Food and Drug Administration
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Department of Health and Human Services
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Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration	)))	Docket No. 2006D-0480

COMMENTS OF TREA SENIOR CITIZENS LEAGUE
(May 29, 2007)

TREA Senior Citizens League, through its undersigned counsel, submits the following comments pursuant to 21 CFR 10.115(h) and 72 Fed. Reg. 29337-38 (May 25, 2007). These comments relate to the following three documents concerning Docket No. 2006D-0480:

1. Food and Drug Administration "Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation" (December 2006). http://www.fda.gov/cber/gdlns/altmed.htm.

2. Food and Drug Administration Notice, "Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation; Availability," 72 Fed. Reg. 8756-57 (February 27, 2007).

3. Food and Drug Administration Notice,"Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation; Availability," 72 Fed. Reg. 29337-38 (May 25, 2007).[1]

[1] The May 25, 2007 Food and Drug Administration ("FDA") notice acknowledged that the FDA created public confusion concerning the comment period, and stated that the FDA would consider all comments on the Draft Guidance submitted through May 29, 2007.

I. TREA SENIOR CITIZENS LEAGUE, AS WELL AS ITS MEMBERS AND SUPPORTERS, HAVE SERIOUS CONCERNS ABOUT THE FDA'S DRAFT GUIDANCE AND THE ADVERSE EFFECT IT COULD HAVE ON SENIOR CITIZENS.

TREA Senior Citizens League ("TSCL") is a nonprofit, non-partisan social welfare organization incorporated under the laws of Colorado, and is tax-exempt under Section 501(c)(4) of the Internal Revenue Code of 1986. TSCL, headquarted in Alexandria, Virginia, is known as one of the largest U.S. seniors groups, engaging in education and advocacy on behalf of senior citizens. Its mission is to educate the public and alert senior citizens about their rights and freedoms as U.S. citizens, to assist members and supporters regarding those rights, and to protect and defend the benefits senior citizens have earned.

TSCL has more than three quarters of a million senior citizen members and supporters. Its activities include monitoring developments in the United States with respect to the interests of senior citizens and defending those interests before government, developing educational materials designed to explain to senior citizens their various rights as U.S. citizens, raising the level of public awareness of senior citizens' rights by conducting surveys and polls, and publishing and distributing informational newsletters to members, supporters, and the public.

TSCL's members and supporters, as well as all American citizens, have a vital interest in the Food and Drug Administration's Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation" (hereinafter "Draft Guidance"). Indeed, TSCL and its supporters are greatly concerned with all government policies and practices affecting "complementary and alternative medicine products," and they have special concern for the policies and procedures by which the complementary and alternative medicine ("CAM") products which are not currently regulated by the FDA might become targets of expensive new regulation, as well as the policies and procedures by which any such regulations might become effective.

CAM use involves millions of Americans, and is particularly important for senior citizens. The Centers for Disease Control and Prevention ("CDC") estimated that, fully a decade ago, the U.S. public spent between $36 billion and $47 billion on CAM therapies in 1997, an amount that was more than the U.S. public paid out of pocket for all hospitalizations in that year, and an amount that was approximately one-half of that paid by the U.S. public for all out-of-pocket physician's services. Further, 36 percent of U.S. adults aged 18 years and over used some form of CAM. *See* Barnes, P., Griner, E, McGann K., Nahim, R., CDC Advance Data Report #343, Complementary and Alternative Medicine Use Among Adults: United States 2002 (May 27, 2004) (http://www.cdc.gov/nchs/data/ad/ad343.pdf). A 2006

survey reveals that almost two out of three persons in the United States over the age of 50 have used some form of CAM.[2]

II. THE FDA HAS CREATED CONFUSION WITH RESPECT TO THE PERIOD FOR COMMENT AND A FURTHER EXTENSION OF THE COMMENT PERIOD SHOULD BE MADE.

The FDA originally prepared the "Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation" sometime in December 2006. However, it is unclear when the Draft Guidance was actually released to the public.

The Federal Register notice of the availability of the Draft Guidance was not published until February 27, 2007 (72 Fed. Reg. 8756-57). Therefore, about two months passed from the time when the Draft Guidance was finalized to publication of the notice of its public availability.

