Case No_____

In The SUPREME COURT OF THE UNITED STATES

CONRAD E LEBEAU,

Petitioner, (Appellant)

v.

UNITED STATES OF AMERICA,

Respondent (Appellee)

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

This petition is filed by Conrad LeBeau, the Appellant and Petitioner, who is representing himself, Pro Se. It is filed timely within the 90 days allowed under Rule 13.

This is an appeal from a final Order of the 7th Circuit Court of Appeals in case No 16-1289 of August 8, 2016 that denied LeBeau's **Petition for an En Banc** hearing. The decision from which LeBeau sought an En Banc review occurred on July 5th, 2016. The July 5th Order affirmed the decision of U.S. District Judge Charles Clevert Milwaukee WI in the district court case of U.S. v. LeBeau (10-cr-00253), a misdemeanor criminal case involving a labeling dispute with the FDA over a health effect statement for a food based nutritional supplement. A plea agreement allowed LeBeau to appeal a number of legal issues.

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QUESTIONS PRESENTED

The first legal definition of "drug" occurred in the Pure Food Act of 1906. The Congressional Record of 1905/06 indicates that the Pure Food Act of 1906 was intended to protect the public from the evils of narcotics (cocaine, morphine, heroin etc.). The Congressional Record indicates that the Act was never intended to include food and water under the definition of "drug". In 1994, Congress passed the Dietary Supplement, Health and Education Act of (DSHEA) to protect dietary supplements from FDA attempts under the Administrative Procedures Act to classify them as "drugs" because of scientific opinion used in labeling thereof, and thus remove them from the shelves.

Today, millions of Americans deal with a variety of gastrointestinal issues including constipation, food sensitivities, food allergies and other health conditions. The government prosecuted LeBeau because of his "speech" (See Doc 1, page 5) about "Perfect Colon Formula" for his use of 3 words "reduces food allergies" a statement derived from scientific literature (Docs 28 and 75) about the probiotics (L Rhamnosus and L Plantarum).

1. **Question on prevention of disease by educating the public about food:** Would it benefit the health and well being of the American people for the purpose of preventing and reducing disease incidents, if distributors of health foods could cite scientific opinion in the labeling of health foods they distribute to their customers?

2. **Question on scientific research cited in "commercial speech" for foods:** Does the First Amendment protect the right of commercial speech to state an "**intended use**" of a food for its health benefits, and including the citing of scientific opinion in the labeling thereof?

3. **Question on restraint of trade:** Is the mandate to file an NDA application with the FDA for pre approval of commercial speech about the intended use of a food for the prevention of disease and other health benefits, "restraint of trade" and an over-reach of government authority not authorized under Art 1, Sec 8 of the U.S. Constitution?

4. **Question on defining a "drug"**: To prevent impairing the First Amendment right of commercial speech, when references or citations of scientific research are used in the labeling of a food and dietary supplement, should the "composition" of a "substance," and not its "intended use" be the primary basis for defining when a substance is a drug?

Parties to the Proceeding

All parties are listed in the caption.

Rule 29.6 Statement

None of the petitioners is a nongovernmental corporation. None of the petitioners has a parent corporation or shares held by a publicly traded company.

Disclosure Statement

Pursuant to Fed. R. App. P. 26.1, Conrad E. LeBeau is a 73 year-old citizen and informs the Court that he represents himself, pro se, as the Petitioner (Defendant-Appellant). Conrad E LeBeau was a natural person in the district court, the 7th Circuit Court of appeals, and will remain a natural person in the U.S. Supreme Court. No corporate interests are involved in this petition for Writ of Certiorari.

Dated: October 13, 2016 Conrad E LeBeau - pro se

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Constitutional Authority

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Statutes and Rules

Conrad LeBeau respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Seventh Circuit.

Opinions Below

The 7th Circuit decision of Aug 8, 2016 denying my Petition for En Banc and Order is in Appendix, pages 1 and 2. The 7th Circuit decision of Jul 5, 2016 affirming the district court decision is in Appendix pages 3 thru 8. The district court decision is in Appendix pages 9 as well as the Judgment of Magistrate William Callahan.

Jurisdictional Statement

This is a Petition for a Writ of Certiorari. On August 8, 2016, a 3-judge panel of the 7th Circuit entered their final Order and denied my Petition for an En Banc hearing. The Petition for En Banc was an appeal of a decision from the same three-judge panel decision on July 5. 2016 that affirmed the district courts review of this case. The district court decision was decided and entered on Feb 4, 2016.

The appeal to the 7th Circuit was from a misdemeanor criminal conviction for a violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(d), 333(a)(1) and 355(a) in the district court first decided by Magistrate William Callahan and then reviewed by U.S. District Judge Charles N. Clevert in his final order of Feb. 4. 2016. LeBeau filed his notice of appeal timely on February 12, 2016.

