UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff

v. Case No 10-CR-253

CONRAD E. LEBEAU

Defendant - Appellant

Defendant LeBeau's Appellate Brief to the United States District Court

I Introduction

This brief was written primarily by the defendant, Conrad LeBeau, representing himself pro se, and was reviewed by an attorney Joanna Perini from the Federal Defender's office for compliance with the Court rules. This appeal is for a misdemeanor criminal conviction and sentence from the Court of Magistrate William E Callahan (Doc 78 on August 7 2012) for the defendant Conrad LeBeau (not Vital Health Products Ltd).

Due to the 30-page limit allowed for this brief, the main issues addressed in this brief from the plea agreement are listed below in bold lettering and are paragraphs 1, 6 and 8, with No 2 referenced because of the FDA practice of merging the terms "drug" and "new drug." The eight original legal issues from the Plea agreement (page 11-12 or paragraph 26) are listed with the leading words of each paragraph, although issue no 7 has been dropped:

1. **Overbreadth – Definition of the word "drug"……..**
2. Arbitrary definition of "New Drug"……..
3. Doctrine of Legal Impossibility
4. Doctrine of Economic Impossibility
5. Public Policy and Third-Party Labeling
6. **Conflicts between FDA policy and the public policy of the NIH and Congress**
7. ~~21 U.S.C. Sec 355 hearing before report of criminal violation~~ (THIS ISSUE WILL NOT BE APPEALED OR ADDRESSED HERE)
8. **Restraint of Trade and violations of the U.S. Constitution (1st, 9th, and 10th amendments)……**

While numerous issues are presented for appeal, the Court is really faced with one main over-riding question: When the FDA's definition of "drug" is so broad and arbitrary that even the salad bar and fruit basket cannot escape their regulatory scalpel; when common foods are treated as drugs because of their health promoting and medicinal value; when the FDA restrains speech and prohibits individuals from providing factually truthful and accurate information on the health benefits of foods and nutritional supplements they distribute; when the intent of the lawmaker is over-ridden by expanding legal definitions of what a "drug" is and what a "disease" is; when the FDA criminalizes the sharing of scientific research from the National Library of Medicine; and assumes powers not granted in Article 1, Section 8 of the U.S. Constitution; is this a violation of the 1st, 9th and 10th amendments?

For purposes of this brief, I will usually refer to the plaintiff as the "FDA." Transcripts for the Jan 13, 2012 plea hearing (Doc 59) and the August 7, 2012 sentencing hearing (Doc 78) are filed as Doc's 96 (Jan 13 2012 plea hearing) and Doc. 97 (Aug 7th 2012 sentencing).

II **BACKGROUND**

A. Wikipedia on Pharmaceutical Industry's influence in Washington

"The top twenty pharmaceutical companies and their two trade groups, Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Industry Organization, lobbied on at least 1,600 pieces of legislation between 1998 and 2004. According to the non-partisan Center for Responsive Politics, pharmaceutical companies spent $900 million on lobbying between 1998 and 2005, more than any other industry. During the same period, they donated $89.9 million to federal candidates and political parties, giving approximately three times as much to Republicans as to Democrats.[1] According to the Center for Public Integrity, from January 2005 through June 2006 alone, the pharmaceutical industry spent approximately $182 million on Federal lobbying.[2] The industry has 1,274 registered lobbyists in Washington D.C. [3]" ……..

"The lobby's influence in securing the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003 was considered a major and controversial victory for the industry, as it prevents the government from negotiating prices with drug companies who provide those prescription drugs covered by Medicare. As a result, 61 percent of Medicare spending on prescription drugs is direct profit for pharmaceutical companies.[4]

The Wikipedia article is well documented with 12 referenced articles and 5 external links. "Pharmaceutical Lobby" is available at (http://en.wikipedia.ord/wiki/Pharmaceutical).

Money buys influence. Money donated to politicians buys face time to promote political appointees within the FDA to key managerial positions. These political appointees are the friends and working associates of Big PhRMA. They include Wall St lawyers as well as many doctors who get paid big bucks to write reports and say nice things about patented pharmaceutical drugs. The Center for Drug Evaluation and Research (CDER) is a key division within the FDA that Big PhRMA wants under its wing.

An interview with a former CDER scientist is published online at **truth-out.org.** The former FDA reviewer is Ronald Kavanagh B.S. Pharm. who worked at CDER from 1998 to 2008. In this interview, he discusses the pressures honest FDA scientists are under from their managers. FDA managers who want speedy approval of new drug applications also help design a regulatory system that eliminates competition from traditional medicine - the use of low cost, non-patentable food, herbs, nutritional supplements, water, and other natural remedies. A link to the truth-out article can be found at keephopealive.org.

B. FACTUAL BACKGROUND

This case evolved from the U.S. Food and Drug Administration allegation against LeBeau that he shipped in interstate commerce a drug that was an unapproved new drug distributed by LeBeau under the brand name of **Perfect Colon Formula** which sometimes included a handout flyer. The contents of the handout flyer had a link to it on the defendant's website under Perfect Colon Formula No 1. Three words "reduces food allergies" on the website at myvitalhealth.info which were reprinted from the handout flyer, is the basis of the FDA's case against the defendant.

The handout flyer had, for several years, been mostly unchanged as to the information it contained. After receiving a letter from FDA attorney Nathan Sabel around November 3rd, 2009 and speaking to him on the telephone later that day, and again a day or two later, he said that "reducing food allergies" was a disease claim for Perfect Colon Formula. I responded by telling him that I was not aware it was a disease claim and would change it. Later that day, I dropped the word allergies and substituted the word "sensitivities" that I felt certain was not a disease claim. The change was also made on my website.

Over a period of the past two years, this case has evolved to have a substantial number of legal issues, possibly even more than the Affordable Patient Health Care Act as decided by the U.S. Supreme Court in June of 2012.

On Jan 13, 2012, a Conditional Plea Agreement (Doc 58) with a plea of guilty (without conscious intent and based on the Court's interpretation of the law) was negotiated a few days earlier between the government and the two defendants as separate agreements, Vital Health Products Ltd, on one hand and Conrad LeBeau, as the other. The conditional plea agreement was accepted by Magistrate William Callahan on Friday, Jan 13, 2012. At the hearing, both defendants were represented by Federal Defender Joanna Perini (Doc 59).

