UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff

v. Case No 10-CR-253

VITAL HEALTH PRODUCTS LTD and CONRAD E. LEBEAU

Defendants.

Request of the defendant, Conrad LeBeau for leave of Court to file a MOTION AND NOTICE OF A PROCEDURAL DEFECT BY THE US FOOD AND DRUG ADMINISTRATION BEFORE THE PROSECUTION WAS INITIATED AND OF FDA FAILURE ON THE FOIA REQUEST AND ITS "OPEN RECORDS" POLICY

To Judge William E Callahan

This is a request for Leave of Court to file the attached notice concerning two defects in the "Information" and an obstruction by the FDA of my earlier FOIA request made in February 2011. The Notice and Motion is attached to this request. The motion is made pursuant to RULE 12 (3) on Pleadings and Pretrial Motions that must be made before Trial

Conrad LeBeau

Sept 26 2011

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Defendants.

MOTION AND NOTICE OF A PROCEDURAL DEFECT BY THE US FOOD AND DRUG ADMINISTRATION BEFORE THE PROSECUTION WAS INITIATED AND OF FDA FAILURE ON THE FOIA REQUEST AND ITS "OPEN RECORDS" POLICY

To Magistrate William E Callahan

The defendant, Conrad E. LeBeau, files this notice of a procedural defect pursuant to RULE 12 (3) on Pleadings and Pretrial Motions that must be made before Trial. This notice and motion alleges a specific defect in instituting the prosecution, **violations of the Freedom of Information ACT** and FDA's **Open Records Policy** as well as a "**lack of a remedy at law**" under the requirements for filing a New Drug Application (NDA) or Abbreviated New Drug Application. NDA requires a patent number under 21 USCS Sec 355 (b) Filing applications; contents.

Rule 12 (3)(A) **"a motion alleging a defect in instituting the prosecution."**

The requirement under Federal Rule 12 (3)(A) does not specify what the defect is, so a motion is required to bring the matter to the Court's attention. A procedural defect has occurred where the FDA failed the statutory requirement to hold a hearing to give a notice to the defendant to appear and explain his views on legal action being contemplated by the

government before reporting to the US attorney in the Eastern District of Wisconsin and recommending prosecution.

Issue No 1 – a Procedural Violation

21 USC Sec 335 states:

Sec 335 Hearing before report of criminal violation

> Before any violations of this Act [21 USCS SS 301 et seq] is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the persons against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

The defendant was never given the opportunity to have a hearing and present his views to the FDA in regards to the contemplated proceeding. The letter from FDA Attorney Nathan Sabel to me and Attorney Paul Kanter is dated Nov 2, 2009. In the letter (see page 29 to 32 in exhibit file), Attorney Sabel stated he was recommending criminal prosecution. The record shows that Attorney Sabel sent his recommendation to Attorney Paul Kanter concurrent with his letter to me and without first giving me an **"appropriate notice and an opportunity to present his (my) views, either orally or in writing, in regard to such contemplated proceeding"** as required by 21 USC Sec 335.

This violation is especially egregious in view of FDA's failure to contact me as promised several times by FDA inspectors Joel Hustedt and Christina Castineyea in Dec of 2008. The last day of the inspection ended on Dec 8th 2008. Joel Hustedt gave me the phone number of Tyra Wisecup, FDA compliance officer in Mpls, MN. I called her the following day, but the phone call was never returned. The failure of the FDA Compliance Officer Tyra

Wisecup to return my phone call is noted in my nine- page reply letter to Attorney Sabel on Nov 15 2009. See exhibits on file.

Case law on Sec 335 Hearing before report of criminal violation

BAD CASE LAW

The oldest case law reported in the law books at the Marquette Law Library cites United States v Dotterweich (1943) 320 US 277. The opinion of the Court in this case contradicted the clear stated intent of 21 USC Sec 355 by stating that **"opportunity to present his views is not prerequisite to prosecution."**

Dotterweich is a favorite case the FDA cites frequently as this Court gave the FDA virtual unlimited power to do whatever it wants. Good case law is supported by an actual reading and application of the laws or a statement of Congressional intent and is consistent with the intent of the lawmakers and the US Constitution. Dotterweich is not consistent with either the intent of Congress and violates the US Constitution because the decision in Dotterweich directly contradicts the requirements of the actual wording of the statute. **Dotterweich is bad case law because no court has Constitutional authority to legislate from the bench.** FDA attorneys either don't care or wrongfully believe that Courts can legislate from the bench. Instead of going to Congress to change the law, they seek to find a judicial lapdog who will grant their request for ever more and expanding regulatory powers.

