UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff

v. Case No 10-CR-253

CONRAD E. LEBEAU

Defendant - Appellant

LeBeau's reply to United States of America's response (Doc. 99) to his Brief for review of this case before United States District Judge Charles N. Clevert (includes Certificate of Service)

The Defendant/Appellant, Conrad LeBeau, representing himself, and with assistance from Federal Defender Joanna Perini, respectfully submits this brief in reply to the United States of America brief (Doc 99) that the government wrote in response to my brief (Doc. 98).

This case is about the future of our Republic and the Constitutional foundation upon which it was established in 1792; it is about how our Federal Government, that started out with specific limited powers, has evolved into a government of unlimited powers; why this Court and the Appellate Courts to follow need to roll-back, unabashedly, the over-reach of the regulatory power to censor or criminalize truthful speech used in interstate commerce; that the censorship of speech under these expanded powers not only does more harm than good, but is not authorized in Article 1, Section 8 of the U.S. Constitution, and thus violates the First, Ninth and 10th Amendments to the Bill of Rights.

In a few words, this case is about the death of personal freedom and liberty through regulatory strangulation and the need to restore our freedom of choice in medicine that existed in 1792, when the United States Constitution was adopted and ratified; it is the right to

distribute and use food as medicine, to provide information on its intended use, and the right to do so without government interference.

THE GOVERNMENT'S ARGUMENTS SUPPORTING ITS UNLIMITED POWERS

I. The government's argument in Doc 99 (pages 1, 2) is that Magistrate Callahan

> "*properly resolved LeBeau's many legal arguments and, accordingly, there is no reason to disturb the judgment*" and added: *"The United States respectfully requests that this Court summarily adopt the reasoning set forth in Magistrate Judge Callahan's decisions dated September 21, 2011, December 7, 2011, and May 29, 2012. See Doc. Nos. 41, 51, and 71.*"

The government then cites the 1991 case U.S. v. Vital Health and LeBeau (page 2) which state that the cases overlap "*as it relates to unapproved new drugs.*"*

> *[if you remove the label claims for hydrogen peroxide in the 1991 case, you can easily determine from the composition of hydrogen peroxide that it is not a food. The issue before this court is not whether Perfect Colon Formula is an unapproved new drug, but rather, whether it is "drug" in the first instance. This is based on reviewing the Congressional Records of 1906 and Congressional Findings approved by Congress in 1994 in passing DSHEA defining dietary supplements into a new classification by composition and not by intent. For these reasons, the government's attempt to transfer factual and legal arguments from the 1991 case to the present one should be rejected]

The government then states:

> *"Magistrate Judge Callahan's reasoning is both compelling and comprehensive. There is no good reason to spill more ink before this case reaches the court of appeals."*

On part II (page 3), the government states:

> *"The Second Circuit's decision in 'Caronia' does not undermine Magistrate Judge Callahan's First Amendment analysis."*

On page 5, line 3, the government states:

> *"LeBeau admitted in the plea agreement that he shipped in interstate commerce Perfect Colon Formula #1, and that it was an unapproved new drug. Doc 58, Plea agreement."*

The government's underlying reasoning, for justifying the presence and continuance of its unlimited powers to censor and regulate speech used in interstate commerce, is that it needs to protect the public from harmful speech that it calls "drugs," that is premised on unapproved speech it brands "unapproved new drugs." What the FDA calls a "drug" in the present case is speech about a food product that they allege [magically] transforms the product into a drug. When the FDA does not approve of the speech, they allege the speech itself transforms the food-based dietary supplement into an "unapproved new drug." It takes a tortuous twist of logic to follow this transformation process. Were it not for three words, "*reduces food allergies,*" that were printed on a handout flyer; (information that was derived from searches of expert opinion at the United States National Library of Medicine), to provide consumers with more information about the potential health benefits of the colon formula, this case would not be in Federal Court today. [This case has nothing to do with drugs or unapproved new drugs, but is really all about protecting the exclusive marketing rights of the holders of patented drugs on Wall St by eliminating competition from food-based medicine.]

THE GOVERNMENT'S TACTIC IN ITS RESPONSE TO MY BRIEF IS: WHEN YOU ARE LOSING AN ARGUMENT, IGNORE OR CHANGE THE SUBJECT

I. The government assertion, that Magistrate Callahan's opinions addressed all the issues in my brief in a manner that is *"compelling and comprehensive,"* is simply not true. After discussing the factual background of the case in pages 3 to 5, I began on page 5 with my first argument that the three-word statement on the handout flyer, *"reduces food allergies,"* was truthful, and not misleading, and that it was based on multiple scientific articles published at the United States National Library of Medicine. The several scientific articles I cited in my brief are admissible as evidence under "Learned Treatises" and allowed under Fed. R. Evid. 803 (18).

As a first point, the government presented no argument in its response brief to counter the scientific research cited by the defendant in pages 5 thru 9. As a second point, none of the government's previous pleadings in Docs 37, 45, 68 and 76 addressed the issue of the scientific research cited by the defendant to support his claim. Even more amazing, the government (FDA) did not offer as an exhibit a written opinion from one of its own scientists. As a third point, none of Magistrate Callahan's decisions cited by the government in Docs 41, 51 and 71 addressed the issue of the scientific research that supported the truthfulness of the defendant's statement about his product – "Perfect Colon Formula." In its response, the government completely ignored the defendant's factual scientific arguments that supported the truthfulness of his statement.