The district court had jurisdiction under 18 U.S.C. § 3231 and the underlying statutes, 21 U.S.C. §§ 331(d), 333(a)(1) and 355(a). The 7th Circuit had jurisdiction over LeBeau's appeal under 28 U.S.C. § 1291. The U.S. Supreme Court has jurisdiction for this Petition under Title 18, Sec 3736 and Supreme Court Rules 33 (2) and Rule 39.

Statutory Provisions Involved

21 U.S.C. §§321(g)

21 U.S.C. §§ 331(d), 333(a)(1) and 355(a)

Statement of the Case

This case is a misdemeanor criminal proceeding involving a dispute with the FDA on the labeling of a nutritional supplement (Perfect Colon Formula), where a health statement (reduces food allergies) was used by the defendant in a handout brochure along with a listing of 12 other health benefits describing the product. The design of the product and the information on the brochure resulted from multiple searches of the scientific literature at the U.S. National Library of Medicine (NLM). Specific disease claims like how fiber helped to prevent heart disease or colon cancer were omitted in writing the brochure to avoid a future conflict with the FDA. The searches were for individual ingredients in Perfect Colon Formula and their health effects, but disease claims were avoided.

In November of 2009, the defendant received a letter from FDA attorney Nathan Sabel alleging a history of violations by the defendant. Defendant called Atty. Sabel the same day he received his letter to discuss his letter. During the phone call, I asked Attorney Sabel why he had not sent me a "Warning Letter." His answer was that it did not matter now and that he was only interested in having me obtain an attorney and for me to sign a consent decree. Mr. Sabel told me that "reduces food allergies" was a disease claim. I told him I never thought of it that way and I said I would discontinue using the term. Later that day, I changed the words " reduces food allergies" to "reduces food sensitivities" after an internet search did not turned up a disease called "food sensitivities."

Scientific abstracts and studies I filed in the District Court in Doc 28 - the original Motion to Dismiss and Doc 75 fully support the truthfulness of the statement "reduces food allergies" for the fiber and probiotic formula "Perfect Colon Formula." From my perspective, the term " reduces food allergies" was not a disease claim but simply a statement of a health benefit that was described in the scientific literature. [A copy of his letter and my written response can be found in Doc 28 in the Eastern District of Wisconsin files.]

In July 2010, I decided to close down my business (Vital Health Products Ltd). In August, I filed Articles of Dissolution for Vital Health Products, a corporation. On Dec 7, 2010, five months after the business closed, "Information" was filed in Federal Court in Milwaukee, WI. I was served with 4 alleged misdemeanor violations of the FDC Act in the last week of December in 2010.

Magistrate William Callahan was assigned to the case and approved allowing me to have a federal defender as I did not have funds available at the time. To make a long story short, I filed a Motion to Dismiss in May of 2011 after dismissing my Public Defender, Brian Mullins, who could not meet court deadlines. I raised a significant number of legal issues in this motion including violations of the first amendment right of speech, specifically commercial speech, violations of the Doctrine of Overbreadth, Doctrine of Impossibility on the patent issue requirement, and the financial requirements for FDA approval of commercial speech in an New Drug Application (NDA), restraint of trade and what Congress considered a "drug" to be under the original Pure Food Act of 1906. (1)

1. Doc 28 and Doc 30 from the district court have reprints from the Congressional Record of 1906. The 1906 Record shows that the intent of Congress was entirely directed at the growing abuse of cocaine, morphine, heroin and other addictive substances and not food and water, as the FDA has since applied its interpretation of the law.

Excerpts from the Congressional Record of 1906

Did Congress intend to include "Food" under Definition of "Drug"?

The use of plants, herbs and food as medicine was clearly part of the common heritage of the signers to the Articles of Confederation (March 1781), the Declaration of Independence (July 4th 1776) and the original U.S. Constitution (Sept 17, 1787). How did food and herbs that were legal to use as medicine when our nation was founded become illegal and when did this happen? Was it on June 30, 1906 when the Pure Food Act was signed into law by President Theodore Roosevelt, or was it after June 30 1906 and before June 25th, 1938, an interim period when FDA attorneys misled the Federal Courts on Congressional intent in 1906, and used the Federal Courts to extend the drug definition into an area never intended by Congress?

Today, the FDA assumes that any thing that has therapeutic value including food is a drug. The legal basis of FDA's over-reaching definition is questioned here as violating the Doctrine of Overbreadth, and the First Amendment right of commercial speech. Since the intent of the lawmakers is the law, we must return to the original meaning of the definition of the word "drug" in 1906 by examining the Congressional Record. Since the FDA as a regulatory agency cannot write regulations contrary to the intent of Congress, any regulations that the FDA wrote in the past century that would define a "food" as a "drug" must be based on Congressional intent and that intent can (not) found in the Congressional Record.

In 1906, Congress equated "drug" with "Patented Medicines" and "Nostrums"

Writing at a website called "Institute for the study of Healthcare Organizations" (institute-shot.com) Lucy Canter Kihlstrom, PhD writes about the early history preceding the Food and Drug Act that took effect on Jan 1 1906:

> "Drug companies wielded substantial influence, especially those in the patent medicines industry. There was little to stop patent medicine makers from claiming anything and putting anything in their products."

