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Response to FDA Allegations and Ecclesiastical NOTICE

Dear Mr. Sherer,

I received a letter from a Ms. Mitchell dated April 13, 2012 regarding alleged violations of the "ACT," as well as a request for a "Regulatory Meeting Request," and this is my response.

I was approached at my home by your two investigators one morning, unannounced, no appointment, no notice, nothing, and expected to take 2-3- hours of my day to satisfy this meeting. I did so, (audio taped) to show my willingness to provide information, and to show my good faith in understanding the issues the FDA seems concerned with.

I also had to rectify at least two errors the agents committed, at my expense, including sending the original copy via mail to the FDA office in Denver. I received no compensation for any of this, but I did so to, again, show I was willing to try to understand and work with the issues.

I am clearly confused as to what point the FDA is making in this letter. First, you mention section 201(g)(1)(b) of the "act." You then go on to state that my "website claims that..." and name several products, "are useful in prevention and treatment of various disease conditions." I cannot locate where such statements are made by me. My position is that of "adjunctive" care, similar to advising people to eat quality food, or stay away from other things that create health threats, so the body can heal itself.

I wish to understand the FDA's position, and need more information to pass on to my legal firm, and to understand where statements are in error. The"35% food grade hydrogen peroxide" and other named products, as far as I can discern, are NOT advertized as a "diagnosis, cure, mitigation, treatment or prevention of disease." "Adjunctive," the word used most often, means something that supports the body allowing it to have the best chance to fight the health threat, whatever it may be.

This is not "advertised" in any way as any of those stated things. There is information regarding how someone can utilize this product (H2O2) for dozens of uses, and I even have a notice that I

do NOT recommend H2O2 for internal use, "except for those with cancer," but I do NOT state it does anything specific for cancer. This is NOT advertising or "labeling." I do not deal with any products or labeling of same. I deal with information on natural health. This in no way is promoting products as a "cure," or anything else but a help for the body. As my site explains clearly, there is no such thing as a magic bullet cure for anything.

People coming to my site are seeking the product because of their own knowledge of the product, and this is a small % of people who purchase the H2O2 product.

Beta Glucan information is based on scientific studies provided on my website. This, too, is information people can utilize to make informed decisions, but is NOT advertising it as a cure, or anything, and I would like to understand how the FDA claims this. There may be logical and reasonable conclusions that can be made, but stating that something will "cure" their issue isn't made.

The Living Stream is a probiotic, and probiotics (having GRAS status) have the most scientific research of virtually any product on the market. It is well established that probiotics provide substances that are many things, including anti-infective in nature. If the FDA needs this research (decades worth) it can be provided. Historical evidence can be presented in the literature to show clearly that what products I'm dealing with have health benefits. I don't dissect how natural health products will benefit the body.

You also state "other product" but do not clarify what these products are and how they are in violation of alleged laws. This is creating a huge burden on me to interpret FDA laws, and I am not an attorney, nor can I afford one.

You also mention the "previous" warning letter dated 5-8-2003, (9 years ago) which I immediately took care of. The FDA had full access to my website, and knew the content then, so why was I not given opportunity to correct issues the FDA had with these "other" pages and products 9 years ago?

Am I to understand the FDA's position, (and that of Congress and the Courts) as the following:

1. That if I stated on my website that vitamin C complex, or an orange, could "cure" scurvy, that this would "cause to be drugs" oranges or vitamin C complex supplements?
2. Or if I stated that whole wheat bread supplying B vitamins could cure beri beri, this would make whole wheat bread a "drug?"
3. That "I" would "cause to be drugs," according to FDA laws, anything in the natural, God-created realm that is well established, over millennia, to help health issues?

If we were to follow the FDA's logic to its inevitable end, the use of cucumbers to remove the "bags" around one's eyes would violate the *Food, Drug and Cosmetic Act*. Water sold for "hydration" would violate the *Food Drug and Cosmetic Act*. Modern plumbing, including sinks

and toilets, which help society cut down on germs and mitigate disease, would be “devices” under the control of the FDA.

The Medical community routinely uses enzymes to dissolve clots in stroke victims because they breakdown clot/plague buildup, and can save the life of the patient, yet the FDA is trying to say that I can’t point people to the use of natural enzymes as a means to minimize build-up in the cardiovascular system under the same science?

The FDA was satisfied with my changes to the website, and did NOT claim I had any other issues. Does the FDA expect all individuals to have full and complete knowledge of FDA code and statutes, and intent? Do you?

How will I know whether I am in full compliance of FDA rules, even if I were to read through every word of the code? I have no idea where I am in violation to date despite the code. I have personal testimonies from hundreds of patients/customers. These are posted for people’s educational benefit. Are these in violation of FDA regulations as well? Free speech is now condemned by the FDA?

