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In the Matter of Ebola and	**}**	**Before the United States**
Natural Solutions	**}**	**Food and Drug Administration**

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Citizens' Petition for Redress

A copy of this Citizens Petition is also being submitted today to the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) as part of Natural Solutions Foundation's Response to the Warning Letter issued on September 23, 2014 by the FTC and the FDA to Rima E. Laibow, MD and Ralph Fucetola, JD, under joint FDA/FTC Docket No. **#14-NWJ-11**; a copy of the Warning Letter is here: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm416051.htm and a copy of the Response to the Warning Letter is attached to this Petition and submitted as part hereof.

Emergency Citizens' Petition

In order to facilitate the international response to the Ebola Epidemic by both governments and NGOs, and to prevent Ebola's spread and subsequent escalation into a world-wide pandemic, the Natural Solutions Foundation and its Trustees, on their own behalf and on behalf of the communicants of the Foundation, hereby Petition the FDA and FTC to exercise regulatory discretion during and following the current emergency.

We hereby Petition the two Agencies, under the First Amendment Right to Petition for Redress, under the Administrative Procedures Act and 21CFR10.30 for an emergency ruling in support of Nano Silver and CBDs as "ethical to offer unproven interventions … [with] a moral duty to also evaluate these interventions".

[A] Actions Requested

(1) Exercise of regulatory discretion to permit free and open discussion of the relationship between Nano Silver, as (1) an approved hard-surface sanitizer, (2) an approved wound dressing, (3) a permitted supportive immune system nutrient and (4) as a permitted nutritional support for the normal impenetrability of cell membranes to viruses that may be present within or upon the body.

(2) Exercise of regulatory discretion to permit the use of the word "cure" or its non-DSHEA statutory alternatives such as "heal" in connection with the ultimate outcome of the use of natural solutions to achieve and maintain a healthy status.

(3) Exercise of regulatory discretion to continue to permit the use of nutritional Cannabidiol (CBD) to support healthy outcomes.

(4) Issue emergency Qualified Health Claim approval for this statement:

"Nutritional Nano Silver supports normal cell membrane impermeability to hemorrhagic and other viruses, maintaining homeostasis. Like other nutrients Nano Silver does not provide a pharmaceutical treatment of disease."

(5) Hold hearing(s), permit Public comments, issue permanent regulations, consistent with our expressive association rights, implementing the emergency discretion and emergency Health Claim on a regular basis.

[B] Statement of Grounds

[1] Statement of Facts

1. Natural Solutions Foundation is a private association organized as a nonprofit Nevada corporation, recognized as exempt by the United States. The Foundation is an international Non-Governmental Organization (NGO) engaged in charitable, educational, literary and scientific research activities.

2. For its private communicant associates it provides access to various natural products, including nutrients, and specifically Nano Silver and CBD products.

3. Nano Silver and CBDs are nutrients which are deemed to be safe when used as directed; there is no significant contrary evidence known to Petitioners.

4. The Foundation communicates to the public what it does in private association, so members of the public may exercise their First Amendment rights and enter into private association with the Foundation.

5. The Medical Director of the Foundation is Rima E. Laibow, MD. Her two co-Trustees are Maj. Gen. Albert N. Stubblebine III (US Army, Ret.) and Ralph Fucetola, JD.

6. As part of the Foundation's expressive association, "Dr. Rima Recommends" various natural solutions. She has practiced drug-free medicine for over forty years as a licensed

physician.

7. She recommends Nano Silver 10 PPM. See Label attached as Exhibit A. In an attempt to conform to the Agencies' public statements/regulations regarding the DSHEA Disclaimer Statement (that the said Disclaimer Statement is lawfully required) the said Label includes the Disclaimer Statement, although its compelled inclusion violates our First Amendment rights.

8. The Foundation asserts that, as applied to us in the current Ebola Emergency and thereafter, the use of the Disclaimer Statement, or its equivalent required by the Warning Letter, infringes upon the Expressive Association rights (Free Speech, Petition for Redress, Association and Assembly) of the Foundation, its Trustees and its associates.

9. Nano Silver is approved by FDA and/or EPA as a hard-surface sanitizer and wound dressing (claims in this regard are deemed substantiated by Letters Patent issued by the United States Patent Office to the manufacturer of this Nano Silver).

10. Nano Silver is a DSHEA-grandfathered nutrient permitted to be sold to support the immune system.

11. The DTRA-sponsored study referenced by the Warning Letter is not a "medical use" study, but rather, shows a *nutrient effect which occurs prior to any disease state*. It is therefore appropriate to view the study as substantiation for the immune system support capacity of Nano Silver. See Exhibit B for the report of the study, with Dr. Laibow's analysis.

12. CBDs are manufactured by the human body as part of normal structure and function and, as such, are nutrients permitted to be sold to support normal levels and support normal immune and other functions.

13. Additional information, both favorable and possibly not favorable to the Petition may be found in public sources such as http://ods.od.nih.gov/Research/PubMed_Dietary_Supplement_Subset.aspx.

14. The Petitioners have researched the literature regarding Nano Silver and CBDs and find no relevant negative information for CBDs as an indigenous part of the human body, nor for Nano Silver 10 ppm, with regard to the subject matter of the Petition.

[2] Legal Authority

1. The Legal Basis for this Petition is the First Amendment to the Constitution of the United States: "Congress shall make no law… abridging the… the right of the people… to petition the

Government for a redress of grievances." This Citizens' Petition is submitted pursuant to 21CFR10.30 and a copy of it, together with a copy of our reply letter and attachments, is being submitted through *http://www.regulations.gov* at Docket No. FDA 2013-S-0610.

2. The Legal Basis for the Proposed Regulatory Discretion is the aforesaid Constitutional principle and Section 3512 of Title 19 and specifically, 19 USC 3512(a)(1) and (a)(2) as applied to the protection of human life through DSHEA, in the context of the WHO August 12, 2014 and other determinations.

"Section 3512. Relationship of agreements to United States law and State law

(a) Relationship of agreements to United States law

(1) United States law to prevail in conflict. No provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect.

(2) Construction: Nothing in this Act shall be construed –

(A) to amend or modify any law of the United States, including any law relating to -
(i) the protection of human, animal, or plant life or health,
(ii) the protection of the environment, or
(iii) worker safety, or
(B) to limit any authority conferred under any law of the United States, including section 2411 of this title, unless specifically provided for in this Act."

3. Additionally, the Statutes authorizing the Agencies contain general provisions that support the actions requested in this petition. Federal Law includes provisions that grant the Cabinet Secretaries broad authority to promulgate rules and regulations "necessary to carry out the Act[s]."

4. The Agencies Should Promulgate the Requested Policy as an Interim Final Rule Without First Completing Notice and Comment, Risk Assessment, and Cost-Benefit Analysis

Under ordinary circumstances, the agency must comply with procedural requirements under both the Administrative Procedures Act (APA) and the USDA Reorganization Act of 1994, including the use of notice-and-comment rulemaking and the completion of a risk assessment and cost-

benefit analysis before issuance of a new rule. However, both acts provide for exceptions to those requirements for circumstances such as those present here, where the Ebola Emergency constitutes an imminent threat to public safety and any delay in policy making would be contrary to the public interest.