After the conditional plea of Jan 13th 2012, new issues were raised by the defendant in a presentence statement he filed on April 17 2012 - in which the defendant sought to have his plea of guilty set aside for 5 reasons (Doc 64), and Magistrate Callahan's Decision and Order of May 29th 2012 that denied this request (Doc 71). The hearing to pronounce sentencing that was scheduled for April 20th 2012 was delayed several times and was eventually set for August 7, 2012.

Finally, a second supplemental statement filed by the defendant on July 26th, 2012 (Doc 75), sought to introduce scientific evidence under **Fed. R. Evid 803(18)** that allows

"**Learned Treatises**" of scientific and medical opinion to be introduced as evidence. The Government's response in (Doc 76) and my reply on August 6th, 2012 (Doc 77) were the last documents filed prior to the August 7th, 2012 sentencing hearing. The court is asked to review the scientific articles and abstracts in Doc's 75 and the government's response in Doc 76 and my final comments in Doc 77 as the very first set of documents to review after reading this brief.

In Doc. 75 LeBeau alleged untruthfulness in the FDA's answer to 2 of 4 Freedom of Information Act requests (FOIA) files sought on Oct 11, 2011. LeBeau alleged in Doc 75 that the FDA untruthfulness of their answers to the FOIA (for files described in 3 and 4) violated his 5th Amendment right to due process by withholding exculpatory scientific opinion from the National Library of Medicine that would assist him in his defense at the jury trial scheduled for Jan 25th, 2012. By denying that any searches of medical databases were done for any of the defendant's products and further refusing to list any medical databases as sources of expert scientific opinion including the Federal Government's own National Library of Medicine (PubMed and Medline), further violated the 6th amendment right to face my accusers. I also sought a court order to enter a number of medical abstracts [Learned Treatises] into the court record as evidence to be reviewed by an Appellate Judge under Rule 803 (18). The Learned Treatises filed supported the defendant's statements about his own product [Perfect Colon Formula]. Judge Callahan did not respond to the second presentence statement filed July 26, 2012 (Doc 75).

III **ARGUMENT**

If the labeling of Perfect Colon Formula had been misleading, untruthful, or not based on published scientific research, there would be no meaningful purpose in filing this appeal.

However, because the alleged offense, (three words on a handout flyer "**reduces food allergies**") a. was one of a 12 benefits or effects listed on the handout flyer for Perfect Colon Formula, and b. this piece of literature was used to help promote the sale of Perfect Colon Formula, and c. the statements on the handout flyer was truthful and not misleading, and d. was based on published scientific research, that my legal right to share truthful scientific research with the public was violated by the FDA.

The right of free speech and press is protected under the First amendment. FDA suppression of this literature obstructs freedom of the press and the end effect of these actions constitutes **"restraint of trade"** by **"restraint of speech**." By branding LeBeau's product as a "drug" and an unapproved "new drug," with the tactic of (Regulatory McCarthyism) or (guilt by association), the FDA censored the intended uses of labeling and advertising for Perfect Colon Formula.

The FDA's actions collectively restrained the ability of the defendant to market Perfect Colon Formula # 1 in interstate commerce. The FDA policy of "restraint of trade" is to pick as winners the marketers of FDA approved patented drugs and to make all the lower cost competition of the use of food as medicine illegal. This practice pre-empts the First Amendment and the ultimate effect is "restraint of trade" that is not a power granted to Congress under Article 1, Sec 8 of the U.S. Constitution. Restraint of trade by abridging freedom of the press violates not only the first amendment rights of the defendant, but also "freedom of choice in medicine" reserved by the defendant under the 9th amendment. It further violates rights reserved to the states under the 10th.

IV. The scientific research that supported the truthfulness of statements made by this defendant about Perfect Colon Formula.

The magistrate court ruled that the truthfulness of the information provided was not relevant to the government's ability to prove the 4 elements of the offense. However, there is no question that the statement at issue is true and supported by a plethora of scientific evidence. For example, the following 14 articles, all references in Document 75, and all found at PubMed at the United States National Library of Medicine (NLM) demonstrate the validity of the claim:

1. **Antiallergic Effects of Probiotics**, by Arthur Ouwehand (Journal of Nutrition -2004)
Page 1 *"Clinical trials have shown that the standard treatment of infants with atopic eczema,….. can be significantly improved through the addition of Lactobacillus rhamnosus GG or Bifidobacterium lactis Bb-12."*
Page 5 *"Prevention of allergic disease. In addition to treatment of allergy, it has been observed that selected probiotics can reduce the risk for the development of allergy*."
Page 6 *"Mechanisms by which probiotics may influence food allergy. 1) Improved mucosal barrier function. 2) Modulation of intestinal microbiota composition and activity. 3) Stimulated production of secretory IgA. 5) Change in mucus production. 6) Direct immune modulation."* (This article is supported with 36 footnotes referencing other articles at the NLM Pubmed)

2. Search terms: plantarum food allergy. **Heat-killed Lactobacillus Plantarum L-137 suppresses naturally fed antigen-specific IgE production by stimulation of IL-12 production in mice**, by Murosaki S et al; J Allergy Clin Immunol, Jul 1998.
("CONCLUSION: our results suggest that L. plantarum L-137, a potent IL-12 inducer, is useful for the prevention and treatment of food allergy.")

