Dec 24 2011
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President Barack Obama
The White House
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My Personal Story - How the FDA drove me out of business

Dear President Obama:

I am a 68 y.o. Senior citizen, semi-retired, who owned a small one person dietary supplement business (Vital Health Products) here in West Allis, Wisconsin, until the FDA forced me out of business in July 2010. What the FDA did was to allege that I had violated the Food and Drug Act by sharing information I retrieved from the United States National Library of Medicine (NLM) with my customers. The information I provided suggested that these health products might prevent or mitigate certain health conditions. The information I used is publicly available online and none of it was classified.

As a result of FDA Good Manufacturing Practices (cGMP) that took effect in June 2010 that would have bankrupted my business, and allegations that I distributed 4 "illegal drugs" in interstate commerce in 2009, I am now a defendant in Federal Court here in Milwaukee in Case no 10-CR-253 that was originally filed on December 7th 2010. The case is a misdemeanor criminal proceeding that is currently scheduled for a jury trial on Jan 25th 2012.

Two of the products (Spirokete and Saccharomyces Boulardii) listed in the "Information" are made by other manufacturers and are available for purchase today in hundreds of retail outlets. The other two health products are a fiber probiotic blend (Perfect Colon Formula) that had an article that stated that one of the ingredients, L. Plantarum, could prevent and reduce food allergies. The other product was an herbal formula for colds and flu. Of the latter product the FDA alleges that the name of the product (LeBeau's Cold and Flu Formula) was a crime because the name suggested its intended use.

Today, FDA practices (based on expansive definitions of what a "drug" is and what a "new drug" is) are so broad and restrictive that even a reference to the title of a scientific publication that is associated with a dietary supplement is considered a violation of the law. Presently, FDA policy is to totally censor and suppress scientific research and opinion on how foods or nutritional supplement prevent or mitigate a health condition or disease. Except for about 4 pages (at fda.gov) of carefully selected language, the FDA censors all information about how wholesome foods and nutritional supplements prevent

disease. Yes, just 4 pages of information are "approved" out of hundreds of thousands of scientific abstracts on how foods, herbs, vitamins, minerals and other dietary supplements prevent or mitigate disease. The articles are available to the public at the U.S. National Library of Medicine. Mr. President, you taught Constitutional law, how can the FDA's policy of total suppression of information on the health benefits of foods and dietary supplements comport with freedom of the press under the First Amendment?

Since Congress released the entire contents of National Library of Medicine to the public since the year 2000, how can the sharing of that scientific research by anyone who manufactures or distributes food products and herbal supplements be a violation of the law? The very same information I provided to my customers for health products I distribute is available to anyone with a computer. Why are people who distribute dietary supplements being treated by the FDA as second class citizens, or even worse, as criminals for doing nothing more than provide expert research and opinion that is already available at the NLM and that was authorized for release to the public by Congress?

The FDA currently sticks with archaic definitions. Their attorneys consider foods to be drugs if they are intended to prevent disease. With these overreaching definitions, the FDA looks for drugs in salad bars, spice cabinets, and fruit baskets. Is this White House policy on where the FDA should be looking for drugs? If that is the case then even the First Lady's Organic garden in the White House lawn may be at risk of an FDA raid. Don't Organic foods prevent disease better than chemically grown foods that are depleted of trace minerals, and laden with pesticides or are genetically modified to produce their own pesticides?

Part I
The National Library of Medicine overflows with scientific research

Since the year 2000, the medical databases at the NLM have been available to the general public. The National Institutes of Health (NIH) published in the Federal Register in 2004 its policy concerning access to and use of this library. MEDLINE/Pub Med is the NLM's database of references to more than 11 million articles, published in 4600 biomedical journals.

How do I know there are hundreds of thousands of scientific articles at the NLM on how foods, herbs, probiotics and other natural non-patentable substances prevent of mitigate disease? A search I did at Pub Med on Dec 25, 2011, by entering the name of an herb yielded these links to scientific articles. Garlic – 2700, Aloe Vera – 1791, Thyme – 1375, Mullein – 112, Parsley – 844, Sage – 4282 and Rosemary – 1152. The total for these 7 botanicals is 13,256 links. Considering that the book "Materia Medica" alone lists over 600 herbs with medicinal properties, the numbers of herbs about which medical articles exist could easily number in the hundreds of thousands. When vitamins A, B, C and D are entered individually, the total links for all 4 vitamins at Pub Med are 254,724.

