DOCKET NO. 2006d-0480

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF

NATIONAL HEALTH FREEDOM ACTION

ON THE FDA DRAFT GUIDANCE

Entitled:

"Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration"

Comments Submitted May 15, 2007

NHFA - Who We Are

National Health Freedom Action (NHFA) is a 501(c) 4 non-profit corporation working to protect maximum health care options for consumers. It works to protect the right of all people to access their favorite health care practitioners and health care products, as well as to protect the right to access many other healing arts products and services that resonate with people's path to wellness. NHFA responds to calls year-round from individuals and groups throughout the country that wish to promote legal reform in occupational laws and regulations having to do with complementary and alternative health care on the state level, and with federal and state product laws and regulations having to do with access to desired products.

NHFA helps individuals and groups form health freedom organizations. It also educates on health freedom principles and on how to develop and pass proactive health freedom legislation that will ensure the rights of health care practitioners to offer their services and of consumers to have access to products, practitioners, and information. NHFA drafts model legislation, testifies at legislative hearings and public policy meetings, and provides strategic support and lobbying assistance, participates in the annual Conference for Health Freedom Advocates, and is a founding member of the World Health Freedom Assembly. NHFA is currently working with groups in over 30 states and seven countries to support health care reform efforts.[1]

NHFA Responding to Draft Guidelines presented for Comment:

NHFA became aware of the FDA Draft Guidance document entitled "*Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration"* through multiple correspondences sent to NHFA from manufacturers, practitioners, consumers, and state health freedom organizations and leaders across the country requesting an explanation of the document. The requests reflected mass confusion amongst readers.

NHFA responded by researching and reviewing the Draft Guidance document and drafting a short explanatory piece regarding it and posting the explanation on our website: www.nationalhealthfreedom.org. NHFA's Board then evaluated whether to give comments to the FDA regarding the Draft Guidance because of it's involvement with Complementary and Alternative Medicine terminology. NHFA Board approved the submission of comments. Given that this would be a new task for our organization requiring additional time to implement the drafting of comments, we requested an extension for comments from the FDA until May 15, 2007. FDA granted the extension to May 15, 2007.

[1] For further information see www.nationalhealthfreedom.org

NHFA works to maximize access to consumer health care options by reviewing, drafting, revising, and generally creating new solution language for public policy documents, legislative initiatives and literary articles. NHFA is an active participant in legal reform and its members have an interest in complementary and alternative medicine and in products used by health care practitioners of all kinds around the world who provide services to consumers. NHFA is therefore providing the following comments.

NHFA Request to the FDA:

NHFA hereby requests that the FDA stop any further work or document development on the Draft Guidance document entitled "*Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration*", Docket No. 2006d-0480, *(Hereinafter identified as the Draft Guidance Document)*, and withdraw the Draft Guidance Document in its entirety, or in the alternative, revise the Draft Guidance Document by eliminating any reference to "Complementary and Alternative Medicine Products" or "CAM Products", and revising in addition according to the concerns presented in these comments.

Summary of NHFA's Concerns:

1. The Draft Guidance Document does not fully address the complexity of the jurisdictional issues that the document raises between state and federal government.

2. The Draft Guidance Document should eliminate the term "CAM products" and "Complementary and Alternative Medicine Products" from the entire draft guidance.

3. The Draft Guidance Document does not accurately articulate the legal and public policy relationship between CAM, the CAM community, and the FDA.

4. The Draft Guidance Document is unclear as to its purpose, as to its audience, and as to the necessity of the document to confine itself to a specific subject area such as CAM.

5. The Draft Guidance Document has the potential for creating mass confusion and mistrust and for doing exactly the opposite of providing guidance to a particular audience.

NHFA's Concerns:

1. The FDA has produced a Draft Guidance Document that does not fully honor and acknowledge the complexity of state regulated health care occupational law as it

interfaces with federal product law, and has produced a document that fails to provide foundational information as to the extent and, particularly, the limitations of the FDA's federal jurisdiction over persons and health care practices, the sensitive line between interstate commerce federal product jurisdiction, and the jurisdiction of states over all healing arts and health care practices, practitioners, and occupational behaviors.

