CNC

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff

v.

Case No 10-CR-00253

CONRAD E. LEBEAU, an individual

Defendant

DEFENDANT'S RESPONSE IN OPPOSITION TO PLAINTIFF'S MEMORANDUM (Doc 114)

August 17, 2015
Conrad LeBeau
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To Honorable Chief Judge Charles N Clevert Jr.
517 E Wisconsin Ave
208 U.S. Courthouse
Milwaukee, WI 53202

STATEMENT OF PURPOSE AND MEMORANDUM

I have nothing to gain financially from this appeal, irrespective of the outcome of this case, as I discontinued my dietary supplement business in July of 2010. My purpose in pursuing this appeal is for the benefit of both present and future generations of Americans who are entangled in a web of laws and regulations that deprive them of healthy choices, and personal health freedom.

It is not my intent to change the law with this appeal, but to restore it; that is to bring the United States Food and Drug Administration into compliance with the United States Constitution including the Bill of Rights: to limit the definition of drug to those substances - opiates (narcotics, cocaine, heroin etc.), patented drugs, and nostrums

(excluding food and nutritional supplements) that were the specific targets of the original FDC (Pure Food Act) of 1906. [The intentions of the 1906 Congress in passing the Pure Food Act are well described in the Congressional Record]; and to further bring the FDA into compliance with the intentions of Congress in passing the Dietary Supplement Health and Education Act of 1994; to stop the FDA from over-reaching its authority, by wrongfully classifying foods and dietary supplements as 'drugs" based solely on speech about their intended use for lawful purposes.

It is undisputed that it is lawful to use health foods and dietary supplements to promote health, well-being, and to prevent disease, and when appropriate, mitigate a disease. [An example that is well known is the use of lemons and oranges as a source of vitamin C for the prevention and treatment of scurvy- a disease] In the Findings of Congress under DSHEA that was approved on a bipartisan basis in 1994,

Congress found that dietary supplements do prevent disease and mentioned specifically heart disease, cancer and osteoporosis. However, since the FDA had used for more than three decades the definition that "articles" intended for the prevention of disease are drugs (21 U.S.C. Sec 321(g)(1)(B), they continued this practice even after passage of DSHEA even though products like the defendant's Perfect Colon Formula were by their composition classified by Congress as dietary supplements (not drugs).

The FDA made no secret of their opposition to the DSHEA of 1994 because this law restricted their power to classify nutritional supplements as drugs. Since the passage of DSHEA, the FDA has continued to do an end run around Congressional intent, by continuing its self-serving policy of dual classification, claiming that dietary supplements that prevent diseases are drugs. Under the law as the FDA applies it, it is illegal to talk

about how foods and nutritional supplements prevent disease if you also distribute those same foods and supplements.

The FDA continues to use numerous illegal tactics under color of law; they take speech on the intended use of a health food or health products and call that speech a "drug." They also brand "unapproved speech" as an "unapproved new drug." In addition, the FDA unabashedly slanders distributors of health foods and nutritional supplements as "drug peddlers." The FDA continues these attacks on speech in a clear violation of the First Amendment. In 1938, the Pure Food Act was amended to include a definition of a "new drug" and the definition of "drug" was itself modified in a significant way.

As described by the government on page 4 of their "Memorandum in Opposition" to my appeal, the government cites 21 U.S,C Sec. 321(g)(1)(B) and states "**articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."** The problem with 21 U.S.C. Sec 321(g)(1)(B) is that it expanded the original definition of the term "drug" passed under Section 6 of the Pure Food Act of 1906 to include speech about substances that are "drugs" based on their composition. The term "drug" in 1906 was defined as follows:

> Sec. 6 That the term "drug" as used in this act shall include all medicines and preparations recognized in the United States Pharmacopeia or National Formulary for internal or external use; also, any substance intended to be used for the cure, mitigation, or prevention of disease. (Source: Congressional Record 1906 page 897 See Exhibits to Doc 28)

In 1938, the definition of the term "drug" was changed to "articles' and this broadened the meaning of the term "drug." The word "articles" used in place of "substance" in the definition of "drug" also included speech and words used on labels. A

scientific abstract is an "article" as is a published learned treatise, as is a book or publication. The word "articles" has multiple meanings, and the FDA uses all of them.