In 1906, the original Pure Food Act published in the Congressional Record defined the word "drug" under Sec 6 as follows:

> "Sec. 6. That the term "drug" as used in this act shall include all medicines and preparations recognized in the United States Pharmacopia or National Formulary for internal and external use: also any substance intended to be used for the cure, mitigation, or prevention of disease."

(See Exhibits in Doc 30– Congressional Record page 897 Sec 6.under Definitions.)

There is no historical evidence that Congress in 1906 specifically intended the original meaning of what is a "drug" under the Food and Drug Act to go beyond controlling, and regulating patented cures and nostrums. Nowhere in the Congressional proceedings is mentioned a single statement about defining foods, water, and edible herbs as drugs. The second word in Sec 6 of the Pure Food Act of 1906 is "any" as in "any substance intended ….."

Why the legal definition of "DRUG" is tied to the meaning of the word "ANY"

In legal cases, the word "any," when applied to the context of how it is used can have several meanings including "all," "every" as well as "some" or even "one." The following legal definition of "Any" is found in the 5th edition of Black's Law Dictionary on page 86 to wit:

> "Word "any" has a diversity of meaning and may be employed to indicate "all" or "every" as well as "some" or "one" and its meaning in a given statute depends upon the context and the subject matter of the statute. Donahue v. Zoning Bd of Appeals of Town of Norwalk 155 Conn 550, 235A.2nd 643, 646, 647".

Also cited in Black's Law dictionary that the definition of "any" can have multiple meanings are: Federal Deposit Ins. Corporation v. Winton, C.C.A. Tenn. 131 F.2nd 780,

782, and Siegel v. Siegel, 135 N.J. Eq. 5, 37 A.2nd 57,58 and the Doherty v. King, Tex.Cuv.App., 183 S.W.2nd 1004, 1007.

After 1906 and before 1938, Federal Attorneys told Federal Judges them that the word "any" meant "all" as in "all substance(s) intended ….." To expand this definition, they used the word "any substance" in a different context from which it was originally intended. The definition of a "drug" in 1906 is more appropriately compared to the Controlled Substances Act (CSA) that would follow several years later. The CSA specifically names drugs by their composition and not their intended use. Edible food and water is not on this list.

After 1906, FDA attorneys wrongly convinced the courts to expand the original "drug" definition beyond opiates, narcotics, cocaine, morphine and heroin and other harmful and addictive substances, to include food, spices, edible herbs, and even water. Why was common sense not applied to set parameters on the vast expansion of the legal definition of "drug"? Why is there no mention of a review of the Congressional Record in the cases cited by the DOJ/FDA to find legislative intent on the context that should have been applied to the words "any substance".

Bad Precedent – the case of Bradley v. United States, 264 F.79 (5th Cir. 1920).

The oldest case cited by the DOJ/FDA attorneys was from 1920 and involved health claims for mineral water in the case of Bradley v. United States, 264 F.79 (5th Cir. 1920). This case is cited in the Plaintiff's brief (Doc 8) in the 7th circuit in reply to my Appellate brief. Unlike most cases cited by lawyers, I actually read the Bradley case. The defendant "Bradley" was right in claiming that mineral water was not a drug. He even offered a money back guarantee to his customers. The Bradley case set the stage for the broad-brush definition of "drug" in use to this day based only on speech about the "intended use"

of a substance, without any regard as to the composition of the substance. Case law cited by the government shows that the expansion of this definition came about as a result of federal judges believing attorneys from the FDA or DOJ that Congress intended the definition to include food and water. The federal attorneys got it wrong and so did the federal judges of the inferior courts that believed them.

The government insists that the definition of "drug" is clear from a direct reading of the law. Ordinarily, this is true, but in this instance, the meaning needs to be restrained and understood by Congressional intent. The government stated on page 14 of their reply brief (Doc 8) that – *"the express language of the law that Congress passed – as consistently interpreted by the courts – controls here."* The problem with the government's argument is that a review of the Congressional Record of 1905/1906 does not support their theory that case laws they cited better represent Congressional intent than the Congressional Record itself.

If the government's argument is correct, then their "hearsay" is credible evidence. Should hearsay from federal attorneys be a basis for changing a law? Hearsay should not replace the original words of members of Congress found in the Congressional Record. According to their argument, the express meaning of the word "any" in the Original definition of "drug" was meant to equal the word "all." The expanded definition of "drug" is one example, but not the only one, where employees from the Executive branch of the government has taken words out of context and changed their meaning.

The conflict between what Congress intended in the "original "drug" definition and how the FDA as a subdivision of the Executive branch the Federal Government and the Federal Courts themselves have interpreted the definition from 1906 forward to the present day warrants a review of Congressional intent by the U. S. Supreme Court

covering a period from 1906 through 1994 when the Dietary Supplement Health and education Act (DSHEA) was passed to protect the availability of supplements from the FDA's over zealous urge to classify all health foods and dietary supplements as "drugs."