I deny that it is “my responsibility to ensure that products marketed by your firm comply...” No person can know all the laws, and that is why the FDA exists, isn’t it. A sole proprietor cannot possibly keep up with FDA rules, and most thinking humans know this. Is the FDA in the business of putting people OUT of business, or in truly protecting people’s health?

I have clearly shown my good faith in complying with the FDA where it is right and logical to do. This is of record. I cannot possibly “correct these derivations” without understanding how they violate common sense, and reasonable thinking, and where they do not conflict with the Constitution and personal rights. There is a clear contradiction in FDA expectations as the example of the oranges and whole wheat bread clearly show.

That being said, let me elaborate on my position and authority to be doing what I do.

First, Article VI, Section 3 in states:

“The Congress shall have Power to dispose of and make all needful Rules and Regulations respecting the Territory or other Property belonging to the United States; and nothing in this Constitution shall be so construed as to Prejudice any Claims of the United States, or of any particular State.”

The Constitution states that only “needful” rules are allowed to be made. The regulations regarding natural products being classified by the FDA are NOT needful, and are burdensome, and border on tortuous interference where the FDA intercedes in personal businesses, if not racketeering.

Second, notice the CALIFORNIA COMMERCIAL CODE, SECTION 9301- 9342, 9307. (h) The United States is located in the District of Columbia. "Citizenship of the United States is defined by the Fourteenth Amendment and federal statutes, ..." Crosse v. Board of Supervisors, 221 A2d 431, 434, citing 19 Md 82, 93.

I do not, nor does Colorado state "belong to the United States." Colorado is NOT a territory of the "United States," and therefore jurisdiction does not extend over me as a Colorado state citizen in this issue. "The United States" is NOT the same as the "united States," the union, which has its own sovereignty, under law and original intent.

"A citizen of the United States is a citizen of the federal government ..." Kitchens v. Steele, 112 F.Supp 383.

I am NOT such a citizen, and thus, the "subject to the jurisdiction..."
"Section. 1. All persons born or naturalized in the United States and subject to the jurisdiction thereof..."

I was NOT born in "The United States," or one of its territories, but was born in Iowa state, and subject to limited state jurisdiction, or personal jurisdiction for most things not authorized in the Constitution which the federal government has ANY authority over in law. I know of NO authority for the FDA to be acting personally against me and my business outside the District of Columbia, or other "United States" territory.

"We have in our political system a Government of the United States and a government of each of the several States. Each one of these governments is distinct from the others, and **each has citizens of its own**...." U.S. v. Cruikshank, 92 U.S. 542 1875. (Emphasis added).

Third, there are countless products of natural, God-created origin that were given for our healing and health, but it seems the FDA is attempting to circumvent God's design, and take upon itself the prerogative of claiming what is a valid health product and what is a "controlled" drug. Is the FDA trying to replace God in the scheme of things? Isn't this infringement of my religious rights to educate and provide for people on my God's created system and substances for good health?

I would NOTICE the FDA that I believe this is an encroachment of my Religious and biblical rights as practiced for over 30 years. The First Amendment clearly states... "Congress shall make no law respecting an establishment of religion, **or prohibiting the free exercise thereof**;" Is the FDA overreaching its authority and purpose, or is the "purpose" to cripple natural, God-designed health care?

In *HOSANNA-TABOR EVANGELICAL LUTHERAN CHURCH AND SCHOOL v. EQUAL EMPLOYMENT OPPORTUNITY COMMISSION* ET AL. Decided January 11, 2012, the Supreme Court ruled (9-0) that ecclesiastical/church court and jurisdiction (Ours is now established in Ft. Collins for our area, called the "Ecclesiastical Court of Justice"), overrides Federal laws where

no damages have been done to property or person.

The issue was of a woman (nonmember of the church) who became sick and had to be away from working for this Lutheran church. When she was better, she went back to her job, but was told that she had been replaced because they needed someone for the position. This gal sued under the Equal Employment Opportunity laws which would normally govern this situation, and it went to the Supreme Court, and she lost the case.

The Courts states...

"In this class of cases we think the rule of action which should govern the civil courts, founded in a broad and sound view of the relations of church and state under our system of laws, (First Amendment) and supported by a preponderating weight of judicial authority is, that, whenever the questions of discipline, or of faith, or ecclesiastical rule, custom, or law have been decided by the highest of these church judicatories to which the matter has been carried, **the legal tribunals (state or Federal) must accept such decisions as final, and as binding on them**, in their application to the case before them." Id., at 727."

