

ORIGINAL



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

_____)
In the Matter of)
)
DANIEL CHAPTER ONE,)
a corporation, and)
)
JAMES FEIJO,)
individually, and as an officer of)
Daniel Chapter One.)
_____)

Docket No. 9329
PUBLIC DOCUMENT

**COMPLAINT COUNSEL'S MOTION AND MEMORANDUM IN SUPPORT OF
THEIR MOTION TO EXCLUDE THE TESTIMONY AND
REPORT OF RESPONDENTS' EXPERT WITNESS JAMES DUKE**

I. INTRODUCTION

Complaint Counsel hereby moves to exclude the expert report and testimony of James Duke, Ph.D. ("Duke") from the trial scheduled for this case regarding the alleged deceptive advertising engaged in by Respondent Daniel Chapter One ("DCO") and its principal, Respondent James Feijo ("Respondents") in their sale of Bio*Shark, 7 Herb Formula, GDU, and BioMixx ("DCO Products), which they claim prevent, treat, or cure cancer and tumors because this testimony fails to meet the criteria for admissibility of expert testimony established in *Daubert*.

Respondents have tendered Duke as an expert witness to "review and offer opinion (sic) supported by evidence and experience on the ingredients of the challenged products; to review the science of herbal efficacy; to clarify the complex nature of herbal science versus the relatively simple science of pharmaceuticals" (Report of Expert Witness James A. Duke, dated

February 4, 2009, p.1) (“Duke Rpt”), attached as Exhibit A. Duke is an “economic botanist” who has catalogued numerous herbs that allegedly show promise in “fighting disease” (Deposition Transcript of James A. Duke, dated February 9, 2009, (“ Duke Tr.”), 91: 1.20-23)¹. Duke’s catalog, the “Multiple Activity Menus” (“MAMs”), provides a “listing of the chemicals in an herb that have been shown or assumed to help with cancer” (Duke Tr. 92: 1.5-11). Each entry on the MAMs also has a notation for the source of the information that an herb helps with cancer. The sources that Duke notes may be “folklore”, “animal” or “in vitro evidence”, among other sources (Duke Tr. 59: 1. 7-21). Duke has also written books on medicinal plants and herbs that are found in the Bible, e.g. “Medicinal Plants of the Bible,” (1983) (Duke Rpt. p.1). In Duke’s opinion there is a “reasonable basis” for Respondents’ claims:

1. [T]hat the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria.
2. T]hat the ingredients of GDU contains (sic) natural proteolytic enzymes (from the pineapple source bromelain) to help digest protein – even that of unwanted tumors and cysts...helps (sic) to relieve pain and heal inflammation. . GDU is also used for ... and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity...”
3. [T]hat the ingredients of BioMixx “boosts (sic) the immune system ... to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatment.

(Duke Rpt. p.3). Duke does not give an opinion on Bio*Shark because it is an animal based product and he does not deal with animal products. (Duke Tr. 63: 1.19-25). Moreover, Duke is “not convinced of the efficacy of shark cartilage in the studies” that he has read (Duke Tr.

¹Complaint Counsel refers the Court to the two copies of the deposition transcript of proposed expert James Duke which was previously filed with the Court 1) as an exhibit to the Motion for Summary Decision and 2) as a proposed trial exhibit. In consideration of not burdening the Court with additional copies and in order to preserve natural resources, Complaint Counsel has not attached the pages referenced in this memorandum.

64: 1. 13-15).

As set forth below, the Court should exclude Duke's report and testimony from the trial in this action because he lacks the knowledge, skill, experience, training or education required to testify as an expert on Respondents' claims that their products prevent, treat or cure cancer or tumors. Further, Duke's opinions are irrelevant to the issues of this case and/or are unreliable as they are not grounded in sufficient facts and data. As a result, the Court should exclude his report and testimony.

II. LEGAL STANDARD FOR ADMISSIBILITY OF EXPERT TESTIMONY

Commission Rule of Practice 3.43(b) requires that evidence must be relevant, material and reliable in order to be admitted. Rule of Practice 3.43(b). With respect to expert witness testimony, a witness "qualified as an expert, by knowledge, skill, experience, training or education" Fed. Rule of Evid. 702, may testify if: "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." *Id.*; *see also*, *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993) and *Kumho Tire Co. Ltd. v. Carmichael*, 526 U.S. 137, 153-54 (1996). Respondents, as the proponents of the expert testimony have the burden of proving its admissibility. *Graf v. Baja Marine Corp., et al.*, 2009 U.S. App. LEXIS 1986 at *21 (11th Cir. Feb. 2, 2009), *citing U.S. v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004).

Moreover, this Court has the authority to exclude expert testimony of any nature, whether it is based on "scientific, technical, or other specialized knowledge," if it lacks appropriate indicia of helpfulness to the fact finder. *Kumho Tire*, 526 U.S. at 141. In exercising

what has been characterized as “general ‘gatekeeping’ authority,” *id.*, the court may reject expert testimony that will not “assist the trier of fact to understand the evidence or determine a fact in issue.” *Daubert*, 509 U.S. at 591. Indeed, the law is well-established that “[e]xpert testimony that does not relate to any issue in the case is not relevant and, ergo, non-helpful.”*Id.*

Respondents cannot meet their burden under the Commission’s Rules of Practice, FRE 702 and the principles set forth in *Daubert* of demonstrating that Duke’s expert report and testimony are admissible. Consequently, the Court should exclude his report and testimony from any trial in this case.

