No 16-1289

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

vs.

CONRAD E LEBEAU,

Defendant-Appellant.

Petition for Enbanc and Petition for Panel Rehearing.

Conrad LeBeau Pro Se
2003 South 96th St
West Allis Wi 53227
414-231-9817
conradlebeau@gmail.com

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7th Circuit Court of Appeals
219 S Dearborn St
Room 2722
Chicago, IL 60604

To the 7th Circuit Appellate Panel Judges:

Second Petition for Enbanc and First Request for Panel Rehearing

A Petition for En Banc was initially submitted along with the appellate brief as required under Rule 35 (c) in the 2010 edition of Wests Federal Criminal Code and Rules. The date the Appeal brief and the Petition for EnBanc were submitted together was March 17, 2016. While the Clerk of Courts filed the Appeal brief, the Clerk returned the Petition for EnBanc to me not filed. There was no explanation as to why it was returned. Possibly the Rule 35 (c) was modified since 2010 or the Clerk returned the Petition in error. A copy of the Petition for Enbanc filed on March 17 2016 is attached in the exhibits.

Pursuant to Fed. R. App. P. Rule 35 (a) (2), and Rule 40, this petition is a combined petition for review. Conrad LeBeau, pro se, requests the 7th Circuit Court of Appeals to grant an Enbanc hearing in this case due to the exceptional importance of the multiple legal issues involved. Besides the original 10 questions, the Final Judgment and Order of July 5th from the 3 Judge Panel of William Bauer, Joel Flaum, and Michael Kanne has opinions within it that the defendant will counter with arguments in this brief.

These counter arguments will be relevant questions for the 9-judge panel to consider. Defendant also requests that the nine-judge panel take the time to read and review both my Appeal brief (Doc 4) and my Reply brief (Doc 9) before writing their opinions.

Defendant request that a date be set for an oral presentation

Defendant requests that he be allowed to make a personal oral presentation in this case as to why the FDA, DOJ, Magistrate Callahan, Judge Charles Clevert, and the 7th Circuit 3 judge panel got it wrong in their findings and opinions. Defendant will also present his reasons why this case can be transformative and change the relationship between the U.S. FDA and the American people for the good of the nation. At stake in this case is the health and well being of over 300 million Americans. Without a change in how the FDCA is applied, the result will be tens of thousands of lives lost each year, The criminalization of commercial speech about how foods and food based natural supplements prevent and mitigate disease continues to be enforced and these deviations from the U.S. Constitution must come to an end. Billions of dollars for health care could be saved each year by allowing food based and other non-patentable remedies to have a level playing field in the marketplace.

I have 10 questions to present to the 9-member En Banc panel. The first exceptional question is–

1. Does the Congressional Record of 1905/1906 support the current FDA/DOJ position that the definition of drug included food and water along with cocaine, heroin and other opiates, and that the law lumped them all together as "drugs" based on their intended use to prevent or mitigate disease?

2. Does this also mean that opiates are drugs only by their intended use and not by their composition? Note: if the panel agrees that it is possible to change a food into a drug by an expression of its intended use, is the revere also possible – can a drug be changed into a food? (e.g. could Oxycontin, Vicoden, Viagra etc. be converted into a salad by labeling them as vegetables?

3. Does the total suppression of "commercial speech" about how foods prevent or mitigate illness run contrary to the First amendment?

4. Does the criminalization of commercial speech on the medicinal value of foods, herbal and dietary supplements restrain trade, and is this selective restraint of trade an authorized power delegated to Congress and the other two branches of the federal government in Art 1, Sec 8 or any other part of the U.S. Constitution?

5. Does the 9-member En Banc panel agree with the 3-judge panel that 21 USC Sec 355 does not mandate a patent number?

a. with the application of a New Drug Application (NDA)? **Or**

b. before final approval of an NDA?

c. Will the 9-member panel consider why the FDA has never approved a food, herb or nutritional supplement as an "approved new drug" in its history (1938 to the present) and has only approved patented drugs (synthetic molecular compounds)? [Note – the DOJ and FDA has refused so far to offer any comment or explanation on this point]

d. Does the 7th circuit agree that a patent cannot be granted to anyone for "intended use" on a natural food product and must also describe the invention or new composition for which the intended use is sought?

e. Does the 7th circuit also agree that for a food product like Perfect Colon Formula, there is no unique molecular compound (e.g. synthetic compound) for which to claim a patent and that the formula is based entirely on non-patentable natural substances?

f. Does the 7th circuit also agree that for every patented drug approved by the FDA, it has more than an intended use, it also had the composition of a drug as a synthetic molecular compound?

6. Does the 7th Circuit panel agree that the following statement requires FDA approval of commercial speech used in advertising and promotional material made on page 5 of the July 5th Decision of the 3 Judge Panel that stated:

> "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."

