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FDA Seeks to Regulate Your Pantry

The FDA is seeking to ban the sale of natural foods if the intended use of the food is to prevent or treat a disease. Based on data that foods exert a potent effect in both the prevention and treatment of many diseases, this proposed ban would outlaw information that Americans need to determine which foods are best for them to consume based on their own medical history. What follows is a review of what the FDA proposes to do and what you can do to help stop it.

The American Association for Health Freedom and the Health Freedom Foundation are very concerned with FDA document 2006D-0480 - Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration (FDA Summary). Read the full text of the CAM Guidance.  (get Adobe® Reader®).

Guidance like this is very confusing and there are legal issues that must be carefully examined and responded to in writing. Therefore, as a first step, we have officially requested that the FDA extend the deadline for comment to July 31, 2007. The time the FDA has provided for comment is simply too short for regulations this complex and important. We are requesting that Congress have the FDA extend the comment period. Read our letter to the FDA requesting an extension.

CLARIFICATION

Much of the regulatory authority proposed in the document is already claimed by the FDA. For example, making health claims as they pertain to dietary supplements and foods is currently not permitted, and people who do so are vigorously pursued by both the FDA and the Federal Trade Commission.

MAJOR CONCERNS

While we have several concerns with the CAM Regulation Guidance, the two biggest are broadening the definition of "health claim" and the desire to pre-empt the states in the regulation of some health care issues.

For example, the document attempts to define how vegetable juice might be defined as a drug: "This means, for example, 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 subject to the requirements for food in the Act and FDA regulations...If the juice therapy is intended for use as part of a disease treatment regimen instead of for general wellness, the vegetable juice would be subject to regulation as a drug under the Act."

The FDA defines a drug as "... (B) articles intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals."

The FDA is stating that it believes that any person (or product) who states "drink some vegetable juice to prevent [insert disease]" is actually making a drug claim; and if vegetable juice is not recognized by the FDA as a legally available drug in the United States, the person (or manufacturer) making the claim is now subject to prosecution if they are not a medical professional licensed to practice medicine.

Who is going to fund a \$50,000 investigational new drug application to get carrot juice approved as a drug, or the follow-on millions in research dollars to conduct a study on the toxicity (\$200,000) and efficacy of carrot juice (\$3 million and up)? Keep in mind that this would have to be done separately for any disease process upon which carrot juice might have an impact.

WHY NOW?

Why did the FDA create this document? There are a couple of theories. One is that the National Center for Complementary and Alternative Medicine (NCCAM) asked the FDA to "harmonize" with its way of thinking. Another is that importation of products (a major concern of the FDA) will soon be a top issue. Functional foods could also be a target (as forewarned by the FDA December meeting on functional foods - read about our response and presentation). Regardless of the why, we do know that the health freedom community was not consulted in the preparation of the document. Furthermore, the lumping together of food, products, medical devices, and therapies makes for an awkward, confusing, and unconstitutional "way of thinking" and does not represent

what is best for the consumer.

THE IMPACT

The draft guidance, when finalized, will represent the agency's current thinking on the regulation of complementary and alternative medicine products. Although it does not change the law, it does represent a potential major expansion with regard to how foods, therapies, and products could be regulated. Of further concern is that this document could be used by health freedom opponents and regulators to pressure Congress to change legislation. The language in the document is of great concern to us and we cannot allow an agency such as the FDA to finalize the document in its present form.

ACTION

The comment period expires on April 30, 2007. It has been our experience that citizens' letters to the FDA during the comment period rarely have an impact on the FDA's decision-making process. This is important to know, since the appropriate response to this situation is not to just be busy (as in writing letters to the FDA) but to be effective. What the FDA has told us is that it wants to hear from practitioner groups and trade associations. Remember that FDA officials are not elected and that generally the wishes of the public fall on deaf ears.

The two things that are most likely to influence the FDA's actions as they pertain to the issues outlined in this document are:

- Members of Congress who have a variety of mechanisms for shaping the authority of the FDA.
- State attorneys general who can threaten legal action if the agency tries to usurp the authority to regulate health care activities within their states.

In consideration of the above, we are taking these actions:

- We are alerting our Congressional allies and asking them to take appropriate action. We will notify you when it is time to write to these elected officials and make your wishes known.
- We have commissioned an extensive legal response to the guidance that has the kind of technical detail the FDA bureaucracy wants (or actually *doesn't* want) to see as it strives to give this document the force of law.
- We are planning to communicate with the proper officials in each state to notify them of the potential for federal interference in state regulatory activities.

If you do write the FDA, please send a copy of your concerns to your representatives in Congress. These elected officials *do* care about your opinion, and your voice matters.

CONTACT CONGRESS!

SUMMARY

We believe the CAM Regulation Guidance would set the tone of the FDA's regulatory approach to functional foods, alternative medicine therapy, devices, and products, and dietary supplements, and could help set the stage for future legislation that would restrict access to all of the above. While public comments to the FDA by individuals are a course of action, we want you to be aware that fighting FDA's "way of thinking" will require a stronger course of action and that we are prepared to follow through. We have fought the FDA before and have been successful.

There are numerous issues facing the health freedom community that need attention and where your action can make a big difference: a draft bill to restrict access to individualized/compounding medicine; the right of the practitioner to practice being threatened by individual states; and Rep. Dingell wanting to "kill" dietary supplements because they are a "snake" to be killed.

Please know that we are working diligently on the important issues facing the health freedom community. It takes both time and money, and your financial support is greatly appreciated.

SUBMIT COMMENTS

If you would like to submit your written comments to the FDA, please use one of the following methods:

MAIL:

Division of Dockets Management (HFA-305)

Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20853

EMAIL:

Contact by email

No matter which method, be sure to refer to **Docket No. 2006D-0480**

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