CNC

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff –Appellee

v.

Case No 10-CR-00253

CONRAD E. LEBEAU, an individual

Defendant – Appellant

AMENDED REQUEST FOR A REVIEW UNDER RULE 58

July 28 2015
Conrad LeBeau
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To Honorable Chief Judge Charles N Clevert Jr.
517 E Wisconsin Ave
208 U.S. Courthouse
Milwaukee, WI 53202

This is an Amended Request for a Review under Rule 58

I understand that the one week time period to write a brief extends through today, July 28th. This morning, after I carefully reading Rule 58 in its entirety, I found that under Rule 58 (g) (2) (D) "Scope of Appeal:" that the scope of the appeal to a District Court Judge from a Magistrate is the same as an appeal to the 7th Circuit court of Appeals in Chicago. Therefore, this amended request for a review overrides in its entirety the "Request for a limited review under Rule 58" that I filed on Monday July 27th (Doc 111?).

Yesterday, I made the limited request to try to limit the workload of Senior Judge Charles N Clevert Jr. in this case and leave the hard legal issues for the

7th Circuit in Chicago. In hindsight, I wish that I had been advised early in the legal process so I could have had this case tried before a United States District Judge instead of a Magistrate. I did not hear about Rule 58 until the Appellate Court in Chicago sent the files in this case back to the District Court in Milwaukee.

On Dec 27, 2012 I wrote a brief in this case as requested by the District Court (Doc 98). The government responded (Doc 99) and I replied to their response (Doc 101). More than 30 months have passed and the court did not write a decision on this review. One reason possibly is because the breadth of this case has grown well beyond a 7-course meal, and the court may have felt it had other more pressing cases to address and write decisions on.

Today, in addition to asking the Hon. Charles Clevert to consider the legal issues raised in this brief, I request a review of the Magistrate's decisions in Docs 41, 51 and 71 respectively (as reported by the government in a recent pleading). If the court agrees or disagrees with any statements or findings in Magistrate Callahan's decisions, it should state so, and write a short statement that it has completed its review under Rule 58.

The primary Issues the court to review

I am listing the legal issues in the order of importance. If the Court agrees with the first issue, and decides the defendant should be allowed to withdraw his conditional plea of "guilty" it need not consider any of the other issues unless it wants too. If the court does not agree with the legal arguments based on the

Doctrine of Impossibility, then it should consider the balance of the legal issues listed on the next page.

1. **The Doctrine of Impossibility** (both factual and legal) as described in paragraph Doc 58 and discussed in Doc 28 (the Motion to Dismiss) and 43.
2. **Doctrine of Overbreadth** and definition of the term "drug" as described in paragraph 1 of Doc 58 and discussed in Docs 28 and 43
3. **Violations of the U.S. Constitution**, 1st amendment right of speech and press, 5th amendment right of due process, and the other issues listed in subparagraph of section 25 (page 12).
4. **Central Hudson 447 U.S. 557-583** Was the government's choice of criminal charges an appropriate remedy at law consistent with the findings in Central Hudson – the 4 part requirements for restricting speech. Was the speech untruthful? Was it misleading? Was the statement in the brochure for Perfect Colon Formula "Reduce Food Allergies" truthful and based on science? (See Doc 28 and 75). Was Perfect Colon Formula by its composition a dietary supplement or was it a drug? Could the government have protected its substantial interest under Central Hudson by filing a more appropriate action consistent with the intent of Congress in passing the Dietary Supplement Health and Education Act of 1994?
5. **United States v. Caronia F.3rd. 2012 WL 5992141 2bds Circuit Case No 090-5006-cr-Dec 3, 2012.** Vacated on first amendment ground was

discussed in Doc 98 and is reprinted here. Arguments from Doc 98 are found on pages 22 to 30.

Some background information

In my first meeting with U.S. Attorney Gordon Giampietro in July of 2010 he offered me plea deal with little or no fine. At the time he stated *"a month ago 4 FDA attorneys were here trying to convince me to file criminal charges against you."*

In November, 2009, after a phone call with FDA attorney Nate Sabel, I dropped the term "reduces food allergies" after he told me it was disease claim. I substituted what I believed was a non-disease statement "reduces food sensitivities" for the statement "reduces food allergies" that the FDA attorney had found offensive. (See Doc 28 for that discussion)

By July of 2010, there no substantial government interest remaining to restrict speech by filing criminal charges against the defendant who had inadvertently made a disease claim prior to his phone call with FDA Attorney Sabel? See **Central Hudson 447 U.S. 557-583** four part conditions for restricting speech.