By default, the government did not challenge the defendant's scientific citations that the three words in the article about Perfect Colon Formula, that it "reduces food allergies," was truthful, not misleading, and was based on expert scientific opinion. While the defendant has the Constitutional right to remain silent, when the government remains silent about the truthfulness of the defendant's foundational argument, it leaves the government with no argument at all on how the public is harmed by being exposed to truthful scientific research and opinion. Because the government has not provided a counter argument, I request that the Court accept the defendant's statement "reduces food allergies" as truthful and based on expert opinion derived from another agency of the Federal Government – the United States National Library of Medicine.

II. The Doctrine of Overbreadth.

The Pure Food Act of 1906: In none of the government's pleadings, nor in any of Magistrate Callahan's decisions, was there any reference to statements in the 1906 Congressional Record that the intent of Congress in first defining the term "drug," was to go

beyond "patented drugs" and "nostrums," and also include food, edible herbs and food-based medicines. The government has not denied that opiates including cocaine and heroin placed secretly in patented drugs and nostrums, and fraudulent claims were the primary targets of the expanded definition of the term "drug."

The government has never opposed the defendant's argument that Perfect Colon Formula, by its composition, is a food product that is properly characterized as a nutritional or food-based dietary supplement. The government has presented no argument to challenge the defendant's assertions that there is no statement in the Congressional Record of 1906 that *"any substance intended to be used for the cure, mitigation, or prevention of disease"* was intended to include food and edible herbs. By default, Perfect Colon Formula, being a food-based nutritional supplement was never intended by Congress to be defined as a "drug," when its intended use is to prevent or mitigate disease.

The government rests its case, that food and food-based dietary supplements like Perfect Colon Formula are drugs, is based on old court decisions they cited in which mineral water, honey and peppermint tea, were declared to be drugs based on their intended use to prevent or mitigate disease. Based on these 3 court decisions, the government claims that all foods that are (intended) to prevent or mitigate disease are drugs. The problem with such a sweeping expansion of the definition of the term "drug" is that it also expands with it federal power to censor and regulate speech in an area that was never explicitly authorized by the Pure Food and Drug Act of 1906 or the U.S. Constitution. This is because only Congress can pass laws by powers delegated to it under Article 1 Section 8 of the U.S. Constitution.

The Executive branch of government, through the Department of Justice, had no Constitutional authority to bypass Congress and go to the Federal Courts to expand the definition of the term "drug" to include traditional low-cost foods and herbs, thus making the

distribution of low-cost food-based medicines illegal in order to secure a market monopoly for the holders of high-priced patented drugs on Wall St. The purpose of branding food, as illegal medicine was payback for the donations politicians received from the pharmaceutical industry and their executives. The suppression of food-based medicine eliminated low-cost competition for extremely profitable high priced patented drugs. The bottom line protected here was not the health of the American consumer, but profits for the drug companies' major stockholders.

Both the Executive branch of government and the Federal Courts that granted government attorneys their wish to expand the "drug" definition, violated the intent of the Congress of 1906, as well as Article 1, Section 8 of the U.S. Constitution, by assuming powers not delegated to either the Executive Branch or the Judicial branch of government. The Doctrine of Overbreadth was breached for the two reasons stated here, and because powers not granted to Congress under Art 1, Sec 8 are reserved to the States under the 10th Amendment, the 10th Amendment was being violated as well. Not as an after thought, but "freedom of choice in medicine" as a basic human right under the 9th amendment, was also violated.

The government has presented no argument to defend the Executive branch's over-reach of regulatory powers, that were approved in earlier Court decisions, to censor and criminalize truthful speech used in interstate commerce. The government's position is that the *"any substance intended…."* definition of a drug for 1906 was to be taken literally, without referring back to the intent of Congress, as published in the Congressional Record of 1906. The government did not present any argument to counter the statement of United States Senator McCumber referred to as Mr. McCumber on page 12 of my brief, when he stated on Jan 23, 1906:

> *"that proper diet, varied to meet the conditions of each individual, is not only the greatest panacea* [medicine] *for* [common ills]*, but also the greatest preventive against evils* [opiates in patented drugs and nostrums] *with which humanity seems to be afflicted*."

I added brackets [ ] within the statement made by United States Senator McCumber to clarify the meaning of the words he spoke. The inclusion of brackets in Mr. McCumber's statement to clarify its meaning was not opposed by the government in its response brief. The government has made no argument to counter my position which is based on the Congressional Record, that food used as medicine, was never intended to be included under the definition of "drug," or intended to be regulated as a drug. Magistrate Callahan's decisions provide no facts from the Congressional Record to support the opinion that foods and food-based dietary supplements are drugs, when they are used, or intended to be used to prevent or mitigate disease. Therefore, I request the Court to find that nothing in the Congressional Record of 1906 supports the current government position that food and food-based dietary supplements are "drugs" based on their intent to prevent, treat or mitigate disease. On this basis alone, two of four elements of the alleged crime in this case are not met. The two elements are the definitions of "drug" and the definition of "unapproved new drug."

The Court is asked to find that speech about Perfect Colon Formula, alone, did not make Perfect Colon Formula (a food based dietary supplement) a "drug." The second point is that, when a substance is not a "drug" by composition, it is not a substance or article that can be lawfully considered as either an "approved drug" or an "unapproved new drug." A food or food-based dietary supplement cannot be considered to be an unapproved new drug by intent alone, unless it is first a "drug" by its' material composition. Defendant asks this Court to find that the government has failed to precisely define what there is about Perfect Colon Formula that makes it a drug.