So far, the inferior courts (the district court and the 7th circuit) have dissed the Congressional Record of 1906 and 1994 while claiming that a review of the legislative history was not necessary. However, the thousands of "Warning Letters" sent by the FDA each year, and the hundreds of cases litigated over the past 96 years on this very issue of the definition of the word "drug" warrants a foundational review by the highest court in the land.

The issue of Congressional intent v. the express language of the law

The next problem with not reviewing the Congressional Record is the even wider range of meanings applied to the word "Articles" that was used in place of "substance" in the 1938 definition of "drug." While the government is correct is stating that I was not charged with violating the Pure Food Act of 1906, but rather the FDCA that followed in 1938 et sequel, the conditional Plea agreement allows me, under the Doctrine of Overbreadth, to raise the issue of the definition of "drug" from its origin in 1906, and the evolution of this term to the date of the signing of the Plea agreement (Doc 58) which was on January 12, 2012.

What about the "express language" of the word "Articles intended"

The definition of "drug" under 21 U.S.C.S. 321 (g)(1)(B) is ***"articles intended for use in the diagnosis, cure, treatment, or prevention of disease in man or animals;***" What follows under 21 USCS. 321 (g)(1)(C) is a long, distorted and unintelligible statement about dietary supplements that no one can understand or even apply any "express language" meaning.

The word “Articles” used in the 1938 altered definition of “drug” has even more meanings than the word “any substance’ used in the 1906 definition. As the FDA has applied its interpretation of the FDCA, “Article” has a double meaning and the FDA uses both meanings. An “Article” can be either a substance or published scientific opinion. If Congressional intent is not important to apply to the meaning of the words in a statute, and the “express language” of the words is all that needs to be considered, then, the very definition of “drug” under 21 U.S.C.S. 321 (g)(1)(B) is unconstitutional as it is a direct attack on speech, and scientific research and opinion.

This is because this is how the law has been applied since the “new drug” definition was passed in 1938. If published scientific opinion in “articles” discuss how any substance can prevent or treat disease, then the article is considered as part of the label, then is the article as a scientific publication the drug? Under this definition, the composition of a substance does not matter, because it is the label and what is said on the label that makes the drug. The problem here is that when opinion as “intended use” is under attack, so is the First Amendment.

In the case of Perfect Colon Formula, the government does not allege that the composition of the product made it a drug but what I as the distributor said (reduces food allergies) about Perfect Colon Formula that makes it a drug. In a 180-degree twist of logic, the government then states that I am not being prosecuted for my speech about Perfect Colon Formula, but the distribution of a drug whose legal status was changed by my speech, although the composition of the alleged drug (Perfect Colon Formula) is identical to what it was before the speech. This makes the definition of a drug based on “intended use” as elusive as defining a “widget.” Lawyers could create the legal term “widget” and apply it to food and water based on its intended use and makes “unapproved widgets” a

violation of federal law. Is the composition of a drug any different than the composition of a widget? To separate legal fiction from reality, it would be prudent to take the time to review the Congressional Record of 1906 and 1994.

The following excerpts from the Congressional Record of 1905/06 indicates that the first definition of "drug" was the precursor of the Controlled Substances Act, not the broad brush of how the FDA attorneys have applied the law since its inception.

Excerpts from the Congressional Record on the "Pure Food Bill"

The Pure Food Act was the beginning of what evolved over time into the US Food and Drug Administration. On Jan 10 1906, Mr. Heyburn, a Pure Food Bill sponsor stated in the U.S. Senate:

> "I now renew my motion that the Senate proceed to the consideration of the bill (S.88) for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes."

In an excerpt from another part of this same statement he made on 1/10/1906, he added:

> "I will not at this time undertake to enumerate the frauds perpetrated upon the people further than to state that, according to a statement which I have before me, received this morning, which is from an official source, in some of the great neighboring States more than 60 per cent of all the drugs that are offered on the market are fraudulent, and not only do they not possess the qualities for which the drug is distinguished, or should be, but they are actually adulterated to such an extent that they are dangerous to use."

See Exhibits Congressional Record 1906 Page 895, Doc 30.)

On Jan 23, 1906, Mr. McCumber made the following statement to the U.S. Senate about the Pure Food Bill and about how a proper diet can help prevent disease that he refers to as "evils with which humanity seems to be afflicted." The statement shows the

intent of a lawmaker that proper food and diet can help prevent disease and that proper food was not the intended target of the Pure Food Act.

