No 16-1289

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

vs.

CONRAD E LEBEAU,

Defendant-Appellant.

AN APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN
THE HONORABLE CHARLES N. CLEVERT Jr, PRESIDING

BRIEF AND REQUIRED SHORT APPENDIX OF DEFENDANT-APPELLANT

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DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1, Conrad LeBeau informs the Court that he represents himself, pro se, as the Defendant-Appellant. Conrad E LeBeau is a natural person in the district court. On appeal, Conrad E LeBeau continues to represent himself although he has the benefit of standby counsel from the Federal Defender Services of Wisconsin, Inc for technical matters on Court Rules and Procedures, and has consulted with the Clerk of Courts in Chicago for the 7th circuit.

Dated: March 17, 2016

Conrad E LeBeau - pro se

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JURISDICTIONAL STATEMENT

This is an appeal from a review of a misdemeanor criminal case by U.S. Judge Charles N Clevert from a case decided by Magistrate William Callahan with a Conditional Plea Agreement. The district court had jurisdiction under 18 U.S.C. § 3231. This Court has jurisdiction on appeal under 28 U.S.C. § 1291 and 18 U.S.C. § 3742 (a)(1) and (2). LeBeau appeals the district court's decision of Feb 3, 2016 affirming Magistrate courts decision. LeBeau timely filed a notice of appeal on February 12, 2016.

QUESTIONS PRESENTED:

1. **Defendants intentions**: Did the defendant intend, as the government alleges, to make a disease claim for Perfect Colon Formula when he used the term "reduces food allergies" in a handout flyer and do the facts about the case as reported in Document 28 (Motion to Dismiss) support or refute this?

2. **Plea Agreement defect, transcript contradictions, and threats from the government**: Does the Plea Agreement (Doc 58) support the government's narrative that the plea of "guilty" meant the defendant intentionally had a "state of mind" to distribute unapproved new drugs in interstate commerce, and does the transcript of the Jan 13, 2012 hearing on the Plea Agreement (Doc 96) support or contradict this narrative?

3. **The Patent issue and the Doctrine of Impossibility**: Why is it that the U.S. Food and Drug Administration has never approved a single vitamin, mineral, herbs, food, nutritional or dietary supplement as an "approved new drug" in its entire history of approving drugs? Does the New Drug Application (NDA) mandate fatally impair the First Amendment right of LeBeau to use speech about a food supplement by placing a regulatory and financial burden for pre-government approval of that speech?

4. **Congressional intent and the Doctrine of Overbreadth**; The Congressional Record on 1906 and as amended in 1938, 1962, 1990 and 1994 show that the original definition of a "drug" had a limited meaning that included, besides patented medicines, cocaine, heroin, narcotics, and nostrums but did not include water, herbs, food, spices, nutritional supplements, vegetables and fruits?

5. **Judicial expansion of the legal definition of drug.** Did the Courts, not Congress, expand the legal definition of "drug" as originally described in the Congressional Record of 1906, and amended (in1938, 1962,1994), to go beyond its original meaning and expand the scope of the definition at the insistence of the Executive Branch of government?

6. **Congressional intent in passing DSHEA in 1994:** Did Congress intend to narrow the scope of health products that the FDA could classify as "drugs" with the passage of DSHEA? After passage of DSHEA, has the FDA done an end run around this law by classifying food and dietary supplements as drugs based on speech they object to that was used in labeling? As the FDA applies numerous case law citations to foods and dietary supplements, is the speech itself the alleged "drug"?

7. **Applying DSHEA to Perfect Colon Formula**: With the passage of DSHEA in 1994, should Perfect Colon Formula be considered by its composition to be a food or dietary supplement and not a drug? Are the words "reduces food allergies" used in a handout brochure the alleged "drug" that the government objects to and found offensive? Based on the scientific research cited in Doc 28 and Doc 75, are the words "reduces food allergies" a truthful and not misleading statement in the context of how they were used?

8. **DSHEA and the Congressional Record of 1994 and other relevant arguments**: When U.S. District Judge Charles Clevert set the date of July 21, 2015 for oral arguments in this case, did he open the door for the defendant to expand his arguments of law to include the Congressional record of 1994 in passing the Dietary Supplement Health and Education Act?

9. **24 questions for the government that it failed to admit or deny**: Did Judge Clevert open the door for further factual and legal arguments when he set the date of July 21, 2015 for oral arguments? Should the 7th circuit consider allowing all of these requests for admissions to be entered into the record as evidence they were "admitted" or "acknowledged" by the government?

10**. Restraint of Trade and Case law on the freedom of speech and press**: How does Central Hudson, the Caronia case, and legal cases discussed in the book "**The Rise of Tyranny'**" by Attorney Jonathan Emord support the defendants first amendment arguments in this case? In 1788, in framing the U.S. Constitution, did the Continental Congress delegate to the new U.S. Congress in Art 1, Sec 8, U.S. Constitution the power to suppress commercial speech about how foods, herbs, water and other traditional natural remedies prevent and mitigate disease?

STATEMENT OF THE CASE

The government alleges the defendant violated the Food Drug and Cosmetic Act by intentionally distributing an unapproved new drug in interstate commerce in violations of 21 USC Sec 331(d), 333(a)(1), and 355(a) – a misdemeanor violation. The case was litigated before Magistrate William Callahan and reviewed under Rule 58 by U.S. District Judge Charles N Clevert.

On Jan 12, 2012, the government reached a Conditional Plea Agreement with the defendant on one count and dropped the other three counts. In the Conditional Plea Agreement, the defendant pled guilty (as the court interpreted the law) to one count of distributing one bottle of Perfect Colon Formula as an unapproved new drug in interstate commerce, although, in the defendant's mind, he was not guilty as he never intended to make a disease claim for Perfect Colon Formula. The Plea agreement was signed under the threat of maximum fines and incarceration if the case went to trial and I lost. The government used a carrot and stick approach to induce me into signing the Plea agreement. The carrot was $100 fine and one year's probation and the stick was $100,000 in fines and one year in jail for each of the 4 counts if convicted.

The Plea agreement allowed the defendant to appeal a number of legal issues in this case, and if successful on any one of them, to withdraw his Plea in the Magistrate Court. Legal issues include the Doctrine of Impossibility – both factual and legal the Doctrine of Overbreadth, and violations of the First Amendment, 5th and 9th amendments and Restraint of Trade.

