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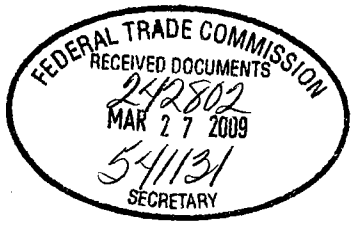

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
DANIEL CHAPTER ONE, **a corporation, and**	)	**Docket No. 9329**
JAMES FEIJO, **individually, and as an officer of** **Daniel Chapter One.**	)	**PUBLIC DOCUMENT**

COMPLAINT COUNSEL'S MEMORANDUM IN OPPOSITION TO RESPONDENTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF EXPERT WITNESS DR. DENIS R. MILLER

I. INTRODUCTION

Complaint Counsel intends to call at trial Denis R. Miller, M.D. as an expert witness in cancer treatment. Dr. Miller has 40 years of experience in cancer treatment and research, (See Expert Report of Denis R. Miller, dated January 28, 2009 ("Miller Rpt.") at pp. 1-4, attached as Exhibit A.) Dr. Miller has also published extensively in the cancer field. (See List of Publications attached as Exhibit B.) As detailed in his report, Dr. Miller reviewed the "substantiation" provided by Respondents and conducted extensive research on his own regarding the efficacy of Bio*Shark, 7 Herb Formula, GDU and BioMixx ("DCO Products") (Miller Rpt. at pp 5-7 and 34-39.) The careful review conducted by Dr. Miller provides an ample foundation for the opinions that he expressed. As explained in his report, after reviewing the information provided by Respondents and the medical literature, Dr. Miller concluded that

there was no competent and reliable scientific evidence to substantiate the disease claims that Respondents make about the DCO Products. Respondents now move to exclude Dr. Miller's testimony. In doing so, Respondents mischaracterize the nature of Dr. Miller's testimony and the legal standards governing this action. Accordingly, Respondents' motion should be denied.

II. THE COURT SHOULD DENY RESPONDENTS' MOTION BECAUSE THEY FAIL TO SHOW THAT DR. MILLER IS NOT QUALIFIED TO TESTIFY AS AN EXPERT OR THAT HIS TESTIMONY IS UNRELIABLE OR IRRELEVANT.

First, Respondents challenge the validity of Dr. Miller's testimony on the ground that he only considered "studies required for drug approval by the FDA" in evaluating the claims of the DCO Products as cancer cures, without considering "other scientific information such as herbal formularies, the herbal Physicians Desk Reference, traditional use..." Motion at p. 2. Respondents misstate Dr. Miller's work. As is clear from his report, Dr. Miller considered the substantiation offered by Respondents and other alternative medicine sources and concluded after reviewing that information that it did not constitute competent and reliable scientific evidence (Miller Rpt. at pp. 5-7.)

Second, Respondents appear to be contesting the legal requirement that they have competent and reliable scientific evidence to substantiate their claims. In doing so, Respondents ignore the ample precedent upholding this standard of proof. *See FTC v. National Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at *77 (N.D. Ga. June 4, 2008) (granting the FTC's motion for summary judgment and finding that since all of defendants' "claims regard the safety and efficacy of dietary supplements; [] they must be substantiated with competent and reliable scientific evidence"). "Competent and reliable scientific evidence" is typically defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and

evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *See, e.g., Brake Guard Products, Inc.*, 125 F.T.C. 138 (1998). Courts have consistently ruled that double-blind, placebo-controlled studies are required to provide adequate substantiation for the truthfulness of various health-related efficacy claims. *See, e.g., FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999) and *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 962 (N.D. Ill. 2006) *aff'd* 512 F.3d 858 (placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted. . . . Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim").

Third, Respondents further argue that Dr. Miller has given unqualified lay opinions about Respondents' claims about the DCO Products and/or that he lacks expertise to give opinions about "the net impression" of the advertising, the "type of claim" Respondents make, any "consequences of a false claim" or "benefits of a truthful claim," and finally, the "amount and type of substantiation that experts in the field believe reasonable" (Motion at p. 3.) Respondents further assert that Dr. Miller opined on the "overall net impression" created by Respondents' statements about the DCO Products (Motion at p. 2.) Respondents clearly misstate the work Dr. Miller performed in this case. As he stated at his deposition, Dr. Miller only evaluated the scientific evidence for the claims which Complaint Counsel had set out in the Complaint. (Deposition Transcript of Denis R. Miller, dated February 6, 2009 ("Miller Tr.") at p. 62: l. 24 - 63: l. 4.)[1] Dr. Miller did not analyze Respondents' advertisements to determine

[1]Complaint Counsel has submitted d a copy of Dr. Miller's deposition transcript as part of the Motion for Summary Decision on February 26, 2009 and therefore, have not attached a second copy to this memorandum.

what claims the ads were making, and Respondents can point to no evidence to the contrary. Accordingly, this challenge to Dr. Miller's testimony must fail and he must be permitted to testify.