The Agencies should avail themselves of those statutory exceptions and promulgate the requested policies without first providing the public with notice and an opportunity for comment and before completing a full risk assessment and cost-benefit analysis. The agency should first adopt the policy as an "interim-final rule," which would become binding upon publication (or shortly thereafter), and subsequently provide for public comment and complete its risk assessment and cost-benefit analysis.

> The Requested Regulations Satisfy the "Good Cause" Exception to the Administrative Procedure Act's Requirement for Notice and Comment.
>
> The APA provides that full notice-and-comment rulemaking is not required when an agency "for good cause finds (and incorporates the finding and a brief statement of the reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. §553(b)(B). The good cause exception "is an important safety valve to be used where delay would do real harm." United States Steel v. EPA, 595 F.2d 207, 214 (5th Cir. 1979). According to the legislative history of the provision, "'impracticable' means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings." S. Rep. No. 752, 79th Cong., 1st Sess., at 16 (1945). As one court has held, determining "impracticality" requires "analysis in practical terms of the particular statutory-agency setting and the reasons why agency action could not await notice and comment." American Transfer & Storage Company v. ICC, 719 F.2d 1283, 1295 (5th Cir. 1983).
>
> There are numerous instances in which courts have upheld an agency's decision to invoke the "good cause" exception and issue a rule without providing for notice and comment where a delay would threaten public safety or the environment. See, e.g., Hawaii Helicopter Operators Ass'n v. FAA, 51 F.3d 212, 214 (9th Cir. 1995) (good cause exception satisfied in view of "the threat to public safety reflected in an increasing number of helicopter accidents"); Northern Arapahoe Tribe v. Hodel, 808 F.2d 741, 750-52 (10th Cir. 1987) (good cause exception satisfied in view of urgent need for hunting regulations where herds were threatened with extinction); Northwest Airlines-v. Goldschmidt, 645 F.2d 1309, 1321 (8th Cir. 1981) (good cause exception satisfied in view of urgent need to allocate landing slots at major airport).
>
> The rationale underlying those decisions, that compliance with time-consuming procedural requirements would "do real harm" by delaying implementation of urgently needed policies to safeguard public health, is equally applicable here, where a Global Health Security Threat has already been declared and delay will have a negative impact on U.S. consumers. Clearly, the exigent circumstances necessary to satisfy the APA's good cause exception are present.

The compelling circumstances include the imminent spread of the deadly Ebola Epidemic to additional countries, including the United States, which became a reality on September 30, 2014, with the announcement by CDC of an index patient hospitalized in Dallas TX who had tested positive for Ebola. These compelling circumstances were underscored by the Director of the US CDC when he testified before Congress recently on this topic that an outbreak of Ebola in the United States is "inevitable". [http://news.yahoo.com/ebolas-spread-us-inevitable-says-cdc-chief-205903838.html]

[C] Environmental Impact

The Petitioners hereby state that the relief requested in this petition will have no direct environmental impact; therefore, an environmental assessment is not required under 21 C.F.R. Section 25.30.

[D] Economic Impact

We are unable to ascertain the economic impact of being forbidden to speak our opinions freely, but believe such chilling effect will reduce voluntary donations to our exempt non-governmental organization. We believe the removal of Nano Silver and CBDs from the market will adversely impact general health levels thereby having adverse economic impact.

Conclusion

In this emergency situation the Agencies must lay aside their historic opposition to Nano Silver and must reconsider the Warning Letter based on the relationship of their position to the *sine qua non* of Truth.

That "there is no approved treatment for Ebola," while technically true, is merely a deceptive and legalistic term-of-art easily misunderstood by those not familiar with the limitations of the regulatory authority of the FDA which does *not* have the power to either approve or reject a nutrient as long as it is unadulterated and both truthfully and legally labeled. The 2010 Food Safety and Modernization Act (Public Law 111-353, 111th Congress) includes an express provision (Section C (2) (g)) exempting DSHEA-regulated nutrients from the enhanced authority provided in that Act.

In truth and in common usage, there in fact is a natural strategy which includes hygiene and nutrition (including large servings of Vitamin C, and supplemental Nano Silver). The FDA lacks the authority to approve a nutrient: nutrients are offered as "therapies that may benefit" not "treatments" so that Nano Silver, a nutrient, cannot be "approved", nor can it be a "treatment".

Thus, although it is a natural therapy, Nano Silver cannot ever be an "approved treatment" for Ebola or anything else under the current oppressive regulatory and legal framework.

The Protocol offered by Rima E. Laibow, MD, the Medical Director of the Foundation, to the health care professionals of West Africa clearly discloses this natural health strategy, showing that Nano Silver is not intended to "treat" Ebola. See Exhibit C, the Protocol.

We reject the notion that such life-saving information should be kept from our associates or the public, and only transmitted to government or health care professionals. This is what the CDC attempted to do when it warned hospitals and airlines that Ebola is potentially transmissible as an airborne virus, but also telling these entities not to share that information with the public. See: http://drrimatruthreports.com/open-letter-to-sierra-leone-yes-you-can-catch-ebola-just-by-breathing/

Further there is more than a scintilla of evidence that Ebola can be transmitted through the air and can remain active for significant periods, in the cooler weather of North America. See: http://drrimatruthreports.com/another-ebola-military-smoking-gun/

Legitimate Government Regulation

The United States Government has no legitimate interest in promoting only FDA-approved interventions.

In the case of *State v Biggs* (46 SE Reporter 401, 1903) the North Carolina Supreme Court dealt with a person who was advising people as to diet, and administering massage, baths and physical culture. In the *Biggs* case, the defendant "advertised himself as a 'nonmedical physician'... [and] held himself out to the public to cure disease by 'a system of drugless healing'..." p.401. That Court held that there could be no "state system of healing" p.402 and while "Those who wish to be treated by practitioners of medicine and surgery had the guaranty that such practitioners had been duly examined...those who had faith in treatment by methods not included in the 'practice of medicine and surgery' as usually understood, had reserved to them the right to practice their faith and be treated, if they chose, by those who openly and avowedly did not use either surgery or drugs in the treatment of diseases..." p.402. Biggs was acquitted.

There is no government interest in controlling non-commercial, non-profit, private associations where people associate together for the improvement of their well-being.

The North Carolina Supreme Court concluded, nearly a century ago in *State v Biggs, supra.*, at p.405:

> "Medicine is an experimental, not an exact science. All the law can do is to regulate and safeguard the use of powerful and dangerous remedies, like the knife and drugs, but it cannot forbid dispensing with them. When the Master, who was himself called the Good

> Physician, was told that other than his followers were casting out devils and curing diseases, he said, 'Forbid them not.'" (p.405).