The Plea Agreement required the defendant to plead "guilty" to one count of distributing an unapproved new drug in interstate commerce. However the statement of "guilty" was qualified to mean -*"because he is factually guilty under the magistrates court's interpretation of the law."* The purpose of adding these 13 words was to remove from the guilty plea the implication that the defendant had "state of mind" in making a disease claim and thus breaking a law. Statements made by me under oath as well as those made by Federal Defender Joanna Perini and OK'd by USA Gordon Giampietro at the Jan 13, 2012 hearing support the position that this qualification of the "guilty" plea was acceptable to all parties. (Doc 96)

Judge Clevert used the term that the defendant "pled guilty" three times in his decision of Feb 3, 2016. He made no mention of the added language that qualifies the meaning of the guilty plea phase and created the misleading impression that the defendant pled guilty as a "state of mind."

The issue of the defendant's state of mind should be considered at two points in time: 1.) When he used the term in 2009 "reduces food allergies" it was used as one of 12 health effects or benefits for using Perfect Colon Formula, It was never intended to be a disease claim and 2.) When he signed the Plea Agreement, he was under threat from the government that they would seek a maximum punishment under the law if he did not sign the Plea Agreement. [Due to the stress the process imposed on me, my health was rapidly deteriorating at the time. In signing the Plea agreement, I accepted the FDA/DOJ's and the court's position that "reduces food allergies" was disease claim; that was how the law was applied by the Magistrate court. However, a disease claim for Perfect Colon Formula was never my intent.]

Attorney Gordon Giampietro noted in the footnotes on page 7 of the Plea Agreement the following:

> There is no state of mind requirement for misdemeanor offenses under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399a. The FDCA was designed as a strict liability statute to protect society at large. The "government need not prove knowledge or awareness that the drugs are misbranded or an intent to deceive or defraud."

SUMMARY OF THE ARGUMENT

As the law has been applied and is being by the FDA today, they use two different standards to define a drug. For patented drugs they use the 1.) A unique material composition of the drug as described in the patent and 2.) Its intended use to prevent or mitigate disease. As the FDA applies the law or drugs it approves, the material composition or method of manufacture is unique and is protected by a patent. Speech alone does not make the drug.

For non-patentable foods, and nutritional products, the FDA only uses its intended use. This dual standard for defining a drug has been in use since 1938. However, the Federal Courts expanded the definition of drug in the period from 1906 to 1938 to include food and mineral water after being urged to do so the DOJ and the FDA. This expansion of the definition of the term "drug" is found in some Federal Court cases where no review of the intent of Congress was undertaken by reading statements of elected officials found in the Congressional Record of 1905 and 1906.

Part 1 Doctrine of Overbreadth

This expansion of the definition of a drug was done before 1938 and was carried over as relevant case law by the FDA after the law was amended in 1938 to require FDA approval of "new drugs" for safety purposes. Defendant contends that this expansion of the definition of "drug" was done by the Federal Courts and not by Congress; that this expansion of the term "drug' has done irreparable harm and caused death to millions of American by denying them information on how foods, and other non-patentable traditional remedies can prevent or mitigate disease. This expansion of the definition of the term "drug" violates the Doctrine of Overbreadth, and violates the intent of the Congress of 1906.

To the extent that the Federal Courts have approved the expansion of the definition of "drug," at the urging of federal attorneys, they have legislated from the bench which is not a power granted to them under the U.S. Constitution. The Executive Branch of the Federal Government by going to the courts to expand this definition did not have legal standing or authority from Congress to do this. The definition of what is included in the "drug" classification needs to be rolled back, not only to include structure and function claims as is currently allowed, by disease claims as well. Since the courts, not Congress, have allowed this definition to expand, it is their responsibility to roll it back to its original meaning.

Part 2 Doctrine of Impossibility

21 USCS 355 (a) states:

"No person shall introduce or deliver for introduction into interstate commerce an new drug, unless an approval of an application filed pursuant to subsection (b) or (J) is effective with respect to such drug."

21 USCS (355) (a) requires the filing of a New Drug Application (NDA) for anyone seeking FDA approval for a new drug. 21 USCS 355 (b) requires a patent number to be provided in the NDA application. This requirement is found in lines 13 to 22 of this paragraph. The use of the word "shall" is repeated 3 times and "required" once. The word "may" is not used. Since natural food items and the defendant's product, Perfect Colon Formula, contains only natural food ingredients and no synthetic compounds, it is not patentable. Hence, the legal requirement to process an NDA application is not possible to complete. Therefore, there is no remedy at law.

The second part of the argument on "Impossibility" is the financial cost of going through the trials for FDA approval. Rep. Bill Richardson of New Mexico (the original sponsor of DSHEA) stated that in Congressional Record on April 7, 1993:

"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."

Part 3 – how the NDA and patent requirement impairs freedom of speech

The NDA requirement, its cost, and the patent mandate in the law directly impair the defendant's First Amendment right of commercial speech for the commodity Perfect Colon Formula, or any other food or non-patentable nutritional supplement. The commercial speech prohibited is an "intended use for the prevention or mitigation of a disease" for a food product

that did not come into existence as an invention or creation of man or government. Used on the label or attached literature. The government mandate for preapproval of speech about a food or dietary supplement for an intended health purpose is a direct violation of the First Amendment.

Since the FDA has admitted in its response to my FOIA filing I did in Feb 2011, it never has approved a single food or other non-patentable health product as an "approved new drug" in its entire history of approving drugs. There is no remedy at law for the defendant in filing an NDA.

Since there is no remedy at law in the NDA path, there is no due process under the 5th amendment that is available to the defendant. There would be due process for the defendant for a health claim for a dietary supplement, because a patent is not required and the standard for a health claim under DSHEA is that the statement is truthful and not misleading.

The suppression of speech with the NDA requirement also violates the 9th amendment right to freedom of choice in medicine. In his opinion of Feb 3, 2016, Judge Clevert did not advance any argument why an NDA and patent requirement would not impair the defendant's First Amendment right of speech and press.

Part 4 – Criminal charges not justified in Central Hudson 447 U.S. 562

Finally, in Central Hudson (447 U.S. 562), *"the government's interest asserted should not be more extensive than what is needed to serve that interest"*. If the government strongly felt it needed to suppress the three words "reduces food allergies" to protect the public, it could easily have done so by writing a "**Warning Letter**" to the defendant. It did not do this. In Doc 28, the Motion to Dismiss I asked this question: Where is my warning letter? The government could

have complied with Central Hudson guidelines by seeking a remedy under DSHEA for a health claim instead of criminal charges.