Mr. McCumber stated:

> "Mr. President: we are coming more and more to understand that our health depends more upon the character of food we consume than upon the medicines that are given to allay and destroy disease. We are coming more and more to understand that proper diet, varied to meet the conditions of each individual, is not only the greatest panacea for, but also the greatest preventive against evils with which humanity seems to be afflicted."
>
> (See exhibits in Doc 30 Congressional Record 1906 page 1415)

On June 23, 1906, only 7 days before Congress passed the Pure Food Act, Mr. Webb, in addressing the U.S. Senate, spoke on the importance of a provision he sponsored in a separate bill that was added to the Pure Food Act to require on the labeling of patent medicines and all drugs addictive substances including alcohol, morphine, opium, heroin, cocaine, chloroform, cannabis indica and other dangerous and addictive substances on the product label. Mr. Webb and many other Senators spoke in favor of requiring the listing of these ingredients on the bottle as many patented drugs and Nostrums did not list these addictive and other deleterious ingredients on the bottle. Mr. Webb said:

> "Mr. Chairman, there is no subject upon which the American people are more rapidly awakened than on the subject of the dangers that lurk in the thousands of patent medicines that are being sold in this country today. The patent-medicine evil is alarming, and should challenge the attention of every thinking man who is interested in the welfare of his people and the perpetuity of his race. "

(See Exhibits Doc 30 – Congressional Record of 1906 page 9071)

Mr. Webb also stated in the same speech the following:

> "The greatest danger to the public lies in the use of these nostrums. It is said that there are something like 5,000,000 people in the United States who buy these various medicines, whose advertising literature appeals to their credulity and their hope. A large number of such people every year become drug habitués, or morphine, cocaine, or opium fiends. A large proportion of

> such nostrums contain alcohol or some narcotic like opium, morphine, cocaine, chloral, eucaine, or some latter-day synthetic nerve stimulant."
>
> (See Exhibits Doc 30 Congressional Record page 9072)

While the Pure Food Act of 1906 prohibited false and misleading or fraudulent statements on the label, nothing in the bill sponsors or in any speech in the Congressional Record on 1906 indicated in the slightest way that foods intended to promote health and prevent disease were to be defined as drugs. In fact, in the statement of Mr. McCumber on Jan 23, 1906, he stated in a reference to how diet may help to prevent disease *"that proper diet, varied to meet the conditions of each individual, is not only the greatest panacea for, but also the greatest preventive against evils with which humanity seems to be afflicted."*

As a food, Perfect Colon Formula is not a drug under the definition of the word as intended in the original Pure Food and Drug Act of 1906.

The Feb 15, 2011 FOIA Request and FDA's Answer

On Feb 15, 2011, I sent a Freedom of Information Act request to the FDA. The FOIA request to the FDA (See Doc 30 page 63) and asked for the following files -

> "A document or file that contain the names of ALL NON-PATENTED DRUGS approved by the US Food and Drug Administration for the prevention or treatment of disease since Jan 1, 1906 through Dec 31, 2010. The files requested are for FDA approved drugs for which a patent was not applied for or granted before, during or after the filing of an application for FDA approval of a new drug."
>
> "A file or document that contains the names of all ingestible items and foods of plant or animal origin from land or sea (including seaweeds, plants, trees, herbs, leaves, bark, essential oils of herbs and flowers, other oils, flowers, roots, seeds and fish, dietary supplements and all other naturally occurring articles) that were approved as new drugs for the prevention or treatment of disease from Jan 1, 1906 through Dec 31st 2010. "

Feb 23, 2011– the FDA's Response is as follows:

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

Excerpts from the Congressional Record of 1993/1994

From Doc 109 and 109-1 in the district court

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

The reason is found in 21 U.S.C.S. 355 that requires a "patent" to receive final FDA approval. Since foods and food- based nutritional supplements are not patented or patentable, this path to FDA approval is a dead end road – it leads to nowhere.

On April 7, 1993, U.S. Representative Bill Richardson of New Mexico who introduced the House version of DSHEA in 1993 made the following statements to the House of Representatives.

Rep. Bill Richardson stated:

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

April 7, 1993, Hon. Bill Richardson:

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

Hon Jim Cooper, who co-sponsored DSHEA, made remarks to the House on October 21, 1993

> "Mr. Speaker….The FDA should not be allowed to remove safe supplements from the market, characterize them as drugs, or require a prescription for them."

Hon. Donald A Manzullo, who co-sponsored DSHEA, made remarks to the House on November 22, 1993:

> "Mr. Speaker….First, it establishes that dietary supplements are not drugs or food additives."

D. Hon. Orrin Hatch statement to the U.S. Senate on Nov. 23, 1993 places in the Congressional Record a letter to Hon Donna E Shalala, Sec of HHS. (See Exhibit 109-1 page 1 and 2) The Letter is signed by Senator Orrin Hatch, Rep Elton Gallegly, and Rep Bill Richardson.

It starts with -

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

Statements of Senator Hatch and others from the Congressional Record of August 13, 1994 comments on the Senate version of DSHEA S.784.

Here is an excerpt from a statement by Hon Orrin Hatch:

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

> dietary supplement health labeling claims would be allowed s long as they are truthful and not misleading and are based on the totality of scientific evidence. Because of FDA's bias against dietary supplement claims, I was not, and am not, comfortable in allowing the FDA the power to approve claims – simply because they won't approve claims, as history as shown."