III. DUKE’S TESTIMONY IN THIS MATTER SHOULD BE EXCLUDED

A. Duke is not Qualified to Testify as an Expert in this Case.

Duke does not have the knowledge, skill, experience, training or education to testify about the serious claims that Respondents make that the DCO Products prevent, treat or cure cancer or tumors. Duke has never been qualified as an expert witness before (Duke Tr. 26: 1.18-21). Duke is neither a medical doctor nor board certified oncologist (Duke Tr. 56: 1.3-10). He has never consulted with any holistic practitioner or with any homeopath on herbal cancer treatments for a patient. (Duke Tr. 19: 1.10-17). Thus, he lacks experience in treating cancer in any respect.

Further, Duke has never managed or participated in any studies to measure the efficacy of an herb that he asserts can be used to treat cancer (Duke Tr. 29: 1.15-22). Neither has Duke ever consulted on any study done to measure an herb’s anti-cancer effects (Duke Tr. 29: 1.23 - 30: 1.2), or ever measured the efficacy of herbs as a treatment for cancer in a controlled patient population (Duke Tr. 55: 1.21-24). Thus Duke has no practical scientific experience with these herbs’ use as a cancer treatment which might make him qualified to serve as an expert in this

case.

Respondents seem to have tendered Duke as an expert merely because he has produced a catalog of herbs and plants. However, this is not sufficient to qualify him to render an opinion on whether there is competent and reliable evidence to support Respondents' cancer claims. Duke then is not qualified to testify about the cancer claims at issue in this case and his testimony should be excluded. *See e.g., U.S. v. 99.66 Acres of Land*, 970 F.2d 651, 657 (9th Cir., 1992)(expert testimony concerning residential appraisals properly excluded where witness had no appraisal experience and "personal unfamiliarity" with underlying data).

B. Duke's Testimony Should be Excluded as Irrelevant.

Duke's testimony is irrelevant to this action for several reasons. First, his testimony relates merely to the cataloging of information about the components of just three of the DCO Products and "the science of herbal efficacy ... and ... to clarify the complex nature of herbal science versus the relatively simple science of pharmaceuticals" (Duke Rpt. p.1). He provides no credible understanding of how these herbs might be tested or how they might assist in treating cancer patients.

Moreover, Duke's views about whether herbs are more beneficial to use than pharmaceuticals (Duke Rpt. p. 6), which is a substantial part of his report, are irrelevant. Despite Respondents' efforts to confuse the issue, this case is not about evaluating the "science of herbal efficacy" or comparing "herbal science" to "pharmaceuticals" (Duke Rpt. p. 1). Instead, this case is about Respondents' claims that the DCO products prevent, treat, or cure cancer or tumors and whether Respondents had competent and reliable scientific evidence to support those serious health claims. Nothing in Duke's testimony will assist the Court in resolving this question. Expert testimony is irrelevant and, therefore, may be excluded if it lacks

appropriate indicia of helpfulness to the fact finder. *Kumho Tire Co.*, 526 U.S. at 141 (1999). Accordingly, Duke's testimony should be excluded.

C. Duke's Opinion Lacks Sufficient Facts and Data and Should be Excluded as Unreliable.

Finally, the Court should exclude Duke's opinions because they are not based on sufficient facts and data to make them reliable under FRE 702 and the *Daubert* principles.

At deposition, Duke testified that he had never heard of DCO before he was involved in this case and did not know what the DCO Products were (Duke Tr. 39: 1.9-10). Duke even erroneously believed that DCO was using herbs that were "Biblical" and only after a few days of working on the case, did he learn this was not the case (Duke Tr. 138: 1.4-10). Duke has never even seen the advertising challenged by the complaint (Duke Tr. 36: 1.23 - 37: 1.2), and never received the products themselves so that he might have reviewed the labels and investigate the quantities of the herbs within the products (Duke Tr. 37: 1.3-5). This information would have been important to help him evaluate whether the herbs were present in a sufficient quantity to possibly be effective. Duke never reviewed the medical records of any patient who claims to have taken the DCO Products to treat or cure their cancer (Duke Tr. 39: 1.1-4). Thus, he had no facts or data about the products on which to base his opinions that the claims Respondents made about the DCO Products are substantiated.

Further, Duke did not know of any studies of any kind performed on the DCO Products to determine their effectiveness (Duke Tr. 109: 1.22-25 - 191: 1.1-4). He did not evaluate whether the combination of the ingredients in each of the DCO Products has any "synergistic effect," (Duke Tr. 190: 1.10-21) which would be significant and necessary information for evaluating the efficacy of the DCO Products. Duke himself did no studies to determine the effectiveness of the products. Duke reviewed the literature and information regarding the DCO

Products and found no evidence that those products or their ingredients had been shown in clinical trials to be effective in the treatment of cancer (Duke Tr. 148: 1.13-19; 155: 1.14-17; 157: 1.6-17; 157: 1.18 - 158: 1.10; 129: 1.12-14; 130: 1. 11-15; 124: 1.11-16; 153: 1.8-14).

Despite a lack of essential information about the DCO products, Duke still concluded that there was a “reasonable basis” for Respondents to make their claims about the three products, 7 Herb Formula, GDU and BioMixx. That conclusion represents pure speculation and therefore should be excluded as unreliable.