By 1943, the year I was born, the Dotterweich Court was dominated by liberal judges appointed by President Franklin Roosevelt. Eight years earlier on May 27 1935, the US Supreme Court had held that delegation of legislative powers to government agencies for new Deal programs was unconstitutional (Louisville Joint Stock Land Bank V. Radford

296 US 661 (1935); Humphrey's v. United States 295 US 602 (1935), and Schechter Poultry Corp v United States 295 US 495 (1935). Roosevelt did not like that the US Supreme Court was voiding laws that vastly expanded the powers of the federal government. As reported by Attorney Jonathan Emord in his book "The Rise of Tyranny" page 25 (See Exhibits) to wit:

> "On February 5, 1937, President Roosevelt responded to the Supreme Court's action by sending Congress the Judiciary Reorganization Act of 1937 …. The bill would add one justice to the Supreme Court for each of seven members who exceeded the age of 70 plus six months. Roosevelt aimed to add six pro-New Deal justices to the court in place of the six justices who voted against the constitutionality of his programs."

Although the bill never became law, it had the desired effect of intimidating two justices on the US Supreme Court who switched sides and joined with 3 others to uphold Roosevelt's legislation from that point on. The Roosevelt era legislation has vastly expanded the powers of the federal government. In the media this became known as **"the switch in time that saved nine."** See "**The Rise of Tyranny**" by Jonathan Emord p.25

A Better Case Law on 21 USCS Sec 355

This Court is asked to ignore all case laws provided by the FDA that modifies or contravenes an Act of Congress, and Congressional intent, or that is not consistent with the US Constitution. Do consider **United States V Durbin 1974 373 F Supp 1136** to wit:

"**21 USCS sec 355 requires is that hearing be reasonably noticed and held and that defendant appear, and be afforded opportunity to present his views."**

This opinion is consistent with the letter of the law and does not attempt to legislate a different meaning from the bench. As for FDA attorney Nathan Sabel, he did not comply with 21 USCS Sec 355 before recommending the criminal prosecution of the defendant to the local US Attorney.

Issue No 2. FDA violates FOIA and its Open Records Policy

The second defect occurred when the FDA failed to provide 17 specific files or documents requested of them by the defendant in his Freedom of Information Act (FOIA) request faxed to them on Feb 8 2011. FDA also failed to provide a written estimate on costs if they exceeded $100. The FOIA request authorized the FDA to provide up to $100 dollars worth of files but the FDA provided no files at all. FDA failure to respond as required under FOIA denies the defendant access to material evidence that defendant would need to obtain a fair trial. Shortly after filing the FOIA, Federal Defender Brain Mullins told me the FDA had an Open Records Policy.

Note: The FDA did respond to my request for answers for two files on the Feb 15th 2011 FOIA Request. A copy of their reply is in the exhibits (page 62). The FDA acknowledged, in writing, after a search in the Orange book, that from 1938 through 2010, **not one non-patented drug was ever approved in its entire history as an agency**. **The same is true of all foods and herbs – not one was ever approved!**

Subsequent to filing the FOIA request, I was able to locate answers to some of the documents I requested. I did not amended my request at the time as I was waiting for a written response, and I was focused on writing my brief and motion to dismiss. I did not receive any cost estimates. However I did find multiple definitions for the word "disease" at FDA's website. As for the statement of Congressional intent in passing the Pure Food and Drug Act of 1906, I found my answer in the Congressional Record of 1906 in the archives after searching for several hours through records at the Milwaukee Public Library. Copies of relevant portions of the Congressional Record are in the exhibits and supported defendant's motion to narrow the scope of "substances" that could legally be defined as "drugs" to "Patented Drugs" and "Nostrums."