3. Search terms: rhamnosus food allergy. **Clinical Indications for Probiotics: an overview**, by Goldin BR et al (Clin Infect Dis, Feb 1 2008)
Abstract: *"randomized double-blind studies have provided evidence of probiotic effectiveness for the treatment and prevention of acute diarrhea and antibiotic-induced diarrhea, a well as for the prevention of cow milk-induced allergy in infants and young children."*

4. Search terms: longum food allergy. **Immunostimulatory oligodeoxynucleotide from B. longum suppresses Th2 immune responses in a murine model**, by Takahashi N et al (Clin Exp Immunol Jul 2006)
Abstract: *"….probiotics might be useful in preventing allergic disease."*

5. Search terms: acidophilus food allergy. **Effect of oral probiotics administration on ovalbumin-induced food allergy mouse model**, by Kim JY et al (J Microbiol Biotechnol Aug 2008)

Abstract: *"The groups treated with probiotics had decreased levels of degranulated mast cell, eosinophil granules, and tail scabs. These results indicate that L. acidophilus AD031 and B. lactis AD011 might be useful for the prevention of allergy."*

6. Search term: plantarum allergy. **Improvements in seasonal allergic disease with Lactobacillus plantarum No. 14**, by Nagata Y et al (Biosci Biotechnol Ciochem Sep 2010)

Abstract: *" We conducted randomized, placebo-controlled, double-blind studies of Lactobacillus plantarum No. 14 (LP 14) in female students with seasonal allergic diseases…in the LP 14 group, the percentage of Th1 cells significantly increased."*

7. Search terms: plantarum allergy. **Suppression of type-1 allergic responses by oral administration of grape marc fermented with Lactobacillus plantarum**, by Tominaga T et al (Immuopharmacol Immunotoxicol Dec 2010)

Abstract: *"These results indicate that oral administration of FGM, prepared from Koshu grape for white wine….. could suppress both phases of type-1 allergic responses."*

8. Search terms; plantarum allergy**. Efficacy of Lactobacillus strain HSK201 in relief from Japanese cedar pollinosis**, by Hasegawa T et al (Biosci Biotechnol Biochem Dec 2009)

Abstract: *"Although this was a preliminary study with 19 employees of our own company serving as subjects, the results suggest that ingestions of the HSK201 strain (L. plantarum) alleviates pollinosis symptoms during the period when pollen exposure is low and the symptoms are mild."*

9. Search terms: plantarum allergy. **Therapeutic advantages of medicinal herbs fermented with Lacto bacillus plantarum in topical application and its activities on atopic dermatitis**, by Joo SS et al (Phytother Res Jul 2009)

Abstract: *"The present study examined whether selected herbal extracts fermented in Lactobacillus plantarum (FHE) possesses anti-AD properties….. the results presented in this study suggest that FHE may have therapeutic advantages for the treatment of AD…"*

10. Search terms: plantarum allergy. **Immunomodulatory properties of Lactobacillus plantarum and its use as a recombinant vaccine against mite allergy**, by Rigaux P et al (Allergy Mar 2009)

Abstract*: "both wild-type or recombinant L. plantarum reduced airway eosinophilia following aerosolized allergen exposure and IL-5 secretion upon allergen stimulation….. L .plantarum producing Der P 1 represents a promising vaccine against house dust mite allergy."*

11. Search terms: plantarum allergy. **In vivo and in vitro immunomodulation of Der p 1 allergen-specific response by Lactobacillus plantarum bacteria**, by Hisbergues M et al (Clin Exp Allergy Sep 2007)

12. Search terms: plantarum allergy. **Recombinant Lactobacillus plantarum inhibits house dust mite specific T-cell responses**, by Kruisselbrink A et al (Clin Exp Immunol Oct 2001)

Abstract: *"recent evidence suggests that chronic exposure to lactobacilli, which are part of the normal intestinal flora, inhibits the development of allergic diseases….. these data suggests that recombinant L. plantarum may be a suitable candidate for the treatment of allergic disorders."*

13. Search terms: plantarum allergy. **Inhibitory effect of Lactobacillus plantarum K-1 on passive Cutaneous anaphylaxis reaction and scratching behavior in mice**, by Jang S.E et al (Arch Pharm Res Dec 2011)

Abstract: *"Based on these findings, LP may improve allergic diseases such as anaphylaxis, atopic dermatitis, rhinitis and Pruritus…"*

14. **Probiotics, prebiotics and synbiotics**, by de Vrese M and Schreaenmeir J, (Adv Biochem Eng Bioechnol. 2008

Abstract: *"Well-established probiotic effects are …..6. Prevention or alleviation of allergies and atopic dermatitis in infants."*

Note - 7 categories of probiotic benefits were listed in this abstract.

This last article also discusses the synergistic benefit of combining prebiotics (soluble and insoluble fibers) with probiotics (strains of friendly intestinal flora). Perfect Colon Formula (1) is an example of a synbiotic – a combination of fibers and inulin and probiotics to maximize the growth and benefits of the probiotics in the formula.

The anti- allergic effects of four of the six probiotics used in Perfect Colon Formula are supported by the 14 scientific articles and abstracts listed here and filed with Doc 75. These "Learned Treatises" establish beyond any doubt that the statements made on a handout flyer about Perfect Colon Formula were truthful, not misleading, and were based on scientific research that was publicly available and retrieved from the United States National Library of Medicine.

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1. Perfect Colon Formula contained a blend of fibers and probiotics including ground Flaxseed, Chicory inulin, plus 6 probiotics including L Plantarum, L. Rhamnosus, L. Acidophilus, L. Salivarius, B. Bifidum, B. Longum, Rice Bran, Apple Pectin, Glucomannan from Konjac Root, Beet Root, Calcium, and Magnesium.

V. The first issue of the Plea Agreement – page 11

1. **Overbreadth - Definition of the word "drug**" from the Food and Drug Act of 1906 (21 USC 321 (g)(1). The FDA's expansion of the definition of the word "drug" goes beyond "Patented Drugs" and "Nostrums" and includes "foods" that were not intended by the Congress of 1906 to be defined as drugs. The FDA's expanded definition of the word "drug" to include "food" violates the Doctrine of Overbreadth, and is an over-reach of regulatory powers. Defendant contends that Perfect Colon Formula was a food, and therefore, is not a substance intended to be regulated as a drug within the meaning of the original Food and Drug Act.

The definition of the word "drug" is overly broad insofar as Perfect Colon Formula was a food, and food was not intended to be regulated as drugs within the meaning expressed by members of Congress from the Congressional Record of 1906. Assuming that the intent of the lawmaker is the law, the Congressional Record of 1906 has relevance in this case. 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 – Congressional Record page 897 Sec 6.under Definitions.)