2. The Draft Guidance Document's purpose, *"...providing guidance as to when a CAM product is subject to the Act or the PHS Act."*[2], is foundationally misleading because the language of the stated purpose contains the misleading term "CAM product", unwisely coined by the FDA for convenience: *(...whether certain products used in CAM (which, for convenience, we will refer to as "CAM products*")[3].

3. The use of the term "CAM Products" in the Draft Guidance Document has the potential for causing mass confusion and misinformation within the public because of its misleading nature and the prominence of its use (the term is used in the title of the draft document as well as used at least 20 additional times throughout the document). The term is used even though there is no such category of product subject to the jurisdiction of the FDA or cited in U.S. Code or regulation, existing product categories are currently well defined as spelled out in the guidance document, and even though the use of such term would naturally raise serious questions by the entire product industry, health care occupations industry, and the U.S. consumer community.

4. The use in the Draft Guidance Document, and the merging of a prominent term such as "CAM", applicable to particular sectors of the health care occupational community and regulated under the states, with the term "product", applicable to FDA jurisdiction over products, has the potential for misinforming its audience. It potentially gives a false impression that somehow there is a new circumstance requiring a new interpretation of law that would give FDA new jurisdiction over certain situations involving CAM practices or practitioners, even though product categories are currently well defined and FDA's jurisdiction is historically and explicitly confined to products in interstate commerce and the production and sale of biological products, cosmetics, drugs, devices, and foods (including food additives and dietary supplements), and even though the individual states (and not the FDA) have jurisdiction over and regulate health care occupations and practices within the parameters of their police power.

5. The Draft Guidance Document does not educate the public as to the legal or regulatory status of the term CAM, or that the definition of CAM that the FDA has chosen to use in the Draft Guidance Document is an agency descriptor definition and has no force of law, that CAM is a term of art in literature, public policy documents[4], and research

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[2] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 1 and 2.
[3] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 1.
[4] For examples see: White House Commission on Complementary and Alternative Medicine Policy, Final Report March 2002, http://www.whccamp.hhs.gov/finalreport.html, and Complementary Medicine, a Report

with multiple definitions and a relative term to an existing or historic form of medicine, that health care occupational law and its defined terms are set forth in the individual states according to state culture and norms, and that the term CAM is just one of many terms used in state statute and regulations to describe a more expansive approach to healing and health care than was promoted by conventional medicine. (Other terms codified in state law or included in regulation and agency compliance guidance documents include but are not limited to: "traditional", "non-conventional", "unconventional", "holistic", and "integrative".[5]

6. The Draft Guidance contains particularly misleading language that gives the false impression that the FDA believes that there may be some situations in which it may have jurisdiction over "CAM practices[6]" or "whole medical systems[7]", or "components of whole medical systems[8]". The way that the Draft Guidance Document is set up and flows focuses on practices rather than products and gives the impression that the FDA is outlining circumstances in which they would have jurisdiction over a particular form of medicine such as "Energy Medicine", as opposed to articulating when they would have jurisdiction over products used in energy medicine.

7. It is unclear in the Draft Guidance Document what is attempting to be accomplished. If the impetus for such a document is based on the fact that FDA has seen increased confusion as to whether certain products used in CAM are subject to regulation under the Act or PHS Act,[9] then it would be important to identify the source of confusion, who exactly is confused (product industry, practitioners, consumers, other) and address the document to that particular audience. In that analysis it would be important to discern whether the confusion is coming from a particular group because of the nature of the group itself, (manufacturers that target CAM practitioners in their marketing, practitioners that practice CAM as opposed to other forms of healing arts, or consumers who utilize CAM in addition to other forms of the healing arts), or simply

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to the Minnesota Legislature, 1999, http://archive.leg.state.mn.us/docs/pre2003/mandated/980251.pdf, and Proclamation State of Florida, Complimentary Health Care Therapies, April 2003, http://www.nationalhealthfreedom.org/InfoCenter/reports/proclamation.pdf.