Of the 17 original files requested by FOIA on Feb 8 2011, I am withdrawing 13 of them except for the following four that are deemed critical for my defense at a trial. This reduces the list for the FDA. The files I am now requesting are #5, #8, #11 and #12

5. Copies of files, regulations, instructions or documents that a Compliance Officer of the US FDA would use to determine when scientific opinions published in medical journals are sufficient to support **a consensus of expert opinion** (**generally recognized as safe and effective per 21 USC S321 (p) 1**) for a functional food, herb or dietary supplement to be used **for the prevention or treatment of disease**; ***and therefore not requiring the filing of a new drug application***.

8. **A file or document that identifies all sources of expert scientific opinion** including medical libraries (examples being the National Library of Medicine, WebMD, Mayo Clinic etc) and sources of expert opinion on alternative medicine (Naturopaths, Herbalists etc) that are recognized by the FDA as expert opinion. Update 9/23/11:Added to this list today is **naturaldatabase.therapeuticresearch.com** Does the FDA recognize this database as a source of expert opinion?

11. Copies or documents that provide the **names, address, phone number and email address of Dr Robert J Moore DO and all other Dept of HHS health care professionals who are Clinical Reviewers** in the Office of Nutrition, labeling and Dietary Supplements that reviewed the labeling of products distributed by Vital Health Products Ltd of 8544 W National Ave #21, West Allis WI 53227 during the years 2008, 2009 and 2010. Also I would llike the email address for Tyra Wisecup ,FDA Compliance Officer in Minneapolis, MN.

12. Copies of medical library database searches (Embase, Medline et al) done by the Office of Nutrition, Labeling and Dietary Supplements for **Perfect Colon Formula # 1** for "**reduces food allergies**" and **Saccharomyces boulardii** for "**for diarrhea related to Clostridium difficile**." Include the names, address, phone number and email address of the individual(s) who done the searches and all search terms used and whether or not quotation marks were placed around these terms and on which library databases the searches were performed. Indicate whether any searches were limited by the use of certain words such as "**male**" or "**randomized**" etc or other terms. Include all search terms used and the results. **This request is amended here to include any searches done for ingredients used in Lebeau's Cold and Flu Formula**.

No 5 is important as the language of 21 USC sec 321(p)(1) is too general and vague to understand who qualifies as "experts, " what criteria is used for evaluation, and do experts determine if a drug is "new" by a new material composition or by a new intended use for preventing a disease or both? Is a composition that is "new" patented or patentable? Is this a

standard procedure used consistently or are these evaluations of possible violations like pornography – you know it when you see it? How does an "intended use" of a commonly used food or herb to prevent a disease convert that food or herb into a drug or an unapproved new drug?

No 8 is very important to the defense so as to be able to introduce full scientific articles and abstracts of expert opinion and file them with the court as "admissible evidence" without the cost burden placed on the defense to hire an expert to read and report on these scientific articles. If the FDA recognizes the published articles themselves as expert opinion and admissible as evidence, then there is no need for the defense to hire an expert to give a professional opinion on what is readable and understandable to a person of average intelligence. I assume that the Judge Callahan has at least, if not better than, average intelligence.

Published expert opinion that contradicts the opinion of FDA employees may create reasonable doubt in the minds of jurors or the judge, if the case is tried to the Court. Knowing what medical libraries contain expert opinion and the qualifications of health care professionals whose testimony is acceptable as expert opinion is critical for a fair trial for the defense.

No 11 is important for the defendant to identify expert witnesses that would be used against him at a trial and to prepare for direct examination and cross examination questions, or with approval of the court by a discovery motion, to allow defendant to submit to these parties written interrogatories, admissions or requests for additional documents before trial.

No 12 is very important as there may be files that contain expert opinion that supports the health claims made by the defendant for the 4 products in question. Searches at the National Library of Medicine will yield vastly fewer results if no quotation marks were places around the search terms. ***I know from personal experience as I have done thousands of searches at the***

National Library since 1994. Scientific articles retrieved from searches by the FDA may contain exculpatory evidence that would benefit the defense.