The Draft Guidance was released with immediate confusion as to the deadline for comment period. The Draft Guidance indicated that comments would be due 90 days from the date of publication in the Federal Register. Since the notice was published on February 27, 2007, that would have set the deadline as May 29, 2007. Furthermore, the FDA's docket report posted on its website specified that the "comment period ends **5/29/07**"(emphasis added).

However, the FDA Federal Register notice set the deadline for 60 days from publication, or April 30, 2007. Nothing indicated that time set in the Draft Guidance was in error.

The FDA initially refused to acknowledge the confusion that it had created. Various individuals and organizations requested either an extension of time or clarification concerning the actual end of the comment period.

Because of the confusion resulting from the FDA's inconsistent notices on the subject (*see* FDA Notice, 72 Fed. Reg. 29337-38 (May 25, 2007), filed a formal request on April 26, 2007 for an extension of time to prepare comments on, to inform its members about, and to

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[2] *See* National Center for Complementary and Alternative Medicine and AARP, "Complementary and Alternative Medicine: What People 50 and Older are Using and Discussing with Their Physicians" (2007) at 5.

provide its members with an opportunity to comment on this proposed FDA proceeding.[3] This extension request, as well as that of others, apparently was granted only in part.[4]

TSCL's Request for Clarification and Extension of Comment Period requested the FDA to extend the filing deadline until July 31, 2007, or otherwise clarify the filing deadline. Then, on May 25, 2007, the FDA officially announced in the Federal Register that it would consider comments on the Draft Guidance filed on or before May 29, 2007 (72 Fed. Reg. 29337). The FDA considered its May 25, 2007 notice as responding to all outstanding extension requests.

Unfortunately, the FDA did not explain why it denied TSCL's request to extend the comment deadline to July 31, 2007. TSCL, in its request, presented good reasons why extension to July 31, 2007 was necessary in order for TSCL's members to have sufficient time to be notified and respond to the FDA's Draft Guidance.

The FDA cited the "large volume of comments to the docket" as the reason for failing to respond to extension requests beyond extending the deadline only to May 29, 2007. However, a large volume of comments already received is an insufficient reason to deny a valid request to extend the deadline.

As TSCL previously advised the FDA in its request seeking an extension of time to submit comments, many TSCL members are extensive users of CAM and, having experienced the use of CAM, are in a unique position to provide the FDA with information and insight regarding the Draft Guidance. Further, while TSCL members appreciate the FDA's expressed concerns about proliferation and confusion of CAM products and practices, they are equally concerned about their freedom of choice among these products and practices which many have found to be beneficial to their health. More time is needed for TSCL's members to prepare and submit comments in this matter, and fixing the end of the comment period as May 29, 2007, did not provide an adequate opportunity for many seniors to respond. TSCL is still within the initial stages of communications with its membership about CAM and the FDA's apparent desire to extend its jurisdiction over CAM use. TSCL expects that the general public, including a great many seniors, will be intensely interested in this subject.

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[3] For example, National Health Freedom Action, Citizens for Health, American Herbal Products Association, and American Association for Health Freedom requested that the comment period be extended anywhere from less than 30 days to July 31, 2007, up to 90 days. However, it appears that the FDA only responded to one request directly. *See* Letter dated April 12, 2007 from Jeffrey Shuren, Assistant Commissioner of Policy, to S. Elizabeth Clay, denying a request for extension.

[4] FDA Notice,"Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation; Availability," 72 Fed. Reg. 29337-38 (May 25, 2007).

TSCL renews its request for an extension, or, in the alternative, requests that the comment period be reopened at a later date with at least a 90-day comment period.

III. THE FDA DRAFT GUIDANCE CREATES CONFUSION AS TO WHICH TYPE OF GOOD GUIDANCE PRACTICES IT INTENDS TO ISSUE.

The February 27, 2007 Federal Register notice states:

> This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the regulation of complementary and alternative medicine products by FDA. [72 Fed. Reg. 8757 (February 27, 2007).]

The Regulation cited in this Federal Register notice indicates that there are two types of guidance documents: "Level 1 guidance documents," 21 CFR 110.115(g)(1)-(3); and "Level 2 guidance documents," 21 CFR 110.15(g)(4). Yet, curiously, the FDA does not identify which type of guidance document it is proposing, even under its own regulations.[5]

Level 2 guidance documents are implemented immediately, unless the FDA indicates otherwise, and comment is requested. 21 CFR 110.15(g)(4)(i)(B). In this case, the Draft Guidance states that only "when finalized" it "will represent" FDA's "current thinking on this topic." Draft Guidance, p. 1.