Finally, by the time the "Information" was filed on Dec 7, 2010, Vital Health Products. Ltd, and the defendant had been out of business since August of 2010. The business was shut down because the parameters of allowable speech including (what a disease is) in marketing health products were secrets known only to FDA insiders and not to the defendant. The FDA has stretched the definition of "disease" to cover almost any health benefit that is described in the scientific literature.

Also, 2010 was the year the FDA would impose financially impossible requirements for manufacturing dietary supplements. The GMPs for supplements that were so costly and extreme, they actually drove over 150 small supplement companies out of business, This was done by not following the Congressional mandate to the FDA in DSHEA to write GMPs for dietary supplements based on the GMPs used for food. At that point I decided - "enough is enough." I no longer wished to be a part of an abusive relationship with my own government.

ARGUMENTS for Question 1 and 2 – Defendant intent, Plea Agreement issues, and a threat from the government

Judge Charles Clevert in his "Decision Affirming Judgment" filed on Feb. 3rd, 2016 began with this statement: *"Conrad LeBeau pled guilty to one misdemeanor count of introducing into interstate commerce a new drug that had not been approved by the Food and Drug Administration (FDA)."* This statement is based literally on the Plea Agreement on file at pacer.gov (Doc 58). Judge Clevert was likely misled by reading directly from the Plea Agreement and may not have read from the transcript of the proceedings on Jan 13. 2012 (Doc 96). Unfortunately, the Plea Agreement currently on file (Doc 58) has an important defect and it is: after the word "guilty"

(Paragraph 37) it is missing this statement – *"because he is factually guilty under the magistrates court's interpretation of the law."*

Federal Defender Joanna Perini proposed these 13 words in final negotiations with the government on the Plea agreement around Jan 9, 2012. (Doc 123, 125 and 127). They were meant to qualify the guilty plea as a how the law was applied by the Magistrate and not as a state of mind by the defendant. In a phone call I received, Ms. Perini informed me that US Attorney Gordon Giampietro had accepted the language change. The added language change was intended for me personally, but not for Vital Health Products Ltd, a corporation that I had dissolved in August of 2010.

The problem is that the added language did not show up in the Plea Agreement filed at pacer.gov, and most likely led to confusion at the Plea hearing 3 days later on Jan 13, 2012. The missing 13 words qualify the plea of guilty to how the law was applied instead of a state of mind could be due to a mistake made in the U.S. Attorney's office or it was done deliberately. This explains the confusion that occurred at the hearing on Jan 13, 2012. This is evident on pages 9 and 10 of the transcript of the proceedings on Jan 13, 2012 (Doc 58).

The transcript of the Jan 13 hearing as excerpted below makes it clear that the plea of guilty was as described by FD Perini was after I was asked by Magistrate Callahan the following question:

THE COURT: And are you pleading guilty of your own free will because in your mind you're guilty?

I replied: "I'm not sure how to answer this." I then asked Miss Perini: "What's the answer I'm suppose to give to this?" Magistrate Callahan then asks Ms. Perini to weigh in.

MS. Perini: "Given the way the Court has currently found the law, based on the motions to dismiss, do you believe that you are guilty under the law as the Court has found it, reserving your right to challenge the law with the seventh Circuit?"

I replied: "That would be correct, yes."

Then the Court asks Atty. Giampietro: "Well, in your mind is it, Mr. Giampietro? In your opinion?"

Mr. Giampietro: "I believe it is, Your Honor."

Ms. Perini: "I believe so."

I raise this issue here because after the Jan 13 hearing, I tried to locate the final version of the Plea agreement that was negotiated between Ms. Perini and the government at pacer.gov where the electronic pleadings are filed. The current version of Doc 58 at pacer.gov does not reflect that final piece of the negotiations on the Plea agreement as I remember it. However, the transcript (Doc 96) pages 9 and 10 have the language as described by MS. Perini nearly identical to the final version.

The government in its response to the two briefs (Doc 98 and Doc 113) filed under Rule 58 for a review by United States District Judge Clevert stated that I had pled guilty to shipping unapproved new drugs in interstate commerce, and Judge Clevert's statement in his decision of Feb 3, 2016 also used this same expression. The implication is clear that both the government and the District Court Judge's use of the term "pled guilty" refers to it as a state of mind on the defendant's part and not as how the Magistrate Court interpreted the law. The transcript of Jan 13, 2012 makes it clear the plea of guilty was how the Magistrate applied the law and not as a state of mind. Thus, the unqualified use of the term "pled guilty" is misleading in both instances.

Judge Charles Clevert's errors on page 8 of his decision.

Judge Clevert is wrong when he stated on page 8 of his Feb. 3 decision the following:

"He admitted in his plea agreement that he made a disease claim for Perfect Colon Formula, which evidenced his intended use for the product. During LeBeau's plea hearing, he acknowledged that a claim of reducing food allergies is a disease claim" Doc. 96 at 20-21.

In reviewing Doc 96 at 20-21 I found that I made no such statement as Judge Clevert alleges and his statement is clearly contradicted on page 17 and 18 of the same transcript (Doc 96 pages 17 and 18) when I stated:

THE DEFENDANT: *"Well, for one thing that information was a flier. It wasn't actually on the product. The product itself is a colon formula. It wasn't an allergy formula. If it were an allergy formula, it would have been called Perfect Allergy Formula. It was called Perfect Colon Formula."*

The next question is - why did Magistrate Callahan accept the Plea Agreement after he heard that statement? At that point Callahan knew I did not intentionally make a disease claim for Perfect Colon Formula. This statement in the transcript of Jan 13, 2012 hearing on the Plea Agreement obviously undermines the government's assertion that I intended to make a disease claim when I quoted from the scientific studies about the effects of two probiotics in the formula. In other words, without intent to make a disease claim, the government's case against me for speech I made about Perfect Colon Formula falls apart.

Judge Charles Clevert "cherry picked" certain parts of the plea agreement to defend his opinion that I had pleaded guilty as a state of mind, but the testimony I gave under oath in answers to questions presented to me tells a different story. In Doc 64, which I filed on April 16 2012, I stated 5 reasons why I signed the Plea Agreement. The 5 reasons I cited did not include that I had intended to make a disease claim for Perfect Colon Formula. I reprinted the actual handout flyer on the next page that became the basis for the government's complaint against me. The following brochure is reprinted from page 9 of Doc 64:

Flax n'flora with Inulin
plus 6 Probiotics

13 reasons to use Perfect Colon Formula™

Each serving contains 12 billion total of 6 strains of friendly flora to help restore normal stools (large diameter stools - floaters) when used one or more times daily.