IV. CONCLUSION

Because Duke is not qualified to testify in this case and his opinions are irrelevant and unreliable, Complaint Counsel respectfully requests that the Court enter the proposed order annexed hereto, excluding Duke from testifying at trial.

Respectfully submitted,



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Dated: March 16, 2009

Exhibit A

REPORT OF EXPERT WITNESS JAMES DUKE
James A. Duke, PhD, Botany
Economic Botanist, US Department of Agriculture (retired)
In the Matter of Daniel Chapter One
FTC Docket #9329

I. QUALIFICATIONS

See attached CV.

II. SCOPE OF WORK

Review and offer opinion supported by evidence and experience on the ingredients of the challenged products; to review the science of herbal efficacy; and to clarify the complex nature of herbal science versus the relatively simple science of pharmaceuticals.

Compensation: \$350.00 per hour or \$2500.00 per day, plus expenses

Prior Expert Testimony: No expert testimony in the last four years.

III. MATERIALS CONSIDERED

A. James Duke Biblical Publications:

Duke, JA. 1983. *Medicinal Plants of the Bible*. Conch Publications. NY. 233 pp.

Duke, JA. 1999. *Herbs of the Bible: 2,000 Years of Plant Healing*. Interweave Press, Loveland, CO. 256 pp.

Duke, JA. 1999. *Herbs of the Bible: 2,000 Years of Plant Healing*. Interweave Press, Loveland, CO. 256 pp. Reprinted Whitman Publications, Duke, Jim. 2000. Herbs of the Bible. *New Living* (June), p. 7.

Duke, JA. 2000. PARACELTUS: Wild Lettuce: A Bitter Herb of Biblical Proportions. *J. Med. Food* 3(3):153-4.

Duke, JA. 2002. Food Farmacy Forum. Some Biblical Herbs. *The Wild Foods Forum* 13(1):8-9.

Duke, JA. 2006. Food Farmacy: Biblical Herbs vs. Pharmaceuticals (Keynote), pp. 51-52 in Medicines from the Earth 2006. (Jun 2-Jun 6, 2006). Official Proceedings Gaia Herbal Research Institute. Brevard NC. 199 pp.

Duke, JA, duCellier, J, and Duke, PA. 2008. *Duke's Handbook of Medicinal Plants of the Bible*. CRC Press, Boca Raton, FL.

Duke, J. A. 1983. *Medicinal Plants of the Bible*. 233 pp. TradoMedic Books, Buffalo, NY. Treats over 100 Biblical species, with illustrations mostly by Peggy K. Duke. Apparently out of print.

Duke, J.A. 1999. *Herbs of the Bible - 2000 Years of Plant Medicine*. Interweave Press, Loveland CO. 241 pp.. \$34.95. ISBN 1-883010-66-7

B. Other James Duke Herbal Publications:

Duke, J. A. 1997. *The Green Pharmacy*. Rodale Press, Emmaus, PA 18098-0099. 507 pp. ISBN 0-87596-316--1(hardcover)ISBN-57954-124-0 (paperback)

Duke, J. A. 1999. *Dr. Duke's Essential Herbs* (13 Vital Herbs You Need to Disease-proof your Body - Boost your energy - Lengthen your Life). Rodale Press. Emmaus, PA 18098. 240 pp. \$24.95 ISBN- 1-57954-183-6 (Hard Cover)

Duke, J. A. 2000. *The Green Pharmacy Herbal Handbook*. Rodale Press. 282 pp. \$19.95 ISBN- 1-57954-184-4

Duke, J. A. 2001. With Michael Castleman. *The Green Pharmacy Antiaging Prescriptions - Herbs, Foods, and Natural Formulas to Keep you Young*. Rodale Press, 560 pages. Emaus, Pa. \$29.95. ISBN 1-57954-198-4(Hardcover)

Duke, JA, Bogenschutz-Godwin, MJ, DuCellier, J and Duke, PA. 2002. *CRC Handbook of Medicinal Plants*. 2nd. Ed. CRC Press, Boca Raton, FL. 936 pp

Duke, JA, Bogenschutz-Godwin, MJ, DuCellier, J and Duke, PA. 2002. *CRC Handbook of Medicinal Spices*. CRC Press, Boca Raton, FL. 348 pp. \$119.95. ISBN-0-8493-1279-5

Phytochemical Database: <http://www.ars-grin.gov/duke>

The Green Pharmacy at: <http://www.mothenature.com/Library/Bookshelf/index.cfm>

C. See Appendix I for additional materials relied on.

IV. SUMMARY OF OPINION

1. There is a reasonable basis for the claims that the ingredients of 7 Herb Formula "..., fights tumor formation, and fights pathogenic bacteria."
2. There is a reasonable basis for the claims that the ingredients of GDU "contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein -- even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ."
3. There is a reasonable basis for the claims that the ingredients of BioMixx "boosts the immune system, ...to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."

V. ANALYSIS AND FINDINGS

I base my conclusions, from my experience and knowledge, on three analytical points:

First, herbal based and nutritional food information can be drawn from the Bible.

Second, herbs, including those from the Bible provide help to the health of people that can be as good as or superior to help provided by pharmaceuticals.

Third, significant science, as set out below, supports herbal use, and a system -- which I call a third arm to a standard pharmaceutical study—could establish the value of herbs to the scientific gold standard urged by conventional science.. Without an approach like the third arm approach, it will never be possible to find sufficient resources to run classical pharmaceutical studies on whole herbs, let alone to evaluate the hundreds of single chemical entities in each herb.