The Agencies should exercise their regulatory discretion to encourage "unproven interventions" and the evaluation thereof during the Global Ebola Emergency, and thereafter. Such access should not be limited to the immediate area of the current epidemic, but since an outbreak in America is "inevitable" (and may be starting in Dallas, Texas - http://www.cnbc.com/id/102037055) the discretion must include the United States. The time to act is now.

Certification

The undersigned certify, that the undersigned is a Citizen of the United States and that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

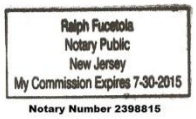
October 7, 2014


Albert N. Stubblebine III


Rima E. Laibow


Ralph Fucetola

Certified True Copy of the Citizens' Petition



Ralph Fucetola - Secretary

Exhibits

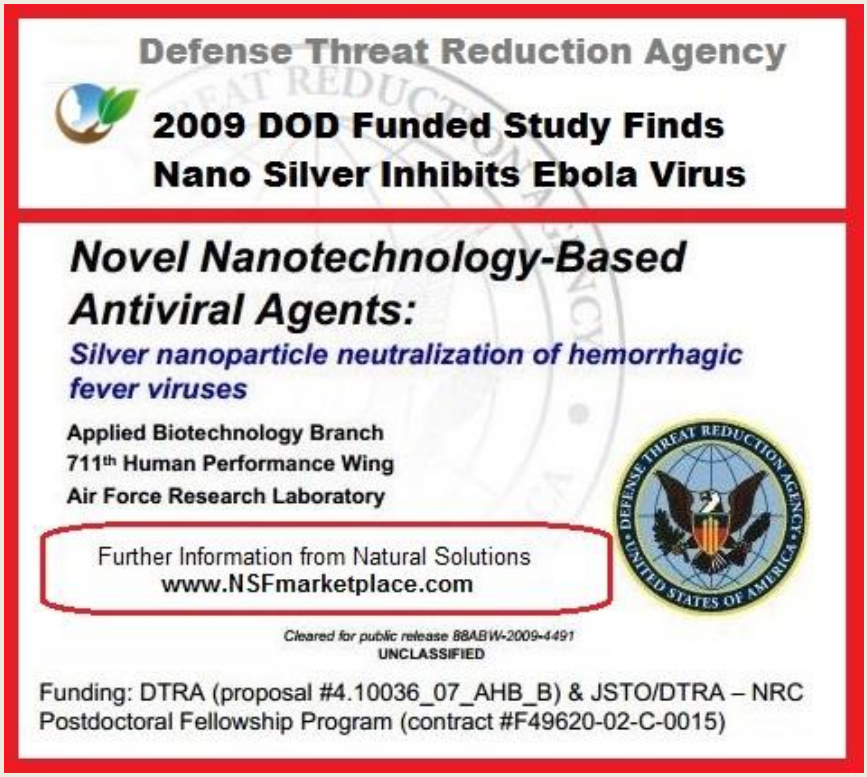
A. Label
B. Study Report
C. Protocol
D. Response Letter to Warning Letter

Exhibits are High-lighted in Beige Tone.

Exhibit A. Label

Exhibit **B. Study Report**

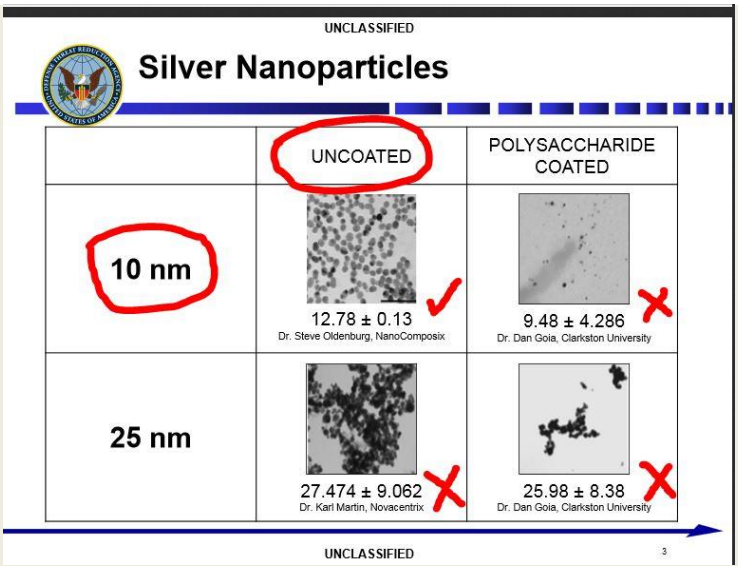
Analysis of DTRA Nano Silver Study



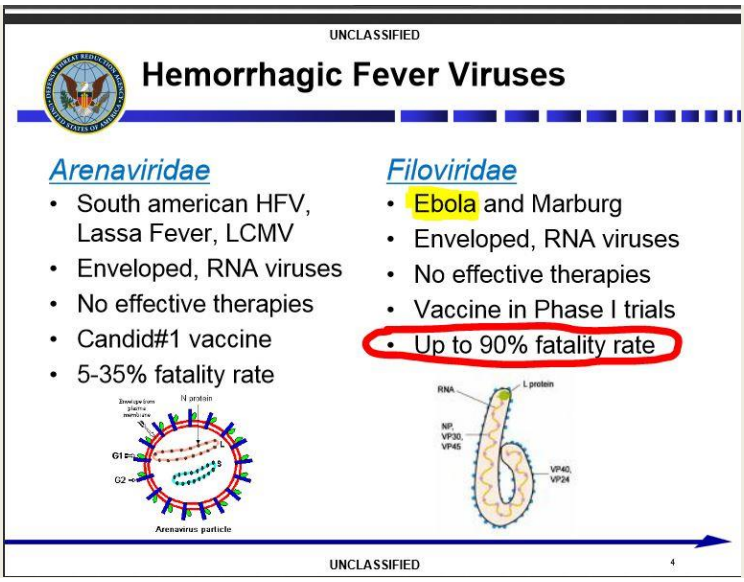
Nano Silver 10 ppm is a micro-nutrient that supports normal immune system function.

What follows is a detailed examination of the greatest health story never told by --

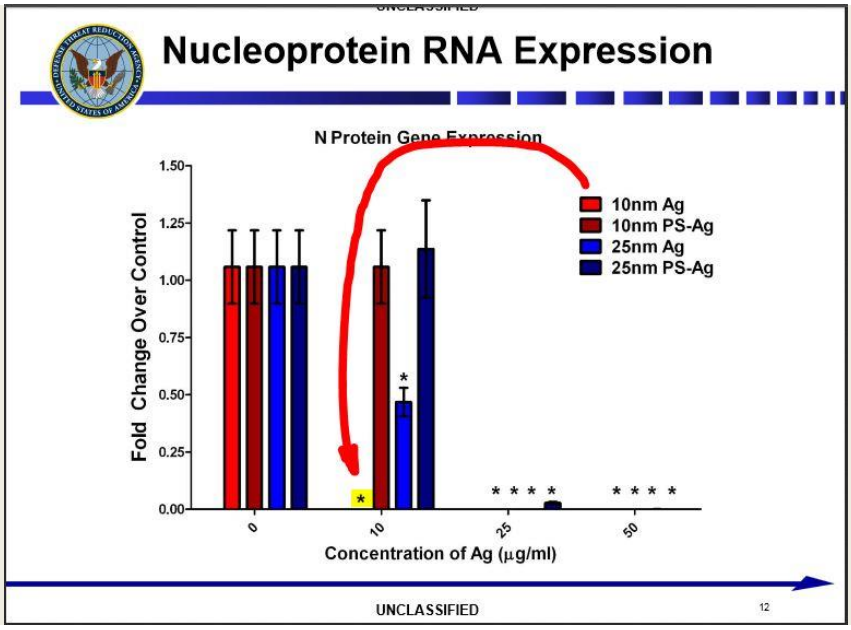
- This research was conducted by the Defense Threat Reduction Agency (DTRA) of the United States Department of Defense
- DTRA's research showed that 10PPM, not 25PPM or 50PPM was by far the most effective amount for down-regulating Ebola virus replication. The mere presence of a particular virus in the body, as part of the microbiome, is not itself a disease. The regulation of the microbiome is a normal body function.