Level 1 guidance documents apparently deal with more serious matters than Level 2 guidance documents, and have more procedural formality. It is suggested that the Level 1 treatment is more appropriate for this proposal. For example, if the Draft Guidance were treated as a Level 1 document, the FDA would "hold public meetings or workshops," and may issue "another draft of the guidance document. *See* 21 CFR 10.115(g)(1)(iii) and (v).

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[5] The May 25, 2007 Federal Register notice states that the public can comment on any guidance at any time, citing 21 CFR 10.115(g)(5), but this subsection applies to both Level 1 and Level 2 guidance documents, and therefore reveals nothing as to the level of guidance being proposed.

IV. THE FDA'S DRAFT INDUSTRY GUIDANCE PURPORTS TO EXERCISE AUTHORITY IN A MANNER INCONSISTENT WITH THE ADMINISTRATIVE STRUCTURE REGARDING CAM CREATED BY CONGRESS.

It is axiomatic that an administrative agency created by Congress "may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'" FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125 (2000). Yet this is exactly what the FDA's Draft Guidance would do.

As recognized by the FDA's own Draft Guidance, in 1992 Congress "established the **Office of Unconventional Therapies**, which later became the **Office of Alternative Medicine**, to explore 'unconventional medical practices.'" Draft Guidance, p. 1. In 1998, this office became the **National Center for Complementary and Alternative Medicine** ("NCCAM"), within the National Institutes of Health ("NIH"). *Id.*

When Congress established NCCAM under Title VI, Section 601 of the Omnibus Appropriations Act of 1999 (P.L. 105-277), amending Title IV of the Public Health Service Act, it provided:

> The general purposes of the National Center for Complementary and Alternative Medicine (in this subpart referred to as the "Center") are the conduct and support of basic and applied research (including both intramural and extramural research), research training, the dissemination of health information, and other programs with respect to **identifying, investigating, and validating complementary and alternative treatment, diagnostic and prevention modalities, disciplines and systems**. [42 U.S.C. § 287c-21(a) (emphasis added).]

Moreover, NIH states that NCCAM is "dedicated to exploring complementary and alternative healing practices in the context of rigorous science; training … CAM researchers; and **disseminating authoritative information to the public and professionals.**" The NIH Almanac - Organization: NCCAM (hereinafter "NIH/NCCAM"), p. 1 http://www.nih.gov/about/almanac/organization/NCCAM.htm (emphasis added).

NCCAM describes itself as "the Federal Government's **lead agency** for scientific research on CAM."[6] Indeed, the Draft Guidance contains extensive information about the basic categories of CAM drawn directly from NCCAM's Internet site entitled "Get the FACTS — What is Complementary and Alternative Medicine (CAM)?" and appears to build its entire presentation around those categories. *See* Draft Guidance, pp. 2-13.

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[6] http://nccam.nih.gov/about/ataglance (emphasis added).

Yet, there is no indication in the Draft Guidance that the FDA has sought the input of, or reviewed what it calls its "current thinking" with, NCCAM before presenting the Draft Guidance for public comment. To the contrary, the Draft Guidance states that it "was prepared by the Office of Policy and Planning, Office of the Commissioner, Food and Drug Administration, with assistance" from four centers within the FDA. Draft Guidance, p. 1, n.1.

Therefore, the FDA appears to represent in its Draft Guidance that its "current thinking" on policy matters regarding the exercise of its enforcement authority with respect to drugs, devices, foods, food additives, dietary supplements, cosmetics, and biological products used in CAM has been developed without any input from NCCAM. *See* Draft Guidance, pp. 7-12. This would be most remarkable, given that the "central mission" of NCCAM is to "distribute scientifically based information on CAM research, practices and findings" to the general public. NIH/NCCAM, pp. 2-3. It also would be remarkable if the Draft Guidance were developed, as it apparently has been, without having first been presented to "[t]he NCCAM Trans-Agency CAM Coordinating Committee (TCAMCC) which was established in May 1999 by the NCCAM Director "to foster the Center's collaboration across the Department of Health and Human Services (DHHS) and other Federal agencies." NIH/NCCAAM, p. 3.