- Reduces food allergies. [**allergies** was changed to **sensitivities** in Nov 2009]
- No dairy, gluten added. No animal products as ingredients.
- Increases mucin production and rebuilds the mucus membranes of the intestines.
- Fiber supports gastro-intestinal mobility and function.
- Pectin chelates heavy metals out of body
- Pectin increases IgA that supports mucosal immunity
- Creates a hostile environment for pathogenic (unfriendly flora) and other undesirable microbes.
- Increases SCFA's (butyrate, lactic acid, acetate and propionate acids) levels.
- Friendly flora produces B vitamins (causes urine to turn yellow)
- Supports mucosal immunity, cell-mediated immunity and Natural Killer cell function.
- Reduces stress on the kidneys by processing ammonia in the stools
- Reduces and prevents stool odor
- Increased oxygenation of the blood due to flax seed oil in formula. Feel more energy and well being.

Q: What is in the original hypoallergenic "Perfect Colon Formula ™?

A: Each serving (7 grams) contains: 12 billion total of the following strains (non-dairy): L. Acidophilus, L. Rhamnosus, B. Bifidum, B. Longum, L. Salivarius and L Plantarum plus freshly ground Organic Flax Seed pwdr, Chicory root (inulin),Soluble Rice Bran, Citrus Pectin, Konjac root (Glucomannan), Beet root, coral calcium and magnesium oxide. Each serving is 7 grams (one rounded teaspoon. Perfect Colon FormulaTM Plus is available in two sizes, 212 grams (30 servings) or 424 grams (60 servings) in the refrigerated section.

Note: Perfect Colon Formula No 1 is unflavored and Fiber, Fruit N flora has raspberry powder added.

Perfect Colon Formula is available from
your local health care professional or health food store

Store product in freezer/refrigerator to extend shelf life.

The information on the Handout brochure was the same as was posted on the Vital Health website except that "Reduces food allergies" was changed to "Reduces food sensitivities" on Nov 3 or 4, 2009, after I was told by FDA Attorney Sabel that it was a disease claim. A reasonable reading of this brochure would leave the average person with the impression that Perfect Colon Formula was designed to improve and promote colon health and would not leave the impression that the fiber formula was intended to treat a disease. By

taking 3 words in this brochure out of context, the government creates a misleading impression that Perfect Colon Formula was designed as a treatment for food allergies. Attorney Giampietro acknowledged at the Jan 13, 2012 hearing on the Plea Agreement, that the actual wording on the bottle of Perfect Colon Formula made no mention of food allergies. (Doc 96)

On page 9 of the Brief in Support (Doc 29) of my Motion to Dismiss (Doc 28), I stated:

"Nov 3, 2009. I received a letter from an FDA Attorney Nathan Sabel written on Nov 2, 2009 in which he stated he was writing to the local US attorney and recommending that criminal charges be brought against me. The letter shocked me as I thought I was in compliance with what the FDA wanted. After reading the letter, I realized I was being dragged into a legal fight. Mr. Sabel left his phone number in the letter in case I wanted to discuss it with him."

"I called him the same day I received his letter. I asked him first why I had not received a return phone call from Tyra Wisecup that I had been promised a year before and second, **why I had not received a warning letter if they thought there were ongoing violations.** He replied that he was the only person I needed to talk to now. I told him that I first carefully searched the database at the National Library of Medicine before using any of that information on my Order Form. He said, "an abstract does not mean anything." He also stated that my claim on Perfect Colon Formula about "reducing food allergies" was a disease claim. I responded that the statements on the handout flyer was based on one or more abstracts I had retrieved from the NLM. **I did not realize that "preventing and reducing food allergies" was a disease claim"**

When the government replied to my Motion to Dismiss, it was signed by USA Gordon Giampietro along with FDA Attorney Nathan Sabel, who did not contradict the details of the conversation I had with him on Nov 3rd. 2009.

The threat from the Government

On Feb 19, 2016, I filed a letter (Doc 123) with Jon Sanfilippo, Clerk of Courts in Milwaukee and requested that Doc. 30 and 31 be transmitted to the 7th Circuit along with a copy of an email I received on Nov. 1, 2011 about the Plea Agreement. U.S. Attorney Jonathan Koenig then wrote to Judge Clevert (Doc 124 to oppose including a copy of this email to be sent to the 7tth Circuit. I replied in Docs 125 and 126 why I felt this was important as I was under intense psychological pressure to reach a Plea Agreement. As of today, U.S. Judge

Clevert did not respond to my two motions. Therefore, I am quoting from the email that I received from USA Gordon Giampietro on Nov 1 2011 as follows:

I refer to paragraph 3 of his email of Nov 1, 2011 that states:

"the terms of the agreement are highly favorable to you. The United States will dismiss the three other counts of the information; recommend one-year probation and a $100 fine. You are also, as discussed above, expressly allowed to preserve your legal arguments for appeal. Ordinarily, they are waived when you plead guilty. ……..you must sign and return the agreement by November 23, 2011. After that date, the United States will require that you plead to all four charges and it will seek the maximum incarceration and fines allowable. Each count carries up to a one-year of incarceration and a $100,000 fine."

In Doc 125, I wrote to Judge Charles Clevert and in reference to the above threat stated in part:

"The choices given me were extreme opposites. One is a small fine and one year's probation while the other is one year in jail and $100,000 in fines for each count. Since there were 4 counts, I could have faced $400,000 in fines and 4 years in jail.

"the absolute voluntariness of the Defendant's Plea of "guilty" in the Plea agreement should be balanced and tempered in the context of the threat in this email of the government seeking maximum fines and incarceration against me if the case went to trial instead of being resolved with the Plea Agreement.

"Since the Plea Agreement required me to state (under oath) that were no threats made against me, it is important for the record to reflect the realty that the tactics of the U.S. attorney placed enormous psychological pressure on me.

"Paragraph 3 of the email of 11/11/11 should be considered by the 7th Circuit.

"The language in paragraph 3 of the email tempers the sting of "guilty" in the Plea Agreement at it loses some of its ethical and moral essence although retaining its legal value to the government. I believe that for the Court of Appeals to properly evaluate this case, needs to read this email and consider the pressures it placed on me when I signed the Plea Agreement about 5 weeks later around Jan 10, 2012.

For the foregoing reasons stated herein, I believe the email of 11/11/11 is relevant in this case and should be added to the record to place the "guilty plea" of the Plea Agreement in balance and perspective. "

[Note: I mistakenly cited as being sent on 11/11/11. It should have been 11/01/11 as noted in its heading of the email. As of today, March 17, 2016, there has been no reply from Judge Clevert about whether or not to transmit this email to the 7th circuit.]