For example, the defendant's brochure that provided information about Perfect Colon Formula was an "article" that I wrote. The FDA used article about Perfect Colon Formula to label it a drug and also an unapproved new drug. They based this on three words printed in the article (brochure) about Perfect Colon Formula, and those three words are listed in the "Information" as "reduces food allergies." A common sense reading of the government's argument is that the brochure as an article was the "drug" and "unapproved new drug" and not the product Perfect Colon Formula (by its composition).

The government never alleged that the product "Perfect Colon Formula" by its composition was a drug, It alleged that words I wrote in an "article" (brochure) about Perfect Colon Formula was both a drug and unapproved speech (equating to an unapproved new drug). Since the product by its composition is not a drug, the words on the label are the "drug" by FDA own standards. This brings me to the next point; that for the government to attach civil and criminal penalties for my use of those words "reduces food allergies" constitutes nothing less than a direct attack on my Constitutional First Amendment rights. Thus, for the government to state that it must preapprove speech about Perfect Colon Formula before that speech may be used clearly creates a precondition of restraint on speech that abridges freedom of the press.

For this reason, the very definition of "drug" under the "articles…" definition of the term "drug" and this law as applied by the FDA should be found unconstitutional, and the governments actions should be reversed and voided by this court.

Under DSHEA, the FDA had another option

In the present case, the government did not have to drag the defendant's through the legal mud as an accused drug peddler. They had the option to charge the defendant under DSHEA for a statement it disagreed with ***if the statement was not truthful or was misleading.*** However, the statement that the defendant used in the article about Perfect Colon Formula was fully supported by scientific research and abstracts retrieved from the National Library of Medicine (See Doc 28 and 75). The statement "reduces food allergies" was clearly truthful, supported by science, and was not misleading in the context of how it was used.

Instead, the government bypassed its legal obligations and restrictions under DSHEA and pursued the extreme character damaging criminal allegations against the defendant. The actions of the FDA were likely politically motivated because they disagreed with the contents of a book on "Hydrogen Peroxide and Ozone" written by the defendant that sold 90,000 copies from 1991 through July 2010. It is apparent to this defendant, and I am sure to the FDA attorneys, that a criminal conviction, even a misdemeanor, would make a good press release to tarnish the defendant's reputation with the public.

Errors and Omissions in the Government's Arguments

In footnote No 6 on page 11 of the government's brief (Doc 114) states:

> 6 "Acknowledging that it might be extremely difficult for Mr. LeBeau to get a drug product approved, if his products were truly the promising cures for food allergy and other diseases that he believes them to be, others in his position have found financial backing to conduct the clinical research needed to prove that a drug is safe and effective to the FDA. Doing so is not "impossible," particularly if the scientific basis for the safety and efficacy of one's drug product is as sound as Mr. LeBeau's professed belief in his formulae appears to be. Further, Mr. LeBeau is simply incorrect that a patent is required in order to submit a New Drug Application."

Error No 1. The word "cure" has never been used on the label or in any attached brochure as regards the health benefits of using Perfect Colon Formula. The defendant never believed that Perfect Colon formula was a "cure" for food allergies, hence the qualified term "reduces food allergies" that was used along with a brief description of a dozen other health effects in an "article" about the product. The word "allergy" does not even appear on the label that is attached to the bottle labeled as Perfect Colon Formula [the product was not labeled Perfect Allergy Formula]. The "Information" filed on Dec 7, 2009 has as the alleged offense the words *"reduces food allergies"* a term that appears in the one page "article" about Perfect Colon Formula.

Error No 2. The government says in this footnote that

> "Acknowledging that it might be extremely difficult for Mr. LeBeau to get a drug product approved, if his products were truly the promising cures for food allergy and other diseases that he believes them to be, **others in his position have found financial backing to conduct the clinical research needed to prove that a drug is safe and effective to the FDA.**" (bolded for emphasis)

Who and where are these "others?" The government was given an opportunity multiple times to provide the names of any foods, dietary supplements or other non-patentable products approved by the FDA since June of 1938 as "approved new drugs," and they have failed to do so. The reply from the FDA to my FOIA request of Feb 8 2011 is found in Doc 28 pages 62 and 63 and in the Exhibits attached to this brief.