There is nothing in the Draft Guidance indicating how the FDA's "current thinking" springs from or relates to the work of NCCAM, nor does the Draft Guidance contain any assurances that the FDA's "current thinking" will **not** interfere with the work of NCCAM, which was originally created by Congress "to investigate and evaluate promising unconventional medical practices." *See* NIH/NCCAM, p. 2. Rather, there is every reason to believe that, operating under the proposed enforcement guidance, the FDA could have an adverse impact on the work of NCCAM, without any meaningful effort to assess such an impact before implementation of the Draft Guidance policies.

In short, it appears that the Draft Guidance may have been prepared and presented to the public for comment by the FDA in isolation from the administrative agency that Congress specially created to address CAM and, thus, that the Draft Guidance was generated "'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'" *See* ETSI Pipeline Project v. Missouri, 484 U.S. 495, 517 (1988). Although it is not clear from the Draft Guidance what NCCAM's role should be in the formulation of the government's CAM policy, the public certainly has the right to expect NCCAM's input in the formulation of government policy regarding CAM. For this reason alone, the Draft Guidance should be withdrawn and reconsidered in light of the primary responsibility of a different agency — NCCAM — to advance congressional policy with respect to CAM.

V. THE DRAFT GUIDANCE CREATES CONFUSION IN THE FDA'S REGULATION OF FOODS AND DRUGS.

The FDA states that the Draft Guidance has been designed primarily to combat the "increased confusion as to whether certain products used in CAM … are subject to regulation under … the Act or the Public Health Service Act ('PHS Act')." Draft Guidance, p. 1. But the Draft Guidance would add to, rather than lessen, whatever confusion allegedly exists.

Central to the FDA's "current thinking" is the proposition that whether a product is regulated as a drug, device, food, food additive, dietary supplement, cosmetic, or biological product depends upon its "**intended use**." *See* Draft Guidance, pp. 2, 3, 4, 6, 7, 8, 9, and 12 (emphasis added). To illustrate this point, the Draft Guidance states that "if a person decides to produce and sell raw vegetable juice for use in juice therapy to promote optimal health, that product is a **food**, [but] [i]f the justice therapy is **intended** for use as part of a disease treatment regimen, instead of for general wellness, the vegetable juice would **also** be subject to regulation as a **drug** under the Act." *See* Draft Guidance, p. 2 (emphasis added). There are serious shortcomings to such a regulatory approach.

A. The Draft Guidance Fails to Provide a Workable Distinction Between a Food and a Drug.

The Draft Guidance **fails to state the criteria** by which the FDA would determine the "intended use" of a product. In its aborted effort to regulate "cigarettes and smokeless tobacco [as] 'drug delivery devices[,] the FDA [determined] that tobacco products are '**intended**' to deliver the pharmacological effects of satisfying addiction, stimulation and tranquilization, and weight control because those effects are **foreseeable** to any reasonable manufacturer." *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. at 131 (emphasis added). If the FDA were to seek to apply such an "intent" standard here, any time it is reasonably foreseeable that a product — ordinarily classified a food — might be used as part of a CAM "disease treatment regimen," such "intended use" would make that product a "new drug," subject to "premarket review and approval by the FDA." *See* Draft Guidance, pp. 7-8. Thus, under a "foreseeability" test, as CAM's multiply, the FDA apparently would seek to regulate as drugs more and more products currently meeting the statutory definition of "food" — even though the overwhelmingly primary "use" of that product would be as a "food." The "foreseeability" test, then, would be **unreasonably overinclusive**, withdrawing from the marketplace of foods a host of different food products because of their "intended use" in a CAM "disease treatment regimen."

In the tobacco case, it was suggested that "**intended** use" should be ascertained by an examination of the "**express claim** concerning the product's therapeutic benefits." *See* FDA v. Brown & Williamson, 529 U.S. at 131 (emphasis added). Under this definition of "intended use," a raw vegetable juice produced and marketed by a manufacturer or CAM practitioner pursuant to a "disease treatment regimen" claim would subject that juice to regulation as a

drug. But the identical juice marketed only to "promote optimal health" would presumably still be considered a "food" and, therefore, remain generally available, even to people who might be purchasing the juice because it has been prescribed by a CAM as part of a "disease treatment regimen." The "claim" test, then, would be **unreasonably underinclusive**, allowing a product to be marketed as a food, even though prescribed by a CAM as part of a "disease treatment regimen."