The government has presented no argument to counter defendant's argument that what is defined as a drug and unapproved new drug is speech about the product Perfect Colon Formula. Since that government has been silent on defendant's position that Perfect Colon Formula by its composition is not a drug, and since the label with its offensive words (based on scientific research) is not intended for ingestion to "reduce food allergies" the label is not a drug either. Therefore, the government has utterly failed to identify the alleged drug in this case. The court is asked to find that foods and food-based dietary supplements have medicinal value to prevent and mitigate disease and this fact alone does make them drugs. Furthermore, it is lawful for doctors and health care practitioners to recommend the use of special foods, herbs, vitamins, minerals, probiotics, fiber supplements, phyto-nutrients, and proper diet to prevent, mitigate and treat disease. It is also lawful for citizens to act on their own to choose foods and dietary supplements to prevent, treat or mitigate their illnesses.

The Caronia case and Magistrate Callahan's Decision (Doc 41)

The case of United States v. Caronia 2012 WL 5992141 (2nd Circuit. 2012) was reversed based on the conviction of a pharmaceutical salesman, Alfred Caronia, who made off-label claims [not FDA approved] for the drug Xyrem. The conviction of Alfred Caronia was reversed based on the Appellate Court's decision that the First Amendment rights of Alfred Caronia to provide truthful information on the off-label uses for Xyrem were violated by the criminal misdemeanor conviction.

On page 3 of the government's response, they write:

> "Although Magistrate Judge Callahan properly rejected LeBeau's First Amendment argument (Doc. 41 pages 7 -9), Caronia was not decided until well after his decision. Nothing in *Caronia* calls into doubt Magistrate Callahan's First Amendment analysis."
> "The Second Circuit decision in *Caronia* must be limited to its unusual facts and does not (nor could it) undermine the First Amendment cases cited by Magistrate Judge Callahan: Central Hudson….v Public Service commission, 447

U.S. 557 (1980); and Whitaker v. Thompson 353 F. 3rd 947 (D.D.C. 2004); and Wisconsin v. Mitchell, 508 U.S. 476"

In rejecting my first Motion to Dismiss (Doc 28), Magistrate Callahan states (in Doc 41) the following on page 5:

> "First of all, LeBeau is not charged with a violation of the Food and Drug Act of 1906. He is instead, charged with violating the Federal Food, Drug and cosmetic Act of 1938, which is codified as 21 U.S.C. Sec 301, et seq."

My comment on Magistrate Callahan's statement is this: He is right that the alleged violation against me was the shipping of "unapproved new drugs" in interstate commerce. However, he is wrong in asserting that the intent of the Congress of 1906 need not be considered in determining whether LeBeau two products in counts 2 (the probiotic Saccharmyces Boulardii) and count 3 (Perfect Colon Formula) were "substances" intended to be defined as drugs. The intent of the Congress of 1906 is relevant because neither Magistrate Callahan nor the government challenged the premise I cited in Motion to Dismiss (Doc 28, p. 40) that "the intent of the lawmaker is the law." As a Doctor of Jurisprudence (J.D.), Magistrate Callahan and the U.S. attorneys should know that. Would any of them not read *"The Federalist Papers"* and other writings by our Founding Fathers to better understand the meaning of the words in the United States Constitution?

To define a substance as a "new drug" under 21 U.S.C. Sec 321 (p)(1), the government must first prove that Perfect Colon Formula was a drug within the meaning of the 1906 Congressional Food and Drug Act. To do this properly, the Court must consider the type of substances meant to be defined as drugs under this Act. A reading of the Congressional Record of 1906 makes it very clear that air, water, and food were not within the parameters of substances defined as drugs by their intended use to prevent or mitigate disease. Senator

McCumber (see the quote I referenced earlier) referred to proper diet as a panacea [medicine] for common ills that also prevented the need to use drugs that contained the evil [opiates].

On page 6 of his decision (Doc. 41), Callahan states:

> "To the extent that LeBeau is arguing that Congress did not intend to include God-made things as "drugs" under the Federal Food, Drug and Cosmetic Act, there is not need for the court to rummage through legislative history and the isolated remarks of legislators from the early 20th century in order to give effect to that Act. The language of the Act is clear and unambiguous and, as such is to be given its clear meaning."

Callahan misses the mark here, because the Food and Drug Act of 1906 was not repealed in 1938, it was amended. Changes included substituting the word "articles" for "substance" in the 1906 Act and adding the word "diagnose" to the definition of drug as well as a definition for a "new drug" based on general recognition among experts that it was "safe." On October 10th, 1962, President John F. Kennedy signed an amendment to the FDC Act introduced by Senator Estes Kefauver that added "'effective" to the definition of a new drug that had previously included only safety considerations.

While the Federal Government has, in the interest of public safety, the inherent right, as do all governments, to protect its citizens from products that are unsafe, including foods and medicines, the U.S. Constitution was not set up for Congress [and federal agencies (FDA) under its wing] to assume more than the basic powers delegated in Art 1, Sec 8. Congress was not delegated the power of medical dictator, and the FDA, as a subordinate agency of Congress, has no Constitutional authority to assume the role of a nanny or paternalistic agency that can impose its opinions of what is or is not effective medicine on everyone else. In any country where the term "liberty" and "freedom" has any meaning at all, it is the right of the people to disagree among themselves on thousands of different topics and they do disagree.