The exhibits attached to Doc 28 include a copy of the original FOIA request and the FDA's answer, which was that - no non-patentable health products (foods, herbs, vitamins, minerals or dietary supplements) have been approved by the FDA in its entire history of approving "new drugs." That spans a period of time form 1938 to 2015 (77 years). So far the government's response for an explanation as to why no food or

nutritional supplements has been approved as an "approved drug" is to fold their hands, remain silent, or change the subject.

A very important consideration for anyone investing millions of dollars in clinical studies is a return on their investment. This requires not only a public demand for the product (approved drug), it also requires the elimination of competition in the marketplace so sufficient sales can be had to recover the investment plus a profit. Because Perfect Colon Formula is composed of all natural non-patentable ingredients, flax seed, chicory inulin, apple pectin, glucomannan from konjac root and 6 probiotics, any competitor could make a similar fiber probiotic formula identical to Perfect Colon Formula, and underprice Perfect Colon Formula so the sales would barely yield a profit at all and certainly not enough to recover the massive investment in FDA-approved studies.

Imagine if the FDA approved-drug Crestor had a competitor who produced the same identical chemical formulation as Crestor and called it Krestor and sold it for 90% less than Crestor. While Crestor required a prescription, Krestor would not and could be sold as a competitive product over-the-counter. The value of a patent is that it prevents this from happening; the patent eliminates competition in the marketplace from a product with the same molecular composition. For the foregoing reasons, no savvy investor, [unless they were high on heroin or Oxycontin], would place money on an investment that guarantees they would lose millions of dollars.

Also, for all the foregoing reasons, the financial constraints and regulatory requirements of the drug approval process would make it impossible to obtain final FDA approval of Perfect Colon Formula as an approved new drug in order to write and use these three words "reduces food allergies" as approved speech for use on the product

label. Since the FDA drug approval process was designed only for patentable synthetic chemical compounds; to also require a natural non-patentable product like Perfect Colon Formula to obtain FDA approval in order to express the product's intended use in labeling, is beyond the pale of what is fair and reasonable, and lawful under our United States Constitution. All such laws are prohibited under the First Amendment. The core problem lies with the abuse and over-reach of the definition of the term "drug."

The term "approved new drug" equates to "FDA approved speech." The FDA drug approval process for a New Drug Application (NDA) concerning a non-patentable health product is not only an extreme regulatory and financial burden that would not be recoverable, it would be solely for the purpose of permitting the defendant to exercise a First Amendment right, a right of speech that the First Amendment itself was intended to protect. The First Amendment was intended to protect truthful speech and prohibits all laws that would impair or obstruct that right. (See U.S. Constitution, Bill of Rights, First Amendment. (See Central Hudson 447 U.S. 557-583)

Error No 3. The government also states in this footnote:

"Mr. LeBeau is simply incorrect that a patent is required in order to submit a New Drug Application"

First of all, it is not I, but the law that states a patent number is required before the FDA can give final approval to a New Drug Application. The law states that if a patent number is not filed with the original NDA, it "shall be" added later on when it becomes available. See 21 USCS Sec 355 (a) and (b). 21 USCS 355 (a) states that an approved application is required to introduce a new drug into interstate commerce and (b) requires a patent number that shall be added to the NDA if it is not available at the

time of filing the original NDA. (See pages 30 to 33 of Doc 28). There are no provisions for obtaining final FDA approval without a patent number.

Under 21 USCS Sec 355 (b), the mandate for adding the patent number is found under **New Drugs (b) Filing application: contents**. in both line 12 through 17 and in line 18. This mandate is listed twice. The second time it is mentioned, the states very clearly that the patent number must be added before approval of the New Drug Application.