A. The Term "Any Substance" Is Ambiguous Because It Is So Broad

In 1906, the term "drug" had only one meaning: patented medicine. The pharmaceutical industry supported the Pure Food Act to include nostrums, that competed in the marketplace with the more expensive patented medicines, to also be defined as "drugs" and thus subject to government regulations that prohibited fraudulent advertising. Today the pendulum has swung so far in the direction of muzzling speech that truthful scientific research and information is censored under the law as currently applied.

I have added language from the Congressional Record to the *"any substance intended*" beginning phrase of the Pure Food Act of 1906 that defines what a drug is to clarify and limit

the breadth of the definition to the intended labeling targets of the law. I have reworded it as follows:

also any patented drug, nostrum or substance (not including food, edible herbs and spices) intended to be used for the cure, mitigation, or prevention of disease.

The above language that I added clarifies the meaning of "what substances" were to be defined as drugs and is consistent with the speeches given by members of Congress on the intent of the Pure Food Act of 1906 and the first legal definition of the term – "drug."

The definition under Sec. 6 says "any substance" but excerpts from speeches found in the Congressional Record of 1906 that I reviewed at the Milwaukee Public Library was that the target of the original "Pure Food Act" was directed at patented drugs, fraudulent quack remedies (snake oil medicine) and nostrums. Nostrums were medicinal formulas with contents and ingredients including opiates that were not disclosed on the product label and were kept secret from the consumer.

The nostrums and quack remedies that made fraudulent claims as well as patented drugs with secret ingredients (opium, morphine, heroin, and cocaine) in the product and other addictive or deleterious substances was the legislative target of this Act. See page 20 Doc 28, and pages 18 through 24 of Doc 28 of the Motion to Dismiss which shows the evidence from the historical record that those two words "**any substance**" in the definition of the term "drug" was not intended to include the air you breathe, the water you drink, or the food you eat. The composition of water and food does not require labeling and is self-identified by virtue of what it is. In fact, food, water, edible herbs, and spices were used as medicine from the time of the ratification of the US Constitution in 1792 and in use in 1906 when the Pure Food Act was passed.

"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 any addictive substances including alcohol, morphine, opium, heroin, cocaine, chloroform, cannabis indica, and other dangerous or addictive substances. Mr. Webb and many other Senators spoke in favor of requiring the listing of these ingredients on the bottles as many patented drugs and nostrums did not list these addictive and other deleterious ingredients on the label. 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 – 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 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, is stated 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* [medicine] *for* [common ills]*, but also the greatest preventive against evils* [opiates in patented drugs and nostrums] *with which humanity seems to be afflicted*."
>
> Note – Words in brackets were added by me to clarify the meaning of the statement within the context of how it was used in the Congressional Record.
>
> End of excerpts from the Congressional Record

Senator McCumber's statement has within it two distinct thoughts - that healthy food and a proper diet will prevent disease which he expressed with these words: "*proper diet …., is not only the greatest panacea for* (medicine for common ills) but "*the greatest preventative against evils"* which "*humanity seems to be afflicted*." This is a reference to the use of nostrums and patented drugs that contain the "evils" (opiates) as the second point of his statement.

The speeches found in the Congressional Record of 1906 provide a compositional description of the kinds of "substances" Congress wanted to be defined and regulated as "drugs" with opiates having the top priority. The list also included formulas described in the National Formulary and United States Pharmacopia plus patented medicines (drugs) and nostrums. What is not found in the Congressional Record is that water, food, spices, and edible herbs that were used for their medicinal value for thousands of years, and continue to be used for their medicinal value to this day.

The U.S. Constitution does not provide for the Executive Branch of Government or the Federal Courts to pass laws. Article 1. Section 8, delegated certain powers to the Congress and reserved the balance of those powers to the States under the 10th amendment. When FDA attorneys under the Executive Branch of Government persuaded the Federal Courts to expand the definition of substances that could be defined as "drugs" they both exceeded their Constitutional obligations. They did it with the best of intentions, to protect the public against what they believed were fraudulent, untruthful, or misleading health claims. For the most part, the Courts trusted the government attorneys that sought to expand the powers of the FDA. However, if foods were never intended by their composition to be defined as "drugs," then what is being regulated in interstate commerce is not drugs but speech.

The current codified law (21 U.S.C. Section 321 (g)(1)(B) that defines "drug" substitutes the word "articles" for "substances" found in the original 1906 Pure Food Act. This change

occurred in 1938 and may have been made to accommodate adding diagnostic medical devices to the definition of "drug." Other changes to the FDCA were made in June of 1938 that included the definition of "new drug."

In its reply to my motion to dismiss, the FDA cited a case from 1920. It was Bradley v. United States, 264 F. 2nd 563 (5th Cir.), a case involving health claims made for mineral water. The mineral water case from 1920 was the oldest one cited by the government before revisions to the FDC Act in June 1938 that defined "new drug." Two other cases cited by the FDA (Doc 37 page 5) were U.S. v. 250 Jars of Honey 218 F Supp 208 (1963) and U.S. v. Hohensee, 243 F. 2nd 367 (1957 peppermint tea). What these 3 cases have in common is that health claims were made for 3 substances that ordinarily would be considered "food."

B. Are peppermint tea, honey and mineral water drugs?

Since 1920 to today, you can legally buy peppermint tea, honey, and mineral water over the counter at just about any grocery store or health food store in any state in the union. These items are foods. Good manufacturing practices (GMP) for these food products, under the FDCA, are based on GMPs for food, not drugs. Mineral water, honey, and peppermint tea not only have value as foods but traditionally have been used for medicinal purposes as well. In all three cases I could not find any judicial mention or reference to the Congressional Record of 1906 that determined the Congressional intent in defining the word "drug."

It should be noted that the oldest case, the one on mineral water from 1920 cited no previous court case from any Federal District or Appellate Court. This case could be the origin or genesis of expanding the definition of the word "drug." Defining mineral water by its intended use for preventing or mitigating disease has had a domino effect on multiple court

decisions that followed. It was small step from defining "mineral water" as a drug to adding honey and peppermint tea to the list, and in the present case – "Perfect Colon Formula."