Because the FDA has not provided under its own "Open Records Policy" the above documents that were requested in an FOIA request on Feb 8 2011, it deprives the defense of evidence it needs to receive a fair trial and therefore violates the defendants due process rights.

Like the old Wendy's hamburger TV commercial, "**Where is the beef**?" **Where are the files and document I requested more than 6 months ago?** As I recall the Court authorized the FDA 60 days or until April 15th to answer my FOIA request and the government did not ask for an extension of time. The request I made authorized $100 worth of documents, and an estimate on any that would exceed that cost. Not only have none of the 17 files I requested arrived, no written estimates have arrived either. Therefore, the trial should not proceed until the FDA complies with these FOIA document requests or this case should be dismissed. **At a status hearing about mid February this year, Attorney Gordon Giampietro told the Court that Attorney Nathan Sabel said the FDA would answer my FOIA request. Six months have since passed.** With this motion I have now reduced the scope of the files I am requesting from the FDA 17 to 4.

In February, I was asked by Attorney Brian Mullins if I would participate in the 3 way phone conference with Attorney Sabel about the FOIA request. I declined and sent Federal Defender Mullins an email stating that he was not authorized to represent me on the FOIA issues. I insisted on a written response as a phone call with an FDA attorney is something I cannot file as an exhibit with the Court. This inaction by the FDA in answering my FOIA request hints that they have something to hide that might benefit the defense. My $100 price limit on

files I requested still stands, and, if the costs exceeds that, I expect a written estimate on the remainder of my requests. This is what Freedom of Information Act requires.

Issue No 3 – "Information" was defective in claiming the NDA remedy

The patent requirement under 21 USC Sec 355 (b) (line 14) for a New Drug Application (NDA) prohibits a **remedy at law** for the defendant. This third defect occurs in the plaintiff's "Information" on page 4 paragraph 11 that states:

"At no time relevant to this Information was there as approved new drug application or an abbreviated new drug application on file with the FDA for any defendant's drugs, no had defendant's drugs qualified for an exemption as investigational new drugs. Accordingly, defendant's drugs were unapproved drugs, within the meaning of 21 U.S.C. Sec 355"

The problem here is that line 14 of 21 USCS Sec 355 states that **"The applicant shall file** with the application the patent number and the expiration date of any patent…" **HOWEVER, FOODS AND HERBS ARE NOT PATENTABLE!!! THEREFORE, THERE IS NO REMEDY AT LAW AVAILABLE TO ANYONE WHO DISTRIBUTES FOODS AND HERBS BY FILING A NEW DRUG APPLICATION BECAUSE THE LAW PROHIBITS THEM FROM MAKING SUCH A FILING WITHOUT A PATENT NUMBER. The law says, "The applicant shall" and does not say that "The applicant may."** There are profound legal differences between the word "**shall**" and the word "**may**." The word "**shall**" is mandatory and "**may**" is optional. As a result of this mandate, the **Doctrine of Impossibility** is invoked here.

It should be noted that if the law allowed foods, herbs and spices to be patented as drugs, then the purchase of such foods at a grocery store would be illegal without a written prescription. The "Information" is misleading by stating that a remedy at law was available to the defendant by filing an NDA or abbreviated NDA in order to obtain FDA approval for the use of language

in the labeling of how the defendant's food and herbal products may either prevent or mitigate disease.

As FDA violations of the law raised in the first two issues of this Notice would result in the FDA going to trial with "**unclean hands**" and **deprive the defendant of exculpatory evidence under the FOIA**, and for the **lack of a remedy at law** discussed in Issue No 3, the defendant asks the Court to either bar the FDA from introducing their evidence at a trial or to dismiss the case.

Conrad LeBeau

Certificate of Service

I, Conrad LeBeau, certify that a copy of the attached Notice of Defects in the Prosecution and Motion was filed with The Clerk of Courts Room 362 and mailed by first class mail to:

Judge William E Callahan Jr
517 E Wisconsin Ave Room 250
Milwaukee, WI 53202

US Attorney Gordon Giampietro
U.S. District Court
517 E Wisconsin Ave Room 530
Milwaukee WI 53202

This document was drafted by Conrad LeBeau

Sept 26h, 2011 _____

Conrad E LeBeau