On line 12, it states:

"The applicant **shall** file with the application **the patent number** and the expiration date of any patent for which the applicant submitted the application…….of the drug"

On line 18 it states:

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

Line 12 through 23 states very clearly that the filing of patent number is required under 21 USCS Sec 355 (b) and is required information before approval of a New Drug application. The government's claim that the filing of a patent number is not required for an NDA is simply not supported by a clear reading of the statute nor is it supported by how the law has been applied by the FDA from 1938 to 2015.

While the FDA can write code under the Administrative Procedures Act (ADA), the FDA is not a legislative body. The FDA does not have legal authority to change the law on its own volition without first going to Congress and asking that the patent

number requirement under 21 USCS Sec 355 (b) be made optional instead of mandatory. This has not been done.

The term "shall" as used in 21 USCS 355 (a) and (b) makes the patent number requirement mandatory

The question of whether or not a patent number is required for final FDA approval of a NDA depends on what the legal meaning of the word "shall" is. If the word "shall" means "maybe" or "may" then there is no mandate and the requirement is optional. However, the government in its response to my brief has failed to find either a statute or case law that states the patent number requirement is not mandatory or that the word "shall" is not really a requirement.

What Black's Law Dictionary (5th ed) states about the word "shall"

"As used in statutes, contracts, or the like, this word is generally imperative or mandatory. In common or ordinary parlance, and in its ordinary signification, the term" shall" is a word of command, and one which has always or which must be given a compulsory meaning; as denoting obligation. It has a peremptory meaning, and it is generally imperative or mandatory. It has the invariable significance of excluding the idea of discretion,….." People v. O'Rourke, 124 Cal. App 752, 13 .2d 989, 992.

The meaning of the word "shall" as derived from the common law

The word "shall" expressed as "shalt" likely originated from the Ten Commandments God gave Moses on Mount Sinai more than 4000 years ago.

From atop Mt Sinai, God spoke to Moses, and gave him 10 commandments that he carved in stone and gave these to the Israelites. The first of these commandments stated: "**I am the Lord thy God, thou shalt not have false gods before me.**" In the other commandments, God uses the words "shalt" or "shalt not" including: "**Thou shalt not steal**"; "**Thou shalt not kill**": "**Thou shalt not bear false witness against thy neighbor**." Nowhere in the Ten Commandments is the word

"may" used. The word "may" is a discretionary word, a weak term without the backbone of a moral structure while "shall' or "shalt" is commanding and mandatory. (See Leviticus 20).

Thus, over the span of many centuries, the word shalt or shall as used in law is compulsory and binding. The arguments set forth herein fully support both branches of the Doctrine of Impossibility – both factually and legally. The government's argument or wish that is the inclusion of a patent number in an NDA is discretionary is without merit, is not supported by any facts, and should be rejected.

What did Magistrate William Callahan say about the Doctrine of Impossibility in Doc 41 and 51.

In Doc 41, filed on the 21st of Sept, 2011, Magistrate Callahan denied the defendant's motion to dismiss (Doc 28). In his decision, Callahan spoke not one word about the Doctrine of Impossibility although I had written about this issue in my Motion to Dismiss (Doc 28) from pages 29 to 33. Overall, Callahan declined to take a position on many of the legal defense I raised in my motion to dismiss citing that the case had not yet gone to trial. The reason I raised most of my legal defenses in my Motion to Dismiss (Doc 28) is because I was told by U.S. Attorney Giampietro as well as my own Federal Defender that issues of law are not presentable to a jury in a Federal Court.

.Callahan's failure to take a position on the Doctrine of Impossibility needs to be addressed by United States District Judge Charles Clevert as he writes his review of this case. However, in Doc 51, page 4 and 5, Callahan addressed the patent issue and the doctrine of Impossibility and stated:

"Finally, LeBeau argues that he could not have complied with the provisions of 21 U.S.C. § 355 by submitting a new drug application for any of his products because (1) §

355 requires that a new drug application include patent information and (2) none of his products are patentable. In other words, Lebeau claims that it was impossible for him to comply with the law. Thus, the Information should be dismissed. Once again, LeBeau is wrong."