In the meantime the public should not be denied access to the information available that certain herbs have credible evidence that they contribute to healing, even for conditions such as cancer. In the absence of resources for massive studies we have to rely on the less expensive science set out below.

1. The Science of Herbs:

I begin with the third point first. Here are three ways I use to establish the efficacy of an herb: one is the Multiple Activities Menu's (MAM's), the second is Indications Evaluations (IE's), and the third is 60 abstracts in PubMed. I am only presenting ways one and two here.

A. The MAM is a listing, recognized worldwide, which I have created and maintained for over 20 years on the United States Department of Agriculture (USDA) website. Information is put into the website about the relationship between an herb and a condition.—in this case cancer. Then the information is drawn out for a review of the current scientific status of the herb in question.

The following are Multiple Activities Menu's (MAM's) for 16 DCO herbs and their relation to cancer as recorded in the USDA website. These can be done online at my USDA website.

DANIEL CHAPTER ONE HERBS MAM's:

MAM: *Actaea (Cimicifuga) racemosa* (Black cohosh) for Cancer (15/14=1.07)

MAM: *Allium sativum* (Garlic) for Cancer (347/147=2.36)

MAM: *Ananas comosus* (Pineapple) for Cancer (73/79=0.92)

MAM: *Arctium lappa* (Burdock) for Cancer (98/61=1.61)

MAM: *Astragalus membranaceus* (Huang qi) for Cancer (110/26=4.23)

MAM: *Camellia sinensis* (Green Tea) for Cancer (483/457=1.06)

MAM: *Curcuma longa* (Turmeric) for Cancer (213/66=3.28)

MAM: *Eleutherococcus senticosus* (Eleuthero) for Cancer (163/43=3.79)

MAM: *Glycine max* (Soybean) for Cancer (483/457=1.06)

MAM: *Nasturtium officinale* (Watercress) for Cancer (3/5=0.6)

MAM: *Rheum palmatum* (Chinese Rhubarb) for Cancer (85/21=4.05)
MAM: *Rumex acetosella* (Sheep sorrel) for Cancer (11/27=0.41)
MAM: *Smilax sarsaparilla* (Sarsaparilla) for Cancer (0/13=0)
MAM: *Tanacetum parthenium* (Feverfew) for Cancer (88/19=4.63)
MAM: *Ulmus rubra* (Slippery Elm) for Cancer (4/17=0.24)
MAM: *Uncaria tomentosa* (Cat's Claw) for Cancer (79/31=2.55)

The number on the right hand side of the “/” is the number of cancer affecting aspects of the herb being evaluated.

See Appendix II for detailed presentation of the MAM's for DCO herbs, such as the following one for Turmeric, presented as an example. (Turmeric, one of the 16 DCO herbs, would certainly be in my meals were I subject to cancer, and I am genetically targeted for colon cancer. Turmeric's curcumin is probably better than Celebrex, which like other synthetic COX-2-I's was once touted off-label for the prevention of colon cancer. There are 66 indications of Turmeric affecting cancer in this MAM. Some are bolded.)

Curcuma longa (Turmeric)

(One of the top 5 medicinal spices, with some anticancer activities, proven to my satisfaction)

INDICATIONS (TURMERIC): Abscess (f1; FNF; TRA); `Achlorohydria (1; KHA); `Adenocarcinoma (1; `HOS; MES); Adenoma (1; `HOS; MES; X7954412); Adenopathy (1; DAD; JLH; X16737669 X7954412); `Alcoholism (1; `TEU; X16691314); Allergy (f1; TUR; WAM; X17569221); X17211725); Alzheimer's (1; COX; FNF); Amenorrhea (f1; BGB; PH2; `TEU; WHO); `Anemia (f; TUR); **Anorexia (f12; BGB; BIB; BRU; PHR; PH2; TUR; X17569218)**; Arthrosis (f1; COX; KAP; MAB; WAM; WHO; X16781571); Asthma (f1; FAJ; MAB; TUR; WHO; `X17569221); X17211725); Atherosclerosis (1; MAB; SKY; VAD; JMF8:246; `X18602074; X17211725); Athlete's Foot (1; FAJ; FNF); `Atony (f; DEP); `Bacillus (1; X10552805); `Bacteria (1; X10552805); `Biliouness (f1; KAB; TUR; VAD); Bite (f; BIB; `DEP; PH2); Bleeding (f; PH2); Boils (f1; DAD; WHO); `Bowen's Disease (1; X11712783); Bronchosis (f; BIB; `DEP; PH2); Bruise (f; DAV; `DEP; IHB; PED; PH2; TUR; WHO); `Burlitt's Lymphoma (1; X18852135); Bursitis (1; SKY); Cancer (f1; JLH; MAB; X17211725); **Cancer, abdomen (1; COX; FNF; JLH)**; **Cancer, bladder (f1; X18342436; X16596191; X11712783)**; **Cancer, breast (f1; COX; FNF; MAB; MES; TUR; `X19138983; X17448598; X16781571)**; **Cancer, cervix (f1; TUR; X17448598;**