[Note: the government never alleged that "reduces food sensitivities" was a disease claim. By July 1st , 2010, I had my fill of second guessing what the FDA would allow or not allow as far as health claims, so I closed the business down and dissolved Vital Health Products Ltd the following month]

In Doc 28, I discussed DSHEA in my original Motion to Dismiss on pages 33 – 39 where I listed the Findings of Congress that were approved with

bipartisan legislation passed by Congress in 1994 as part of DSHEA and signed by President William Jefferson Clinton. In Doc 28, I commented on some speech restrictions in DSHEA that impair the first amendment right of speech but those restrictions pale in comparison to the extreme parts of the FDC Act "as applied" by the government for drugs and new drugs.

The drug claim by the government is based solely on speech that it found offensive, even though the speech was truthful and not misleading. Truthful speech is protected under the first amendment. See **Central Hudson 447 U.S. 557-583 and the Caronia case**

Question: Should the issue of speech (a health statement for a dietary supplement or a food) have been more properly addressed by the government under DSHEA rather than under the part of the FDC Act that defines drugs and new drugs?

[At the end of the first meeting with U.S. Attorney Gordon Giampietro in July 2010, he told me he had the option and could have filed charges against me under DSHEA. He added that the FDA claimed the right of dual classification, and could classify a dietary supplement as a drug based on its intended use]

I question if the use of the term *"reduces food allergies"* was really a disease claim as a disease claim for Perfect Colon Formula was never intended. I personally believe it was a structure/function claim that was truthful and not misleading, was protected speech under the First Amendment, and was allowed under DSHEA even with its speech restriction as a "function' claim.

The Plea Agreement and the issue of "guilt"

In the Plea Agreement, the defendant signed a statement that "reduces" food allergies" was a disease (drug) claim, but that was as the court applied the law on the definition of drugs and new drugs and not as "a state of mind." (See the transcript quoted in Doc 71 page 7 paragraph 7) In reality, the defendant never believed he was guilty of any wrong doing, because the statement "reduces food allergies" was not perceived to be a disease claim at the time it was used, but was in fact a truthful statement based on scientific research (cited in Doc 28 and Doc 75).

The defendant also believes then and now that truthful statements are protected speech under the first amendment, and that first amendment rights are also protected under the 9th amendment right to freedom of choice in medicine – although the U.S. Supreme court has yet to rule on this aspect of 9th amendment rights.

Defendant acknowledges that structure function claims under DSHEA could also infer the prevention of a disease but that would not make it a drug because Congress in its Findings in DSHEA states that dietary supplements do prevent disease.. [Structure function claims under DSHEA are also allowed by Congress in Public Law 103-417 – the Dietary Supplement Health and Education Act of 1994]

The Core Arguments about the Doctrine of Impossibility

The main issue is the "Doctrine of Impossibility" reserved under Doc 58 with arguments of both a factual and legal nature. Both aspects of the Doctrine of

Impossibility are discussed in my Motion to Dismiss (Doc 28) on pages 30, 31 and 32. This doctrine is also listed as reserved in the conditional Plea Agreement (Doc 58 under paragraph 25).

Paragraph 11 of the Information filed by the government on Dec 7 2010 states:

"At no time relevant to this Information was there an approved new drug application or an abbreviated new drug application on file with the FDA for an of the defendants' drugs, nor had defendants' drugs qualified for an exemption as investigational new drugs. Accordingly, defendants' drugs were unapproved new drugs within the meaning of 21 U.S.C. Sec 355."

On page 31 (Doc 28) I stated:

"there is an economic obstacle. The cost of FDA approval of a new drug is estimated to be in the millions of dollars for controlled studies. The investment to obtain FDA approval would not be recoverable in the private market as the owner on an approved drug would not have a captive market for sales.....of a food item."