Statement of Senator Tom Harkin to the U.S. Senate on Oct 7, 1994:

Hon Sen. Tom Harkin:

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

The Dietary Supplement Health and Education Act of 1994 was signed by President William Jefferson Clinton On Oct 25, 1994. Since 1994, the FDA has continued to prosecute individuals for health claims for foods and dietary supplements as "drug" claims, contrary to the intent of Congress in passing DSHEA in 1994. The FDA has done this even though DSHEA has provided a regulatory framework for health claims for dietary supplements that are far less restrictive than the regulatory standard for drugs.

As the petitioner, I am seeking a review of all the Constitutional and legal arguments in this case with primary consideration of the suppression of scientific research used in commercial speech as well as lesser restrictions of commercial speech under DSHEA. I look forward to making a presentation before the court.

In addition, I discussed the pattern of the FDA over reaching its authority under subsequent amendments in 1938 (defining a new drug for safety standards), 1962 (adding efficacy to the new drug standard). In 1991, the FDA outright sabotaged the Nutrition Labeling and Education Act (NLEA) as reported in the Congressional Record of 1993 and 1994 on DSHEA and turned the meaning of the law around by 180 degrees. See Doc. 109

and 109-1 (pages 9 and 10) for quotations and exhibits from the Congressional Record of 1993 and 1994 on why Congress wanted to pass DSHEA.

In 1994, the Dietary Supplement Health and Education Act (DSHEA) did not stop the FDA from continuing its prior practice of classifying health foods and nutritional supplements as "unapproved new drugs" by their intended use" and not as "dietary supplements" by their composition. By their actions, the FDA has continued to overrule the intent of Congress when they passed DSHEA in 1994. DSHEA was intended to protect dietary supplements from FDA's arbitrary "drug" classification.

Congressional Intent in passing DSHEA in 1994

On April 7, 1993, while Senator Orrin Hatch introduced the Senate version of DSHEA, U.S. Representative Bill Richardson of New Mexico introduced the House version of DSHEA in 1993 and made the following statement in the Congressional Record -

> "The FDA has repeatedly used implied health claims to prosecute dietary supplements as drugs. The regulatory framework Congress created many years ago regarding health claims works for only one type of product – synthetic patentable drugs. Dietary supplements are natural, non-patentable substances. The current 200 million- dollar, 12 year-long drug approval process simply does not work for non-patentable products like dietary supplements." (1)

If the U.S. Supreme Court agrees with Rep. Richardson, who introduced DSHEA in the House in 1993, and other members of Congress, the only issue is whether the speech about Perfect Colon Formula is truthful and based on scientific literature. (Docs 28 and 75 contain scientific articles about the role of two probiotics, L. Rhamnosus and L. Plantarum in the prevention or mitigation of food allergies.

(1) This and several other excerpts from the Congressional Record of 1993 and 1994 can be found in Doc 109-1 (filings in the district court in Milwaukee 10-CR-00253)

These were two key ingredients in the fiber probiotic formula. Statements about these probiotics based on scientific opinion should be recognized as "commercial speech" protected under the First Amendment.

DSHEA did not stop the FDA from continuing the practice of classifying foods and dietary supplements as "Drugs" based on the dubious theory of dual classification. Under NLEA, the FDA turned the meaning of the law around 180 degrees and attempted to remove several hundred herbs, vitamins, minerals and other nutritional supplements from the market which they had intended to do until Congress intervened. See statements of Senator Orrin Hatch and others in the Congressional Record of 1993/94. (Doc 190-1)

The Plea Agreement – as the law was applied, not a state of mind

By the end of 2011, with the motion to dismiss (Doc 28) having been denied by the Magistrate, I was under increasing pressure to reach a plea agreement after receiving a threatening email from then U.S. Attorney Gordon Giampietro who said if the case went to a jury trial, and I lost, the government would ask for maximum penalties of $100,000 in fines for each count and one year in jail. I was offered "favorable terms" of a $100 fine and one year's probation if I pleaded guilty to just one of the 4 counts in the Information. I considered the Plea agreement "guilty" plea as how Magistrate Callahan applied the law and not as a state of mind (See my arguments in Doc.4 my Appeal brief to the 7th circuit)

A plea agreement was reached in January 2011 that allowed me the right to appeal this case based on a number of legal issues reserved within the Plea agreement plus others in Document 28, the original Motion to Dismiss. An exhibit list to Doc 28 included reprints of speeches from the Congressional Record of 1906 that proves conclusively that Congress passed the 1906 Act to empower the FDA to protect the American people from cocaine, heroin and other narcotics. Not one word can be found in the Congressional

Record of 1906 that support the government's position that the definition of "drug" was also intended to include food, water, fruits, vegetables, grains, herbs, and spices.

The vast expansion of the definition of "drug" is only found in early case decisions where FDA attorneys used the Federal Courts to extend the "drug" definition in an area never intended – food and water. This case challenges this expanded legal definition of "drug" to include food, herbs, fruits and vegetables and water and place them wrongly in the same category of "drugs" like cocaine, morphine, heroin, other narcotics, and secret formulas called "nostrums."