X11712783); Cancer, colon (f1; COX; FNF; JLH; JNU; MES; `X X18794115; X18423603; 17448598; X17201158; X17044774; X16820928; X16781571; X16737669; X16712454); Cancer, duodenum (f1; `TEU; X7954412); `Cancer, epithelium (1; X17448598); \Cancer, esophagus (f1; JAC7:405; `TEU; TUR); `Cancer, intestine (f1; JLH; `TEU; TUR); Cancer, joint (f1; JLH; MAB); Cancer, kidney (f1; JLH; TUR); \Cancer, liver (f1; `TEU; JAC7:405); \Cancer, lung (f1; TUR; X16521985); Cancer, mouth (f1; COX; FNF; JLH; TUR; `X 17448598); Cancer, nose (f1; COX; FNF; JLH); Cancer, ovary (f1; JLH; X17174384; X163765850); `Cancer, pancreas (1;18347134 `X 17448598; X17440100) Cancer, prostate (f1; JLH; MES; TUR; `X 17448598; X17332930); Cancer, rectum (1; X17044774); Cancer, sinew (f1; COX; FNF; JLH); \Cancer, skin (f1; MES; `TEU; X16781571 X16712454; X7954412); \Cancer, stomach (f1; TUR; JAC7:405; X17448598; X16712454); \Cancer, uterus (f1; `TEU; X11712783);` Candida (f1; TUR); `Carcinoma (1; TUR); Cardiopathy (f1; AKT; MAB; TUR; `X15622377; `X19153099); Cataracts (f1; MAB; `TEU); Catarrh(f; `DEP; UPW); `Cerebrosis (1; `TEU); `Cervical Dysplasia (1; WAF); Chestache (f; PH2); `Chickenpox (f; TUR); Childbirth (f; DAD); **Cholecocystosis (12; APA; KOM; PHR; SHT; TUR; VAD; WHO; `JAF51:6802); `Cholera (f; SKJ); \Circulosis (f; BOW); Cold (f; `DEP; KAP; NPM; PH2); Colic (f; APA; PED; PH2; TUR); `Colitis (1; X17429738; X17276891); Coma (f; DAD); Congestion (f; APA; BIB; `DEP); Conjunctivosis (f; KAB; MAB; PH2; SKJ; SUW; `TEU), Constipation (f; PH2; `X18484280;); `Convulsion (f; IHB); `COPD (1; X17569221) Coryza (f; `DEP; KAB); `Cough (f; NPM); Cramp (f1; AKT; BIB; DAD); `Crohn's (1; X16387689);` Cystic Fibrosis (1; X16239599); Cystosis (f; PH2); `Depression (f 1; X18420184; `X 17955367; X16504000; X17134862; X17022948; X16651723; X16171853); `Dermatomycosis (1; `TEU); Dermatosi (f1; AKT; `DEP; MAB; PH2; SUW; `TEU; WHO; WOI; `X18484280;); \Diabetes (f1; BOW; JMF8:251; `X18484280; X17226069); Diarrhea (f1; APA; `DEP; IHB; WHO; `X18484280;); `Dipsomania (1; (X16691314); Dropsy (f; DAD); Duodenosis (1; X7954412); `Dysentery (f; IHB); Dysgeusia (f; `HOS; KAB); `Dyskinesia (f 1; VAD; X18022680); `Dyslactea (f; SKJ); Dysmenorrhea (f1; AKT; APA; DLZ; FAJ; PED; WHO; 17569218); **Dyspepsia (f12; KOM; MAB; PH2; SKJ; WHO; `X18484280); Dysuria (f; ADP; DAD); `EBV (1; `HOS; TUR); Eczema (f1; BGB; FAJ; KAP; MAB; `TEU); Edema (f1; KAP; PH2; `TEU); Elephantiasis (f; DAD); `Embolism (X18611416; X18826584) Encephalomyelitis (1; TUR); Enterosis (f1; AKT; DAD; PH2; `TEU; WHO); Epilepsy (f; WHO; X16028990); Epistaxis (f; DAD; PH2); `Epithelioma (1; X17448598); `Escherichia (1; TUR); \Esophagosis (1; JAC7:405); Fever (f1; APA; BIB; `DEP; COX; `TEU; TUR); Fibrosis (1; BGB; MAB; X17569221; X19152370); `Fistula (f; SKJ);`Fit (f; DEP); Fungus (f; BIB; PH2); Gallstones (f1; APA; MAB; `TEU); Gas (f1; APA; IHB; PH2; TUR); Gastrosi (f1; PH2; VAD); `Gingivosis (1; X18929638); Glioma (1; X17562168 ;X17395690); Gonorrhea (f; BIB; KAB); Grey Hair (f; HAD); \Fungus (1; LIB); Headache (f; PH2); `Helicobacter (1; TUR); `Heartburn (f; TUR); Hematemesis (f; DAD; PH2); Hematuria (f; DAD); Hemorrhage (f; PED); Hemorrhoid (f; FAJ; MAB); **Hepatosi (f12; AKT; APA; DAD; DEP; `HOS; MAB; MD2; PED; PHR; PH2; PNC; `TEU; TRA; `X19152370; `X19069843 ; `X18484280; X17569218`X16691314); `Herpes (f; EGG); High Blood Pressure (1; KAP; MAM); High Cholesterol (1; AKT; APA; KHA; MAB; TRA; VAD; JMF8:246); High******