[5] For examples see over 30 State Statutes and Administrative Codes for licensed professionals: Texas "integrative and complementary medicine", Ohio "alternative medical treatment"; Colorado "alternative medicine"; Oregon "alternative medical treatment"; Georgia "experimental" and "nonconventional"; Washington and Oklahoma "nontraditional"; Alaska "unconventional"; New York "nonconventional". And for examples for unlicensed health care providers see: Minnesota "Unlicensed complementary and alternative health care practitioners"; Rhode Island "Unlicensed health care practitioners"; Louisiana "providers of foods, dietary supplements and homeopathic remedies"; California, Oklahoma, and Idaho "Exemptions from violations of practice of medicine.

[6] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 6, para 3.

[7] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 6, para 5.

[8] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 6, para 5.

[9] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 1.

coming from a lack of publicly disseminated informational materials regarding existing FDA law in an expanding marketplace that has ever increasing volume in the use of products for health care purposes. The second stated impetus for a Draft Guidance Document is even more puzzling (the fact that there are more products imported into the United States that are used by CAM practitioners[10]). It is not clear as to why that would be of concern to the FDA. We are certain that it is often the case that the volume of some product imports is greater depending on market demand. In that case increased public dissemination of informational materials regarding existing FDA law and jurisdiction would seem to be adequate to address the volume.

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8. Additional multiple and specific incidences throughout the verbiage of the Draft Guidance Document could be the source of the mass confusion generated by the document:

   a. "*You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance*."[11]

   These statements give the impression that the FDA is speaking to and giving guidance to individual persons, practitioners or consumers who are utilizing health care options outside of conventional medicine, regarding their use of health care alternative approaches. Yet the title of the document states it is "Guidance for Industry" about product regulation. The FDA is not an authority on the use of alternative healing arts approaches and should confine its comments to whether a product is in compliance with FDA laws and regulations.

   b. "*First, depending on the CAM therapy or practice, a product used in a CAM therapy or practice <u>may</u> be subject to regulation as a …*"[12]

   This statement found in the early part of the Guidance Document gives the impression that whether a product is subject to regulation has to do with what type of CAM therapy or practice the product is used in as opposed to the more straightforward explanation for whether a product is subject to regulation found in the second portion of the Guidance Document illustrating how the Act or the PHS Act might apply to any products based on the statutory definitions of the category of drug, device, etc. The second half of the Draft Guidance Document is much clearer because it provides that FDA authority might apply to any product in the market place and does not confuse the issue with what type of healing art the product is associated with. Note: All products under the jurisdiction of the FDA or the PHS Act in the marketplace are used in

[10] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 1.
[11] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 1.
[12] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 2.

multiple ways, and are not confined to use by CAM practitioners or other particular groups.

c. *"B. What Is Energy Medicine?"* [13]

The above is a section header of the Guidance Documents and the section includes five paragraphs, three of the five paragraphs talk about the FDA's regulation of medical devices. It would have been much clearer to have a heading that states: "B. What Is Energy Medicine and What Jurisdiction Does FDA Have Over Products Used in Energy Medicine.?" Similarly other headers are misleading and should be clarified: "C. What Are "Manipulative and Body-Based Practices and What Jurisdiction Does FDA Have Over Products Used in Manipulative and Body-Based Practices?".

d. "*Our intent, in part IV of this document, is two-fold: To indicate which CAM domains might be subject to regulation under the Act or the PHS Act; and…*"[14]

This statement goes straight to the source of misinformation and confusion throughout the document and the need for revision of the document. "CAM domains" will *never* be subject to regulation under the Act or the PHS Act because CAM domains are occupational domains not subject to federal jurisdiction.[15] The FDA must be vigilant throughout a document such as this to maintain language that clearly states their jurisdiction over products and not over health care practices and domains. This is critical to the understanding of the document and if the FDA would like to address this issue as to when it would have jurisdiction over a person doing a particular act, then it should do so in a forthright manner and explain what type of action against a person doing a particular act it would take and under what circumstances and what authority it has to do so.

e. "*In general, CAM practices in this domain would not be subject to our jurisdiction under the Act or the PHS Act. As with the manipulative and body-based practices domain, however, any equipment or other products used as part of the practice of*

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[13] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 4.

[14] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 7.