Above all, it is the right of the people to disagree with their own government and that includes the FDA.

Our forefathers set limits on the powers of the federal government for one basic reason – original sin - the greed and corrupt tendencies of human beings – the insatiable appetite for money, power and control over other human beings. The rights of dictators and the majority never need protection – in a free society, it is the rights of minorities and dissidents that need protection. The Courts, as the third branch of government, have the power, but not a record, of vigorously protecting those rights.

The amendment of Senator Estes Kefauver in 1962 created a medical dictatorship within the FDA that vastly expanded its regulatory powers to impose FDA opinions of what is or is not effective medicines (drugs) on the entire nation. What Magistrate Callahan and the FDA do not "get" is that *freedom of choice in medicine* is the natural and inherent right of all humans. Freedom of choice in medicine should never be doled out as a privilege of government. Embedded within the preamble of the Declaration of Independence – the right of all people to life, liberty and the pursuit of happiness includes *freedom of choice in medicine* - the inherent right of all people to use any food, any herb, any substance that has been used as medicine in the entire history of the human race and wherever it is recorded - the Bible, the Talmud, the Koran, Materia Medica, Stone tablets, or books like "Back to Eden" written in the 1880's by Jetro Kloss, hundreds of other books written on food, proper diet and health, and by ongoing research and discoveries, or by word of mouth passed down from generation to generation.

The only substantial government interest is that the products are safe to use as labeled. Efficacy is another issue way beyond the powers delegated to Congress under Article 1, Sec 8 of the U.S. Constitution. Tyrants, dictators and kings may assume the power to impose

medicine on their subjects and limit their choices in medicine, but in a free society, such powers have proven to have disastrous consequences.

The consequences of the Kefauver amendment are millions of deaths from FDA approved drugs in the past half century.

Specifically, public records in medical journals including the AMA, indicate there are over 100,000 deaths annually from the side effects of all FDA drugs, including 20,000 deaths from the misuse of narcotics and opiates, plus another 17,000 suicides from FDA approved opiates as reported by the CDC (and quoted by Dr Sanjay Gupta on CNN in an interview with former President Bill Clinton that aired in Jan, 2013). The total figures include FDA approved drugs (Vioxx is one example) that caused an estimated 30,000 deaths from heart attacks, until it was removed from the market. An entire industry of lawyers (1-800 bad-drug and many others) that specialize in suing drug companies has emerged from the use and marketing of FDA approved drugs that were suppose to be safe at the time of FDA approval but were later determined to be not safe resulting in numerous fatalities. This is beyond incompetence – it is corrupt activity for pure profit and it should be called what it is - criminal activity.

Defendant's reply to the government's arguments in U.S. v. Caronia

Back to Magistrate Callahan's Decision of Dept 21, 2011. On page 7, Callahan cites Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993) and states:

> "the Supreme Court held that the First Amendment does not prohibit the evidentiary use of speech to prove motive or intent. Thus, to the extent that LeBeau is arguing that what he may have said, or claimed, about what his products did cannot be used against him at trial to show his motive or intent in marketing them, he is wrong."

Callahan's argument misses the mark again by changing the subject. *Wisconsin v Mitchell* has nothing to do with the issue of whether or not Perfect Colon Formula is a drug. The

Wisconsin case is about whether speech can be used to show intent to do an illegal act {ship an unapproved new drug] in interstate commerce. This is a non-existent issue, because Perfect Colon Formula, as a food-based dietary supplement, [not a drug} was perfectly legal for LeBeau to ship in interstate commerce. The *Wisconsin* case does not resolve the dispute about whether LeBeau's speech [reduces food allergies] as a label linked to Perfect Colon Formula, was lawful activity. The *Wisconsin* case cited by Callahan is completely irrelevant to the two issues before this court – did the composition of Perfect Colon Formula make it a drug?; and was LeBeau's speech about Perfect Colon Formula truthful and not misleading, and therefore, protected under the First Amendment?

On page 8, Callahan cited Whitaker v. Thompson, 353 F. 3rd 947 (D.C. Cir. 2004) as the right of the government to use speech as proof of intent to commit an illegal act. That argument is the same as was made in *Wisconsin v. Mitchell* and is irrelevant to the issue of whether truthful speech alone can turn a food or dietary supplement into a harmful drug and thus an illegal substance to market in interstate commerce.

Julian Whitaker, a licensed medical doctor, sought to market Saw Palmetto, an herb as a dietary supplement for supporting prostate health, under the Dietary Supplement, Health and Education Act of 1994 (DSHEA). In response to massive public pressure to stop the FDA from classifying all herbal, nutritional and dietary supplements as "drugs," Congress passed DSHEA in 1994, and it was signed into law by then President William (Bill) Jefferson Clinton. Whitaker's labeling petition for Saw Palmetto, under DSHEA, was made to the FDA, and was denied. At that point, he sued the FDA for violating his First Amendment rights.