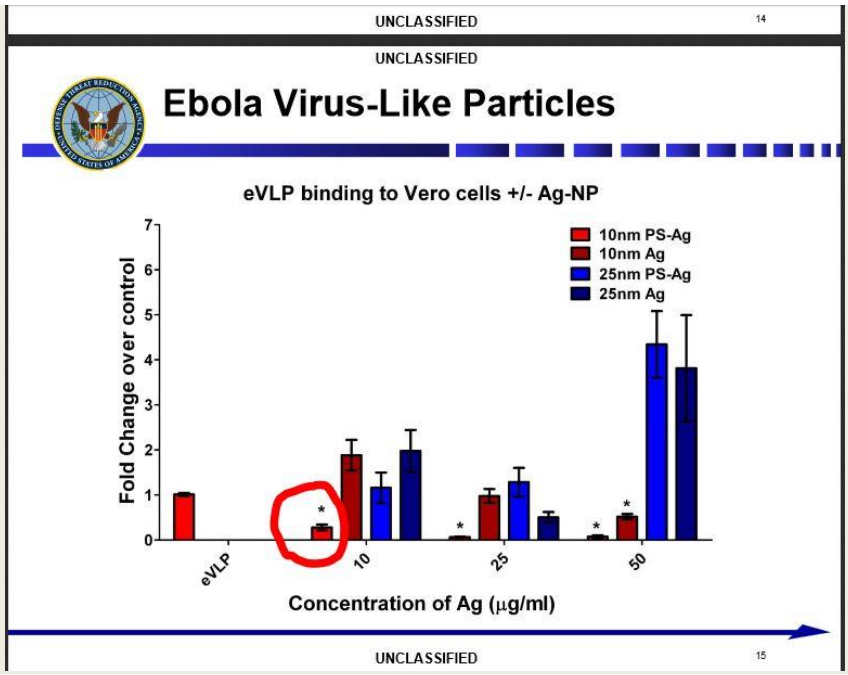
- Protein coated or other types of preparations were much less effective than uncoated Nano Silver (identical to the nano silver in Dr. Rima Recommends™ The Silver Solution, by the way)
- DTRA's research was carried out specifically on Ebola Virus as well as other deadly hemorrhagic (bleeding-inducing) viruses. The results were the same: Nano Silver at 10 PPM was the most effective agent at regulating normal cell membrane impenetrability to the virus.



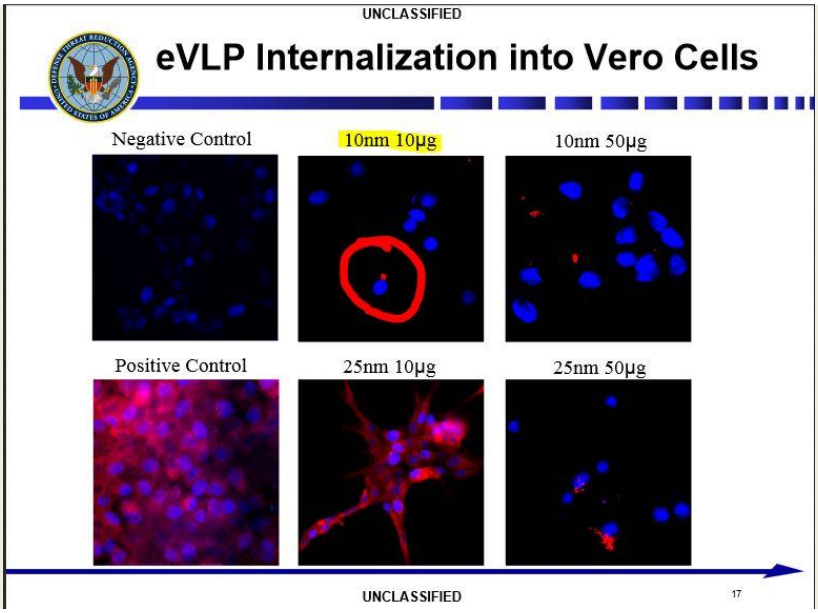
- When 10 PPM Nano Silver was applied, all of the Ebola Virus was affected (None of its genetic material remained, compared to the other nano materials).



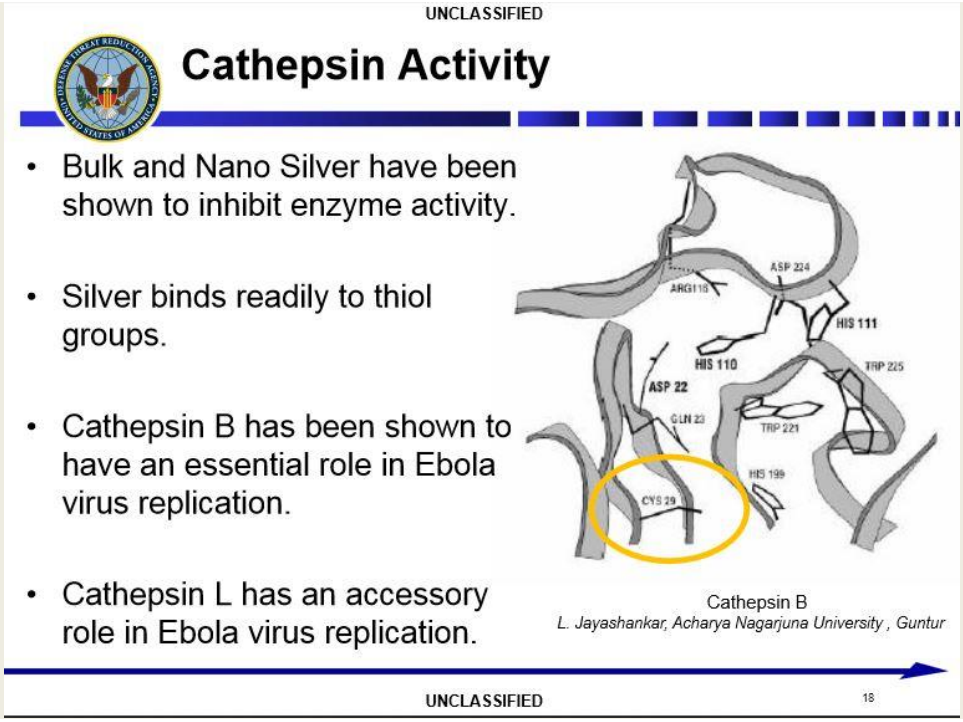
- Among other 10 PPM silver preparations, the one that is identical to *Dr. Rima Recommends The Silver Solution* regulated Ebola particles cell binding best. If the viral particles do not bind to cells, they cannot replicate. It is the "viral" replication that leads to the disease symptoms. Otherwise, they are just another part of the microbiota, maintained in a normal state by the nutrient silver.