[15] See Minnesota Statute 146A for the use of the term "domain" in the definition Complementary and alternative health care practices. (a) "Complementary and alternative health care practices" means the broad domain of complementary and alternative healing methods and treatments, including but not limited to: (1) acupressure; (2) anthroposophy; (3) aroma therapy; (4) ayurveda; (5) cranial sacral therapy; (6) culturally traditional healing practices; (7) detoxification practices and therapies; (8) energetic healing; (9) polarity therapy; (10) folk practices; (11) healing practices utilizing food, food supplements, nutrients, and the physical forces of heat, cold, water, touch, and light; (12) Gerson therapy and colostrum therapy; (13) healing touch; (14) herbology or herbalism; (15) homeopathy; (16) nondiagnostic iridology; (17) body work, massage, and massage therapy; (18) meditation; (19) mind-body healing practices; (20) naturopathy; (21) noninvasive instrumentalities; and (22) traditional Oriental
practices, such as Qi Gong energy healing."

mind-body medicine may be subject to FDA regulation, depending on the nature of the product and its intended use.[16]

This statement is an example of how the Guidance Document flips back and forth between statements of whether CAM practices and domains would be subject to jurisdiction or whether only equipment or products would be subject to jurisdiction. The first sentence is misleading because there is *no* situation where the FDA would have jurisdiction over CAM practices in this domain.

f. "Although it is unlikely that a whole medical system itself would be subject to regulation under the Act or the PHS Act, products used as components of whole medical systems may be subject to FDA regulation for the reasons described above."[17]

This statement is inflammatory and reflects the lack of sensitivity the Draft Guidance Document displays to the FDA's jurisdictional boundaries. It is not only "unlikely", it is completely impossible that a whole medical system, or for that matter a portion of a medical system, would be subject to FDA regulation, since FDA could never claim jurisdiction over a medical system, but only over products.

g. "*If the juice therapy is intended for use as part of a disease treatment regimen instead of for the general wellness, the vegetable juice would also be subject to regulation as a drug under the Act*.[18]

This is a statement where it is critical to know to whom the FDA is speaking. The product industry is well aware of the impact of the intended use of products and the FDA Draft Guidance Document Section IV spells it out once again. However, if the audience of the Draft Guidance Document is practitioners or consumers, this statement, without further jurisdictional comment, could be alarming and confusing to the reader. Is FDA claiming they have jurisdiction over practitioners and consumers who use vegetable juices to cure ailments? Is FDA jurisdiction limited to the production, marketing, and selling, of such products? Is FDA suggesting that even if a product is properly marketed and sold in compliance with FDA, that the FDA can go further and claim jurisdiction over a promoter or user of the product in further settings? The manufacturer and seller of products does not control the use of products by buyers. Is FDA thinking they will police the use of properly marketed products? State law protects important personal rights in the arena of health care including patient-client relationships, privacy, free speech, and the right of access to health care options and the right of state governments to regulate health care occupations and the use of healing

[16] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 6.
[17] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 6.
[18] Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006, page 2.

agents in health care practices. The Draft Guidance Document needs to be sensitive, line by line, to these very important implications, and if it goes ahead in the further development of the Draft Guidance Document, must revise the document to clearly limit its jurisdictional guidance to products.

In Summary:

NHFA respectfully urges, and strongly encourages, the FDA, the Office of Policy and Planning, the Office of the Commissioner, Food and Drug Administration, the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Food Safety and Applied Nutrition, to cease any further work on the Draft Guidance Document, and to officially withdraw the Draft Guidance in it's entirety with notice to the public. If the FDA sees a perceived need to clarify its jurisdiction as to which products are subject to regulation as a biological product, cosmetic, drug, device, or food (including food additives and dietary supplements), under the Act or the PHS Act, then it should do so in a forthright manner without focus on one particular group or another and without confusion as to infringement of state laws and regulations of health care systems, domains, practices, and practitioners. In the alternative, if the document continues to be developed, NHFA hopes that the FDA will seriously consider its comments and those of our colleagues in the field of health care and health freedom, and revise the documents accordingly. Should the FDA wish to directly communicate with NHFA regarding suggested language of such a document NHFA is open to remaining in communication regarding this process.

NHFA expresses its deep gratitude for the opportunity to provide comments.

Respectfully Submitted:

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