A question for the government and the court:

Is it practical for the government to expect a defendant who could not afford to hire his own attorney in a criminal case to conjure up millions of dollars and file an NDA as well as pay for subsequent controlled studies to obtain FDA approval? Where would the defendant obtain the millions of dollars to comply with this demand under the law? Is not a demand that would impose an unrealistic and extreme economic burden on the defendant to comply with the law beyond the realm of what is possible? For what purpose would such a demand be placed and what substantial government interest would be served by such demands? Would it be that the defendant could then speak about the

intended use of his health product (Perfect Colon Formula), for a government approved purpose and thus be allowed to exercise his first amendment rights?

The government's position is this: the defendant could have avoided this economic dilemma by not making health claims (statements of intent) that the government found offensive. In order words, the government, by placing economic demands on the defendant that he had no financial means to comply with, is forced to self-censor his own speech to avoid civil and criminal accusations and penalties.

The government demands to file an NDA run up directly against the right of freedom of speech and press preserved under the 1st amendment. The court should note that the government did not allege that the statement in the brochure about Perfect Colon Formula that certain probiotics in the formula "reduces food allergies" was not truthful or was misleading. Under the first amendment, speech that is truthful and not misleading is protected speech (See Central Hudson 447 U.S. 557-583)

The government's position is that freedom of speech about how foods and dietary supplements prevent disease is granted as a privilege of government, and is not a natural inalienable right from God. This position is contrary to the preamble of the Declaration of Independence signed by our forefathers on July 4, 1776, a document that led to the revolt against the tyranny of King George and has his oppressive laws and secretive Start Chamber proceedings.

The government's position is simply this: Freedom of choice in medicine is not an enumerated right in the Bill of Rights. You can only exercise speech about

how foods, dietary supplements, and other non-patentable substances prevent or mitigate disease if you are rich, very rich, and file the right forms and do the multi-million dollar studies we demand for your health product. However, there is one more catch – you need a patent number for our final approval of your intended use for your food or health product. There is one big constitutional obstacle to this regulatory scheme – it is prohibited by the First Amendment.

. 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; it is found in the Congressional Record. Rep. 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."

Supporting my statement here and Rep. Bill Richardson's statement is the FDA's response to an FOIA request I mailed them on Feb 15, 2011. A copy of the FOIA request and the FDA's response in found in the Exhibits list attached to Doc 28 and it is discussed on pages 62 and 63 of Doc 28. Here is an excerpt:

On Feb 15, 2011, I sent an FOIA request to the FDA (See page 63 in the Exhibits file in support of the Motion to Dismiss) and asked for the following files -

1. **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.

2. **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 to my FOIA Request after a search of the "Orange Book" 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."

Based on the foregoing statements, and the complete utter failure of the FDA to even cite one case where a non-patentable health product was approved as an FDA approved new drug since June 1938 speaks volumes that this remedy for obtaining FDA approval for speech about the health benefits of a food or dietary supplement must be extremely difficult or impossible to obtain, as no one has been able to do it under the demands of the new drug section of the FDC Act since its inception in 1938.

The court should also note that the government has had more than one opportunity to explain why no one who distributes a non-patentable substance with an intended use for preventing an illness has been able to comply with the NDA requirements cited in the Information, and obtain final FDA approval. On this topic, the government has chosen to exercise its right to remain silent.

This brings us to the next question – the Doctrine of Legal Impossibility

The Doctrine of legal impossibility means that even if you were in the fraction of 1 percent of the population who could afford the investment to file an

NDA and pay millions of dollars to comply with the studies the FDA wanted, it is still impossible to obtain final FDA approval because of the laws that requires patent number.

The following is excerpted from Doc 28 on the Patent issue and the Doctrine of Legal Impossibility (See 30 -34)

The Plaintiff's Allegations on page 4, paragraph 11

On page 4 of the "Information" served by the Plaintiff in the name of the (United States of America) on the defendants - Vital Health Products Ltd and Conrad LeBeau is paragraph 11 that states:

"At no time relevant to this Information was there a approved new drug application or an abbreviated new drug application on file with the FDA for any of the defendants' drugs, nor had the defendants' drugs qualified for an exemption as investigational new drugs. Accordingly, defendants' drugs were unapproved new drugs, within the meaning of 21 USC S 355."

Defendants Reply to Plaintiff's Allegations paragraph 11

The following two mandates required of the defendants to obtain FDA approval for a New Drug Application are not legally possible for the reasons explained below.

Mandate No 1. Approval of application 21 USCS Sec 355 (a) states:

"**Necessity of approval of application**. No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."