Now, here are the differences between the Whitaker case and LeBeau's case before this court. First, there is no saw palmetto or any herbs in Perfect Colon Formula. In the Motion to Dismiss, LeBeau did not seek dismissal of Counts 1 and 4, as both of these products were

strictly herbal supplements. Whether or not saw palmetto was ever used as a food, and thus not a substance intended to be classified as a drug under the 1906 FDC Act, is unknown and not an issue before this court. Second, Whitaker's case was civil and the present case with me is criminal. Third, in the Whitaker case, the Court did not rule on the constitutionality of extreme restrictions on speech found in Sections 5 and 6 of DSHEA, because the FDA alleged that Whitaker's proposed health claims were disease claims, and therefore drug claims. FDA ignored the fact that Congress stated in its Findings at the beginning of DSHEA that nutritional, herbal and dietary supplements prevented disease. Thus, in 1994, Congress said what Senator McCumber said earlier in 1906 about proper diet as a panacea [medicine] for common ills. In fact, the Congressional findings in DSHEA in 1994 were disease claims, and therefore also drug claims, made for nutritional and dietary supplements.

"Articles" that prevent disease are considered drug claims under the current definition of "drug." Section 5 and 6 of DSHEA contained speech restrictions that were written and promoted by lobbyists for the pharmaceutical companies who did not want dietary supplements competing with patented drugs in the marketplace. The issue in this case is not drugs and new drugs but is about marketing rights. The drug industry did not want distributors of foods and dietary supplements making medicinal claims for their products that competed with the same medicinal claims the drug industry made for its highly profitable patented drugs.

By siding with drug industry, the FDA over ruled Congressional intent and again violated the Doctrine of Overbreadth, in carrying out its legal responsibilities under DSHEA. They violated this doctrine, by branding dietary supplements that prevent disease as drugs. In so doing, the FDA exceeded Art 1, Sec 8 powers and violated the 1st, 9th and 10 amendments.

Congressional intent in passing DSHEA was to create a "safe harbor" (See Pearson v. Shalala 130 F. Supp 2nd 105 D.D.C. 2001)* and protect health foods and dietary supplements

from being yanked off the shelves of health food stores and tossed into a garbage can as "unapproved new drugs." *See Doc 30 for a reprint of the Pearson v. Shalala case.

The opinion in the Whitaker case makes no mention of the Congressional Findings in Section 2 of DSHEA, in which Congress makes and repeats its findings that nutritional and dietary supplements prevent disease. The FDA, by suppressing Congressional Findings No 2, 3, 7 and 8 (see page 34-35 of Doc 28), completely blocks the use of scientific research from the National Library of Medicine from being shared with the public by distributers of health foods and dietary supplements, thereby defying Congressional intent in passing DSHEA.

On page 8, Callahan quotes from the Whitaker case: "*….the key step is the FFDCA principle that classification of a substance as a "drug" turns on the nature of the claims advanced on its behalf."*

The Whitaker case did not look at the Congressional Record of 1906 or consider that dual classification of a substance may be unconstitutional, nor did the Whitaker Court discuss the findings of Congress in DSHEA that nutritional and dietary supplements do prevent disease (drug claims). Congress was OK with "drug claims" that dietary supplements prevent disease. Why is FDA not OK with it? The most obvious answer is that managers in key positions within the FDA have conflicts of interest and divided loyalties between serving the best interests of all the American people and the marketing privileges of their former employers (banks and drug companies) on Wall St.

Page 8 of Callahan's decision quotes from the *Whitaker* case on Central Hudson v. Public Service Commission 447 U.S. 557 (1980) that *"commercial speech enjoys First Amendment protection only if it concerns lawful activity and is not misleading."*

The sale and use of saw palmetto and other herbs was lawful activity when this nation was founded in 1792 and has been lawful activity ever since. Last summer, I purchased a bottle

of saw palmetto from Walgreens for my personal use, and the label said – "supports prostate health." What was there about Whitaker's proposed language that was so different than this? [Idiotic decisions to suppress truthful speech occur when FDA minders are given unlimited authority to micromanage speech].

The use of saw palmetto is classified as an herbal dietary supplement under DSHEA. What the *Whitaker* court failed to do is that once recognizing that the substance "saw palmetto" was lawful to sell, purchase and use was to determine if the information (labeling) about this intended use was truthful and not misleading. This is the genesis of the issue that was not addressed in *Whitaker*. The *Whitaker* case failed to discuss the scientific research that supported the proposed claim by Dr. Whitaker, M.D. that saw palmetto supports prostate health. Dr. Whitaker was, himself, an expert witness about his own product. The *Whitaker* court allowed the FDA scientist, who evaluated the proposed claim for saw palmetto, to override other medical experts, published scientific research, and Dr. Whitaker's own experiences. By allowing the FDA to classify the proposed truthful speech as a "drug," instead of a dietary supplement, the Whitaker decision arbitrarily removed Whitaker's saw palmetto herbal supplement from the "safe harbor" protection of DSHEA (See Pearson V. Shalala 130 F. Supp 2nd 105 D.D.C. 2001).

[In consideration of all the preceding facts, logic, and arguments of law presented, defendant asks United States District Judge Charles Clevert not to leave Magistrate Callahan's decisions in this case undisturbed, as suggested by Attorney Gordon Giampietro, but to independently evaluate this case, the merits of the various arguments of fact, logic and law, and pen your own decision.]