Callahan than states: "Section 355 does not require that a "drug" for which a new drug application is filed have been patented at the time the application is submitted. Rather, § 355 requires that an applicant file along 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." § 355(b)(1).

"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." End of excerpt from Magistrate Callahan.

Where Magistrate Callahan erred in his opinion

Callahan's statement in Doc 51 (page 4) deals only with the initial filing of the New Drug Application. He is correct to the point that the initial filing of the application does not require a patent number. However, he does not deal with the final approval of the drug application that does require a patent number under 21 USCS 355 (b) to be filed later. He also does not deal with the fact that CIDER (Center for Drug Evaluation and Research) to comply with the statutory patent number requirement would not give final approval of an NDA without a patent number. If Callahan read my brief in its entirety and briefly scanned through the exhibits he would have also found the FDA's answer to my FOIA requesting the names of all non-patented drugs approved by the FDA from 1938 to the present time to be zero. That should have raised an alarm bell, but he simply glossed it over. Instead, he should have called a special hearing and asked the government to provide evidence that the patent requirement is optional and not to simply take their word that it is optional but to demand proof.

He also quoted 21 USCS 355 (b) in part of the law and avoided discussing line 12 which states: "The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application…." His elimination of the first sentence where the word "shall" is used raises a question that he may have realized that the government could have a legal problem with this issue. Callahan avoided the part of 21 USCS 355 (b) that requires the applicant of an NDA to add the patent number later on and before final patent approval. (See Doc 28, page 31 and 21 USCS 355 (b).

The government agrees that legal impossibility is a valid defense

On page 11, paragraph 2, the government states:

To clarify the doctrine of impossibility, at common law, "distinguished between legal and factual impossibilities, providing that the former is a defense and the latter is not." United States v. Tyarsky, 446 F.3rd 458, 465 (3rd Cir. 2006).

What the government stated in referring to the Tyarsky case is that the doctrine of legal impossibility is a valid defense. We both agree on that point. However, without reading and reviewing the Tyarsky case, I cannot agree that factual impossibility is not also a valid defense considering the extreme financial obligations that would be imposed on the defendant under an NDA application for a non-patentable nutritional supplement in order for the defendant to lawfully exercise a first amendment right.

However, on the Doctrine of Legal Impossibility, I cannot agree with the governments position that the word "shall" as used in 21 USCS 355 (a) and (b is optional. The term "shall" as used in law is always mandatory and is not discretionary.

The court must decide which position most accurately reflects

Congressional intent. If the word "shall" is optional, then the government wins; if the word "shall" as used in the law mandates a patent number, then the defendant wins and this case should be reversed on the patent issue and the Doctrine of Legal Impossibility.

How the financial, regulatory and patent requirements of 21 USCS 355 (a) and (b) affects the defendants other Constitutional rights

Directly linked to the Doctrine of Impossibility is how the alleged violations cited in the "Information" fatally obstruct the defendant's right of speech and press under the First Amendment, his right to due process under the 5th Amendment, and his right to freedom of choice in medicine under the 9th amendment. In addition to this, all the foregoing actions under color of law restrains the distribution of the defendant's products in interstate commerce, under threat of civil and criminal penalties.

Restraint of trade, by prohibiting speech about the health benefits of foods, herbs, nutritional supplements, traditional and non-patentable substances, is not an enumerated power delegated to Congress under Article 1, Section 8, of the U.S. Constitution. To pick winners and losers in the market place, and thus restrain trade is not a power delegated to Congress nor were any legislative powers delegated to the Executive or Judicial branches of the Federal Government. Under the U.S. Constitution, only Congress has the authority to write and pass laws.

The mental and physical effects of both civil and criminal penalties or the threat of such penalties for not complying with the New Drug Application process, that is impossible to comply with, are a direct violation of the First Amendment. The price for compliance as the FDA sees it is to censor ones own speech or be silent, or simply go

out of business. The cost of repression through self-censorship makes a mockery of the term "freedom of speech" and directly violates the prohibition of all such laws under the First Amendment.

The First Amendment states:

"Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances."