Triglycerides (1; KHA; MAB; TRA); `HIV (1; `HOS); `Hyperacidity (f; ADP);
 `Hyperemesis (f; `TEU); `Hyperhomocysteinemia (1; X15622377); `Hyperkinesia (1;
 X18022680); **Hyperlipidemia (12; MAB; PHR; JMF8:256)**; `Hypoacidity (1; KHA);
 `Hypothermia (f; SKJ); Hysteria (f; DAD; `DEP); `IBD (1; TUR; X17569223); IBS (1;
 PED); **Infection (f12; MAB; MPI; PH2)**; **Inflammation (f12; APA; `DEP; `HOS; KOM;**
 PHR; PH2; `TEU; TRA; WAM; WHO); `Ischemic (1; X17955367 ;X16504000); Itch (f;
 APA; KAP; PH2; TUR); Jaundice (f1; `ADP; DEP; MAB; `TEU; TRA; TUR;
 X17569218); Laryngitis (f1; BIB; COX); `Leishmania (1; `TEU; X10865470); Leprosy
 (f; PH2; TUR); Leukemia (f1; AKT; `HOS; TUR; X18396784; X17448598; X17201156;
 X16521985; X16364242); Leukoderma (f; DAD; `X18484280); `Leukoplakia (1;
 X11712783); Lichen Planus (f; X17604143); Lymphoma (1; BIB; COX; `HOS;
 X17182546); Malaria (f; KAB;KAP; PH2; WOI; `X18484280); `Measles (f; TUR);
 `Melanoma (1; `HOS; TUR); `Metastasis (1; `HOS); Morning Sickness (f1; FAJ; MAB);
 Mucositis (f; PH2; TUR); `Multiple Sclerosis (1; X17569223); `Mycobacteria (1; TUR);
 Mycosis (f1; `DEP; FAJ;PH2; X8824742); `Multiple Sclerosis (1; X17569223);
 `Mycobacteria (1; TUR); Mycosis (f1; `DEP; FAJ;PH2; X8824742); `Myelodysplasty(1;
 `X18324353) `Myeloma (1; `X18324353 ; X17404048); `Nausea (1; `HOS); `Nematode
 (1; X8221978); `Nematode (1; X8221978); Nephrosis (f1; AKT; PH2; X17002671);
 `Nicotinism (1; (X16691314); `Nyctalopia (f; SKJ); Ophthalmia (f1; AKT; DAD; `DEP;
 IHB; PH2); Orbital Pseudotumor (1; PR14:443); **Osteoarthritis (f12; KHA; MAB;**
 `TEU; X12723628); Osteoporosis (1; X17182546); `Otorrhea (f; DEP); Ozoena (f;
 KAB); Pain (f1; ADP;BIB; `DEP; COX; FAJ; `TEU; TUR; WHO; X16028990);
 Pancreatitis (1; TUR; X17900536); `Papilloma (1; `TEU;);Parasite (f; BIB; DAD; KAP
 LIB); `Parkinson's (1; X17900536); `Periodontitis (1; X18929638); Plasmodicide (1;
 X10865470); Polyp (f1; COX; JLH; JNU; MES); `Proctitis (f; SKJ); `Pseudomonas (1;
 TUR); Psoriasis (1; FAJ; FNF; MAB; `TEU; `X18484280; `X17569223; X16387689);
 Puerperium (f; FAJ; MAB; `TEU); `Pulmonitis (1; X17569221); `Respirosis (1;
 X17569221); Radiation (1; AKT); Restenosis (1; MAB); Rheumatism (f1: BIB; COX;
 SKY; `TEU); Rhinositis (f1; COX; JLH); Ringworm (f; APA; BIB; `DEP; KAP; PH2);
 `Salmonella (1; TUR); `Sarcoma (1; `HOS); **Scabies (f12; BGB; `DEP; KHA; TUR);**
 `Schistosoma (1; `X19143127; X17948736; X 17907745); `Shock (1; TUR); `Sinusitis
 (f; ADP; TUR); Smallpox (f; DAD; TUR); `Snakebite (1; JAF51:6802); **Sore (f12; KHA;**
 PH2); Sore Throat (f; PH2); `Sortase-A-Inhibitor (1; X16277395); `Spasm (f; IHB);
 Sprain (f1; DEP; IHB; MAB; SUW); Staphylococcus (1; FAJ; MPI; TUR; UPW); `Sting
 (f; DEP); `Stomatitis (f; X17604143); Stone (f1; HHB; MAB); `Stress (1; `HOS; TUR;
 X17022948); Stroke (f 1; BOW; PH2; X18611416); Swelling (f1; AKT; COX; NPM;
 PH2; TUR); Syphilis (f; DAD); `Thalassemia (1; X17897073); `Thrombosis (f1; TUR;
 VAD; X18611416; X18826584); `Thrush (f1; TUR); `Tonsillitis (f; NPM); Trauma (f;
 AKT; X16028990); `Tuberculosis (1; X15203565; X11591115); `Tumor (1; `HOS);
 Ulcer (f1; BIB; COX; FAJ; `HOS; PED; WHO; X16327153); `Unconsciousness (f; SKJ);
Uveitis (12; AKT; `TEU; X18421073); VD (f; BIB; DAD); Vertigo (f; BIB; `DEP;
 DAD; FAJ); `Virus (1; `HOS; X10389986); Vomiting (f; PH2); Wart (f; JLH); Whitlow
 (f; JLH); `Worm (f1; `DEP; X8221978); Wound (f1; APA; BGB; IHB; PH2; SUW;
 WAM; `X18929638; `X18655004; X17900536; X16286372); Yeast (f1; PED; TUR).