Perfect Colon Formula as a food-based Dietary Supplement

I critiqued DSHEA in my Motion to Dismiss in Doc. 28 (pages 33 through 40), and the government said in response that DSHEA had nothing to do with this case. I disagree. Perfect Colon Formula, by its composition, is a food-based dietary supplement. Under DSHEA, Congress defined dietary supplements by their composition, not by their intended use. Foods, nutritional and dietary supplements have always had medicinal value in the prevention of disease, and Congress acknowledged this in its findings on dietary supplements. See the actual reprint of the entire DSHEA bill in the Exhibits I filed in support on my Motion to Dismiss. This exhibit file (Doc 30) is so large it could not be filed electronically so it was manually filed and bound together with a spiral plastic.

Argument: if Congress wanted the FDA to classify dietary supplements as drugs, DSHEA would have never passed Congress in 1994 with bipartisan support, including co-sponsors Rep. Bill Richardson and U.S. Senators Orrin Hatch and Tom Harkin. Of the DSHEA, Senator Orrin Hatch and Senator Tom Harkins, primary sponsors of DSHEA, stated in the Congressional Record that dietary supplements are not drugs (Source: www.gpo.gov/fdsys/pkg/CREC-1994-08-13/html) of August 13, 1994 [I want especially to draw the attention of the court to Section 2 Findings and Purpose -No 15 (2) a, b]:

> [Congressional Record Volume 140, Number 113 (Saturday, August 13, 1994)] [House] [Page H] From the Congressional Record Online through the Government Printing Office [www.gpo.gov]
>
> [Congressional Record: August 13, 1994] From the Congressional Record Online via GPO Access [wais.access.gpo.gov]
>
> AMENDMENTS SUBMITTED
>
> DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994
>
> HATCH (AND HARKIN) AMENDMENT NO. 2562

Mr. HATCH (for himself and Mr. Harkin) proposed an amendment to the bill (S. 784) to amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes; as follows:

Strike out all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ``Dietary Supplement Health and Education Act of 1994".

SEC. 2. FINDINGS AND PURPOSE.

(a) Findings.--Congress finds that--

(1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;

(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;

(3)(A) there is a definitive link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and

(B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;

(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;

(6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and

(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;

(7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;

(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;

(9)(A) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition; and

(B) nearly all consumers indicate that dietary supplements should not be regulated as drugs;

(10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;

(11) the United States will spend over $1,000,000,000,000 on health care in

1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;

(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

(B) the industry consistently projects a positive trade balance; and

(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000;

(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose regulatory barriers limiting or slowing the flow of safe products and needed information to consumers;

(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.

(b) Purpose.--It is the purpose of this Act to--

(1) improve the health status of the people of the United States and help constrain runaway health care spending by ensuring that the Federal Government erects no regulatory barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements;

(2) clarify that--

(A) dietary supplements are not drugs or food additives;

(B) dietary supplements should not be regulated as drugs;

(C) regulations relating to food additives are not applicable to dietary supplements and their ingredients used for food additive purposes, including stabilizers, processing agents, or preservatives; and

(D) the burden of proof is on the Food and Drug Administration to prove that a product is unsafe before it can be removed from the marketplace;

(3) establish a new definition of a dietary supplement that differentiates dietary supplements from conventional foods, while recognizing the broad range of food ingredients used to supplement the diet;

(4) strengthen the current enforcement authority of the Food and Drug Administration by providing to the Administration additional mechanisms to take enforcement action against unsafe or fraudulent products;

(5) establish a series of labeling requirements that will provide consumers with greater information and assurance about the quality and content of dietary supplements, while at the same time assuring the consumers the freedom to use the supplements of their choice;

(6) provide new administrative and judicial review procedures to affected parties if the Food and Drug Administration takes certain actions to enforce dietary supplement requirements; and

(7) establish a Commission on Dietary Supplement Labels within the

executive branch to develop recommendations on a procedure to evaluate health claims for dietary supplements and provide recommendations to the President and the Congress.

Congressional intent - Section 2 Findings and Purpose -No 15 (2) a, b

(2) clarify that--
(A) dietary supplements are not drugs or food additives;
(B) dietary supplements should not be regulated as drugs;
While I grant that the pharmaceutical lobby successfully got the House Committee drafting DSHEA to delete from the final bill presented for voting Paragraph (2)(A) and (B) in paragraph 15, there was no actual vote to delete the language of paragraphs 15 (2) A and B from the bill. Furthermore, the final version of DSHEA did not authorize the FDA to arbitrarily classify dietary supplements as drugs, when health claims are provided that are based on scientific research and are truthful and not misleading, and very importantly, the Findings that Congress passed in the final version of DSHEA recognized that foods and dietary supplements prevent disease, and the public should have access to scientific research and data.

In the year 2000, six years after DSHEA was passed, Congress directed the National Library of Medicine (NLM) through the National Institutes of Health (NIH), to release directly to the public, via their own personal computers, millions of articles of scientific research paid for in full or in part by taxpayer money. Hundreds of thousands of these scientific articles provide expert opinion on the use of foods, herbs, probiotics, enzymes, vitamins, minerals, special nutrients and dietary supplements to prevent, mitigate, treat and even cure disease. Also, scientific research on the off-label use of drugs is also directly available to the public online, and this is the way it should be in a free society.