Attorneys from the Executive Branch of government used their position to pressure federal judges to expand the definition of "drug" in an area never intended by Congress. In effect, FDA attorneys use the Federal Courts as a legislative body. This violates the Doctrine of Over-breadth. The alteration of the definition of "drug" by expanding the breadth of the definition violates not only the framework of the division of powers found in the United States Constitution, it directly violates the intent of the Congress of 1906 when it passed the Pure Food Act.

From the case of Bradley v. the United States in 1920, 264 F.79 5th Cir, a series of court decisions followed like a chain of dominos over a period of 74 years to 1994. All the cases after Bradley quoted Bradley and those other cases that followed. Now, you can add 22 more years to 1994 to reach 2016 and this continuing over reach of authority. The passage of DSHEA in 1994 was to protect dietary supplements and the American people from the FDA over use and abuse of its drug classification authority.

By refusing to review the Congressional Record of 1905/1906 and 1994/1994, the lower district court and the 7th circuit have allowed the DOJ/FDA legal opinions to use a series of earlier court decisions where Federal Judges were misled by federal attorneys to

bypass the First Amendment and Congressional intent while claiming in the same breath to do neither. Apparently, the DOJ/FDA are content with changing half-truths into full lies.

7th Circuit July 5th 2016 Decision.

The following statement was made on page 5 of this decision:

> *"the government is not prosecuting LeBeau for having made claims about his products. Rather, it is prosecuting LeBeau for his acts—his attempt to profit from the sale of a product—which he represented to have palliative properties—without having received approval to do so."*

The wording of the statement is contradictory. The 7th circuit panel states that the government is not prosecuting LeBeau *"for having made claims about his products."* If the government is not prosecuting LeBeau for the statement ***"reduces food allergies"*** did the government prosecute LeBeau for making a *"profit from the sale of a product – which he represented to have palliative properties – without having received approval to do so."* What "palliative properties could the 7th circuit have possibly referred to in its statement other than "reduces food allergies," or did the 7th circuit state it was illegal for the defendant to sell a food based supplement and make a profit *"without having received approval to do so"*?

The first part of the statement was LeBeau was not prosecuted for having made claims (reduces food allergies) about his product - Perfect Colon Formula while the last part of the statement suggests that LeBeau was prosecuted for making a profit from the use of this health claim without receiving prior approval from the FDA. The 7th circuit panel says in one breath that LeBeau was not prosecuted for his speech about "Perfect Colon Formula" being "reduces food allergies", but was prosecuted for making a profit from the use of the health claim in distributing the fiber formula.

However, the facts of this case starting with Doc 1, the "Information" filed on Dec 7, 2010 and the Plea Agreement make it absolutely clear that the alleged offensive conduct was "speech". The FDA/DOJ has totally failed to explain how commercial speech on the intended use of a food converts it into a drug. The government never claimed a change in the composition of Perfect Colon Formula occurred either before of after the alleged offensive conduct of the health statement "reduces food allergies."

Since I was prosecuted for the use of the health claim "reduces food allergies;" this case is clearly a First Amendment case. The issue is-not one of drugs but rather the FDA action of total suppression of scientific research used by the defendant in commercial speech about Perfect Colon Formula

Caronia was convicted for sharing scientific research not preapproved by the FDA in regards to the off label use of Zyrem, Although convicted by a jury, on appeal, the case was reversed on First Amendment grounds.

On page 9 of my Petition for En Banc I wrote:

The similarities of US v. Caronia and US v. LeBeau

> The similarities are that 1.) The FDA did not preapprove commercial speech that was used about either product. 2.) In both cases, the defendants asserted a defense based on the First Amendment. 3.) The alleged offense involved commercial speech about two different products either shipped, or intended for shipping in interstate commerce.
>
> In both Caronia and in my own case, the government sought to criminalize commercial speech that was supported by scientific research and was truthful and not misleading and was publicly available at the United States National Library of Medicine. The 2nd Circuit upheld Caronia's First Amendment right to share expert scientific opinion that was truthful and not misleading about "off label" uses for Xyrem.
>
> Although the products are different in composition, with Xyrem being a patented drug, and Perfect Colon Formula being a food supplement, both defendants share a common defense of their products by sharing of scientific research. In both cases the FDA, by criminalizing the use of commercial

speech, violated Caronia and LeBeau's First Amendment right of freedom of speech and the press.

Commercial Speech - Central Hudson v. Public Service Com (447 US 562)

A First Amendment case on commercial speech

The government's action is suppressing speech about Perfect Colon Formula and the continued total suppression of scientific research from the National Library of Medicine is opposed, although in a different context, in the case of Central Hudson regarding the Public Service Commission opposition to advertising by Central Hudson to promote the use of electricity at a time when energy conservation was state policy.

In Central Hudson Gas and Electric Corp v. Public Service commission of New York (447 U.S. 562) it was Held:

> *(a) Although the Constitution accords a lesser protection to commercial speech than to other constitutionally guaranteed expression, nevertheless, the First Amendment protects commercial speech from unwarranted government regulation, For commercial speech to come within the First Amendment, it must concern lawful activity and not be misleading….."*

Note: LeBeau's distribution of Perfect Colon Formula as a food-based supplement was lawful activity, and the use of the term *"reduces food allergies"* was not unlawful activity as the statement was truthful and based on scientific research cited in Doc. 28 and Doc. 75 and filed in the district court.