Questions for the 7th Circuit

Can you have a drug when the composition of the product is not a drug and the definition of "drug" turns on its "intended" use for preventing/mitigating a disease and the alleged offense cannot be proven by intent? In other words, how can you have a conviction for a misdemeanor violation of the FDC Act, even one based on a Plea Agreement, when the intent to make a disease claim was never there in the first place, and the alleged drug is not a drug by composition? When the intent to make a disease claim does not exist, and the composition of the product is not a drug, does not the alleged new drug self-destruct in the absence of provable intent? This is why I have spilled considerable ink on this point: without the composition of a drug and without intent to treat a disease, there is no drug. The Plea agreement should accurately reflect the state of mind of the defendant. Since there is no provable intent to distribute unapproved new drugs in interstate commerce, there never was a drug except in the mind of the FDA attorneys who inserted their own intent into my words..

When I was told that "*reduces food allergies*" was a disease claim, I changed it to "*reduces food sensitivities*" a functional claim that is authorized under the Dietary Supplement Health and Education Act of 1994. By its composition, Perfect Colon Formula was a dietary supplement, not a drug and "reduces food sensitivities" is a lawful functional claim under DSHEA.

However, I am not asking for a dismissal of the Plea Agreement due to its many defects, I prefer that the court rule that the law as applied must not violate and usurp basic U.S. Constitution rights, and the intent of Congress when it was passed, and not as changed later-on

by the FDA and DOJ who did not have legal standing to change the meaning of the law in the first place by expanding the definition of "drug" to include food and water.

Question 3 – the Patent issue, the Doctrine of Impossibility and the price of speech about a food based dietary supplement

Judge Clevert's comments on pages 8 through 11. On page 9 , he states that "LeBeau could raise money to find an investor for necessary studies and trials. …..In any event, that tests and trials may cost a substantial amount of money is not a basis for ignoring the approval process."

There are several issues that Judge Clevert ignored.

1. First is the premise of Judge Clevert's argument. LeBeau never intended to make a disease claim for Perfect Colon Formula when he passed on information in the scientific literature that probiotics in the formula had beneficial effects for persons with food allergies, intolerances or food sensitivities. Why would he file a New Drug Application when he considered his product to be a food-based nutritional supplement, and not a drug? Also his statement "reduces food allergies" was modified to "reduces food sensitivities" on the same day (Nov 3, 2009) I had a conversation FDA Atty. Nate Sabel informed me the term was considered by the FDA to be a disease claim. Apparently "reduces food sensitivities" that I used for the last 9 months I remained in business (Nov 2009 thru July 2010) was not a disease claim or the government would have mentioned it in its Information on Dec 7, 2010. .

2. Who would invest millions of dollars for the government privilege of using 3 words (reduces food allergies) when the product is called Perfect Colon Formula?

3. A common sense evaluation of this proposal by the FDA and Judge Clevert is that you would not find investors that would gamble a million dollars or more on a proposition that is guaranteed to lose money. Are we to assume that the public upon seeing the 3 words "reduces

food allergies" on a handout flyer which lists more than a dozen other health benefits would immediately fall into a hypnotic trance and sleep walk their way to the casher register to make a purchase?

4. Why is it that neither the FDA, the DOJ or Judge Clevert can cite a single example where this has happened, even once, in the entire history of the FDA approving patented synthetic molecular compounds as an "approved new drug?" The question that begs to be answered is why the FDA is insisting that foods and nutritional supplements go through the FDA approval process for drugs when they cannot even cite a single case of anyone running this gauntlet?

5. The clear mandate in 21 USCS 355 (a) is that –

"No person shall introduce or deliver for introduction into interstate commerce an new drug, unless an approval of an application filed pursuant to subsection (b) or (J) is effective with respect to such drug."

Judge Clevert and Magistrate Callahan both ignored the patent mandate ("shall file") requirement in 21 USCS 355 (b). Callahan stated the following in Doc 51, page 4:

"A common sense reading of the statute demonstrates that, if there is a patent, the identifying information of such patent must be disclosed. If there is no patent, then obviously no patent information need be disclosed. In other words, a new drug application does not require that there be patent on the drug for which the application is being submitted."

Callahan and Clevert are both wrong in claiming that a patent requirement is not required. Since Clevert ignored addressing the obvious meaning of the law and my arguments on the meaning of the word "shall" in Doc 113, I will repeat it here -

The law under 21 USCS (355) (b) states:

line 13 "The applicant **shall** file (bolded 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."

Line 18 “If an application is filed under this subsection for a drug and a patent which claims such drug or method of using such drug is issued after the filing date but before final approval of the application, the applicant **shall** amend the application to include the information **required** by the preceding sentence,”

Line 22: “Upon approval of the application, the Secretary **shall** publish information submitted under the two preceding sentences.”

The word “shall” is used 3 times in 21 USCS 355 (b) in sentences that directly follow one another. The word “required’ is also used. It is apparent that for food, water, and dietary supplements, that as regards the law as applied under FDCA since 1938, there is no remedy at law available under USCS 355 (b) for a non-patentable product as a “new drug.” The non-existence of a remedy at law under the “drug” and “new drug” definitions is why Congress in 1994 passed the Dietary Supplement Health and Education Act. (DSHEA) See Doc 109 for the defendant’s list of 24 questions (admissions) for the government to answer at the hearing for Oral Arguments set for July 21, 2015 by Judge Clevert.

6. Why does the FDA continue to over-ride Congressional intent and purpose in passing the Dietary Supplement Health and Education Act of 1994 by continuing to classify foods and nutritional supplement as “drugs” and “unapproved new drugs” based solely on speech about their intended use? Why do they continue to keep a regulatory padlock on scientific research on file at the National Library of Medicine? Does not the First Amendment prohibit this suppression of speech?

Why did Judge Clevert ignore my argument (Page 8 and 9, Doc 113) that the FDA demand to file an NDA fatally impairs my First Amendment rights?

On the second paragraph on page 9 of his decision, Judge Clevert partially quotes from my brief (Doc 113) on page 7 where I question the practicality of requiring the filing of an NDA for a non-patentable food product and ending with this sentence:

“Is it not a demand that would impose an unrealistic and extreme economic burden on the defendant to comply with the law beyond the realm of what is possible?

Clevert then adds: 'In any event, that tests and trials may cost a substantial amount of money is not a basis for ignoring the approval process. The FDCA is a consumer-protection statute."