The Draft Guidance does not even begin to address this problem. Instead, it assumes that a "herbal product that is intended to treat arthritis in humans" would, as a **new drug**, be subject to "premarket review and approval by FDA," without regard to the fact that the same herbal product would otherwise also be subject to regulation as a **food**, because it is also "intended" to be used "to promote optimal health." *See* Draft Guidance, pp. 7-8. The Draft Guidance offers no solution to such an apparent contradictory regulatory policy.

B. The FDA Definition of a Drug Based upon a Product's "Intended Use" Would Be Unreasonably Intrusive.

According to the Draft Guidance, "the practice of CAM has increased in the United States." Draft Guidance, p. 1. If true, it would appear that more and more "food" products will become "drugs." Thus, by whatever criteria the FDA would determine a product's "intended use," the Draft Guidance portends significant and extensive changes in the ways that ordinary food and drink would be marketed in the United States. As CAM's multiply, more and more "food and drink" — from organically produced vegetables to raw vegetable juice to distilled water — would become potentially "new drugs" and, therefore, would be subjected to "premarket review" and FDA approval.

Although the FDA could limit such an intrusive disruption of the food marketplace, by limiting its regulation of a food as a drug only to a food that is actually being prescribed by a CAM practitioner as part of a "disease treatment regimen," such a regulatory approach would depart from the Draft Guidance's repeated assurances that it would regulate only the product or device, not the CAM practice itself — the latter being outside the FDA's jurisdiction. *See, e.g.,* Draft Guidance, pp. 5-6. These matters need to be thought through more thoroughly than they have been, based upon what appears in the Draft Guidance. Moreover, such thinking needs to be explained to the public, and the current Draft Guidance is devoid of any such explanation.

VI. THE DRAFT GUIDANCE RAISES ISSUES OF LEGISLATIVE POLICY THAT ARE FOR CONGRESS, NOT THE FDA, TO RESOLVE.

According to 21 U.S.C. Section 321(f), "[t]he term 'food' means … articles used for food or drink for man or other animals." According to 21 U.S.C. Section 321(g)(1)(B), "[t]he term 'drug' means … articles intended for use in the diagnosis, cure, mitigation, treatment, or

prevention of disease in man or other animals." While this statutory distinction between "food" and "drug" has effectively identified two separate categories of products in a past world of "conventional" or "allopathic" medicine, the Draft Guidance argues that the statutory distinction has collapsed with the influx of "unconventional medical practices" into the United States.

In response, the Draft Guidance attempts to make the old statutory distinction work, treating the problem of categorization it faces to be a matter of administrative policy. As demonstrated in Sections V.A. and B. above, however, it is apparent that the current statutory distinctions are insufficient regulatory benchmarks. It is not the task of the FDA as an administrative agency to create new benchmarks. Rather, it is for the FDA to bring any perceived inadequacies of statutory language to the attention of Congress.

In light of these concerns, it is apparent the Draft Guidance has addressed a policy issue that only Congress may address, at least under the apparent direction proposed by the Draft Guidance, because to implement the Draft Guidance would necessarily change the legal definition of "food" in 21 U.S.C. Section 321(f)(1) by the application of the "intended use" language defining "drug" in 21 U.S.C. Section 321(g)(1)(B).

VII. THE DRAFT GUIDANCE INFRINGES UPON THE CONSTITUTIONALLY-GUARANTEED LIBERTIES OF THE PEOPLE.

With the advent and growth of CAM in the United States, the separation of the physical and the spiritual worlds upon which regulation of food and drugs has been dependent is being seriously challenged. Of the five CAM categories identified in the Draft Guidance, three merge the physical and the nonphysical in a holistic approach to the health of the human body. *See* Draft Guidance, pp. 4-5, 6-7 ("Energy Medicine," "Mind-Body Medicine," and "Whole Medical Systems."). This synergetic emergence of the observable and invisible worlds is especially pronounced in "Mind-Body Medicine" and "Whole Medical Systems," each of which, the Draft Guidance acknowledges, contains a "spiritual" element. *See* Draft Guidance, pp. 6-7.

