UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff –Appellee

v. Case No 10-CR-253

CONRAD E. LEBEAU, an individual

Defendant – Appellant

Defendant's List of Questions for July 21st Oral Argument hearing

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A list of questions is provided here about twelve days in advance of the court hearing for oral arguments set for July 21st 2015. The purpose of this list is to fill in some blanks on non-responses from the government to some of the legal issues I raised in the course of this case, and to seek a government response in those area. In particular, where FDA application of the law deviates and over reaches Congressional intent as it applies to the definition of a drug in 1906 as to whether Congress intended that definition to include food used for the prevention or mitigation of disease?

Why in 1994 did Congress create a new category in the Food and Drug Act in classifying health products by "composition" as "dietary supplements" in

the Dietary Supplement Health and Education Act (DSHEA) of 1994? Why did lawmakers intended to treat dietary supplements separately and differently from drugs?

This list is provided here; as it is likely that you will want consult with the Food and Drug Administration (FDA) on how to reply. Also, the extent of legal issues on which we disagree will easily exhaust the time allowed for oral arguments on July 21st. The questions are divided into separate groups, the first being the Plea Agreement and Perfect Colon Formula. If you need to ask for a week or two extension of time to deal with these questions and ask Judge Clevert for a delay in the hearing by a week or two, that would be OK with me.

Questions for the plaintiff (U.S. Food and Drug Administration)

1. Does the FDA acknowledge that when the U.S. Constitution was ratified on June 21 1788, that the American people had complete freedom of choice in medicine with unencumbered access to all medicines, the use of food and herbs as medicine and no restrictions of speech in labeling about their intended use to prevent or treat disease? If the answer No, then please explain why you think freedom of choice in medicine did not exist at the time the U.S. Constitution was ratified in 1788?

2. Does the government acknowledge that three words, *"reduces food allergies"* that were in a handout brochure about Perfect Colon Formula #1 and also on the defendant's web site caused the FDA to classify the product as a drug because it

objected to the term *"reduces food allergies"* that it considers a disease claim and part of the product label? ____ Yes ____No.

3. Setting aside the health claims that the FDA objects to, would or does the FDA classify Perfect Colon Formula #1 as a food because of its composition? _____yes _____no, and at the same time does the FDA also classify Perfect Colon Formula #1 as a "dietary supplement" because its composition as a nutritional supplement is as described in the Dietary Supplement Health and Education Act (DSHEA) of 1994? _____ yes_____no

4. After receiving a letter from FDA attorney Nathan Sabel in November 2009, and phone calls I initiated to discuss the letter with him, the defendant was told by Mr. Sabel that the term *"reduces food allergies"* was a disease claim. The following day, I changed the language in the brochure to *"reduces food sensitivities"* after an Internet search failed to find a disease named "food sensitivities." That change in labeling occurred a day or two after the phone call to Mr. Sabel. The labeling change continued until the defendant closed the business down 6 months later [in July of 2010].

Question: Did or does the FDA consider "reduces food sensitivities" as it applied to Perfect Colon Formula to be lawful speech or not?

Answer_____

5. Does the government acknowledge that excerpts from speeches of members of Congress in 1906 [and quoted extensively in my Motion to Dismiss filed on May 26, 2011], that the original Food Drug and Cosmetic Act was primarily intended to define and classify as “drugs” patented medicine, and secret formulas called Nostrums that contained opiates (including cocaine, heroin, morphine and other addictive substances) and that these addictive substances were evil as they created drug addicts whose lives were ruined by these opiates, and that the addictive substances were often not listed on the product label? Yes____ No_____

6. Does the government admit that a review of the speeches of Congress (from the Congressional Record of 1906) in passing the original Food, Drug and Cosmetic Act finds no mention of Congressional intent in speeches published in the Congressional Record to include food, edible herbs and spices under the definition of “drug” even though healthy food choices as part of a proper diet were used and intended to promote health and “prevent disease”? Admitted _____ Denied_____ (explain your answer if denied)

7. After reviewing the Congressional Record of 1906, does the FDA acknowledge that they have over-reached their authority in stretching the definition of “drug” to include foods intended to promote health and “prevent disease”? Yes_____ No_____ Explain your answer if it is No.

8. Is it correct to state that the FDA considers classification of foods or dietary supplement as “drugs” based on speech about their intended use to prevent disease as “dual classification”?