B. Indications Evaluations (IE's) Summary: Review of Indications of 16 DCO

Herbs. (See Appendix III for comparison of herb indications to pharmaceutical indications)

Actaea (Cimicifuga) racemosa (Black Cohosh). Widely sold and respected for menopausal difficulties.

**Allium sativum* (Garlic): My most important herbal medicine, useful at preventing all the major killers and sepses.

Ananas comosus (Pineapple); Bromelain, the proteolytic enzyme, has many proven activities.

Arctium lappa (Burdock); Contains antilymphomic lignans.

Astragalus membranaceus (Huang Qi/ Yellow Root): Widely sold in America and China as an anticancer immunomodulator.

Camellia sinensis (Green Tea): Food pharmacy item widely and scientifically promoted for many indications.

**Curcuma longa* (Turmeric): One of the top 5 medicinal spices, with some anticancer activities, proven to my satisfaction.

Eleutherococcus senticosus (Eleuthero) Sold widely as an alternative to ginseng, adaptogenic tonic.

Glycine max (Soybean): Studied by the late Judah Folkman and widely sold as a food pharmacy item, in part for its mix of antiangiogenic isoflavones and quercetin.

**Nasturtium officinale* (Watercress): Like most crucifers (members of the Brassicaceae), this nutritious edible species is properly touted as a cancer preventive.

Rheum palmatum (Chinese Rhubarb); Sold as laxative and in Essiac formula, touted for cancer.

Rumex acetosella (Sheep sorrel) Sold in Essiac formula, touted for cancer.

Smilax aristolochiifolia (Sarsaparilla) Widely sold, e.g., for Lyme Disease; contains compounds which can be converted to hormones.

Tanacetum parthenium (Feverfew) I think it's about as good for migraine as pharmaceutical sumatriptan.

Ulmus rubra (Slippery Elm) Sold in Essiac formula, touted for cancer.

Uncaria tomentosa (Cat's Claw) Famed immunomodulator from Latin America; proofs possibly more promotional than scientific.

Half of the new pharmaceuticals will be relabeled (with stronger warnings) or partially or completely recalled within a decade. Meanwhile, more expensive pharmaceuticals will continue to cause many more deaths than are caused by the safe herbs we are led to believe are dangerous. They are not! Check the Bextra, Celebrex, and Vioxx, and, let me predict, soon-to-be-heard statin, stories (three close friends of mine, too old to be worried about cholesterol, have been hospitalized from statins) and head counts of iatrogenic fatalities. The Null Numbers: The total number of annual iatrogenic deaths in America is 783,936. (Null et al, 2003).

Remember, pharmaceuticals have been with us less than 150 years. If our ancestors left Africa via the Holy Land 2000 years ago (for faith-based literalists), or maybe a million years ago (for the less literal), then our genes, tracing back to our African/Holy Land ancestors, have had at least 10 times more temporal experience with Biblical herbs (e.g., cinnamon, coriander, garlic, grape, mint, milk thistle, myrrh, olive, onion, saffron, turmeric, and the like). Pharmaceuticals and synthetic food additives are relatively new to our genes. Our bodies have had thousands, perhaps millions, of years of evolutionary experience with the thousands of phytochemicals in these species. Our bodies may even require many of them. In many cases, by my educated guess, the body has evolved homeostatic mechanisms for maintaining homeostatic balances for these phytochemicals. Our bodies can sequester them from our dietary millieux if we need them, excreting them if we do not. We can prove this for simple elemental chemicals like selenium and zinc. I believe it is the case that homeostatic balancing activities exist for hundreds of many long-familiar dietary components. We just, as Congress, signed an RDA for choline in the last decade. The farther we get from our Paleolithic diet, and

(more importantly) the more synthetic pharmaceuticals and food additives we ingest, the more liable we are to suffer imbalances. It's not only food additives that hurt us; it is the subtractives as well. The subtractive phytochemicals are those important nutrients reduced or lost in food processing:

"Of the 12 micronutrients which were plentiful in the natural grain, including vitamins B1, B2, B3, B5, B6, folic acid, E and the minerals iron, zinc, copper, manganese and selenium, less than 30%, and in some cases less than 10%, have been retained in the wheat products we eat. (Levin, 1996)"

Restoring chemical balance may require getting back to basics, those primitive Paleolithic foods rich in phytonutrients. At the same time, we should reduce over-processed nutrient-poor junk foods, avoiding additives and even pharmaceuticals where possible and plausible. I'm not saying there is no place for pharmaceuticals. But I will say that in many cases there are balanced Biblical foods that are pharmacologically competitive with unbalancing pharmaceuticals, and these food farmaceuticals should be drugs of first resort, and the pharmaceuticals last resort.

And if you believe in me and my Biblical food farmaceutical shotgun more than you believe in your allopath and her/his expensive pharmaceutical silver bullets, there's a better chance that my natural approach will help you. Believing is half the cure. Can you believe in a company whose \$2-billion-a-year drug was shown in JAMA (Journal of the American Medical Association) back in 2002 to be no better than placebo for major depression? Can you believe that now, three years later, that company still has the premier lead-off ad page for the JAMA, touting the \$2-billion-a-year drug as so trusted, so reliable, so efficacious? I suspect you'd be better off with Biblical walnut oil and

Biblical saffron, nourishing AND medicating your body, attenuating the depression with few or no consequential side effects. If you count all the possible side effects reported in the fine print of that ad for the \$2-billion-a-year pharmaceutical, there are more than a hundred.