While millions of Americans access the NLM, not everyone has a computer. The public better served by having more information, not less. Presently, FDA policy is to totally suppress the release and use of information from the NLM by distributors of foods and dietary supplements. At the same time, the NLM has a different policy and makes all this

information available to anyone who wants it at the click of a mouse. Shouldn't the policies on the use of medical data from the NLM be synchronized so that FDA policy is the same as the NLM and not be polar opposites? Is it not time for the White House to advise the FDA to remove their padlock from the NLM? The continued suppression of information from the NLM by the FDA results in millions of people who use dietary supplements being deprived of medical research that would enhance the quality of their life and improve their health in more ways than can be imagined.

President Obama, I am presenting my case here and ask you to consider appropriate responses including issuing Executive Orders to the FDA, as well as to consider sending legislation to Congress to reform the following areas of FDA policy. They are:

The right of manufacturers and distributors of dietary supplements (food, herbs etc) to use and share expert scientific opinion from the US National Library of Medicine (NLM) with their customers without any preapproval or preconditions from the FDA except for adding any appropriate disclaimer. I ask that you direct the FDA to use the same disclaimer that the National Library of Medicine uses on its website for readers who read and download scientific abstracts and articles at Pub Med and Medline and that is to "See a health care professional for more information**."** I request that you direct the FDA to allow anyone (including manufacturers and distributers of foods and dietary supplements) to use and share expert research and opinion from the NLM with their customers, and that the same disclaimer used by the NLM is appropriate to add to a product's label to direct the consumer to consult with a doctor about the information so provided. Whether the health information is obtained directly from the NLM or from the product label, there would be no difference as to the information's effect on the consumer of a product's intended use.

Distributors of dietary supplements should have First Amendment rights to share the health effects of the products they distribute based on scientific research and expert opinion derived at the US National Library of Medicine, and the FDA should stop treating them like lawbreakers for doing so.

Mr. President, I am requesting that you issue an Executive Order stopping the FDA from pursuing civil or criminal sanctions from citizens like myself who have shared information from online searches at the NLM with their customers. Is it not time to remove FDA's padlock from the NLM and let consumers have access to scientific research paid for by US taxpayers?

American citizens have a first amendment right to research and opinion as part of the product label. Distributors should not be told that they need to file a 'New Drug Application" in order to share expert health opinion that is already publicly available through the NLM. The FDA is doing irreparable harm to millions of people by withholding hundreds of thousands of scientific articles from the public on how foods, herbs, minerals, enzymes, probiotics etc prevent and mitigate illness. The FDA policy of total censorship of scientific research on foods and dietary supplements makes no sense. It deprives the public of the very information they need to make informed dietary and supplements choices to better improve their health. You have the power, President Obama, to change FDA policy that serves the bottom line of the privileged 1%? Will you

defend the interest of the other 99% who need greater access to safe, effective and low cost supplements to help prevent disease?

What the White House can do to address these issues

Labeling -

1. Issue an Executive Order allowing "references to scientific articles" or suggested "search terms" at the National Library of Medicine including "the name of a nutrient" and a "named disease" and to allow this to be part of the product label in a black box notice for any food or dietary supplement when accompanied with the website address of Pub Med or NLM gateway, and an appropriate disclaimer such as -"The U.S. Government advises consumers who access medical articles at Pub Med or other NLM databases to take copies to a health care practitioner for consultation and advice." This disclaimer is similar to the one now used by NIH at the NLM website as advice to people who retrieve articles from Pub Med or Medline.