FDA attorneys, DOJ attorneys, all other government attorneys, all elected members of Congress, the President of the United States, and all Federal Judges have all taken an oath to uphold and defend the Constitution of these United States. Reality is that while all public officials take this oath, not everyone upholds it, and there is no practical remedy at law for those who violate their oath. However, there are, from time to time, some brave public servant, who will stand on principal, and not allow themselves to be bullied by usurpers of the U.S. Constitution and the rule of law.

Since our government was founded in 1792, the government of the many has thus become the government of the few. Our democratic republic has drifted into the quick sands of an economic oligarchy controlled from behind the scenes by lobbyists whose influence is fueled by obscene financial donations to the campaigns of selected politicians in both major political parties. Only the judicial branch of government is not corrupted by the power and influence of campaign donations. Federal judges have the power to make decisions that are in the best interest of all the people instead of a privileged few; However, it takes extraordinary political and moral courage for any Federal Judge to go against the wishes of the Executive branch of government or the Department of Justice.

The restrictions on speech are 100% when health foods or supplements are branded by the FDA as "drugs." There are also speech restrictions for dietary supplements under DSHEA, but they are possible to meet as no patent is required and there is no requirement to spend millions of dollars on studies to obtain FDA approval of speech about the structure or function of a food or dietary supplement.

While it is impossible to comply with the New Drug Application process for all the foregoing reasons cited earlier in this brief, it is possible to make some health claims, statements that are truthful and not misleading, and structure/function claims under DSHEA. Structure/function claims including those that imply the prevention of a disease is already supported in the "Findings" of Congress as published in DSHEA as Public Law 103-417 (See Doc 28 pages 34, 35).

The current FDA policy is to use older case law on drug definitions that was expanded through judicial opinions from 1906 through 1993 and use these case laws to override the classification of "dietary supplements" under the DSHEA of 1994. There is a small problem here; none of the case laws before 1994 gives the FDA the power of dual classification for the DSHEA of 1994 because Congress in 1994 classified LeBeau's Perfect Colon Formula and all similar products by its composition as "dietary supplement" and not "drugs." The pre-1994 case law defining "articles" as "drugs" is based solely on "intent" and not on their composition. This quasi-judicial activity of the FDA is now obsolete ands illegal because Congressional intent in passing DSHEA was to protect foods and dietary supplements from FDA's arbitrary classification of these nutritional health products as "drugs."

The FDA's current policy of dual classification is clearly contrary to Congressional intent in passing DSHEA. FDA actions that continue to classify foods and

dietary supplements as drugs are an end run around the Dietary Supplement Act that Congress passed in 1994. DSHEA was passed for the very purpose of preventing the FDA from classifying dietary supplements as drugs. The FDA has, for more than 5 decades, labeled foods and nutritional supplements that prevent diseases as "drugs." This blatant over-reach of regulatory power has been repeated so often that it has had a brainwashing effect on FDA employees.

On page 11 of the government's brief (Doc 114) paragraph 2, the government makes the absurd and untrue statement that I am invoking the doctrine of legal impossibility because I want to sell *"unapproved new drug products without first getting those drugs approved by FDA and without facing legal sanction."* On page 10 (Doc 114), the government takes out of context a reference to the plea agreement and says it *"rests on the admitted and agreed fact that he distributed an unapproved new drug in interstate commerce"*

The government knows better from a reading of the transcripts that the "guilty" plea was on how the law was applied and was not as a state of mind; that the defendant never intentionally sold any drugs, either approved or unapproved in interstate commerce. This is a fact of the court record in the transcripts about the "Conditional Plea Agreement."

If there were no Doctrine of Impossibility, would the FDC Act as applied still violates the defendant's rights?

1. First Amendment: Yes, it would still violate the first amendment right of speech and press because requiring the filling out of an application and FDA approved

studies and the expenditures of millions of dollars so three words could be used on a product label is a gross infringement that "abridges" first amendment rights.

2. Fifth Amendment: A law that is impossible to comply with also clearly violates due process under the 5th amendment.

3. Ninth Amendment: A law that muzzles speech about the use of foods and nutritional supplements for their medicinal value also violates freedom of choice in medicine under the 9th amendment. There are no provisions for "government minders" in Article 1, Sec 8 to allow or require federal employees to restrain speech that is truthful..

