDA.

Requests for Relief

42. Wherefore, the Plaintiffs herein petition this Honorable Court for an opportunity to be heard on an application for injunctive relief, binding upon the Defendants, and all subordinate agents and agencies thereof, restraining the Commissioner et al., until further Order of the Court, (1) staying the unapproved Medical Device determination under 21 USC 321; (2) a Declaration that the said determination is void; (3) an order that the judicial determination voiding the FDA action is contingent upon clear Disclaimers and Disclosures mandating informed consent and voluntary use of Holistic Candles solely as a traditional use holistic relaxation and comfort modality, and not as a "treatment of disease" or other Medical Device use, so that the citizens' First and Fourteenth Amendment and other rights shall be preserved, and (4) for such other and further relief to which the Plaintiffs may be entitled.

COUNT TWO

43. The Plaintiffs re-allege and repeat all of the allegations in Counts One through Three as though fully set forth herein.

44. Plaintiffs or some of them use Holistic Candles as part of the ordinary activities of their religion, or as part of private expressive association activities.

45. Defendants administrative acts and threats of action discriminate against those observing particular religious beliefs or private associational beliefs, customs and traditions.

46. Some users of Plaintiff's products have such deep convictions that include a belief in and-use of natural alternative modalities such as Holistic Candling. The right to said lawful use of Plaintiff's products is protected by the Religious Freedom Restoration Act of 1993. 42 U.S.C. § 2000bb

47. Based upon the foregoing liberty and secured rights, the FDA determination to outlaw Holistic Candles can and would impose arbitrary burdens upon these religious or private associational beliefs in violation of the Free Exercise Clause.

Request for Relief

48. Wherefore, the Plaintiffs request on this Count, in addition to the relief sought in the previous Count, a Declaratory Judgment that does not limit the rights of Plaintiffs to manufacture, distribute, use or consume Holistic Candles on private associational or religious grounds.

COUNT THREE

49. The Plaintiffs re-allege and repeat all of the allegations in Counts One through Three as though fully set forth herein.

50. Defendants have violated Plaintiffs' Ninth Amendment rights that have been left to the

people individually.

51. The Ninth Amendment's protection of fundamental rights includes private rights to communicate about, obtain, use and enjoy natural, alternative, choices that are inherent in man's natural tendency to seek and obtain a stable equilibrium between interdependent elements.

52. Defendants knew or should have known that their administrative actions would abrogate the liberty and rights of the people as secured by the Constitution for the United States of America, Amendment 9.

Request for Relief

53. Wherefore, the Plaintiffs request the determination and order of this Court, in addition to the relief sought in the previous Counts, a Declaratory Judgment that the FDA determination that Holistic Candles are unapproved Medical Devices violates their Ninth Amendment rights.

Dated: April 9, 2010

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Of Counsel: Ralph Fucetola, JD

Exhibit A.
A Brief History of Holistic or Ear Candling
Statements from Consumers and Practitioners
Prepared by the HCCA
Holistic Candlers and Consumers Association

1. Holistic Ear Candling has been an ancient practice through the ages; generations of families around the world agree, the Holistic Ear Candle modality is a rewarding holistic relaxation technique; many cultures report the use of ear candles or similar techniques.
2. Tom Bluewolf has used ear candles personally since he was 16 years old. He is approximately 55 years old and can testify that he used ear candles prior to 1976.
3. Ebenezer Hills, Clarksville, Arkansas, has been open since 1968. Cecelia Bankhead does not remember when she started selling ear candles but is sure that it is before 1974 as she has 'always had them' in her family.
4. Dr. Berryhill went to the Royal Hospital of London on 144 Fleet Street in 1976. He was working in the pediatric clinic (which is friendly towards homeopathy) where he learned about ear candling from Dr. Christopher (a surgeon). He has been here since 1975 using and promoting holistic ear candles.
5. The teachers of Anne Tatum affirm that they taught Anne Tatum (who sold her company to White Egret and has been candling for over 25 years). These teachers have been candling since before 1974.
6. Bandos, Marie Bando, Beaumont, TX. As a young person her cousin (who was Lebanese and his wife was Italian) remembers that her mother in law taught her cousin how to make ear candles by rolling up something and burning it down in the ear. Debbie is her mother. She remembers getting her ears done in 1953 by Jake (believed to be her cousin)
7. Serendipity, Kingston, NJ, Jeannie Nastus, her mother learned in Sicily, Italy how to make ear candles. They took a pencil, cut up a handkerchief and wrapped it around the pencil and

melted wax over it to use as an ear candle. Her mother in law, Rosaria Mastus (over 85 years of age) came over from Italy 38 years ago.

8. Leonora Cook stated on March 8, 2010. (Midvale, UT) She was the original owner of Bobalee-Mfg.com. She learned about ear candles from Dr. Christopher in the late 1950's. In the early 1980's she purchased ear candles from Vae Dansie. who was a massage therapist in FL. She will testify that she learned from Dr. Christopher in the late 1950's.
9. Gary Crumpler, www.earcandle.com has a receipt from 1975 with the sale of ear candles prior to May 28, 1976! He had submitted it to the FDA in 1997/98 when they got their first letter. After providing this proof of use, FDA did not further reply to Mr. Crumpler.

Each of these Practitioners and Consumes is prepared to testify to the truthfulness of these statements.