In light of this acknowledged merger of the spiritual with the physical, one would expect the Draft Guidance to recognize the constitutional limits placed upon the federal government to regulate the mental and spiritual aspects of life. What is remarkable about the Draft Guidance, however, is its cavalier assumption that FDA could regulate the "equipment or other products used as part of mind-body medicine" or "the products used as *components* of whole medical systems," without interference with the integral "spiritual" aspects of the two kinds of medical systems. *Id.* (Italics original.) It is not surprising that the Draft Guidance

has caused concern and confusion about FDA's regulation of religious practice.[7] Anyone who is familiar with the traditional healing practices of various religions is aware of the fact that the use of physical items — like prayer cloths, rosaries, and even the communion elements of wine and bread — is inextricably linked with prayer and other spiritual activities. Yet, the Draft Guidance appears to have little regard for the threat to religious freedom posed by its intrusive policy directives.

For example, in Employment Division, Dept. Human Resources of Oregon v. Smith, 494 U.S. 872 (1990), the Supreme Court ruled that the free "'exercise of religion' often involves **not only** belief and profession, but the performing of (or abstention from) physical acts." *Id.*, 494 U.S. at 877 (emphasis added). Further, Congress has recognized the high value placed upon the free exercise of religion, limiting Government intrusions upon spiritually-conceived and motivated practices unless such intrusions advance a **compelling** government interest in the **least intrusive** way. *See* Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal, 546 U.S. 418, 163 L.Ed.2d 1017 (2006).

More centrally, the Draft Guidance misconceives the very nature of CAM. All kinds of persons, religious and nonreligious, turn to CAM because traditional medicine does not have the answers to their health needs. If the policies set forth in the Draft Guidance were implemented, then it would lead inevitably to the imposition of unreasonable restrictions upon CAM, lessening the availability of complementary and alternative healing options to conventional and allopathic medicine. Indeed, if implemented, the apparent policies set forth in the Draft Guidance would make Americas more dependent than ever upon a regulatory regime governing food and drugs built upon a government-imposed health care orthodoxy. As Justice Holmes wrote in the first U.S. Supreme Court opinion concerning the limits on federal authority to govern the choices that the American people make in maintaining their health, the Government should not be too quick to "establish… criteria in regions where opinions are far apart." *See* United States v. Johnson, 221 U.S. 488, 498 (1911).

VIII. THE DRAFT GUIDANCE WOULD ASSERT REGULATORY CONTROL OVER BLOCKS OF WOOD AND FROZEN WATER, AND VIOLATE PRINCIPLES OF FEDERALISM.

In the FDA's Federal Register notice extending the comment period on the Draft Guidelines (72 Fed. Reg. 29337-38), the FDA said "we want to consumers and CAM practitioners to understand that the draft guidance … does *not* affect any state licensing

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[7] According to the 2004 nationwide government survey referenced above, when prayer for health reasons is included in the definition of CAM, the percentage of U.S. adults using some form of CAM rises from 36 percent to 62 percent. *See* http://nccam.nih.gov/news/2004/052704.htm.

requirement for any CAM practitioner…." (Italics original.) However, this FDA reassurance is highly misleading. The Draft Guidance asserts:

> To the extent that manipulative and body-based practices involve practitioners physically manipulating a patient's body, **without using tools or machines**, we do not believe that such practices are subject to regulation under the Act or the PHS Act. If, however, the manipulative and body-based practices involve the use of **equipment** … or the application of a **product** … to the skin or other parts of the body, those **products** may be **subject to regulation** under the Act, depending on the nature of the product and its intended use. [Draft Guidance, p. 6 (emphasis added).]

According to this statement, one chiropractic technique that would be under their jurisdiction would be the Sacro Occipital Technique ("SOT"). SOT, *inter alia*, is a method for analyzing patterns of structural distortion which are the underlying cause of the patient's symptoms. This method of analysis also assesses for dysfunction in the dural sheath that protects nerves and spinal cord. Through this complex analysis the practitioner is able to determine the severity and longevity of spinal joint dysfunctions that the chiropractic profession refers to as subluxations.

The SOT practitioners correct these subluxations using **wedge-shaped blocks**. The principle behind the use of the blocks is same as it is for the use of any lever. Using the block as a lever, work is produced using the least amount of energy or force. In this case, the work equals the movement of the misalignment bone and the force is gravity and the patient's own body weight. The blocks are positioned under the patient in such a way as to accomplish the correct repositioning.

The block is no more than a **wedge-shaped piece of wood.** It is covered by a cushioning material and then wrapped with leather or a similar covering material for patient comfort. This apparently would be classified as a "product" or "machine" or medical equipment subject to regulation under the new guideline. Does the FDA really want to assert jurisdiction over a block of wood?