In my Motion to Dismiss (Doc 28), I argued why the release directly to the public of all this scientific research makes mute FDA arguments that it should censor and block scientific research from the public's view, in order to protect the public from misleading information. By

taking this position, that the sharing of this information creates unapproved drugs in the minds of the public, as regards foods and dietary supplements, is pure legal fiction and contrary to the intent of Congress. That argument would have had more traction before the year 2000, as the FDA could claim that the public should not read this information first, only their doctors, who could then filter what they wanted their patients to see. The NIH policy statement published in the Federal Register (See Doc 30) rejects that argument with this one line statement about all abstracts and full text articles retrieved from the NLM – see your doctor for more information. (See Doc 28 page 49)

Doc 41, page 8, Callahan's comment on *Central Hudson v. Public Service Commission 447 U.S. 557*. Magistrate Callahan's comments briefly quote from the Central Hudson case that commercial speech under the First Amendment is protected only if it concerns lawful activity and is not misleading.

On page 60 (Doc 28) I quote Judge Huvelle in the case of *Alliance for Natural Health v. Sebelius, - - - F. Supp. 2d - - -, 2010 WL 2110071 (D.D.C. May 27, 2010)*. Huvelle quotes the 4 conditions in Central Hudson where government may regulate commercial speech in footnotes on page 6 of her decision (1):

> (1) The *Central Hudson* analysis, as clarified by the Supreme Court in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), consists of four parts: 1) "whether 'the speech concerns lawful activity and is not misleading;'" 2) if the speech is protected, "whether the asserted government interest [in regulation] is substantial;" 3) "whether the regulation *directly* advances the governmental interest asserted;" and 4) "whether [the regulation] is not more extensive than is necessary to serve that interest." *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 8-9 (D.D.C. 2002) (quoting *Western States*, 535 U.S. at 367; *Pearson I*, 164 F.3d at 657).

The government, in its response to my Motion to Dismiss (Doc 28), failed to present arguments on 4 prongs of Central Hudson that justified its action against me in bringing this

criminal misdemeanor case. In Magistrate Callahan's decision, he mentions on page 8 the case of *Central Hudson*, but presents no arguments or opinions on why the speech about Perfect Colon Formula reached the threshold of criminal activity, and then goes on to discuss the *Whitaker* case. A close look at the 4 prongs of Central Hudson explains why the FDA over reach of its regulatory powers, tramples the First Amendment rights of the defendant. First, it is lawful activity to distribute a food or food-based dietary supplement with the ingredients found in Perfect Colon Formula. It is lawful to ship this product in interstate commerce. It is lawful, not only for health care professional, but the public, to use fiber and probiotic supplements, either individually or in combination. The activity itself is lawful. The alleged unlawful activity was speech about the product contained in the article I wrote and distributed as a handout flyer to promote sales of Perfect Colon Formula.

Since the alleged offensive language in the article "reduces food allergies" is itself provided by the government for multiple probiotics ingredients in Perfect Colon Formula, and this expert opinion is available to the public through online searches at PubMed through the NLM, the government has no substantial interest is censoring this information. This is because the government itself is the source of the scientific information that the defendant used in the article. On prong No 2 of Central Hudson, the speech about ingredients in Perfect Colon Formula and their health benefits is not protected or classified as "secret." Prong 3 is not relevant because the government, through the NLM, was the source of the speech. Prong 4 is relevant as the government could have written a letter to the defendant, but instead chose to launch a secret criminal investigation against the defendant.

On page 5 of the government's response to my "Appellate brief" (Doc 99), the government states - *"Caronia's speech was truthful and concerned lawful off-label use on an approved drug."* Then the government goes on to state that in the plea agreement Doc. No 58,

"that he shipped in interstate commerce Perfect Colon Formula #1 and that it is an unapproved new drug."

First of all, the government threatened me with $100,000 in fines and one year in jail for each of the counts I was convicted of if I did not accept the plea offer of paying a $100 fine and serve one years probation. I reprinted the email I received with these threats and attached a copy to my letter to Magistrate Callahan on April 17, 2012 (Doc 64). A copy of my letter requesting to withdraw the plea agreement with the written statement of "guilty" is in the exhibits attached to the letter.

The second problem with the plea of "guilty" in the criminal misdemeanor plea agreement is that the word "guilty," as used, did not mean "guilty," as a state of mind. As I recall, the amended plea agreement for me that I signed in the Office of the local U.S. Attorney Gordon Giampietro, on either Jan 11 or 12, 2012, language was added to the plea agreement to that effect. The added language was proposed by Federal Defender Joanna Perini and agreed to by Atty Giampietro. It was similar to the language that Joanna Perini stated on the meaning of the word "guilty" at the Jan 13, 2012 hearing. The qualifying language agreed upon at the signing of the plea agreement was missing in the copy I downloaded from pacer.gov. However, Joanna Perini paraphrased the qualifying phrase in the transcript on Jan 13, 2012, as quoted below in Doc 96. The following is an exchange quoted from the transcript of Jan 13, 2012, starting on page 9:

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

THE DEFENDANT: I'm not sure how to answer this. I reserve the right to appeal a number of legal issues that are in the Agreement.

THE COURT: I understand that.

THE DEFENDANT: Okay.

THE COURT: But aside from that, are you pleading guilty because in your mind you believe you're guilty? Setting aside those reservations on the appeal issues? Miss Perini, do you want to weigh in on this?

THE DEFENDANT: [I turned to Ms Perini and asked:] What's the answer I'm supposed to give to this?

THE COURT: Well, because I want to make sure that you are pleading guilty voluntarily, and knowingly, and intelligently, and with your eyes wide open.
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 that law with the Seventh Circuit?