"In this country the full and free right to entertain **any religious belief, to practice any religious principle, and to teach any religious doctrine which does not violate the laws of morality and property, and which does not infringe personal rights, is conceded to all**. The law knows no heresy, and is committed to the support of no dogma, the establishment of no sect. The right to organize voluntary religious associations to assist in the expression and dissemination of **any religious doctrine**, (free to choose) and to create tribunals for the decision of controverted questions of faith within the association, and for the ecclesiastical government of all the individual members, congregations, and officers within the general association, is unquestioned. All who unite themselves to such a body do so with an implied consent to this government, and are bound to submit to it. **But it would be a vain consent and would lead to the total subversion of such religious bodies, if any one (FDA) aggrieved by one of their decisions could appeal to the secular [344 U.S. 94, 115] courts and have them reversed**. It is of the essence of these religious unions, and of their right to establish tribunals for the decision of questions arising among themselves, that those decisions should be binding in all cases of ecclesiastical cognizance, subject only to such appeals as the organism itself provides for. Id., at 728- 729." (Emphasis added throughout).

The entire premise of natural health care and naturally created remedies, or remedies based on the natural God-created order I have been working with for decades, are ALL God-given for mankind, and are to be used for such. (Gen 1:29 "And God said, "See, I have given you every herb that yields seed which is on the face of all the earth, and every tree whose fruit yields seed; to you it shall be for food." NKJV.

Gen 3:18 "And you shall eat the herb of the field." NKJV.

Ezek 47:12 “Along the bank of the river, on this side and that, will grow all kinds of trees used for food; their leaves will not wither, and their fruit will not fail. They will bear fruit every month, because their water flows from the sanctuary. Their fruit will be for food, and their leaves for **medicine**." NKJV (Emphasis added).

Rev 22:2 “In the middle of its street, and on either side of the river, was the tree of life, which bore twelve fruits, each tree yielding its fruit every month. The leaves of the tree were for the **healing** of the nations.” NKJV. (Emphasis added).

Our biblical and religious position is well based in scriptures, and in historical records, and Congress has long established that there can be “NO” laws established against our beliefs and practices... “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof;”

Article 1, Declaration of Rights, §11 of the Constitution of the state of Washington provides that:

“Absolute freedom of conscience in all matters of religious sentiment, belief and worship, shall be guaranteed to every individual, and no one shall be molested or disturbed in property on account of religion... [AMENDMENT 88, 1993 House Joint Resolution No. 4200, p 3062. Approved November 2, 1993]. (Equal protection clause for all state’s citizens).

For the FDA and medical profession to corner the practice of health care and attempt to change these laws and the authority of God, cannot stand. If the FDA can show cause where there is an injured party, or damage done, then this would have merit, but only through lawful “Due Process” channels, rather than “administrative” rules and procedures, which are an egregious violation of civil rights.

Mr. Sherer, I want to work with the FDA on these issues where they are truly damaging to human health and doing harm. What do arbitrary “rules” about what is promoted using long-standing knowledge (centuries of prima facie evidence) of natural products have to do with “human services?” I asked then, and I ask now, in good faith, where am I doing damage to people or doing harm in any way? I can provide many testimonials and affidavits to “PROVE” that I am not harming others, and if this must be brought into our court of law, and before a jury, (with full discovery of all FDA actions against natural health and food, among other things) then it will be. I am only focused on truth and helping people, (now for 39 years) not on harming others.

FDA approved drugs killed over 452,000 people between 200-2010. (21 CFR 310.305, 314.80, 314.98, 600.80) and Forms FDA 3500 and 3500A). This doesn’t include medical “errors” causing deaths of over 200,000 per year.

The JOURNAL of the AMERICAN MEDICAL ASSOCIATION (JAMA) Vol 284, No 4, July 26th 2000 article written by Dr Barbara Starfield, MD, MPH, of the Johns Hopkins School of

Hygiene and Public Health, shows that medical errors may be the third leading cause of death in the United States.

The report apparently shows there are 2,000 deaths/year from unnecessary surgery; 7000 deaths/year from medication errors in hospitals; 20,000 deaths/year from other errors in hospitals; 80,000 deaths/year from infections in hospitals; 106,000 deaths/year from non-error, adverse effects of medications - these total up to 225,000 deaths per year in the US from iatrogenic causes which ranks these deaths as the # 3 killer.

On top of that, genetically modified (GMO) foods and seeds are a scientifically proven major threat to human and animal health according to extensive research, but these threats that are proven real, the FDA ignores, and allows Monsanto to threaten human and environmental survival through GMO's and chemical poisoning of our land, yet, the FDA is concerned about my small natural health and wellness online/internet website business being a "threat" to human health? Or, is it a threat to saving people from using drugs that have a 10,000% better chance of killing them than taking a probiotic, or herb or other natural substance?