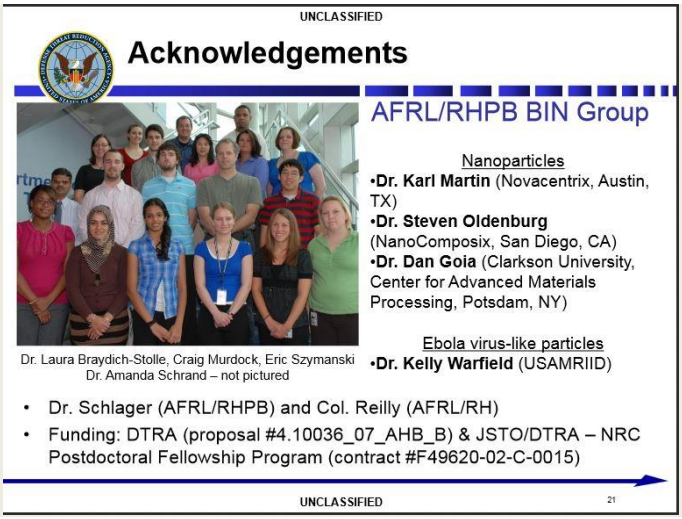
- Even if the virus did bind to, and enter, the cell, viruses faced with the correct type and size of Nano Silver showed very little activity. Red indicates viral activity below the Control.



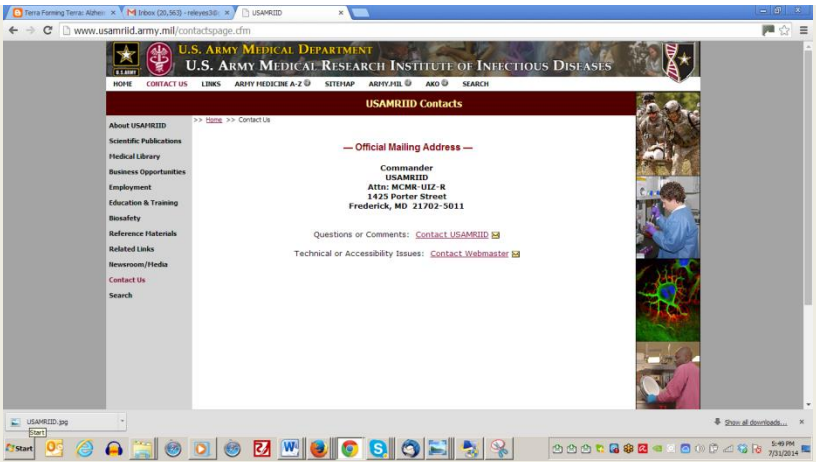
- Not only was the absolute effect of the correct Nano Silver on Ebola virus established in DTRA's research, the precise mechanism of nutrient action was determined



- Information showing the authors and their affiliations reveals the following critically important information:
  - At least 24 people participated in the study that demonstrated it!



  - The authors were part of a group (AFRL/RHPB BIN Group) carrying out research
  - Dr. Kelly Warfield was affiliated with the United States Army Medical Research Institute of Infectious Disease (USAMRIID), located in Fredrick, MD



- USAMRIID's bibliography shows at least 85 scientific papers on Ebola Virus, the earliest going back to 2000, the first year for which their online list of scientific publications is available. The first paper listed in 2000 is

> Bray M, J Driscoll, JW Huggins. 2000. Treatment of lethal Ebola virus infection with a single dose of an A-adenosyl-L-homocysteine hydrolase inhibitor. *Antivir Res* 45:135-147.

- Bray, et al, is a paper about the treatment of Ebola infection, as are at least half of their Ebola-related publications.

> Gunther S, Feldmann H, Geisbert TW, Hensley LE, Rollin PE, Nichol ST, Stroher U, Artsob H, Peters CJ, Ksiazek TG, Becker S, ter Meulen J, Olschlager S, Schmidt-Chanasit J, Sudeck H, Burchard GD, Schmiedel S. Management of Accidental Exposure to Ebola Virus in the Biosafety Level 4 Laboratory, Hamburg, Germany. *Journal of Infectious Diseases* 2011 Nov; 204(Suppl 3): S785-S790

- There can be no doubt whatsoever that at least one agency, USAMRIID's research was yielding treatment options for Ebola virus since at least 2000.
- The collaboration with DRTA was carried out sometime before 2009 when the research cited above was declassified.
- A search on the USAMRIID site reveals 22 citations for "antiviral", the second of which, Gene - Specific Ebola Therapies Protect Nonhuman Primates from Lethal Disease, dates back to 2006.

I find it impossible to believe that with the resources of at least these two agencies, both with substantial budgets, that no known cure, prevention or treatment for Ebola virus was found in at least 14 years of intensive research. The natural solution to all infectious disease has been available all along. It is a nutritional therapy that also recognizes the value of topical nano silver during outbreaks. My Nano Silver Pro-Immunity Nutritional Protocol is available upon request.

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Exhibit C. Protocol

The Dr. Rima Institute for Health Advancement
Santiago de Chile © 2014

Advanced Nano Silver 10PPM Nutritional Pro-Immunity Experimental Humanitarian Protocol for Immune Support in Epidemic Situations Including Ebola, MERS, Malaria and Similar Conditions

Rima E. Laibow, MD
International Medical Director

The Natural Solutions Foundation is a recognized nongovernmental not-for-profit organization registered in the United States with activities in Benin, Chile, Panama and the United States. The **Mission of the Natural Solutions Foundation: "Discover, Develop, Demonstrate, Document and Disseminate Natural Solutions…"**

The Dr. Rima Institute in Santiago de Chile serves people seeking well-being and health. Our clients come from all over the world. We provide unique, drug-free protocols to deliver information, nutrients and energy to assist in gaining, or regaining health. We help return the body to normal structure and function and detoxify recent or long-term toxins which are reducing optimal function. We use a variety of modalities, all of which are non-toxic, drug-free, to support heath and function. Health restoration, rejuvenation and preventive protocols are areas of significant focus.