THE DEFENDANT: That would be correct, yes.

MS. PERINI: Is that sufficient, Judge?

THE COURT: Well, in your mind is it, Mr. Giampietro? In your opinion?

MR. GIAMPIETRO: I believe it is, Your Honor.

THE COURT: In your opinion is it, Miss Perini?

MS. PERINI: I believe so.

THE COURT: I understand that you disagree with some of the decisions that I've made in your case. That would be fair, right?

THE DEFENDANT: Absolutely.

THE COURT: Reasonable people can disagree, right?

THE DEFENDANT: That's true. That's true.

THE COURT: And I understand that at least with respect to the personal Plea Agreement, the Conditional Plea Agreement that you're entering into on behalf of yourself --

THE DEFENDANT: -- right --

THE COURT: -- that you're reserving the right to raise, in the Court of Appeals, certain legal issues that I found against you.

THE DEFENDANT: Right.

THE COURT: But as -- but with respect to the information on the law as I determined it to be, you're pleading guilty because in your mind you're guilty?

THE DEFENDANT: Well, under the law Mr. Giampietro said that you don't have to have a state of mind of being guilty, or even knowingly violate the law. That's the way this law is. So under the law I'm guilty.

THE COURT: I'm not trying to play games.

THE DEFENDANT: No. I understand. I just --

THE COURT: I just want to make sure. And I understand the issue you've raised.
THE DEFENDANT: Okay.

THE COURT: If I'm wrong, the Seventh Circuit may very well tell me. Okay. Now, Mr. Giampietro could you please set forth the penalties. My understanding is Mr. LeBeau is pleading guilty to Count 3 of the Information, both on behalf of the Corporation, and personally. Would that be correct?

MR. GIAMPIETRO: That's correct, Your Honor.

Defendant's comments on this exchange of Jan 13, 2012

The "Conditional Plea Agreement" I signed that reserves my right of appeal on numerous legal issues is at tension with itself on the issue of the meaning of the word "guilty." Ordinarily, a plea of guilty is appropriate when the defendant admits wrongdoing as a state of mind. However, as noted in the footnotes of the plea agreement (page 5 or 7), written by U.S. Attorney Giampietro that -

"*there is no state of mind requirement for misdemeanor offenses under the Federal Food, Drug, and Cosmetic Act (21. U.S.C. Sec 301-3991. The FDCA was designed as a strict liability statute to protect society at large."*

Just as the meaning of the word "drug" and "new drug" are at issue in this case, the meaning of the word "guilty" in a misdemeanor criminal case was modified either by Congress or by court decisions a few years after the FDC Act of 1906 when government attorneys found it nearly impossible to get felony convictions against persons whom they accused of making fraudulent claims for the medicines they marketed. U.S. Attorneys could not convince juries that the defendants intended to defraud the Public. As a result, the law was changed to one of protecting the public as a strict liability based on the opinions of FDA scientists.

It should have been apparent to Magistrate Callahan that the guilty plea of this defendant was not a "state of mind" so why did he persist in asking and re-asking this same question (Are you guilty?) again and again? If the defendant believed that he had done something wrong, he would not be appealing this case at all on the factual, logical and legal issues involved. I believe that a reasonable reading of the transcript of Jan 13, 2012 was that the guilty plea was as how the court applied the law (as explained by Ms. Perini) that did not include a state of mind, because it should be obvious that this defendant disagreed with the law as applied in entering the plea agreement.

Defendant asks this honorable court not to pass this case on undisturbed to the 7th Circuit Court of Appeals, but carefully consider all the facts, the logic of the arguments of fact and law, and to make its own decision. That is what I believe is the purpose of this review. This case has the potential to restore true freedom of choice in medicine as it existed for the first half of our Republic, from 1792 to beyond 1892 and beyond, to limit the power of the FDA to continue to impose their medical views on the nation and to limit the public's access to scientific research, information and treatment options. In a society worthy of the name "free," it curbs the power of paternalistic government, and favoritism in the marketplace for the very wealthy, those with deep pockets who can buy political influence and are always more than adequately represented. It is not the 1% on Wall St that need to be coddled and protected, it is the 99% of us on Main St that need equal protection under the law.

In the case of *Central Hudson* 447 US 562 (1980), the United States Supreme Court said of the First Amendment and paternalistic government:

> "In applying the First Amendment to this area, we have rejected the "highly paternalistic" view that government has complete power to suppress or regulate speech. [P]eople will perceive their own best interests if only they are well enough informed, and…the best means to that end is to open the channels of communication, rather than to close them.." Id., at 770; see Linmark

> Associates, Inc V. Willingboro, 431 U.S. 85, 92 (1977)., Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all. Bates v. State Bar of Arizona, supra, at 374."

My concluding thoughts are thus:

"May God Bless United States District Judge Charles N. Clevert with patience (to read and consider the voluminous legal arguments presented here), wisdom (to separate truth from fiction and not be misled by the opinions of men that usurp the U.S. Constitution), conviction (to defend liberty and justice for all) while upholding the rule of law (the intent of the lawmakers), and judicial courage as he writes his decision."

Conrad LeBeau _____ Feb 13, 2013

Certificate of Service

I, Conrad LeBeau, certify that a copy of this Reply Brief was filed on Feb 13, 2013, with the Clerk of Courts Room 362 and a copy mailed by first class 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
Milwaukee WI 53202

X_____ Feb 13, 2013