7. Question: Is not the mandate for FDA approval of commercial speech used to educate the public about the product Perfect Colon Formula also "restraint of trade" and an unconstitutional exercise of government power?

The second sentence then states that – "*the government is not prosecuting LeBeau for having made claims about his products*" is directly contradicted by page 5 of the "Information" filed on Dec 7, 2010 and from the Plea Agreement. In both documents, 3 words are listed as offensive conduct and those words are "reduces food allergies" a reference to a brochure about Perfect Colon Formula. On page 5 of the Plea Agreement under a paragraph titled "**Offense conduct**" is stated -

" In particular, and as it relates to court three of the Information, the defendants claimed on their website that use of the product "Perfect Colon Formula" #1, reduces food allergies."

The 7th circuit 3 Judge panel also stated that "*the government is not prosecuting LeBeau for having made claims about his products,"* is contrary to the "Offense conduct" written in the Plea agreement. Also, for the 7th Circuit judges to further state that the government

"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"

Since both the price of FDA approval is cost prohibitive and the patent mandate under 21 USCS 355 is impossible to meet for a natural food product, the combined effect of these mandates is "restraint of trade."

To the 7th Circuit 9 judge panel:

8. Does not the suppression of commercial speech by mandating preapproval of speech not only violate the First Amendment and also impair sales by prohibiting statements on the intended use of a health food product; is not this suppression also "restraint of trade"? Did not the 7th Circuit 3 judge panel as much as admit this in their statement on page 5 of their July 5th decision?

9. Does the En Banc panel agree or disagree with the following statement from Rep Bill Richardson who sponsored the DSHEA of 1994 and if it does, does it also agree with my argument that DSHEA over-rides and reverses the FDA policy of classifying foods as drugs based on their intended use?

The following statement is excerpted from my Appeal Brief (Doc 4) to the 7th Circuit

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

> "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."

If the 7th circuit agrees with Rep. Richardson, who introduced DSHEA in the House in 1993, then the only issue is not whether Perfect Colon Formula is a drug but whether the speech about this product is truthful and based on scientific literature.

10. After reviewing the scientific literature cited in Docs 28 and 75 in support of health claims made for Perfect Colon Formula in the U.S. district Court, does the 7th circuit agree that the term "reduces food allergies" is truthful and not misleading?

b. Does it also agree that it is commercial speech that is protected under the First Amendment as speech about a food supplement?

c. Does the 7th Circuit panel agree with Central Hudson v. Public Service Comm of NY (447 U.S. 557 to 566) that commercial speech that is truthful is protected speech under the First Amendment?

The Order of July 5 (Doc 5) clearly sided with the FDA and the DOJ legal positions in this case; but to a greater extent, did not fairly present or discuss with objectively the defendant's legal arguments. Statements were taken out of context, half truths were used, and the Caronia case (United States v. Caronia 703 F.3rd 149 2nd Circuit 2012) was completely ignored.

There was a total failure to read and evaluate the two most important documents in this case – the Congressional Records of 1906 where the definition of drug was first passed into law to regulate narcotics and opiates, and in 1994 that led to passage to the Dietary Health Supplement and Education Act (DSHEA) – the latter legislation was intended to limit the power of the FDA to classify foods and dietary supplements as drugs and remove them from the market. Under DSHEA, Congress created a different regulatory scheme by classifying health foods and nutritional supplements by their composition as "dietary supplements" and not as "drugs."

Characteristically defiant, the FDA has thumbed its nose at Congress since 1994 and continues to wrongfully classify foods and dietary supplements as drugs based on speech about

their intended use in preventing/mitigating illness. The defendant's case now before the 7th Circuit has nothing to do with drugs; it is a First Amendment case about how case law, FDA regulations and the laws as applied suppress First Amendment rights by criminalizing the expression of "commercial speech." Defendant asks the court to recognize the obvious – that the FDCA act as applied cannot override the First Amendment within the framework of the limited powers granted to Congress under Art1, Sec 8.

The First Amendment and the Caronia Case
"U.S. v. Caronia 703 F. 3rd 149" (Dec 3, 2012 2nd Circuit 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).

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.

Central Hudson 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 Central Hudson (447 U.S. 562) Justice Powell stated:

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

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

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

For all the forgoing reasons, LeBeau asks the 7th circuit panel to reject Judge Clevert's decision of Feb 3, 2016, and that of the 3-judge panel decision of July 5th, 2016, and write its own decision on the issues presented. Defendant urges the 9-judge panel to take all the time necessary, several months, if necessary, to get this decision right. Thank you considering this case.

Conrad LeBeau
2003 S 96th St
West Allis, WI 53227

Attachments:

1. Copy of July 5th Order (Doc 15)

2. Certificate of Service