9. Does the FDA acknowledge that all “new drugs” approved by the FDA since 1938 and listed in the “Orange Book” all have two requirements and they are 9a. a unique (synthetic) composition protected by a patent number, and 9b. an intended use to prevent or treat a disease? Yes_____ No_____

10. Does the FDA acknowledge that if one of the two requirements in 9a or 9b is missing such as a unique composition protected by a patent number, that it is not possible under the law to approve the drug for its intended use as a new approved drug? Yes_____ No_____

11. Does the FDA acknowledge, therefore, that no food, spice or herb or other un-patentable substance can be approved under the FDC Act as an approved new drug because it is natural and not synthetic and is not patentable? Yes_____ No_____

12. Can the FDA cite any statements by any members of Congress who either sponsored or voted for the Dietary Supplement Health and Education Act of 1994 (DSHEA) that stated in the Congressional Record, and before passage of this Act, that the FDA could [after passage of this Act] continue to classify foods or

dietary nutritional supplement as drugs based on speech about their intended use to prevent disease?

13. In the present case of the United States vs. LeBeau, did the plaintiff have a remedy at law under DSHEA (21 USCS Sec 321(g)(1)(C) for speech it objected to concerning the food based supplement called “Perfect Colon Formula” ? Yes_____ No_____

14: If your answer is ‘no” to the preceding question, then explain why the speech and labeling restrictions of DSHEA (21 USCS Sec 321(g)(1)(C) would not have addressed the government’s objections to the term “reduces food allergies” concerning Perfect Colon Formula? Does the government believe that this term did not meet the “truthful and not misleading” requirements for a dietary supplement health claim? Your answer_____

15: Does the FDA acknowledge that the DSHEA of 1994 that defines foods and dietary supplements by composition, and creates a new legal category called “dietary supplements,” that are distinguished from “drugs,” and that Congress in its “Findings” under DSHEA recognizes that healthy food choices and dietary supplements do prevent many diseases and that dietary supplements are not drugs? Yes_____ No_____

16: Does the FDA agree with the Congressional Findings of DSHEA under Public Law 103-417 (Oct 25, 1994) 3A *"there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such s cancer, heart disease, and osteoporosis…?*

Note: If you do not agree with the Congressional Findings in DSHEA, then explain why Congress is wrong and why health foods and dietary supplements that help to prevent disease are drugs and not the dietary supplements that Congress has classified them to be?

17. Does the FDA acknowledge that structure and functions claims under DSHEA often discuss the use of certain foods or dietary supplements for the prevention of named diseases, and that Congressional intent found in the (Congressional Record 1993-94) under DSHEA supports the distribution of scientific information and research on how dietary supplements help prevent disease, and not current FDA policy that prohibits the release of scientific research to the public? Yes_____ No_____

18. Does the FDA admit that when structure function claims or a claim to prevent a disease are made, the FDA lacks authority under DSHEA to classify a food or dietary supplement as a drug solely because it disagrees with the speech, and that to carry out its legal obligations under DSHEA, the FDA must pursue any objection to language they disagree with that is used for a food or dietary supplement with under the health claims provisions of DSHEA as codified in Title

21 USCS Sec 321(g)(1)(C) and not the strict “intended use“ drug definition or 21 USCS Sec 321 (g)(1)(B)?

19. Does the FDA admit that since passage of DSHEA in 1994, that it has never brought a complaint against any individual or corporation for speech it objects to in the labeling of a food or dietary supplement the under the provisions of DSHEA as codified in 21 USCS Sec 321(g)(1)(C), but has instead brought its complaints under the strict drug definition of 21 USCS Sec 321 (g)(1)(B)?

Statement of Facts about the FDA misleading the public and the Courts

For more than 60 years, the FDA has prosecuted individuals for speech about how foods and nutritional supplements prevent or mitigate disease and has told the public, and the Federal Courts that a person who marketed drugs and unapproved new drugs did not file an IND, or a “New Drug Application.” The FDA implication was very clear – that there was a path to FDA approval though the “New Drug” application approval process. However, this has turned out to be a lie and a deliberate misrepresentation of the law to the American people and the Federal Courts.