4. Article 1, Section 8 authority exceeded: The above actions collectively restrain the trade of health foods, herbs, vitamins, minerals and nutritional supplements in interstate commerce. The threat of civil and criminal penalties for speech not preapproved by the government has a chilling effect in the marketplace. There is no Constitutional authority for any branch of the federal government to pick winners and losers in the market place, and certainly not based on the size of their political donations. The reality is that this happens all too often in the federal government - and under the color of law.

Doctrine of Overbreadth

On page 6 of Doc 114, the government quotes Callahan as stating that:

"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 no 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. If, as LeBeau maintains, certain food stuffs were not intended by the 1906 Congress to be potentially included as "drugs" under the definition of that term in the Food and Drug Act, his argument misses the mark because, as previously noted, he is

not charged with a violation of the Food and Drug Act of 1906. Rather, he is charged with a violation of the FDCA."

What Callahan missed by not reviewing the excerpts from the Congressional Record was that the quotes in Doc 28 were authentic reprints of statements in the Congressional Record of 1906. The Exhibit file with Doc 28 had reprints of the relevant portions of the Congressional Record. He would have learned that the substances the lawmakers wanted classified as drugs in 1906 were narcotics, opiates and secret formula called Nostrums and certainly not mineral water, peppermint tea or honey. What Callahan misses in my argument is that the Executive branch of government through the DOJ went to the courts after 1906 and got them to "legislate from the bench" by expanding the meaning of the term "drug" to include substances (food and water) along with opiates, patented drugs and nostrums under the term "drug."

By not reading the excerpts I provided from the Congressional Record of 1906, Callahan shows disrespect for the intentions of the Congress of 1906. Instead, Callahan makes the mistake of only considering the opinions of court citations provided by the government instead of going to the originating source. He did not need to rummage through the material I provided as he indicated. The exhibits, while voluminous, were neatly bound, and organized for him to read and consider.

Callahan states that I missed the mark by not realizing that I was not charged with violating the Pure Food Act of 1906 but rather the FDCA. The point Callahan misses is that the FDCA did not just drop out of the sky and land in the law books. It had a beginning that started in 1906 and it was amended and added on to, changed and modified at key intervals over the past 109 years. Years of significant changes to FDCA were in 1938, 1962, 1990 and 1994 - with the passage of DSHEA. Callahan also may

have not realized that the oldest case cited by the government on Mineral Water (Bradley v. United States 264 F.79-82 5th Circuit 1920). This was when the definition of drug used was still based on the 1906 definition of the term. This case was decided without the court reviewing the Congressional Record of Congress in 1906 to find out what the law had actually intended.

Once a court had decided that water was a drug, then, the sky soon became the limit as government lawyers sharpened their knives to go after anyone who made a statement they did not like about the use of any food or nutritional supplement to prevent or mitigate an illness. That is how the court decisions, egged on by the DOJ and the FDA, change the meaning of the law and expanded the regulatory powers of the FDA. Basically, it was a shift from "rule by law" to the rule by the biases and whims of men who are federal employees.

Having discussed in this brief legal issues of disagreement with Magistrate Callahan's decisions in Docs 41, 51 and 71, I hereby withdraw my earlier request for a complete review of all his decisions, and leave the extent of any review of Callahans's Decisions to the discretion of the court, while I ask that the issues raised in Doc 113 and in this reply brief be addressed by the United States District Judge Charles N Clevert Jr.

Respectfully submitted this 17th day of August, 2015.

Conrad E LeBeau

Conrad Eugene LeBeau – representing himself pro se

Standby Counsel Danial Stiller - Federal Defender.

Certificate of Service

I, Conrad LeBeau, certify that a copy of the attached Defendant's Response in Opposition to Plaintiff's Memorandum was filed on August 17, 2015, with the Clerk of Courts in Room 362. A copy was mailed by first class mail to Chief Judge Charles Clevert and to the local US Attorney.

Chief Judge Charles N Clevert Jr
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X Conrad LeBeau August 17, 2015