Mr. Sherer, I am a disabled veteran. I am barely making a living using my expertise in health and wellness, having been a doctor, but now cannot practice due to my Navy back injury. I am taking care of my disabled mother, and from the looks of all this, it seems that the FDA is in the business of putting people out of business rather than caring for their health. The "request" to come to Denver "to show cause" is very premature. Why would the FDA take "enforcement action" against a flea in the scheme of things? Why would the FDA be bothered with my almost insignificant very small business, while millions of people are damaged by drugs and practices in the medical field and GMO field?

I cannot afford to take two days off my part-time work, and spend $150 in gas and another $50-$100 for a motel room for such a meeting. I also have trouble sitting for long period of time in such a drive, and this would increase the drive time to 6-7 hours, each way. That is creating a huge hardship on me, and even if this becomes a court case, I likely wouldn't have to appear in person. If necessary, and to help clarify FDA positions on all my web pages, we can certainly do a Skype call, or conference call to address these things without all the expense.

The burden of proof on the FDA is in showing that my actions or the products made by a dozen or more manufacturers ARE causing health threats or injury, or is a crime under existing laws. If there is no injured party, there can be no crime...

"For a crime to exist, there must be an injured party. There can be no sanction or penalty imposed upon one because of this exercise of Constitutional (or religious) rights." Sherar v. Cullen, 481 F. 945. (Emphasis added).

Innocent until proven guilty of a real crime. The FDA cannot take "enforcement action" without a court order and without evidence in fact of a crime, and an injured party, who personally has

standing in any case against me, or they are in violation of due process laws, plain and simple. (Please see Affidavit of Status, and Notarial Affidavit, herein).

This will certainly open a huge can of worms if you decide to unconscionably "attack" me in this issue, (rather than discussion) as it will go across the country, and the FDA, and all known persons involved, will have to defend against infringing on religious freedoms and rights, not to mention civil rights, or plain unfair and unjust actions. I prefer to not have to be confrontational in any of this, but if premature, unlawful actions occur against me or my business, outside Due Process of law, (my constitutional and civil right in your forum), then I will sue for compensatory and punitive damages, before a jury OF MY PEERS, and bring this to the Ecclesiastical Court of Justice, and court of public and Church opinion, as well as NOTICE all the Churches across the country of this issue and their remedy in law against these actions against our beliefs.

If you are prepared for this, then so am I, and will call upon the Private Attorneys General* laws under 14 U.S.C., as part of the Department of Justice, and bring in people across the country to represent the people offended by the FDA, against this continued attack against natural health care. Truth is all that matters, and I have to presume that the FDA also believes in such.

I look forward to your response.

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Jeffrey T. Maehr

CC: LaTonya Mitchell considered NOTICED in this response and potential action.

Foundation for Truth in Law

* Civil Rights Attorney's Fees Award Act of 1976, 42 U.S.C. § 1988.

"In rejecting a significantly different focus under RICO, therefore, we are honoring an analogy that Congress itself accepted and relied upon, and one that promotes the objectives of civil RICO as readily as it furthers the objects of the Clayton Act. Both statutes share a common congressional objective of encouraging civil litigation to supplement Government efforts to deter and penalize the respectively prohibited practices. The object of civil RICO is thus not merely to compensate victims but to turn them into prosecutors, "private attorneys general," dedicated to eliminating racketeering activity. 3 Id., at 187 (citing *Malley-Duff, 483 U.S., at 151*) (civil RICO specifically has a "further purpose [of] encouraging potential private plaintiffs diligently to investigate"). The provision for treble damages is accordingly justified by the expected benefit of suppressing racketeering activity, an object pursued the sooner the better." [*Rotella v. Wood et al., 528 U.S. 549 (2000)*].

42 USC § 2000bb - Congressional findings and declaration of purposes

(a) Findings
The Congress finds that—
(1) the framers of the Constitution, recognizing free exercise of religion as an unalienable right, secured its protection in the First Amendment to the Constitution;
(2) laws "neutral" toward religion may burden religious exercise as surely as laws intended to interfere with religious exercise;
(3) governments should not substantially burden religious exercise without compelling justification;
(4) in Employment Division v. Smith, 494 U.S. 872 (1990) the Supreme Court virtually eliminated the requirement that the government justify burdens on religious exercise imposed by laws neutral toward religion; and
(5) the compelling interest test as set forth in prior Federal court rulings is a workable test for striking sensible balances between religious liberty and competing prior governmental interests.
(b) Purposes
The purposes of this chapter are—
(1) to restore the compelling interest test as set forth in Sherbert v. Verner, 374 U.S. 398 (1963) and Wisconsin v. Yoder, 406 U.S. 205 (1972) and to guarantee its application in all cases where free exercise of religion is substantially burdened; and
(2) to provide a claim or defense to persons whose religious exercise is substantially burdened by government.