The reason is found in law that requires a “patent” to receive final FDA approval. Since foods and food- based nutritional supplements are not patented or patentable, this path to FDA approval is la dead end road – it leads to nowhere.

The patent issue and the FDA proposed drug IND remedy – legal fiction

On Feb 15, 2011, I sent an FOIA request to the FDA (See page 63 in the Exhibits file in support of the Motion to Dismiss) and asked for the following files -

1. **A document** or file that contain the names of **ALL NON-PATENTED DRUGS** approved by the US Food and Drug Administration for the prevention or treatment of disease since Jan 1, 1906 through Dec 31, 2010. The files requested are for FDA approved drugs for which a patent was ***not applied for*** or ***granted*** before, during or after the filing of an application for FDA approval of a new drug.
2. **A file or document that contains the names of all ingestible items and foods of**

plant or animal origin from land or sea (including seaweeds, plants, trees, herbs, leaves, bark, essential oils of herbs and flowers, other oils, flowers, roots, seeds and fish, dietary supplements and all other naturally occurring articles) **that were approved as new drugs for the prevention or treatment of disease from Jan 1, 1906 through Dec 31st 2010.**

Feb 23, 2011– the FDA's Response to my FOIA Request after a search of the "Orange Book" is as follows:

"Records of the Food and Drug Administration began in 1938. A check of the records of the Center for Drug Evaluation and Research did not locate any files which contained non-patented drugs or ingestible items and foods of plant of (or) animal origin from land or sea." See first exhibit page for the original letter.

20. Does the government admit that it would be legally impossible for the defendant to succeed in obtaining final FDA approval thorough the New Drug Application process [if Perfect Colon Formula was a drug] as Perfect Colon Formula is neither patented or patentable and, therefore, the remedy the FDA says exists under this part of the FDC act does not exist at all?

Please take your time to explain why the FDA believes this remedy actually exists in view of the patent requirements in 21 USCS 355 (b)

21. On April 7, 1993, U.S. Representative Bill Richardson of New Mexico who introduced the House version of DSHEA in 1993 made the following statement to the House of Representatives: (See Exhibit C.R. 1, page 2, paragraph 6 from the top). Rep. Bill Richardson stated-

"The FDA has repeatedly used implied health claims to prosecute dietary supplements as drugs. The regulatory framework Congress created many years ago regarding health claims works for only one type of product – synthetic patentable drugs. Dietary supplements are natural, non-patentable substances. The current $200 million-dollar, 12 year-long drug approval process simply does not work for non-patentable products like dietary supplements."

Question: Does the FDA agree with Rep. Richardson statement that the current drug approval process only works for patentable synthetic drugs and (not for foods or dietary supplements as they are not patentable)? Your comment _____

See page 31 of my original Motion to Dismiss (May 26 2011)

The requirement for a patent number on the NDA is found in 21 USCS 355(b) and states:

line 12 “The applicant **shall** file (bold added for emphasis) with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug.”
This same paragraph goes on to add that if a patent is granted after the filing of the NDA and before approval of the NDA, then the applicant shall amend the NDA to add the patent number. Section 2 and 3 follows on claims for uses made under a patent cited in the NDA and other matters related to patents and patent infringements. Since the 4 products in question are not patentable and are not the invention of a person, they are not “new drugs” and since they are not patentable the current law prevents the processing of a New Drug Application (NDA).

22. If the remedy the FDA says exists really does exist, then will the FDA explain to the court why it has not approved a single non-patentable food, herb, vitamin, mineral or nutritional, substance or dietary supplement in its entire history of approving new drugs from 1938 to the present time?

23. The mandate for a patent number in applying for an NDA violates due process as there is no remedy at law as no food or herb is “patentable,” and therefore, **no remedy at law is available** to obtain FDA approval of a new drug that is a food or herb intended to prevent or treat disease. For this reason alone, should not this case should be dismissed, as Perfect Colon Formula was a food-based nutritional supplement. As such it was not either patented or patentable?

24. Will the FDA state whether it agrees or disagrees with the following Statements from the Congressional Record of 1993 -1994. They are numbered alphabetically A thru

A. Rep. Bill Richardson on April 7, 1993 (See Exhibit C.R.1. page 1, paragraph 3) stated:

Hon. Bill Richardson: "Mr. Speaker…Many Americans are using dietary supplements in order to prevent disease and to maintain health and wellness. Scientific research findings continue to show that supplementation of certain nutrients can significantly reduce the incidence of chronic disease."