This mandate is then followed by the requirement under 21 USC Sec 355 (b) that requires a patent number to be part of the "New Drug Application" or NDA. Because foods, herbs and other naturally derived substances are not "new" they are not patentable; therefore, no NDA can proceed.

There is also an economic obstacle. The cost for FDA approval of a "new drug" is estimated to be in the millions of dollars for controlled studies. The investment to obtain FDA approval would not be recoverable in the private market as the owner of the approved drug would not have a captive market for sales of the drug when the drug is a food item like garlic, cayenne, thyme, flax seed, broccoli, carrots, honey or an herb like aloe vera or echinacea and can be purchased over the counter at your nearest farm market or grocery store.

Mandate #2. 21 USCS 355 (b) requires a patent for filing a New Drug Application

The Doctrine of Impossibility. The requirement for a patent number on the NDA is found in 21 USCS 355(b) and states:

> line 12 "The applicant **shall** file (bold added for emphasis) with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug."
>
> This same paragraph goes on to add that if a patent is granted after the filing of the NDA and before approval of the NDA, then the applicant shall amend the NDA to add the patent number. Section 2 and 3 follows on claims for uses made under a patent cited in the NDA and other matters related to patents and patent infringements. Since the 4 products in question are not patentable and are not the invention of a person, they are not "new drugs" and since they are not patentable the current law prevents the processing of a New Drug Application (NDA).

The mandate for a patent number in applying for an NDA violates the **Doctrine of Impossibility** as no food or herb is "patentable," and therefore, **no remedy at law is available** to obtain FDA approval of a new drug that is a food or herb intended to prevent or treat disease. However, expert opinion at the U.S. National Library of Medicine is what was used to determine the intended use of the products in Counts 2, 3 and 4 of the "Information." FDA policy clearly conflicts with NIH policy and Congressional intent for

public access to access to all the information available at the NLM whether studies are "randomized" or not.

Patented or patentable chemical compounds are "new drugs" whose intent and labeling can be lawfully controlled by the Federal Government because patented products exist as a privilege of government, since they offer the patent holder a marketing monopoly for purposes of making a profit. However, does that also mean that the Federal Government has the power to censor the speech about items that do not exist as a privilege of government?

Herbs, botanicals, vitamins, minerals, antioxidants, probiotic, enzyme or foods of plant or animal origin exist in nature and are available to benefit everyone. Non-patented medicines compete in the marketplace with each other keeping prices competitive. The savings from using generic drugs and natural medicine is huge which is why Pharmaceutical companies that manufacture drugs want the FDA to suppress the competition that threatens their bottom line.

The effect of the amended FDC Act in 1938 and 1962 was to create a monopoly of expensive patented medicines and deny the public knowledge of and access to hundreds if not thousands of low cost non-patentable alternative natural products. This arrangement favored the drug companies (major political campaign contributors), while discriminating against the medical needs of the poor and the uninsured.

A Summary of my Argument on the Doctrine of Impossibility

Since the defendant could not afford to hire his own attorney to represent himself in this case, how could he be reasonably expected to conjure up millions of dollars for an NDA, controlled studies made to FDA specifications and multiple

other regulatory requirements fro government approval of three words in a product flyer? The obvious answer it that is would be financially impossible. In addition how could the defendant obtain a patent number of a food product that is natural and not patentable to complete the new drug application process?

The clear implication is that the law as applied fatally impairs the defendants right of speech under the first amendment. It also impairs the right of due process under the 5th amendment as the demands of the laws alleged to have been violated in the Information would have been impossible to full fill for all the reasons cited in this brief.

For my arguments on the Doctrine of Overbreadth, see Doc 28 and 43 for the applicable sections. For a comparison of the Caronia case to mine, see Doc 98. pages 22 to 30.

The balance of all the other legal argument reserved in Doc 58 and in Docs 28 and 43 may be reviewed and commented on at the Courts discretion.

Conrad LeBeau

Certificate of Service

I, Conrad LeBeau, certify that a copy of the attached Defendant –Appellants **Request for a limited review under Rule 58** on July 28th, 2015, with The Clerk of Courts Room 362 and mailed by first class to:

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

US Attorney Gordon Giampietro or successor
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July 28, 2015 Conrad LeBeau

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