When that study was printed back in 2002 showing the pharmaceutical no better than placebo, almost nobody heard that the drug failed too. The news was instead blaring out "St. Johnswort no better than placebo." True, St. Johnswort (SJW) fared no better than placebo in this clinical comparison of SJW, Zoloft, and placebo. But that's the half of the story that Joan Q. Public heard a thousand times, while maybe once or twice hearing that the pharmaceutical failed too. Do I think there is a pharmaceutical/PhDA/press conspiracy? I will say that they are all singing the same song, and the song is wrong, and is hurting Americans. Their monotonous song drives American consumers from the safer food, herb and spice farmaceuticals to the more expensive, more dangerous synthetic pharmaceuticals. All this at the expense of our health and the health of our planet. Even our rivers and lakes, and consequently our water supply, are now cocktails of pharmaceutical residues.

2. Some Biblical Herbs and Spices: Potential Alternatives to Pharmaceuticals

The following is a partial list (for more examples see Appendix IV) of long-known plants that by some definitions might be considered spices or culinary herbs. I also list here a disease or malady in which they have shown some promise, and a competitive pharmaceutical for that disease. I am campaigning for a third arm mandate, empowering a comparison of a third, herbal, arm with the pharmaceutical in any new clinical trials. Until such clinical trials, we don't really know that the pharmaceutical is

best. . The herb is almost always safer and cheaper. Pharmaceuticals and/or iatrogenesis (medically-caused adverse effects) related to conventional treatments kill 100,000 to 740,000 Americans a year, according to some published sources. Hurley in the New York Times (Feb, 2007) suggested that fewer than 30 are killed annually by herbs, nutritional supplements and vitamins.

Herb/Drug Contrast (for a continuation of the list see Appendix V)

Allium cepa - Onion - Osteoporosis - Caltrate [[Weak but possible competitor]]

Allium sativum - Garlic -Hypercholesterolemia - Lipitor [[Garlic may be as good with diet and exercise as lipitor with exercise and diet for some patients]]f

Anethum graveolens - Dill - Gas - Mylanta [[Probably equivalent]]

A Armoracia rusticana - Horseradish - Sinusitis -Sudafed (Bronchosis Robitussin) [[Probably equivalent]]

Artemisia herba-alba - White Wormwood - Malaria - Chloroquin [[Probably NOT as good]]

Boswellia sacra - Frankincense - Arthrosis - Celebrex [[Possibly equivalent due to COX2Is equivalent]]

Brassica nigra - Black Mustard - Cancer - Lorenzo's Oil? [[Neither real promising]]

Capparis spinosa -Caper - Cancer -Tamoxifen

Carum carvi - Caraway - Cancer - Tamoxifen

Ceratonia siliqua - Carob - Diarrhea - Kaopectate [[Probably equivalent]]

Cichorium intybus - Chicory - Dyspepsia - Mylanta [[Probably equivalent]]

*Cinnamomum aromaticum - Cassia - Diabetes -Avandia [[I'd bet on Cinnamon/Cassia]]

*Cinnamomum verum - Ceylon cinnamon - Diabetes -Avandia [[I'd bet on Cinnamon/Cassia]]

Citrus medica - Citron - Asthma -Allegra [[Possibly equivalent]]

VI. SUMMARY AND CONCLUSIONS

Reviewing the MAM's and the IE's for the constituents of the DCO products in the manner that I have reviewed thousands of uses for hundreds of herbs for several decades, it is clear that significant evidence in support of the following uses exists:

There is a reasonable basis for the claims that the ingredients of 7 Herb Formula, "..., fights tumor formation, and fights pathogenic bacteria."

There is a reasonable basis for the claims that the ingredients of GDU, "contains natural proteolytic enzymes (from pineapple source bromelain) to help digest protein -- even that of unwanted tumors and cysts. This formula also contains ingredients known to help relieve pain and heal inflammation. GDU is also used for. . .and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ."

There is a reasonable basis for the claims that the ingredients of BioMixx, "boosts the immune system, . . .to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."

February 4, 2009

[Approved for signature by Dr. Duke on February 4, 2009. Signature page to follow.]

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**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES**

In the Matter of)	
)	
DANIEL CHAPTER ONE,)	
a corporation, and)	Docket No. 9329
)	
JAMES FELJO,)	Public Document
individually, and as an officer of)	
Daniel Chapter One)	
)	
)	

[Proposed] ORDER GRANTING MOTION IN LIMINE

On March 16, 2009, Complaint Counsel filed a Motion in Limine to exclude the testimony and reports of Respondents' expert witness James Duke from any trial in this case.

IT IS HEREBY ORDERED that Complaint Counsel's Motion in Limine is **GRANTED**.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Dated:

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 16, 2009, I have filed and served **COMPLAINT COUNSEL'S MOTION AND MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE THE TESTIMONY AND REPORT OF RESPONDENTS' EXPERT WITNESS JAMES DUKE** and **[Proposed] ORDER GRANTING MOTION IN LIMINE** upon the following as set forth below:

The original and one paper copy via overnight delivery and one electronic copy via email to:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., N.W., Room H-159
Washington, DC 20580
E-mail: secretary@ftc.gov

Two paper copies via overnight delivery to:

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., N.W., Room H-528
Washington, DC 20580

One electronic copy via email and one paper copy via overnight delivery to:

James S. Turner, Esq.
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