To do so, the FDA would need to designate staff to learn the intricacies of this segment of the chiropractic profession. The FDA and its new bureaucracy would need to analyze, as well as to measure and create their own standards. Then they would have publish these standards and implement and enforce the new regulations. This would need to be repeated for thousand of inert devises that are now being used without the slightest hint of a problem.

SOT has been used around the world to effectively and safely care for many thousands of patients for 50 years. The practitioners of this technique adhere to very complex and

precise standards of analysis to assess their patients. The blocks are already manufactured to precise standards established by those practitioners who use them.

The standard of care as established within the chiropractic profession is regulated effectively by the state boards within each state. There is no basis to believe that Congress wants the FDA to become a super-regulator exercising authority over health-related professions which are **already regulated by the several states**. Such over-regulation would not add to the effective or efficiency of the treatment, but would do violence to principles of **federalism**.[8]

It would not add to the safety of the practitioners, their staff, or their patients. It would not lead to improvements in the equipment. It would not add to the quality of care that the patient receives. In all likelihood it would do the opposite in most cases. It would add to the cost of equipment and ultimately to the patient. Some may be forced to receive less care due to increase costs, resulting in less quality care to the patient, and less quality of life for the patient.

A similar argument could be made for common adjunct therapies such as **cryotherapy**. The application of **cold packs**, or **bags of ice,** to relieve pain or swelling to an injured area. Even children realize the benefit of putting ice on a swollen ankle after they have turned their ankle while playing. Yet the Draft Guidance would assert jurisdiction over a mother or child who uses such a product.

IX. THE DRAFT GUIDANCE FAILS TO TAKE INTO CONSIDERATION ITS POTENTIAL ADVERSE EFFECT ON MEDICARE.

Currently CAM procedures, treatments, therapies and substances are readily available and, for the most part, are relatively inexpensive, particularly when compared to their counterparts in conventional allopathic medicine. For example, a $10,000 back surgery may be averted by a series of $50 chiropractic adjustments, and the conventional alternative to a $6 homeopathic remedy could be a prescription medication costing multiples of that amount. Moreover, conventional medicines and treatments can have undesirable side effects, which are much less common with CAM approaches.

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[8] States regulate CAM professionals in various areas, such as chiropractic, massage, naturotherapy, acupuncture, midwifery, etc. *See*, *e.g.*, Virginia Board of Medicine, Professions Regulated by the Board, http://www.dhp.state.va.us/medicine/medicine_occupations.htm; and Florida Department of Health, Information on Regulated Professions, http://www.doh.state.fl.us/mqa/proflist.htm.

If the FDA were to regulate CAM as it does allopathic medicine, then the cost of CAM necessarily would increase substantially. All CAM suppliers and CAM medical providers effectively would be forced to re-enter a new and different market, this time complying with the new FDA regulation with a much higher barrier to entry. As in any market, this higher barrier to entry clearly would keep some (if not many) CAM suppliers, distributors and providers from re-entering the market. The result would be fewer remaining producers and providers, each subject to more regulation (meaning higher costs) than before.

Moreover, if the FDA chooses to limit access to CAM by, for example, classifying CAM products as drugs, the cost of access would increase, as consumers may have to visit and pay a doctor for a prescription, instead of being able to choose their own vitamins, minerals and dietary supplement intake. The cost of a doctor's visit to achieve the same result as before (*e.g.*, obtaining Vitamin C for a cold) simply would be an indirect way of adding to the prices paid for the vitamin or dietary supplement.[9]

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[9] It is interesting that the FDA seeks to exert authority over the regulation of vitamins, minerals and dietary supplements. If the mission of the FDA is to protect consumers, it naturally follows that if the FDA chooses to protect consumers from something, that something must have some sort of inherent danger associated with it. But when it comes to some of the most pervasively used CAM — vitamins, minerals and supplements — this is clearly not the case. In fact, they overall could be three of the safest products consumed by Americans.