Notification

This Protocol Document is prepared as a private communication to governmental and non-governmental agencies and persons with a need to know. It is provided as part of the Mission of the Natural Solutions Foundation, an international non-governmental organization (NGO). The Protocol Document is issued under the aegis of the Dr. Rima Institute. Reproduction is freely permitted so long as full attribution to www.NaturalSolutionsFoundation.com is given. **This Protocol is intended for use with Nano Silver 10 PPM. The Research upon with this Protocol rests was performed with Nano Silver 10 PPM and cannot be generalized to other forms of nutrient silver.** *Dr. Rima Recommends The Silver Solutions* is identical to the Nano Silver used in the DTRA study: **http://drrimatruthreports.com/wp-content/uploads/Analysis-of-DTRA-Nano-Silver-Study.pdf**

This Protocol Document is intended to provide a standard of therapy for the use of topical Nano Silver sanitizer and the use of nutrient Nano Silver 10PPM as a dietary supplement Medical Food, for the dietary management of inflammatory and related processes. Communication regarding the nutrient use is protected under the United States Orphan Drug Act of 2005.

For a detailed analysis, with citations to the scientific literature, regarding Nano Silver 10PPM as a pro-immunity nutrient see: http://tinyurl.com/StopEbola.

Nano Silver 10PPM is a potent natural nutrient. Similar to pro-biotic nutrients supporting normal biological terrain, by supporting normal microbiota, Nano Silver is a pro-immunity nutrient that supports normal immune system response, regulating normal cell membrane impenetrability.

Nano Silver offers the following advantages:

- All evidence suggests that Nano Silver 10PPM will help where vaccines do not exist or fail and are beneficial even when the immune system is impaired, such as in AIDS.
- While there are some vague suggestions of mild risks to the environment, our research shows that they are unfounded.
- Nano Silver 10PPM is widely used around the world for its ability to regulate the microbiota such that pathogenic organisms may not trigger disease symptoms. Nano Silver 10PPM is, in fact, approved by the United States government as a surface cleaner for hospitals, food service and other health-sensitive areas because of its notable efficacy and non-toxic profile. For reference to the 2009 DTRA study: http://drrimatruthreports.com/wp-content/uploads/Analysis-of-DTRA-Nano-Silver-Study.pdf
- Sufficient short term protection for an individual outbreak cluster is provided by the use of Nano Silver that an epidemic may be effectively avoided even after infection clusters have been established.
- Therapy can be started after infection, and normal immune function, including GI flora, is left intact to assist in recovery and prevent opportunistic co-infection.
- Nano Silver 10PPM is stable at room temperature.
- Nano Silver 10PPM offers a potentially beneficial therapy when concerned with virtually all types of viruses, bacteria and other pathogens (including malaria, and dengue), is self-sterilizing, reducing its cost and increasing its usefulness in challenging circumstances.
- Nano Silver 10PPM is a pro-immunity nutrient.

GENERAL NANO SILVER PROTOCOL

Based on the above-noted factors, and considering the cost-effectiveness of food-grade Nano Silver 10PPM and of surface-sanitizing Nano Silver applications, the standard of care for infection, inflammation and contamination includes both topical and ingested Nano Silver.

Ingested Nano Silver 10PPM may be considered a dietary supplement Medical Food as defined by the US statute and accepted by the US FDA:

"which is formulated to be consumed or administered orally or via intravenous means under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific

principles, are established by medical evaluation...." Section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3))

This Protocol includes the requirement to strictly adhere to all quarantine and containment protocols.

Nano Silver 10PPM may be mixed with water or juice if desired, but since it is odorless and tasteless, it may be consumed as is.

Although Nano Silver is self-sterilizing it is prudent to continue all isolation, containment and decontamination efforts to avoid exposing others who may not be within the reach of the Nano Silver Protocol.

Note on Dilution: The concentration of Nano Silver must be noted and amount given adjusted accordingly to conserve resources.

If higher concentrations than 10 PPM (Parts Per Million) of Nano Silver are used, the amount given to each person should be reduced to achieve the same Nano Silver administration results.

For example, a 20 PPM Nano Silver 10PPM solution would be diluted 1:1 and administered as 1 teaspoon of 10 PPM x 3/day as described above OR given undiluted (20 PPM) as ½ teaspoon, reducing the amount given for higher concentrations so that the effective amount delivered = 1 teaspoon of 10 PPM Nano Silver. Although Nano Silver 10PPM inhibits water-borne pathogens, in-so-far as possible, sterile water is recommended for dilution.

Additional Nutritional Considerations

As with all health promotion strategies, natural solutions require that the remedy work with nutritional status. Thus, the better the overall nutrition, the better the patient will respond. With hemorrhagic fevers the anti-inflammatory benefits of high levels of Vitamin C cannot not be overstated. Ideally, IV is best with acute conditions, but in any event, even a few grams orally a day can be of benefit. In addition, general anti-free radical supplementation is advisable. Nutritional enhancement with nutrients such as Cannabidiol (CBD) will support the endogenous cannabidiol system to support normal immune function.

General Protocol Instructions

[1] Ingested Nano Silver 10PPM

(A) Either before or after exposure:

A standard serving of Nano Silver10PPM consists of 1 US teaspoon (tsp) = ⅙ ounce = 5 cc = 1 capful of 10 PPM Nano Silver before likely exposure or after exposure: 3 servings a day is recommended.

(B) For promotion of health after symptoms have developed:

Give 1 standard serving orally every other hour from around the clock until symptoms resolve, for up to three days. The Nano Silver 10PPM should be held in the mouth for at least a half minute and then swallowed (12 CC daily).

[2] Topical Nano Silver

(A) For oral and skin lesion:

1) Skin Lesions: Apply dressings and saturate with Nano Silver 10 PPM solution, cover with occlusive dressing as appropriate or apply directly to lesion

2) Oral Lesions: If recipient is capable of participating in oral care, Nano Silver 10 PPM solution should be used as a mouthwash and either swallowed or expectorated. Since the Nano Silver 10PPM will sterilize the expectorant, it can be disposed of with other hospital waste but requires no special precautions beyond ordinary isolation protocols.

If recipient is not capable of participating in oral care, Nano Silver 10 PPM Solution should be applied directly to oral lesions.

(B) For decontamination of surfaces:

Wash all potentially contaminated contact surfaces with standard surface-sanitizing concentrations of Nano Silver (typically 30 PPM). Rinsing is not necessary since no toxic residue remains.

Sheets, gloves, food service items and other reusables may be decontaminated as well. Disposables should be decontaminated with Natural Solutions before being released into the waste stream.

Full Disclosure: The Dr. Rima Recommends™ brand of Nano Silver 10PPM is available for public health and personal options.

Yours in health and freedom,

Dr. Rima

Rima E. Laibow, MD
Medical Director
Natural Solutions Foundation

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View DTRA analysis here:
http://www.thesilveredge.com/pdf/defensethreatreductionagencysilvernanoparticlesneutralizehemorrhagicfeverviruses.pdf

Rev. 6.1 - 08.05.14This Protocol document expresses Dr. Rima's understanding of the subject and is not intended as individualized medical advice. Dr. Rima is licensed to practice medicine in the States of New York, Connecticut and Washington in the United States and is recognized worldwide as a leading Psychiatrist, Environmental Physician and Health Adviser. She is a registered Health Assessor in the Republic of Chile. She does not hold a Chilean Medical License.