An example for a supplement called "Alpha Lipoic Acid" would be:

[Medical research on "Lipoic Acid" and "Alzheimers"]

[Scientific articles published at the US National Library of Medicine at **www.ncbi.nlm.nih.gov/pubmed** using the search terms "**alpha lipoic acid**" and "**alzheimers**" indicates there are (number) links to scientific abstracts on this subject. The U.S. Government advises consumers that access medical abstracts at Pub Med or other NLM databases to take the articles to a health care practitioner for more information]

In the above example, a search done at Pub Med using term "lipoic acid" and "alzheimer" together yield a total of 40 links to medical articles where these two word terms appeared. Lipoic acid usually refers to the dietary supplement "alpha lipoic acid." The benefits of adding this information to the product label of a dietary supplement are

a. Scientific abstracts at the NLM that are brought to the attention of the public and health care professionals benefits everyone by increasing the base of knowledge and the scope of treatment possibilities.

b. Taxpayers have a right to this information as they pay for it and should not be deprived of it by a policy of total suppression of medical research about the health benefits of non-patentable foods, herbs, enzymes, minerals, vitamins and other natural health products for the prevention of disease.

c. Millions of people will benefit from the knowledge gained by greater access to scientific articles among the more than 11 million medical abstracts published at the NLM.

2. Amend Title 21 USC Sec 321(g)(1) that defines what a drug is to exclude from the definition of drug any non-patentable substance including foods, herbs and dietary supplements intended for the "prevention of disease." This will allow expert opinion from the NLM to be used by distributors of dietary supplements in labeling to better educate and inform the public on the health benefits of wholesome natural foods and botanicals.

3. Amend 21 USC Sec 321 (p)(1) [passed originally in 1938] that defines a "new drug" by adding to the definition of new drug language that a "new drug" is [any drug the composition of which is such that such drug is "new, patented or patentable or of unknown composition, and" is not generally recognized, among experts……..] Adding these words to the definition of "new drug" will allow foods, herbs and other non-patentable substances to be excluded from the definition. Limiting the definition of "new drug" to drugs with "a new material composition" will allow non-patentable natural health products intended to prevent disease to be defined as "Food" or "dietary supplements" and not as new drugs. This will allow manufacturers to provide truthful information based on scientific research on how these products prevent disease to be included with the products they manufacture and distribute as part of the product label.

In the application of the law as it now stands, all new drugs approved for use in treating disease since 1938 have been patented and also have a new material composition. In fact the law as written does not allow a New Drug Application to have final approval without a patent number. For this reason, not a single food or herb or other non-patentable health product has been approved by the FDA as an approved new drug in the entire history of the agency (from 1938 through 2011).

The time is long overdue to end this arbitrary standard and level the playing field between patented drugs that have market monopolies, and non-patented natural health products that compete in the marketplace, and in comparison, are very low in cost.

It is also time to end censorship of the press in regards to the words a manufacturer chooses to place on the labels on its non-patentable health products and commodities. Why does the FDA think they have a compelling state interest in preventing the dissemination of scientific research and expert opinion from the National Library of Medicine when this same information is already disseminated on the Internet and is available to anyone with a computer and access to the World Wide Web?

4. Issue an Executive Order to the FDA to not prosecute anyone who shares research from the NLM with the public including distributors of foods and dietary supplements.

Part II

FDA's Good Manufacturing Practices for Dietary Supplements are insanely costly and do not advance the safety of nutritional products

Good Manufacturing Practices (cGMP) were allowed, but not mandated by Congress, under the Dietary Health Supplement and Education Act of 1994. DHSEA allowed the Secretary of HHS to promulgate GMPs for dietary supplements based on the GMPs used for food. However, the GMPs promulgated by the FDA were based, instead, on standards for pharmaceutical drugs, except they were substantially more costly and detailed than those even for FDA approved drugs. The GMP for foods has applied to all dietary supplements since the 1930's. The GMP's for dietary supplements, as written by the FDA under the Administrative Procedures Act, failed to follow the Congressional mandate by basing them on pharmaceutical drugs instead of foods.

The GMPs for dietary supplements took effect first in June 2008 for companies with over 500 employees, then in June 2009 for midsized companies (20 to 500 employees) and in June 2010 for companies with less than 20 employees.

Owners of small businesses that make nutritional and herbal formulas that I have spoken report the upfront cost imposed by the FDA is about $100,000 per business. This is because every ingredient of every product has to be tested along and the final product that has to be tested again. Exact records of each test have to be maintained and another test of the finished products is also required. So much record keeping is required that for small batches, it takes more time and money for record keeping than the actual making of the product. In June 2010, small companies including mom and pop operations had these draconian mandates dropped on their head causing many to close their doors. As each small company goes out of business, the products they make are disappearing from the shelves of health food stores.