As for the FDA's reference to Vital Health's 1993 products "White Birch Mineral Water" and "Licorice Root Tea," (page 6 Doc 37) being affirmed as "drugs" in the 7th Circuit Court of Appeals, the defendant was not aware and did he bring up the issue of Congressional intent from the Congressional Record of 1906 as a legal argument. Therefore, neither the opinions of the District Court of Honorable Robert Warren nor the 7th Circuit Appellate Court were asked to address this issue. Thus, those cases are not binding on this court as it relates to the issues of this brief. Food based medicine has been around for many centuries and was lawful here in the United States from 1792 to 1892 plus about 20 more years.

C. Why the definition of "drug" violates the Doctrine of Overbreadth

1. First, the overly broad definition of "drug" used today that includes "foods" that are intended to prevent disease exceeds the intent of the Congress of 1906.

2. The second violation of the Doctrine of Overbreadth is that enumerated powers granted to Congress under Article 1, Section 8, U.S. Constitution, does not give Congress the power to abridge or censor speech about the medical value of traditional medicine (foods, spices and edible herbs) that are distributed interstate. To assume the power to regulate commerce does not include the power to regulate speech about that commerce. If such an expansion of powers were intended, they are not only prohibited under the First Amendment, they are not granted to Congress in Article 1, Section 8, of the U.S. Constitution. The balance of powers not delegated to Congress in Art.1, Sec. 8 are reserved to the States under the 10th Amendment.

Congress has the right, under national security, to protect the public from fraudulent advertising, and from foods, drugs, and other products that are inherently dangerous to the

public health and safety. The safety of citizens are primary responsibilities for all three branches of the government. The Federal Government has a right, for purposes of national security, to stop someone from marketing instructions to the public on how to build a weapon of mass destruction, like a nuclear bomb. That is not the issue here.

The issue is that overly heavy-handed paternalistic laws and regulations are picking winners and losers in the private marketplace. The powerful pharmaceutical companies, with their army of lobbyists, promotes attorneys and the doctors it favors to key positions of authority within the FDA. Heavy political donors get something poor people don't get – face time with the political leaders in power. PHARMA has a vested interest in having their friends employed in the food division and CDER within the FDA. CDER is the Center for Drug Evaluation and Research.

Employees within the FDA that serve the interests of the big drug companies have had an effective strategy for increasing PHARMA's bottom line - profits. The overall strategy is to make patented drugs the only products that can be legally marketed for preventing or mitigating disease, and to make lower cost competing products that provide the same health benefits illegal. With employees within the FDA favored by Wall St, this is easily accomplished with the following 5 conditions.

First, define as a "drug" any article (substance, thing) that prevents or mitigates disease. Second, to expand regulatory powers of the FDA over competing products, define every possible health condition, even the most minute, as a "disease." Third, define "labeling" in the broadest of terms that includes literature not actually attached to the product, but also includes books and articles shipped separately. Fourth, write regulations under the Administrative Procedures Act (APA) that impose cost burdens impossible to recover for un-patentable foods and other health products. Fifth, require a patent number, for final FDA approval of a New

Drug Application (NDA) that is impossible to obtain from the patent office for food, spices and herbs that are not patentable because they are natural and not new in composition. On the other hand, modern FDA approved drugs are patentable because they are man-made synthetic molecular compounds.

The preceding 5 conditions create an exclusive market monopoly for the owners of patented drugs with no restrictions on the prices they charge consumers. This is bad public policy as it serves the financial interests of rich men of Wall St while denying access to other low cost treatment options (traditional medicine, proper diet, nutrition, food and herbs) for the poor and the middle class on Main Street.

D. Three questions for the FDA and the Court to decide

1. Does the composition of Perfect Colon Formula (PCF) make it a drug?
2. Does the label change the material composition of Perfect Colon Formula into a drug?
3. Is the "article" I wrote about Perfect Colon Formula (the handout flyer) the drug?

E. Defendant's arguments on the first question

On the first question, defendant is not aware of any ingredient in Perfect Colon Formula that is a drug by its composition. Flaxseed, inulin from chicory root, pectin from apples or citrus rind, beet root powder, glucomannan (a fiber form konjac root), two minerals calcium and magnesium, and the 6 probiotics in the formula are not patented or synthetic in origin. Does the FDA agree that this blend of fiber and probiotics are not drugs by their composition?

On the second question, the handout flyer I wrote to promote sales of Perfect Colon Formula listed 12 or more health effects and benefits that included these 3 words "reduces food allergies." Did the use of those 3 words in the handout flyer cause a material change or transformation of the ingredients inside the bottle of Perfect Colon Formula? Did the FDA find

any Zyrtec, Claritin, or Allegra or other drugs to treat allergies inside the bottle of Perfect Colon Formula?

Now, in Doc 75, in the attached exhibits pages 242 to 244 are a written report of searches done by clinical reviewer, Robert Mozersky, for "food sensitivity" and "food sensitivities" for various ingredients in Perfect Colon Formula. The result was that nothing was found in the database searches at PubMed, Medline and Embase. However, the defendant was not charged with violating the FDCA by writing on the handout flyer that PCF "reduces food sensitivities" but rather it was "reduces food allergies" that appears on the Information. In the 3-page statement by Robert Mozersky, I could not find any stated opinion that the expression "reduces food sensitivities" was a disease claim. Both versions of Perfect Colon Formula No 1 were marketed in 2009; one with "reduces food allergies" on the handout flyer. After my phone conversation with FDA Atty Sabel on November 3rd, 2009, I changed the wording to "reduces food sensitivities." By the FDA's actions, I assume that the handout flyer for PCF that said: "reduces food sensitivities" was not a disease claim while the expression "reduces food allergies" was considered a disease claim. Since the material composition of PCF was identical under both labels, the only element here that was allegedly illegal was the expression "reduces food allergies." Thus, speech as labeling is being regulated and not the contents of the bottle.

F. Argument on the 3rd question. Is the label (handout flyer) the drug?

What I wrote about Perfect Colon Formula that in the handout flyer was clearly the target of this criminal proceeding. Those 3 words "reduces food allergies" a reference to scientific opinion about the probiotics L. Plantarum and L. Rhamnosus was the alleged illegal action that the government says transformed Perfect Colon Formula into not only a "drug" but also an "unapproved new drug." The definition of "new drug" first requires the "substance" or "article" to first be a drug.