What Clevert ignored in his opinion is the balance of my arguments that the NDA filing requirement and all that goes with it fatally impair my first amendment rights. It places a very hefty price tag on my right of speech about Perfect Colon Formula, and the FDA mandate for filing an NDA turns a right of speech under the First amendment into a privilege of government.

Clevert cites at least 5 court cases to support his opinion, but does not claim any of the citations address the issue in this case – being that the burden of the NDA approval process impairs speech for a food product that is not a drug by composition. Second, the DSHEA of 1994 is also part of the FDCA, and the FDA continues to do an end-run around this law by classifying foods and dietary supplements as drugs based on speech.

The following excerpts from my brief (Doc 113 pages 7, 8, 9) that Clevert ignores is this:

"Would it be that the defendant could then speak about the intended use of his health product (Perfect Colon Formula), for a government approved purpose and thus be allowed to exercise his first amendment rights?

"The government's position is this: the defendant could have avoided this economic dilemma by not making health claims (statements of intent) that the government found offensive. In order words, the government, by placing economic demands on the defendant that he had no financial means to comply with, is forced to self-censor his own speech to avoid civil and criminal accusations and penalties.

"The government demands to file an NDA run up directly against the right of freedom of speech and press preserved under the 1st amendment. The court should note that the government did not allege that the statement in the brochure about Perfect Colon Formula that certain probiotics in the formula "reduces food allergies" was not truthful or was misleading. Under the first amendment, speech that is truthful and not misleading is protected speech (Central Hudson 447 U.S. 557-583)

"The government's position is that freedom of speech about how foods and dietary supplements prevent disease is granted as a privilege of government, and is not

a natural inalienable right from God. This position is contrary to the preamble of the Declaration of Independence signed by our forefathers on July 4, 1776, a document that led to the revolt against the tyranny of King George and…his oppressive laws and secretive Start Chamber proceedings.

."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; it is found in the Congressional Record. Rep. 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."

Rep Bill Richardson's statement as the original sponsor of the Dietary Supplement Legislation in the House of Representatives, along with Senator Orrin Hatch (and others) make it very clear that DSHEA gives you its intended purpose – to create a safe harbor for speech about foods and nutritional supplements that is separate from drugs. DSHEA passed Congress on a bipartisan basis after over one million letters arrived from constituents demanding that Congress take action to stop the FDA from classifying hundreds of nutritional supplements and herbs as drugs and removing them from the market. [See excepts from the Congressional record on DSHEA in the 24 questions I submitted to the government to answer on July 21. 2015 (Doc 109)]

In his Feb 3rd decision, Judge Clevert failed to address how the NDA mandate would not impair my First Amendment rights. He simply ignored my arguments, and went on to discuss his views on the Doctrine of Overbreadth.

Questions 4 and 5 –

The Doctrine of Overbreadth, FDA expansion of the term "drug," and the role of the Courts in expanding this definition by legislating from the bench

Both Magistrate Callahan and Judge Clevert in their decisions in this case said I should take my legal issues to Congress if I wanted to change the law. They both said that I was not charged with violating the Pure Food Act of 1906 but for violating the FDCA. However, Judge Clevert in role as an "appellate judge" under Rule 58 had an obligation to examine the Congressional Record of 1906 as this legal issue was retained in the Plea Agreement. (Doc 58). Clevert also failed to acknowledge the obvious - that without the Pure Food Act of 1906 having been passed, the FDCA would not exist today. FDCA did not drop out of the sky and into the law books; amending the original Pure Food Act of 1906 in 1938 and again in 1962, and later on as well created it.

Both Magistrate and Clevert not only failed to acknowledge the obvious – that the courts themselves early in the last century expanded the definition of drug to include food items like tea, honey, fruits and vegetables, and even water and this expansion of the term "drug' came not from Congress, but from the Court themselves at the behest of Federal Attorneys and FDA attorneys.

The DOJ representing the FDA never cited a single statement from an elected member of Congress in the last 100 years, either from the Congressional Record, or the Findings of Congress in passing DSHEA in 1994, that water, food, vitamins, minerals, herbs, vegetables, and fruits are drugs and that the FDA should regulate them as drugs. It is little wonder that they did not want to look at the Congressional Record of 1906 or 1994 and avoided commenting on the Findings of Congress in passing DSHEA. Based on the opinions of both Magistrate Callahan and

Judge Clevert, apparently the opinions of the FDA and DOJ lawyers replaces the need to go to Congress to change the law to suit their narrative.

The expanded definition of "drug" had only one practical purpose, and protecting the public it was not, but rather to use the FDA as a regulatory agency to create a system of regulations and codes to protect a market monopoly for the holders of patented drugs who just happen to be major financial contributors to certain elected officials in the Federal Government. To create this monopoly and keep the financial contributions coming from the big drug companies, it means that the use of food, water, herbs, fruits, vegetables and nutritional supplements fro their medicinal value had to be suppressed; otherwise the financial contributions may stop - and with it the perks of being an elected official.

Both Callahan and Clevert cited numerous court cases to support their position that speech the FDA disapproves of transforms a food into a drug. However, they never describe in detail what the drug is; However, they state that words about the product that they disapprove of changes it into a drug. How does speech about a product transform the contents inside the bottle into a drug? How does this transformation take place? As for the handout brochure, one needs to consider what was said before and immediately before an after the alleged disease claim to determine if a disease claim was actually intended.

Intent of the lawmakers - the Congressional Record of 1906

The reason both Callahan and Clevert did not want to read or acknowledge what was said in the Congressional Record of 1906 or in the Congressional Hearing leading to passage of the Dietary Supplement Act in 1994 is that the Congressional Record does not support the FDA/DOJ narrative in this case. Both Callahan and Clevert did not want to tell the government that they have usurped the U.S. Constitution in multiple ways. 1.) they twisted the meaning of the word – drug, and 2.) over- reached their authority under Pure Food Act and FDCA as

amended to date, and have 3.) misapplied their enforcement of these alterations of law for the past 75 years.

For these reasons, both Callahan and Clevert have rationalized their positions with dozens of court cases where the rule of law has been deviated from by the Federal Courts who used multiple opinions to complement each other without ever going back to the source of the law – Congress. The DOJ, the FDA and the Federal Courts are not legislative branches of the federal government under the U.S. Constitution. It is true that it takes judicial courage to not follow the crowd, and to examine the intent of the lawmakers at its source – de novo – the legislative history. It was cowardly for federal attorneys to take the words of lawmakers and twist the meaning of those words into a purpose and narrative that was never intended – the classification of foods as "drugs" based on speech.