Many small companies, including mine, that have been in business for decades are being forced out of the marketplace by the FDA's new cGMPs. These products have been safely made for decades under the GMPs standards used for food. Today, an era of fear of the FDA and their intimidation tactics is sweeping the nation. One by one, store shelves are being emptied of these health products as small entrepreneurs are being driven out of business by these oppressive regulations.

Mr. President, the FDA is under your control, and you will be blamed for their restrictive policies unless you do something to stop their oppressive policies now. Congress in their "Findings" that preface the DHSEA of 1994 stated that dietary supplements were safe. Here is what I am asking you to do.

Good Manufacturing Practices - the Code of Federal Regulations

Relief requested: issue an Executive Order to exempt small dietary supplement companies, those with 1 to 20 employees, from the FDA's cGMP that took effect in June 2010, and allow them to continue to manufacture their products under the GMP for foods that they have been doing for over half a century with almost no safety production issues. This will spare over 300 small companies from extinction under the extreme costs (over $100,000 up front imposed on even the smallest mom and pop businesses) by the FDA requiring multiple testing and record keeping with tortuous details under the new cGMP.

In fact, these FDA regulations require even the smallest businesses to hire a "quality control" person for their business. This adds another 20 or 30 thousand dollars of annual expenses that simply cannot be absorbed by small businesses. The midsized and larger dietary supplement companies have passed these added costs on to the consumers. While the costs have gone up, the safety has not been improved from these burdensome and extremely expensive record-keeping requirements.

Second, to reduce the needless and repetitive testing as they apply to all manufacturers of dietary supplements with more than 20 employees, and that is to order the FDA to require one test only of the final finished product for each batch of dietary supplements manufactured. Under GMPs for food products, a sample of the product with a lot

number is saved so the FDA can test it themselves if it is deemed necessary at some future date. These changes will save the dietary supplement industry hundreds of millions of dollars that is currently spent to test each ingredient in a formula before the product is made. It should be pointed that distributors or raw materials to manufacturers of dietary supplements are required now to test and to send a Certificate of Analysis with each lot number they distribute. One test (not thousands of costly and needlessly repetitive tests) is all that is needed. The savings will be passed on to consumers with lower prices on nutritional supplements. This will also vastly simply record keeping.

Part III
FDA approved synthetic heroin and other opiates

FDA approved synthetic heroin Oxycodone (OxyContin) and other opiates have resulted in 22 million people becoming drug addicts resulting in over 15,000 deaths annually. With 7% of the US population (22 million people) now addicted to either prescription or street drugs, it is ruining the lives of families all across the nation and it is overwhelming local law enforcement resources. Serious reforms are needed here immediately. OxyContin is the most dangerous of all opiates approved by the FDA and the CDC Morbidity and Mortality weekly report (Vol 60 No 28) as the leading cause of deaths among opiate users, even more than the cocaine and heroin smuggled into the US from Mexico. OxyContin is followed by the narcotic Alprazolam as the second leading cause of death among opiate users. These two opiates have the worst track record of all FDA approved opiates and the FDA is asleep at the safety switch as millions more Americans become addicted to these two drugs.

Your intervention, Mr. President, is needed now to curb their use.

(1). Specifically, I suggest an Executive Order or seek a Congressional mandate if necessary barring any doctor from prescribing either opiate drug to a patient who has no history of having had a prescription for either drug, and

(2), to mandate that no new patients are to be given prescriptions for either addictive drug unless they have a terminal illness and a life expectancy of less than 6 months.

(3). That the FDA mandate that doctors first use non-opiate pain relievers and to test all that are available on the patient before prescribing any addictive narcotics.

The FDA should further list the least to the most addictive narcotic pain relievers and advise physicians to use the least addictive ones first and only if they fail to respond to treatment to consider prescribing a stronger opiate for pain relief.

Your attention to my concerns raised in this letter will be greatly appreciated.

Thank You

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