EXHIBIT D

NATURAL SOLUTIONS FOUNDATION
58 PLOTTS ROAD - NEWTON, NJ 07860

Maj Gen Bert Stubblebine III (US A., Ret.) President
Rima E. Laibow MD Medical Director
Ralph Fucetola JD Legal Director
US Exempt NGO No. 20-0982110

October 7, 2014

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission
Washington, DC

Via: healthproducts@ftc.gov

Ref: **#14-NWJ-11**

Associate Director Engle,

[I] Initial Response to Warning Letter

This letter memorandum constitutes the Natural Solutions Foundation's initial response to the Warning Letter issued on September 23, 2014 by the Federal Trade Commission and the Food and Drug Administration to Rima E. Laibow, MD and Ralph Fucetola, JD, copy here: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm416051.htm.

I communicate with you in my private capacity as a Trustee of the Foundation and not in any public or representative capacity as an attorney at law, since I am a retired lawyer. The Natural Solutions Foundation is a private association whose Mission is to "Discover, Develop, Demonstrate, Document and Disseminate Natural Solutions" to the problems facing society.

My letter of September 25, 2014, acknowledging receipt of the Warning Letter, stated, "It is the intent of the Foundation to provide an initial written response to the Warning Letter within the period specified therein, including our plan to be in compliance with legal requirements."

Introduction

The Foundation and its Trustees reserve all rights. While we strongly disagree with both the facts and law as cited in the Warning Letter, and assert our Expressive Association right to make truthful and not misleading statements about health and food to our communicants, we are concerned that the writers of the Warning Letter may have misunderstood our communications.

Nevertheless, without prejudice, we offer this initial responding letter as a Plan of Compliance, to allay the expressed concerns of the Agencies in question. Therefore, we are undertaking the following steps:

Plan for Compliance

1. We no longer offer the two products lines cited in the Warning Letter for direct sale at our organization shopping cart, www.NSFmarketplace.com where there are several thousand products listed. There will be at least "two clicks" between the organization shopping cart or any opinion page and any web page where communicants may obtain these products.

2. We are currently performing a search of our blog entries and video/podcast postings to remove any direct "one click" links from opinion postings to the products in question. Given the hundreds of videos and podcasts, and the several thousand pages of blog postings, this process will take about ninety days from the date of this letter.

3. For our communicants' benefit, as an expressive association, we continue to privately provide some or all of the products in question, without making any specific claims other than those related to "Nutritional Immune System Support." We offer to include the disclaimers, "As a dietary supplement Nano Silver has not undergone FDA testing." and "As a dietary supplement, CBD has not undergone FDA testing".

4. We will continue to provide clear Disclosures and Disclaimers with regard to any further discussion of the US Department of Defense's Defense Threat Reduction Agency (DTRA) sponsored *in vitro* study, declassified in 2009 (Declassification Number 88ABW-2009-4491), which showed that various hemorrhagic viruses, including Ebola, did not replicate in the presence of Nano Silver 10 ppm.

5. Pursuant to *Pearson vs Shalala*, 164 F.3d 650 (D.C. Cir. 1999) we are willing to offer said Disclosures and Disclaimers to explain that the action of Nano Silver is purely nutritional and that there is no intent on our part to consider Nano Silver as a "prevention" or "treatment" for Ebola. The science shows that Nano Silver supports homeostasis by stimulating normal cell membrane impenetrability to viral replication. In this context, we offer this Qualified Health Claim:

   "Nutritional Nano Silver supports normal cell membrane impermeability to hemorrhagic and other viruses, maintaining homeostasis. Like other nutrients Nano Silver does not provide a pharmaceutical treatment of disease."

6. Since the mere presence of a virus is not a disease, the nutrient action of Nano Silver occurs prior to any disease process so there is no disease to "prevent" or "treat". Even if the person taking the Nano Silver has clinical signs and symptoms, since the Nano Silver acts at the level of the viral penetration of the cell, so that the intracellular replication of the virus cannot proceed, but does not act on the physiology of the patient in any way, the Nano Silver is therefore providing neither treatment nor prevention. The consequences of halting viral replication may be positive for the person involved or may not be, but the presence of a non-replicating virus is not synonymous with disease or with the prevention or treatment of a disease. The absence of, or elimination of, a replicating virus is, similarly, not a "cure."

7. We believe that the use of the word "cure" is protected by the First Amendment, but, to accommodate the concerns of the Agencies, without prejudice to our claim that the requirement chills our speech rights, we are searching our sites to replace the word "cure" with a term such as "heal" which is not found in DSHEA or the Regulations under it. Nonetheless, we submit this proposal under protest and reserve our right to seek judicial redress with regard to the use of the words which we believe Congress (or the FDA and FTC) unconstitutionally sought (seeks) to mandate in DSHEA (through its enforcement).

8. We are posting the following language on any web page where our communicants may obtain any nutrients:

   "Nutritional strategies to achieve and maintain a healthy status may be powerful

and effective in certain situations. Since the options for selection of nutrients and serving sizes can be confusing, we suggest that all of you who choose to be in private association with us take time to learn about your own nutritional needs. Nutrients are food and when used to supplement the diet are not subject to drug approval procedures by any government agency.

We advise prudent due diligence by the consumer using all available sources of information including the internet (e.g., google, yahoo.com and similar) as well as scientific studies (e.g., pubmed.com and similar) to see all viewpoints. The National Institutes of Health and PubMed have cooperated on a web site that includes large numbers of nutrient studies. You may find that here: http://ods.od.nih.gov/Research/PubMed_Dietary_Supplement_Subset.aspx .

We also recommend consultation with professionals trained in nutritional strategies for health and well-being (e.g, www.AAEM.org, www.ACAM.com and similar)."

Matters for Further Discussion

It is our position that, among the Disclosures and Disclaimers that might be reasonable for a food product, the statement, *"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."* (hereinafter, the "Disclaimer Statement") is *not* a reasonable requirement.

Any stipulation, regulation or statute that purports to require the inclusion of the Disclaimer Statement violates our First Amendment expressive association rights as well as our first amendment rights to free speech. This violation infringes upon the rights of all of the communicants of the Foundation and the Foundation Trustees. Our private association communicants have the right to receive our communications. *Virginia State Pharmacy Board v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976) in which the United States Supreme Court held that a state agency could not limit pharmacists' right to provide information about prescription drug prices as that would limit the rights of the recipients of that communication, who brought the case. This was an important case in determining the application of the First Amendment to "Commercial Speech" in which the Court held that there is no government interest in promoting "consumer ignorance."

The unreasonableness of the statutory Disclaimer Statement is especially egregious when applied to a recognized, exempt Non-Governmental Organization (NGO) engaged in responding to a declared, nationally and internationally recognized world health emergency. We fear the Agencies want to compel us to make statements that we would consider to be *not* truthful and therefore would be actively misleading. Can the Government compel us to lie? We believe not.