Questions 6 through 10 – Dietary Supplement, Health and Education Act (DSHEA) – applying DSHEA to Perfect Colon Formula

(Pages 12 to 24 of Judge Clevert's Decision)

While Judge Clevert cited numerous court cases including Supreme Court cases dating back 75 years of longer that classify foods as "drugs" based on speech or information about their health benefits and intended use, not one of the cases he cited claims to have reviewed the Congressional Record of 1905/1906 to find out what was the intent of Congress was in defining the term "drug." Why did Congress pass the Pure Food Act of 1906? Without the 1906 Pure Food Act, the FDCA would not exist today. The problem is with the very earliest of the Federal Court cases where the attorneys for the government without as much as a facial reading of the Congressional Record, took the words of the "drug" definition and twisted into a purpose never intended; that was to broaden the scope of the drug definition to include thousands of foods, herbs, plants, fruits and vegetables under the umbrella of the "drug"

definition. This was done for the purpose of suppressing the use of speech on the medicinal value of food, herbs and other natural remedies under the threat of civil and criminal remedies with the ultimate effect being restraint of trade.

The 1920 case that got it wrong

While Clevert said I was not charged with violating the definition of drug under the 1906 definition of "drug, the government, in its response to my Appeal Brief to Clevert (Doc 113), was to cite the case of *Bradley v. United States*, 264 F. 79, 80-82 (5th Cir. 1920). They wrote *"mineral water was considered a drug where the product was marketed as a substance that "possesses certain elements or ingredients which are curative, or at least alleviative, for the diseases named in the label."* In 1920, the FDCA as currently codified had not yet passed Congress. That would first happen in 1938 when the term "new drug" entered the legal lexicon and FDA approval for safety purposes would be mandated. In 1962, the FDCA was amended again to include proof or efficacy of a new drug.

One problem with the 1920 case was that neither the DOJ, the FDA or the Court took to time to review the Congressional Record of 1906 to determine whether the range of substances intended to be classified as drugs could be inflated beyond opiates, narcotics and nostrums and include food, spices, herbs, fruits and vegetables distributed for their medicinal value in preventing and treating disease. This 1920 case is still being cited by the FDA today.

The 1920 court erred by not asking the government to provide proof of Congressional intent to classify items like mineral water as a drug based on its intended use to prevent or treat a disease. This case acted like a springboard or snowball for other courts to pile and extend the definition of drug beyond the original Congressionally authorized parameters. Being prodded by government attorneys, Federal Judges bowed to the pressure of FDA attorneys and

expanded the meaning of the term "drug" in ways never authorized by the Congress of 1906. It is well accepted by Constitutional scholars that expanding the power of the Executive branch of the Federal Government by judicial fiat is not authorized under the U.S. Constitution.

Since foods and edible plants, (with the exception of controlled substance like cocaine and heroin), are not opiates or narcotics, the original meaning of "drug" was profoundly changed with these early court cases. The broad-brush definition of "drug" served only the market monopoly interests of the holders of patented drugs and narcotics. In incremental steps, the FDA moved even in the 1940's to classify vitamins as drugs. This classification of foods as drugs was a reward to big drug companies for the generous donations they gave to the political coffers of both Republican and Democrat presidents, and select members of Congress. Today, Michael Taylor, former vice president of Monsanto Corporation, is in charge of foods and dietary supplements at the U.S. FDA. I have no doubt that because of lavish donations from Monsanto Corp. to both President Clinton and George Bush was why Michael Taylor got appointed to a managerial position at the FDA in charge of foods and dietary supplements. He holds his position at the FDA with obvious conflicts of interest

The Golden rule "to do unto others as you would have others do unto you" does not apply at the FDA; instead the money power on Wall St has this version - "he who has the gold rules." Yesterday, and today, the Federal government in Washington, DC is both conflicted and corrupted - it has been for sale for a long time. However, but why have so many Federal judges who do not faced elections feel so obligated to bend over backwards in their opinions to please federal attorneys? Did they forget that they took an oath to uphold the U.S. Constitution and the laws passed by Congress? Neither Clevert nor Callahan indicated in their opinions that they read and reviewed the Congressional Record of 1906 or DSHEA passed in 1994.

[I did read and review both the Congressional Record of 1906 and the Congressional Record of 1993/94. I did not one word mentioned in either Congressional Record that intended foods to be classified as drugs based on speech about their intended use.]

The sale of foods is lawful activity and the use of food for medical purposes is also lawful activity. However, speech about the use of food for medicinal purposes is deemed by the government to not be lawful activity if you distribute these foods in interstate commerce. The law "as applied" censors speech about a product distributed in interstate commerce.

Clevert failed to develop an argument why the government's interest in this case would not have been adequately served under DSHEA as a nutritional supplement. The FDA could have said that I was making health claims that were not authorized under DSHEA; However, I was not charged under that part of the FDC Act.

The Oral Argument Hearing for July 21 2015

It is the right of every defendant under the U.S. Constitution to confront his accusers. Judge Clevert gave me this right for the first time since this cased started when he set the date of July 21, 2015 for Oral arguments. Should the 7th Circuit consider the government's failure to admit or deny any of the 24 questions I submitted in advance to USA Gordon Giampietro to be entered into the record as admitted? By the government's silence, should the 7th circuit consider the following questions and statement from the Congressional Record as admitted?

1. By their refusal to answer this first question, does the government admit that when the U.S. Constitution was ratified on June 21, 1788, the American people had complete unencumbered freedom of choice in medicine and no restrictions on speech about the intended use of foods, edible herbs and spices to prevent or treat disease that were shipped in interstate commerce?

5 and 6. By their silence, the government apparently agree with the defendant that the Congressional Record of 1906 does not support the theory that Congress intended to include a broad brush definition of "drug" to include food, water, edible herbs and spices?

7. By their silence, does the government admit that they over-reached their authority in defining "drug" to include foods intended to promote and prevent disease?

8. By their silence, does the FDA/DOJ acknowledge that the way the FDA applies the law to drugs it approves as "new drugs" they use more than an intended use to prevent or treat a disease but also require a unique synthetic composition protected by a patent number?

9. By their silence, the government admit that in discussing the Dietary Supplement Health and Education Act (DSHEA) of 1994, that the FDA cannot cite any statement in the Congressional Record or in the Findings published in DSHEA that they were given the arbitrary authority to classify foods and dietary supplements as drugs based on their intended use to prevent disease instead of the "dietary supplement" classification.?