The American Association of Poison Control Centers ("AAPCC") publishes an annual report on the "Toxic Exposure Surveillance System," which combines data from the various Poison Control Centers around the country, which themselves have investigated and determined the probable causes of unknown consumption-related deaths. The AAPCC's studies for the last several years show, over a four year period from 2001-2004, only 77 persons (an average of 19 per year) died in any way thought related to consumption of these vitamins, minerals, or dietary supplements. "Dietary supplements/ herbals/ homeopathic" accounted for half (50.6 percent) of total deaths, while "Electrolytes & Minerals" accounted for 37.7 percent and vitamins for 11.7 percent (9 deaths). Even if true, this is close to the same number of persons who have **died** in recent years from "hyponatremia," or simply **from drinking too much water**. Some of these deaths have come as a result of saline IVs in hospitals, others have been marathon runners, and still others have been desert hikers. Perhaps the most famous death came as the result of a radio show contest. Thus, one could argue that, if the FDA seeks to regulate the availability of vitamins, minerals and supplements, and require a prescription to obtain them, the FDA also should regulate the availability of water, and require a physician's prescription for its consumption.

Perhaps FDA instead should re-focus its limited resources on dealing with other prescription drugs which, although already regulated, and even when properly prescribed and taken, account for over 100,000 deaths annually. "Incidence of Adverse Drug Reactions in Hospitalized Patients," Journal of the American Medical Association, Vol. 279, No. 15; April

The FDA also should consider the impact that such regulation would have upon the financial stability of the Medicare program.[10] Currently, few CAM approaches are reimbursed by Medicare and are therefore paid out of pocket by the consumer.[11] On the other hand, if vitamins and minerals were regulated as "drugs," Medicare might be required to pay for those same vitamins and minerals. Such a simple change in status for CAM theoretically could cost the federal government billions of dollars annually.[12]

One of the main purposes of CAM is not the treatment of disease, but rather good health — and the prevention of disease. If the costs of obtaining CAM were increased by FDA regulation, there would be less demand for CAM. This could lead to an overall increased rate of occurrence of disease and other ailments, when such health problems could have been combated at an earlier stage, or prevented completely, by inexpensive and readily-available CAM.

Similarly, some consumers who otherwise might choose to use a CAM therapy to combat a health problem, in the event of decreased CAM availability, might choose to pursue conventional and often more expensive treatments. For example, instead of trying to combat a common cold with Vitamin C, which would first require a doctor's visit and a prescription for the "drug," a person might choose instead to obtain a prescription for a conventional cold medicine, further increasing the cost to Medicare. In other words, considering the cost of the doctor's appointment a sunk cost, a patient may choose to jump directly to the strongest treatment in order to combat otherwise-simple ailments.

15, 1998.

[10] Medicare, it should be noted, already is facing increasingly large unfunded obligations. *See* "2006 Annual Report of The Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," Centers for Medicare & Medicaid Services, Department of Health and Human Services, April 23, 2007. http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2007.pdf.

[11] "Medicare … covers chiropractic but does not cover what it calls 'alternative therapies,' giving as examples acupuncture, chelation therapy, biofeedback, and holistic medicine." NCCAM, "Paying for CAM Treatment," National Institutes of Health, U.S. Department of Health and Human Services, November 2006. http://nccam.nih.gov/health/financial/D331.pdf.

[12] CDC reports that "the U.S. public spent between $36 billion and $47 billion on CAM therapies in 1997," of which "between $12.2 billion and $19.6 billion was paid out-of-pocket…." U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, Vital and Health Statistics, "Complementary and Alternative Medicine Use Among Adults: United States, 2002" (Number 343, May 27, 2004). http://nccam.nih.gov/news/report.pdf.

CONCLUSION

In sum, the Draft Guidance presages the taking away of the right of control over one's body, a right that has deep roots in the common law. As William Blackstone, the venerable commentator on the common law, wrote: the right to "personal security" includes "a person's legal and uninterrupted enjoyment of his life, his limbs, his body [and] his health," as well as "the preservation of a man's health from such practices as may prejudice or annoy it." I. W. Blackstone, Commentaries on the Laws of England 125, 130 (1767). This right is especially precious when one is ill and faces the reality that no ordinary treatment will avail, as oft-times occurs in persons who are in the senior years of their lives.

For the foregoing reasons, TSCL respectfully submits that the Draft Guidance should be withdrawn, and not reissued until the concerns discussed above be addressed, requesting public comments and establishing meetings and workshops in which such matters can be further addressed.

Respectfully submitted,

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William J. Olson
Herbert W. Titus
John S. Miles
Jeremiah L. Morgan
WILLIAM J. OLSON, P.C.
8180 Greensboro Drive, Suite 1070
McLean, Virginia 22102-3860
(703) 356-5070

Counsel for TREA Senior Citizens League