Would, or could, the FDA and FTC seek to compel us to lie? Yes, we beleive that intentionally or not these Agencies would and are attempting to compel us to lie. No, we do not believe that the Constitution allows them to do so.

There are several court precedents that rely on the *sine qua non* of truth in "Commercial Speech" -- even compelled "Commercial Speech."

In *Thompson v. Western States* Medical Center (535 U.S. 357, 2002) the majority held,

> "If the First Amendment means anything, it means that regulating speech must be a last - not first - resort."
>
> "We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."
>
> "Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown."

The basic rule, announced by the case, to determine constitutionally permitted government restrictions on "Commercial Speech" (speech that makes or is about an offer for a transaction) is a Two Prong Test: the first prong is to ask two questions: (1) is the speech in question about unlawful activity and (2) is the speech misleading. If "no" to both, the speech is entitled to protection unless the Government can carry its burden and prove (1) the governmental interest involved is "substantial", (2) the regulation must "directly advance" the governmental interest and (3) the regulation of Commercial Speech cannot be "more extensive than is necessary to serve that interest" (quoting *Central Hudson v Public Service*, 447 US 557, at 566).

The Disclaimer Statement requirement violates our right to state that any particular Natural Solution is or could be, in our opinion, a "cure." The statutory Disclaimer Statement (and the regulations that incorporate it and are the basis for the Warning Letter) is not a lawful disclaimer as described in *Western States*. The *Western States* Supreme Court authorized disclaimer is a **fact**-disclaimer, stating what the government has not done ("testing") and that the risks are unknown. The statutory Disclaimer Statement is compelled speech requiring us to express, or, more precisely, to deny, our "intent" without any factual reference. Some might hold that Congress can compel factually true "Commercial Speech," but there is no Supreme Court, legislative or regulatory authority for the proposition that the Court, Congress, or Agencies acting under its authority, can compel expressed *opinion*.

To be very clear, our objection to the Disclaimer Statement and the Warning Letter is that you seek to compel us to express an opinion that we do not hold, and that such compulsion is a clear violation of our First Amendment expressive association rights and those rights of our communicants as well as our first amendment right to free speech.

The vast preponderance of our speech has been and continues to be primarily opinion speech regarding how nutrients can help people achieve and maintain a healthy homeostatic status, even in the current Ebola world health crisis, and not "Commercial Speech."

The Warning Letter, in effect, gives us an unacceptable choice: speak the Truth as we see it, *or* provide the products in question to our communicants and misstate the truth of our belief. It is also possible to interpret the Warning Letter as forbidding *any* speech about the relationship of any nutrient and the current Ebola crisis. Such an interpretation further chills our fundamental rights and endangers the health of our communicants.

Thus the Warning Letter must have a chilling effect on our speech rights, or our association rights, or both. Whether or not your arguments apply to a for-profit commercial organization, seeking to regulate us as though we were a commercial operation must restrict our Expressive Associational rights. Restricting truthful, fact-based speech and/or forcing us to choose between speaking and doing is an intolerable infringement on Expressive Association. Allowing us to speak and act only privately, but not to tell the public what we know and have, is a violation of our privacy rights. Speaking clearly and sharing what we know is a moral duty. We have a right to invite the public to enter into private association with us and a right to share our opinions, truthful fact speech and information with them.

Where, as here, there is more than a scintilla of evidence in support of our position there can be no fraud. With the DTRA study, various patents held by the manufacturer, and other studies of the nutrient benefits of Nano Silver, there is ample compelling evidence of potential benefit. Similarly, the traditional use and scientific studies which support the easing of discomfort through the use of CBD products and the presence of immune- and pain-regulating endo-cannabinoids which function through their endogenous receptors in humans, supports normal structure and function, as do the exogenous supplements to that system, make it clear that with regard to CBDs as well as Nano Silver, there can be no fraud.

Due to the declared Ebola health emergency, the World Health Organization (WHO) proclaimed on August 12, 2014, that "…the panel reached consensus that it is ethical to offer unproven interventions …There was unanimous agreement that there is a moral duty to also evaluate these interventions" http://www.who.int/mediacentre/news/statements/2014/ebola-ethical-review-summary/en/

Responding to this urgent appeal which was echoed by the CDC, we redoubled our efforts to warn people that, while technically, there is, as FDA has repeatedly stated to the public, "no approved Ebola treatment…" there are natural strategies for dealing with these sorts of situations. That is why Dr. Laibow truthfully stated her medical opinion, "None need die from Ebola." (along with similar opinion statements throughout the Foundation web presence). Under her published Protocol, including proper hygiene and nutritional support, with large servings of Vitamin C, and Nano Silver to support immune function and normal cell membrane impermeability, her opinion statement is truthful and not misleading.

Similarly, her statements about the comfort enhancement and immune support of exogenous CBDs because they replete the body's own endogenous CBDs are also truthful and not misleading.

For our Foundation to have known of the DTRA-sponsored study, and that the study was about the same Nano Silver as "Dr. Rima Recommends" (which recommendation was made years prior to the current Ebola Outbreak) and suppressed that information, to not have told the world, would have been unethical according to our own moral compass and that of the WHO/CDC position. In fact, we urged clinical demonstrations under controlled conditions for Nano Silver to properly evaluate the strength of its ability to support normal immune structure and function by replicating *in vivo* the support provided *in vitro* in total compliance with WHO/CDC's position.

We are taking appropriate steps to provide Nano Silver to health care professionals in the Ebola Epidemic areas so that a Clinical Demonstration will show that Nano Silver can play two important roles in this crisis:

First, as an FDA/EPA-approved hard-surface sanitizer and wound dressing.

Second, as a nutrient long-known to support normal immune system function, and to specifically support normal cell membrane impermeability to the viruses that may or may not be part of the microbiota.

We expect to report the results of the Clinical Demonstrations, if they are permitted to occur.

United States government interference with this important international effort will be duly noted to the watching international community. In fact, the whole world is watching how the major nations respond to this Global Health Security Threat. The failure to explore, and support the exploration of, every option must be seen as tantamount to genocide.

Cannabidiol

In addition to the Agencies' concerns regarding Nano Silver, the Warning Letter also singles out Cannabidiol (CBD). This dietary ingredient is found in Industrial Hemp and other sources. An analogue is also directly made by the human body and is an important neurotransmitter in the Endo-cannabidiol System, where it mediates normal response to pain and supports normal neurological and immunological function. It has been part of the human body and diet since before the adopting of the Dietary Supplement Health and Education Act (DSHEA).

Dr. Laibow recommends CBD supplementation to support normal recovery and minimize discomfort. The Protocol which she authored and which the Foundation has made available focuses on hygiene and nutrition, including such essentials as Vitamin C supplementation. We do not find any specific reference in our opinion statements that CBDs prevent, treat or cure any specific medical condition. If there are any such references, we undertake to remove them.

We are willing to offer a fact-based Disclosure with regard to this nutrient: "CBDs support normal neurological and immunological function."

[II] Citizens' Petition for Redress

[Redacted – Same as Petition Above]