The definition of drug as defined in the Information under 21 U.S.C. Sec 321 (g) as:

"**articles** intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals or intended to affect the structure or any function of the human body"

Congressional intent is important when there is ambiguity in how a word is used in the law. Ambiguity can also occur when the same word has multiple meanings both in common use and in the dictionary. Ambiguity in how to interpret a word can lead to arbitrary application of the law. In Black's Law Dictionary, "substance" is defined as "Essence; the material or essential part of a thing, as distinguished from form."

The word "articles" unlike the word "substance" has multiple meanings that could be interpreted as labels and articles written about a substance. The word "article" could also mean a material thing as in the composition of a drug, or it could mean a published scientific article or the hand-out flyer, the article that accompanied Perfect Colon Formula. A literal reading of the definition of the word "drug" could mean it refers to an article written about a substance and not the substance itself or it could have both meanings simultaneously - one being the article as a material thing and the other being the label and its intended use.

G. What the FDA found offensive is the label: is the label itself the drug?

The FDA's position is that speech about how to use proper food and diet to prevent disease is criminal behavior. What the FDA finds offensive is not Perfect Colon Formula's composition, but the labeling of Perfect Colon Formula. In fact, the handout flyer about Perfect Colon Formula was not even physically attached to the bottle. To make a criminal case here, the FDA attorneys selected 3 words on the flyer and took them out of context and figuratively blew them up and glued them over the name "Perfect Colon Formula" and renamed it "Perfect Allergy Formula."

What is FDA is regulating here is not Perfect Colon Formula by its material composition as a drug, but by what was said about Perfect Colon Formula that they claim changed it into a drug. What the FDA does not explain is how speech about a food supplement transforms it into an illegal class of substances called "drugs." Since the facts clearly indicate that the composition of Perfect Colon Formula is not a drug, it is the label that has to be the drug. In plain English, it is labeling outside the bottle that is the alleged "drug." Since the government does not agree with 3 words used in the hand-out flyer, they allege it to also be an "unapproved new drug."

There is one small problem here – the label is not intended for ingestion. There are no instructions to throw away what is inside the bottle and eat the label to "reduce food allergies." Therefore, there is nothing about Perfect Colon Formula that is a drug. Its composition is not a drug and the label that has words on it that violate the law as it is currently applied is not intended to be ingested, therefore the label is not a drug either. The handout flyer as an article I wrote is not intended for ingestion so it is not the drug. So what is the drug?

As FDA attorneys apply the law, it is "unapproved speech" about Perfect Colon Formula that is called a drug and "unapproved new drug." The effect of making speech illegal by calling it a drug is to lessen and restrain the sales of Perfect Colon Formula. The law as the FDA applies it not only makes truthful scientific speech a crime, it also picks winners and losers in the marketplace. By restraining the sales of food for its medicinal value, it increases the sales of FDA approved drugs and the profits from marketing patented drugs. What the FDA is regulating here is not drugs or new drugs shipped in interstate commerce, but is regulating and censoring truthful speech about health products shipped in interstate commerce.

H. The reality test for a "drug"

In FDA's mind-set, the definitions of "drug" and "new drug" merge into one action of criminal illegality, although the statutes define "drug" and "new drug" separately. The reality test for any alleged drug is to remove the label or the language on the label that the FDA objects to and ask this question: Is the product by its composition (without the label) a drug?

The logical conclusion of these observations is that the product, Perfect Colon Formula; by it composition is not a drug. However, the handout flyer, described by the FDA, as an extension of the label on the bottle is the alleged illegal component associated with PCF. Since 3 written words are the only alleged offensive component of the product, it is speech that the FDA says is illegal. From a logical analysis, what the FDA calls the drug is the handout flyer, since it describes all the benefits and effects of using Perfect Colon Formula including the expression "reduces food allergies." It is speech about the product Perfect Colon Formula that the FDA says is illegal. It is because the FDA attacks the defendant's speech about Perfect Colon Formula, the FDA clearly shows its intent to violate the defendant's first amendment rights and does so with deliberate awareness of this violation. The FDA further knows that by prohibiting the printing of Perfect Colon Formula's health benefits, the FDA will reduce and restrain the sales of this product. Since the product by its composition is not a drug, the FDA is restraining and censoring written speech that accompanies a product shipped in interstate commerce. "Intent" is "thought" that is expressed in oral or written speech. When the FDA censors the intended use of food or nutritional products, it censors speech. What the FDA is doing under the banner of labeling is censoring speech on the label, accompanying literature, and advertising of a product shipped in interstate commerce.

The FDA position is that labeling, (written or oral speech), is not protected under the First Amendment when you are talking about a health or food product. The FDA position is

that you have the right to write about a health product as long as you do not manufacture or distribute it in interstate commerce. The flip side of FDA's position is that you can distribute the health product in interstate commerce but cannot tell anyone how it might benefit their health because almost every possible health benefit imaginable has been converted by the FDA into an illegal disease claim.

FDA uses a guilt-by-association method of reasoning by implying that certain words about a product cause the product to instantly become an illegal substance. In the 1950's, persons who talked to or traveled with a communist were communist sympathizers by the friends they kept, according to the late Senator Joseph McCarthy. Today, the FDA practices [Regulatory McCarthyism] better than Senator Joe McCarthy practiced his own brand of slander through guilt by association. With past court decisions that found mineral water, honey and peppermint tea to be drugs, they claim that any substance with medicinal value is a drug. In one broad and sweeping definition, they made illegal what was legal in the first century of our republic – the use of food and herbs as medicine.