B. Hon Jim Cooper, who co-sponsored DSHEA, made remarks to the House on October 21, 1993 (See Exhibit C.R. 2, page 1)

Hon Jim Cooper: "Mr. Speaker….The FDA should not be allowed to remove safe supplements from the market, characterize them as drugs, or require a prescription for them." (Note: if time permits please indicate whether or not you agree with all the comments in Mr. Cooper's one page statement.

C. Hon. Donald A Manzullo, who co-sponsored DSHEA, made remarks to the House on November 22, 1993 (See C.R. 3, page 1)

Hon Donald Manzullo: "Mr. Speaker….First, it establishes that dietary supplements are not drugs or food additives." Paragraph 7, also see and comment on paragraph 10

D. Hon. Orrin Hatch statement to the U.S. Senate on Nov. 23, 1993 places in the Congressional Record a letter to Hon Donna E Shalala, Sec of HHS. (See Exhibit C.R. 4, page 1 and 2) The Letter is signed by Senator Orrin Hatch, Rep Elton Gallegly, and Rep Bill Richardson.

It starts with "Dear Madam Secretary. One of your agencies, the Food and Drug Administration, has consistently demonstrated an anti-dietary supplement bias over the past three decades. That bias has threatened consumer's access both to dietary supplements and to information about the beneficial health effects of those products."

Does the FDA agree or disagree with this first paragraph - the premise of this letter and why?

E. Statements of Senator Hatch and others from the Congressional Record of August 13, 1994 (See Exhibit C.R.6, page 3, third paragraph from the bottom) comments on the Senate version of DSHEA S.784.

See Exhibit C.R. 6 – four pages are excerpted. Here is a short excerpt from a statement by -

Hon Hatch: "Mr. President….. As you know, S. 784 makes clear that dietary supplements are not food additives or drugs, and that the burden of proof shall be on the FDA to prove that a product is unsafe."

F. Statement of Senator Tom Harkin to the U.S. Senate on Oct 7, 1994 (See C.R. 7. Page 1, paragraph 6 marked in brackets)

Hon Sen. Harkin: "Mr. President….I have been a long-time advocate of preventive health care. And this proposal is an important part of that. We don't have a health care system in this Nation. We have a sick care system. We spend billions patching and mending. But we flunk when it comes to helping people stay healthy in the first place. If all we do is change how we pay the bills, we're just rearranging the deck chairs on the Titanic. We're going down. The only way we'll really get costs under control is to emphasize prevention and giving people the wherewithal to stay healthy."

The Dietary Supplement health and Education Act of 1994 was signed by President William Jefferson Clinton On Oct 25, 1994.

Conrad LeBeau July 9 2015

Certificate of Service

I, Conrad LeBeau, certify that a copy of the attached **Defendant's List of Questions for the Plaintiff with attached Exhibits** was filed on July 9, 2015, with the Clerk of Courts Room 362 and a copy was emailed to US Attorney Gordon Giampietro, and a printed copy was sent by Fedex on July 9th 2015 to Attorney Giampietro. A copy was also mailed by first class mail to:

Chief Judge Charles N Clevert Jr
517 E Wisconsin Ave
208 U.S. Courthouse
Milwaukee, WI 53202

US Attorney Gordon Giampietro
U.S. District Court
517 E Wisconsin Ave Room 530
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X_____ July 9, 2015

Exhibit List

1. LeBeau's FOIA Request to the FDA on Feb 15, 2011 and the FDA response on Feb 23, 2011.

2. Congressional Record (C.R.) 1 page 1 thru 3. April 7, 1993

3. Congressional Record C.R. 2 page 1 ……Oct 21, 1993

4. Congressional Record C.R. 3 page 1-2 …….Nov 22, 1993

5. Congressional Record C.R. 4 pages 1-2 ……Nov 23, 1993

6. Congressional Record C.R. 5 page 1……..March 3, 1994

7. Congressional Record C.R. 6 pages 1-4 ……August 13, 1994

8. Congressional Record C.R. 7 page 1 …….October 7 ,1994

9. Statement by President William Jefferson Clinton on Oct 25, 1994, in signing

The Dietary Supplement, Health, and Education Act of 1994