13. By their silence, does the government admit that it had a remedy at law under DSHEA for speech it was opposed to for the food-based supplement - Perfect Colon Formula?

20 and 21. By their silence, does the government admit they agree with the following statement from Rep Bill Richardson of New Mexico (House sponsor of DSHEA) who stated on the House floor in the Congressional Record on April 7, 1993?:

"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."

24. By their silence, does the government admit that it does to challenge or disagree with the following statements from the Congressional Record on 1993/94? (See the full list of questions and exhibits in Doc 109)

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 as follows:

"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."

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."

Applying the 4 parts of Central Hudson (447 U.S. 562) to U.S. V. LeBeau

First the case of unintentionally making a disease claim for Perfect Colon Formula

1. First, the government makes the mistake of classifying Perfect Colon Formula as a "drug" based on speech about Perfect Colon Formula (PCF) PCF. However, by its composition PCF is a food marketed as a fiber-probiotic based nutritional supplement. PCF contains no controlled substances like narcotics or opiates; it is not contaminated with synthetic drugs like

Allegro or Flonase and it contains no preservatives. It is a pure natural food product. Under the First Amendment, speech, including commercial speech, about Perfect Colon Formula should be protected. The government has no substantial interest in suppressing speech about scientific research on the health benefits of ingredients in this product. The statement "reduces food allergies," even though not-intended as disease claim, is a true statement based on scientific studies referred to in Doc 28 and Doc 75. Either statement "reduces food allergies" or "reduces food sensitivities" is not misleading in the context of how they were used.

2. For reasons stated above, the government's interest would not be substantial in suppressing scientific research about specific ingredients in Perfect Colon Formula including L Plantarum and L Rhamnosus help prevent and reduce food allergies as this information is also available publicly at the U.S. National Library of Medicine through PubMed.

3. The regulations under the food and dietary supplement sections of the FDCA would advance the government's interest to protect the public from untruthful or misleading information of a dietary supplement or food.

4. The government's interest asserted should not be more extensive than what is needed to serve that interest. If the government strongly felt it needed to suppress the three words "reduces food allergies" to protect the public, it could easily have done so by writing a "warning letter" to the defendant. It did not do this. In Doc 28, the Motion to Dismiss I asked this question: Where is my Warning Letter? The government further strayed from the Central Hudson guidelines by seeking criminal charges against the defendant instead of seeking a remedy under DSHEA.

CONCLUSION

1. Since "reduces food allergies" was not intentionally used as "disease claim" in a leaflet about the Colon Formula, without intent, there was no drug.

2. The language in Plea agreement that Perfect Colon Formula was a drug is contradicted by my testimony under oath on Jan 13, 2012, that there was no state of mind to market the product as treatment for a disease, but rather, to promote colon health.

3. "Reduces food allergies" like "reduces food sensitivities" are functional claims for a food-based supplement.

4. The FDA response to my Feb 2011 FOIA request is that its entire history of approving drugs from 1938 to Feb 2011 is it has never approved a food or other non-patentable article as an "approved new drug."

5. A clear reading of 21 USCS 355 (b) is that a patent number is required before final approval of a New Drug Application (NDA).

6. In his Feb 3rd opinion, Clevert failed to address my argument that the required filing of a NDA for prior FDA approval of speech about a food product fatally impairs the defendant's first amendment right of commercial speech.

7. Neither Magistrate Callahan nor Judge Clevert commented on what members of Congress said in passing the Pure Food Act of 1906, an act passed to protect the public from the evils of opiates and narcotics. A review of the Congressional Record of 1906 does not support Judge Clevert's opinion that Congress wanted food, water and herbs be classified as "drugs." based on their intended use to prevent or mitigate disease. Also, a reading of Article 1, Sec 8 of the U.S. Constitution finds no provision that delegated authority to Congress to mandate preapproval of speech on the use of food and water for medicinal purposes.

8. The government's action is suppressing speech about Perfect Colon Formula and the continued total suppression of scientific research from the National Library of Medicine is opposed, although in a different context, in Central Hudson 447 U.S. 562 Justice Powell stated:

"In applying the First Amendment to this area, we have rejected the 'highly paternalistic' view that government has complete power to suppress or regulate commercial speech."

In the same case, Justice Blackmun concurring at p. 557 stated:

"If the first amendment guarantee means anything, it means that, absent clear and present danger, government has no power to restrict expression because of the effect its message is likely to have on the public."

For all the forgoing reasons, defendant asks the 7th circuit to reverse Judge Charles Clevert's decision of Feb 3. 2016

Dated March 17 2016

Conrad E LeBeau

CIRCUIT RULE 30(d) STATEMENT

Pursuant to CIRCUIT RULE 30(d)(7thCir.),Defendant-Appellant Conrad LeBeau states that he has bound all of the materials that CIRCUIT RULE 30(a) and (b) required in the short appendix to this brief. Dated: March 17, 2016

Conrad E LeBeau Pro Se
Defendant-Appellant

CIRCUIT RULE 25(b) CERTIFICATION

The undersigned hereby certifies that he has mailed and filed 4 hard copies of this brief pursuant to CIRCUIT RULE 25(b). The 4 versions of this brief and all of the appendix items available in printed form were mailed priority USPS to - CLERK'S OFFICE, U.S. **Court of Appeals,** Room 2722, 219 S. Dearborn Street Chicago, IL 60604.

Phone: (312) 435-5850 Dated: March 17, 2016

Conrad E LeBeau
Defendant-Appellant

CERTIFICATE OF COMPLIANCE

Pursuant to FED. R. APP. P. 32(a)(7), Defendant-Appellant certifies that this brief complies with the type-volume limitations of FED.R.APP.P.32(a)(7)(B), because it contains no more than 14,000 words. Specifically, all portions of the brief other than the disclosure statement, table of contents, table of authorities and certificates of counsel contain no more than 11,123 words.

Dated: March 17, 2016

Conrad E LeBeau Pro Se
Defendant-Appellant

PROOF OF SERVICE

The undersigned Defendant-Appellant, Conrad E LeBeau, hereby certifies that on March 17, 2016, a copy of Defendant-Appellant's Brief and Required Short Appendix, was served on AUSA Jonathan Koenig,, 517 E. Wisconsin Avenue-Room 530, Milwaukee, Wisconsin 53202, counsel for the government in this action by mailing a copy by priority mail today.

Dated: March 17 2016

Conrad E LeBeau pro-se

Defendant-Appellant Conrad E LeBeau

INDEX TO SHORT APPENDIX