The Federal Court of Appeals decided an important case on Dec 3, 2012 that is relevant to one of the issues discussed here – freedom of speech. It is the case of United States V. Caronia decided Dec 3, 2012

VI. United States v. Caronia _F.3rd._2012 WL 5992141 2nd Circuit Case No 09-5006-cr - Dec 3, 2012 - vacated on First Amendment grounds

This case was an appeal from a judgment based on the conviction of a jury for the United States District Court for the Eastern District of New York (Eric N. Vitaliano, J.) convicting defendant-appellant Alfred Caronia of conspiracy to introduce a misbranded drug into interstate commerce. On Dec 3, 2012, in a 2 to 1 decision, the case was VACATED and

REMANDED on the grounds that the First Amendment protected speech about the off label use of a prescription drug intended to be shipped in interstate commerce.

Background: Alfred Caronia was a pharmaceutical salesman who was marketing the FDA approved drug Xyrem for a condition (cataplexy - weak muscles) associated with narcolepsy. In a sting operation, a government agent recorded statements made by Caronia in response to questions on uses other than those that were FDA approved. This is known as off-label uses. Other uses suggested by Caronia included restless leg syndrome, fragmented sleep, and even Fibromyalgia. Because his speech suggested off label uses for Xyrem, the FDA charged him with misbranding and intent to ship a misbranded drug in interstate commerce. Caronia had a jury trial and was convicted. He appealed on the grounds that "he was convicted for his speech – for promoting the off-label use of an approved prescription drug – in violation of the First Amendment."

In Caronia, the Appellate court applied a four-part test to the government's case against Alfred Caronia based on the premier US Supreme Court case on the First Amendment known as Central Hudson (*Cent. Hudson*, 447 at 562). On page 37 of the Caronia Dec 3rd Order, Circuit Judges Raggi and Chin stated:

"Central Hudson sets forth a four-part test to determine whether commercial speech is protected by the First Amendment. *Cent. Hudson*, 447 U.S. at 566. First, as a threshold matter, to warrant First Amendment protection, the speech in question must not be misleading and must concern lawful activity."

"Second, to justify regulations restricting speech, the asserted government interest must be substantial."

"Third, the regulation must be directly advance the governmental interest asserted. i.d., to a material degree."

"Fourth, the regulation must be narrowly drawn and may not be more extensive than necessary to serve the interest. *Cent. Hudson*, 447 at 565-56."

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

The differences are: 1.) In the Caronia case, the product, Xyrem, had a unique material composition as a drug and it had a black box warning while Perfect Colon Formula was a natural food product that contained nothing new or original in its material composition and was not, therefore, either patented or patentable, and 2.) Xyrem was an FDA approved drug for a specific approved purpose (treating cataplexy caused by narcolepsy) while Perfect Colon Formula (PCF) was a lawfully produced food supplement containing a blend of fibers and probiotics for supporting colon and intestinal health. While Xyrem had marketing exclusivity and no competition, Perfect Colon Formula had no market exclusivity and was a low priced food supplement competing with other fiber formulas like Metamucil and probiotics products like Philips Colon Health and even yogurt.

The similarities are that 1.) Speech that was used about both products was not preapproved by the FDA. 2.) In both cases, the defendants asserted a defense based on the First Amendment. 3.) The alleged offense involved speech about a two different products either shipped, or intended for shipping in interstate commerce. In both cases, the additional speech that the FDA found offensive was not physically attached to the product's bottle. Actually, for Perfect Colon Formula offered on the defendant's website at myvitalhealth.info, it was a link to a reprint (in computer bytes) on the handout flyer that the FDA found offensive.

B. It takes more than words or computer "bytes" to turn foods into drugs

The defendant's central argument here is that it takes more than speech alone to transform a food into a drug; it would also take a change in material composition to transform a food into a drug. It is not humanly possible for speech alone or any label to change the composition of a substance inside a bottle. If that were possible, then fools gold could be

turned into real gold and an old car into a new car by speech alone. The Bible, as an historical document, reports that Jesus of Nazareth turned water into wine at the wedding feast at Canaan some 2000 years ago. Many of us believe that Jesus, as the son of man, was also the Son of God and had Divine powers, and could do that. Neither this defendant nor the government possesses these extraordinary powers.

At the time of passage of the Pure Food Bill of 1906. the only products called drugs were patented medicines. The Pure Food Bill expanded the definition of "drug" to include secret formulas called "nostrums" but no mention was to include food under the drug definition can be found in the Congressional Record of 1906. (See reprints from the Congressional Record in Doc. 30 – filed in hard copy due to its size)

C. Arguments: Why "Central Hudson" defends the speech "reduces food allergies" as applied to the marketing of Perfect Colon Formula.

First, based on *Central Hudson*, the speech "reduces food allergies" as used in context with other benefits listed in a handout flyer is truthful, not misleading, and is based on scientific research cited in Doc 75. The sale and use of a blend of probiotics and fibers as a food product is lawful activity.

Second, based on *Central Hudson,* the government interest here is not substantial as the products components are consumed daily. Examples being high fiber breakfast cereal, fiber supplements, whole grains, yogurt, and probiotic powders and capsules as sources of friendly flora. Also, there have been no claims of side effects or injury from the use of the aforementioned products or Perfect Colon Formula. There are no complaints from customers about this product.

Third, based on *Central Hudson,* it makes no sense for one branch of the U.S. government to allege criminal activity for sharing information about a formula with probiotics

that has anti-allergic effects when the U.S. government itself makes this same information directly available to anyone with a computer. The FDA, by categorizing scientific research shared with the public that was derived by the defendant from the United States National Library of Medicine (NLM) as criminal activity, contradicts the policies of Congress established in the year 2000 to make scientific available to the public. FDA policy of keeping a padlock on the NLM is contrary to the current public policy of Congress and the First Amendment. The FDA versus the NLM is akin to a house divided against itself. Prior to the year 2000, very few Americans lived close enough to the NLM to have direct access to it. Prior to the year 2000, online access required a password.

As a researcher and writer, I obtained a password from the NLM in 1994 and used it until about the year 2000 when a password was no longer needed. I have done thousands of searches at the NLM and read thousands of abstracts and many full text scientific articles in the past 17 years. See my arguments in Doc 28 and my reply to the government's brief (Doc. 40). Current FDA policy not only needlessly censors scientific research since the year 2000 but also runs counter to the open-to-the-public-direct-access-policy of Congress. Current FDA policy constitutes a regulatory padlock and censorship of expert information derived from the U.S. National Library of Medicine.