Justice Powell also stated in Central Hudson:

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

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

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

Reasons for Granting this Petition for Writ of Certiorari

1. The 7th Circuit 3 judge panel decision conflicts with a decision of the United States Supreme Court. In the case of **Central Hudson v. Public Service Com (447 US 562)**l the Supreme Court found that total suppression of commercial speech violates the First Amendment. Total suppression of scientific research used in commercial speech is current FDA policy.

2. Conflicts over the legal definition of "drug" between several court cases and the Congressional Record of 1906.

3. Conflicts between Congressional intent indicated in the Congressional Record in 1994 in passing DSHEA and the FDA's persistence in classifying food and nutritional supplements as "drugs" based on "speech" instead of their composition based on the law (DSHEA).

4. The panel decision of July 5th conflicts with the findings of the Caronia case. In "**U.S. v. Caronia 703 F. 3rd 149"** (Dec 3, 2012 2nd Circuit 2012) the 7th Circuit panel ignored the First Amendment arguments that were upheld on appeal in Caronia. In my Appeal brief, I presented my arguments on the similarity of my case and Caronia on the issue of citing scientific research and the use of it in commercial speech. It should include, if the First Amendment has any meaning at all, the right to use in "***commercial speech***" published scientific opinion, testimonials, and medical hypothesis on how food, water and other natural non-patentable remedies may affect structure, function, the prevention of disease, and other health benefits.

Total suppression of commercial speech is not "government of the people," but a government of a privileged wealthy class, millionaires, billionaires, banks, and big drug companies who are major donors to the campaign coffers of politicians. Suppression of speech and restraint of trade is tyranny. Tyranny does not belong in a free society.

5. **The financial benefits of this case has national importance.** Since the passage of the Affordable Health Care Act, the cost of insurance has skyrocketed. The beneficiaries of "Obamacare" have been the very poor who receive free health care, and for persons with preexisting condition. No doubt, those with pre-existing conditions and persons living in poverty needed this government intervention. However, everyone else, including the middle class, has had insurance premiums double and even triple since the passage of Affordable Health Care Act.

The economic burdens placed on the shoulders of the middle class would be reduced substantially if government policy emphasized prevention of major illnesses. Prevention requires education. Education is blocked if the dissemination of scientific research is deemed illegal. This can be achieved with a decision of the U.S. Supreme Court that recognizes that defining a drug by intent alone directly suppresses commercial speech and is counter to the very purpose of the First Amendment. If the Supreme Court finds that a drug must have the material "**composition of a drug**" to be a drug, it will end the continuing violation of First Amendment rights of commercial speech. It will remove FDA's regulatory padlock from the National Library of Medicine.

The public will become more educated about the relationship between food and their health and will be able to make better-informed choices and decisions. By supporting the opinion of the 2nd Circuit in the Caronia decision, it will also free up both patented and generic drug manufacturers to share current scientific opinion about the drugs they

manufacture and distribute them without the expense and delay of seeking government approval of commercial speech through the New Drug Application process.

New information will flow from scientific research to the public from manufacturers of patented drugs, generic drugs, dietary supplement manufacturers, food distributors and other non-patentable natural remedies. These basic changes in how the law is applied will level the playing field for all and protect the right of manufacturers and distributers to state the intended use of their respective products and cite scientific research in commercial speech.

With over 100 million people using dietary supplements, health foods, patented and generic drugs, getting the federal government out of the way in stopping the flow of scientific research and opinion would be in everybody's interest. Because of its national importance in the potential release of millions of scientific studies from the National Library of Medicine, and other published and unpublished studies, this case has national importance and should be certified for review.

Conclusion

For all the foregoing reasons, Petitioner asks the U.S. Supreme Court to certify this case for review. Thank you for your consideration of this request.

Dated this 13th day of October, 2016

Conrad E LeBeau Pro Se
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Certificate of Supreme Court Rule 12(2) Certification

The undersigned hereby certifies that Petitioner has prepared this Petition under Rule 33.2 and mailed 10 hard copies of this Petition for Writ of Certiorari and 10 copies of the Motion to Proceed *In Forma Pauperis* by PRIORITY MAIL USPS to –

CLERK'S OFFICE, U.S. Supreme Court, 1 First St NE, Washington DC 20543

Dated: Oct 13, 2016

Conrad E LeBeau
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CERTIFICATE AND PROOF OF SERVICE

The undersigned Petitioner (Appellant), Conrad E LeBeau, hereby certifies that on Oct 13, 2016, pursuant to Rule 29, one copy of my Petition for Writ of Certiorari was served on AUSA Jonathan Koenig,, 517 E. Wisconsin Avenue-Room 530, Milwaukee, Wisconsin 53202, counsel for the government in this action by mailing the copy by priority mail to AUSA Jonathan Koenig.

Dated: Oct 13, 2016

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