Fourth, based on *Central Hudson*, the FDA has not narrowly regulated speech based on health information that is untruthful or misleading, but broadly suppresses the referencing, printing and sharing of all scientific research on how foods, edible herbs, and spices prevent or mitigate illness; substances that are not drugs but their composition, but happen to share one characteristic with drugs and that is they also prevent and mitigate disease, just like drugs do, even though they are not drugs.

D. The broad brush of FDA's regulatory powers also violates the 9th and 10th amendments to the Bill of Rights, U.S. Constitution.

The effect of FDA's broad brush is to regulate and censor the shipment of speech, as used in the labeling of health products that are shipped in interstate commerce. Because the interstate commerce of the U.S. Constitution does not grant the FDA through Congress the authority to regulate and thus criminalize truthful speech used in interstate commerce, FDA attorneys use arguments based on the pure legal fiction that offensive speech magically changes food, spices and edible herbs into something that is harmful to the public, and therefore, warrants lawful penalties. Those who distribute foods, spices, edible herbs, and nutritional products with truthful information are then slandered by branding them as "criminals."

In 1792, when the U.S. Constitution was ratified, freedom of choice in medicine was a fact of life and the traditional use of food and herbs as nourishment as well as medicine was also a fact of life. Freedom of choice in medicine existed for this nation's first century from 1792 to 1892 plus about 20 more years, until the courts, at the urging of government attorneys, expanded the definition of drug to include substance beyond its original target of patented drugs and secret formulas known as nostrums, to also include food.

E. Censoring Commercial Speech causes Restraint of Trade

The book Materia Medica, originally written over 1000 years ago, was in print in 1792. It lists over six hundred botanicals used as medicine that was based on centuries of experiences. The book, Materia Medica, is even mentioned on FDA website at fda.gov. I mention Materia Medica here because it demonstrates that food and plant based medicine was the norm at the time of the ratification of the U.S. Constitution in 1792. If the founding fathers wanted Congress to regulate and restrain speech about the use of foods and herbs that were used for

their medicinal value, they would have said so. The fact that this is not mentioned as an enumerated power granted to Congress under Article 1, Section 8, of the U.S. Constitution, or in The Federalist Papers, and that the 10th amendment reserves to the states all powers not delegated to Congress, is an additional argument that the FDA has over-reached its regulatory powers under our Constitutional form of government. It is not reasonable to assume that the interstate commerce clause included the inherent power to censor truthful speech because that speech is linked to products shipped in interstate commerce.

Restraint of Trade is the end result of censoring speech about health products and foods shipped in interstate commerce. It is no secret that food-based medicine competes with the sale of high priced patented drugs due to their lower cost by a factor of 100 to 1000 to 1. It is in the public's best interest to have less expensive as well as less costly medicines that are also safe and effective. While the use of food for it medicinal value is lawful activity, the law as applied, makes the use of speech about how to use food for its medicinal value unlawful activity.

In the *United States v, Caronia*, the Second Circuit Appellate Court agreed with the First Amendment arguments of the defendant, Alfred Caronia, even though the defendant's speech was about the product, Xyrem, that was a drug by its composition. On the other hand, Perfect Colon Formula, by its composition is a food, not a drug. I would think that a First Amendment defense would be even more appropriate here. Defendant asks the court to find that censorship of speech that restrains trade in interstate commerce is not an enumerated power granted to Congress under Art 1, Sec. 8, violates freedom of the press under the First Amendment, violates the right of freedom of choice in medicine under the 9th amendment, and powers reserved to the states under the 10th amendment.

The 9th amendment is a source of unenumerated rights and "freedom of choice in medicine" is an universal human right as is "freedom of religion," which is an enumerated right

under the 1st amendment. While the 9th amendment is rarely used in jurisprudence, it was cited in *Roe V. Wade* 410 U.S. 113 (1973) to support the abortion rights of women. Should not Ninth Amendment rights also extend to include "freedom of choice in medicine" for all people?

VII. Concluding Comments and Requests

Besides finding that speech alone does not change food into an illegal drug, and that the censorship of speech about food restrains trade by inhibiting sales of food products, the court is also asked to cite, in writing its opinion, that the 9th amendment is a source of rights retained by the people as a protection against paternalistic government and regulatory tyranny. "Freedom of Choice in Medicine" simply means the right to have access to foods, spices, edible herbs and other non-patentable health products as well as unobstructed information in the labeling of these products for their intended use, including their use in preventing and mitigating disease.

Defendant requests that the court find that there are two criteria needed to determine if a non-patented or non-patentable article is a drug. First, the article under examination must be a drug by its material composition, and second, the article also must be intended for use in preventing, treating or mitigating a disease. The standard that should be applied is to remove the label or disease claim, and then determine if the article by its composition is a drug.

The same test should not be applied to the question of whether the drug is an "unapproved new drug," because if the court determines that a food or food based product is not a drug by its composition, then the product does not have the prerequisite legal status of "drug" to be further evaluated on its labeling as a "new drug."

However, if the article without the label and by its composition is determined to be a drug, then the Government has a substantial interest in informing the pubic of any adverse effects from using the drug, but should not limit speech on its therapeutic benefits. This

defendant agrees with the Court's Caronia decision and the First Amendment protection of off label uses. The substantial government interest should only be the safety of the drug and not its range of therapeutic benefits. In the Caronia case, the article, Xyrem, was a drug by composition and had a mandated black box warning. The same warnings were given for any intended use.

When an article under examination (edible foods, spices or herbs) is not a drug by composition, then truthful information about its use for the prevention or mitigation of common ills should be protected speech under the First Amendment.

For all the foregoing reasons stated in this brief and well as others reserved in the Plea agreement, the defendant, Conrad LeBeau, requests an Order from this Court to be allowed to withdraw his conditional guilty plea of Jan 13, 2012.

Conrad LeBeau _____ Dec 27 2012

Certificate of Service

I, Conrad LeBeau, certify that a copy of the attached Defendant's Appellate Brief for Appeal was filed on December 27, 2012, with the Clerk of Courts Room 362 and mailed by first class mail to:

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X_____ Dec 27, 2012