Finally, throughout their Motion, Respondents imply that Dr. Miller somehow is not qualified to offer opinion testimony in this case and that his testimony is not relevant. Even a cursory review of Dr. Miller's report indicates that is not the case. As fully set forth in Dr. Miller's report and his deposition testimony, Dr. Miller reviewed the appropriate scientific evidence to determine whether there was "competent and reliable scientific evidence" to support Respondents' claims. He conducted "extensive searches of Google and Memorial Sloan Kettering, Dana Farber, ... Stanford HighWire, PubMed, clinical trials.gov [which] gives you all the clinical trials ongoing by different disease entities" as well as searched various medical journals to see if there was scientific support for Respondents' claims (Miller Tr. at p. 58: l. 14 - p.59: l. 5.) Dr. Miller opined that there is no competent and reliable scientific evidence to substantiate the claims that the products at issue, treat, cure or prevent cancer (Miller Rpt. at p. 7.) Dr. Miller's testimony is highly relevant to the Court's determination of whether Respondents' claims were deceptive, and it should be allowed.

Moreover Dr. Miller is qualified to testify as an expert under Federal Rule of Evidence 702 and the *Daubert* principles. Dr. Miller has the knowledge, skill, experience, training and education to testify about the serious claims that Respondents make regarding the DCO Products. Dr. Miller has practiced medicine for more than 40 years as a board certified hematologist oncologist (Miller Tr. at p. 14: l. 22 - p. 15: l. 8), treating both children and adults (Miller Tr. at p: 17: l. 20 - p. 18: l. 10; and p. 22: l. 1 - l. 24.) In the last 20 years, Dr. Miller has been engaged in conducting research directly or has been responsible for approving research

projects that analyzed the efficacy of cancer treatments (Miller Tr. at p. 28: l. 22 - p. 32: l. 16.) He is fully familiar with the effective treatments available to cancer patients and how different medicines operate on the disease. As well, Dr. Miller is familiar with the scientific steps necessary to prove a treatment effective and has even conducted a reputable scientific study to determine the efficacy of shark cartilage, the key component of Bio*Shark, in treating cancer patients (Miller Tr. at p. 44: 1. 12 - p. 48: l. 22.)

Further, Dr. Miller had sufficient facts and data about the DCO Products to render an opinion about them. Dr. Miller studied the labels for all of the products and attempted to determine what was in each product and how much of the herbs were contained therein (Miller Rpt. at p. 5.) He reviewed the Complaint and was familiar with the claims for each product and rendered his opinion accordingly (Miller Rpt. at p. 7.) Dr. Miller's expert testimony is soundly based, is relevant and will assist the Court in determining whether Respondents had a reasonable basis for making their serious health claims.

III. CONCLUSION

For the foregoing reasons, Complaint Counsel respectfully request that the Court enter the proposed order annexed hereto denying Respondents' motion to preclude Dr. Miller's testimony.

Respectfully submitted,

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Dated: March 26, 2009

Exhibit A

EXPERT REPORT OF DENIS R. MILLER, MD

I. QUALIFICATIONS

As detailed in my curriculum vitae, I am a board certified pediatric hematologist/oncologist and am licensed to practice medicine in the State of New Jersey. Currently, I am on the voluntary faculty (Clinical Professor of Pediatrics) at Robert Wood Johnson School of Medicine (New Brunswick, NJ).

For over 40 years I directed clinical care, education, laboratory and clinical research, and administration, heading divisions or departments at University of Rochester Medical Center, New York Hospital-Cornell Medical Center, Memorial Sloan Kettering Cancer Center (MSKCC), and Northwestern University Medical School (Chicago, IL). My major area of clinical and laboratory research was hematopoietic malignancies. I was the recipient of research grants from the National Cancer Institute, private foundations, and other organizations. As Chairman of the Department of Pediatrics at MSKCC, I directed one of the largest pediatric oncology/hematology programs in the world and held an endowed chair. Our department was heavily involved in more than 25 Phase I studies annually. Many of these investigational agents are now cornerstones in cancer treatment.

From 1990 to 1996, I served as Associate Medical Director of Cancer Treatment Centers of America (CTCA) and from 1993 to 1996 I was the Scientific Director of CTCA's Cancer Treatment Research Foundation (CTRF). In both capacities, I was involved actively in designing clinical research protocols for patients with a wide variety of malignancies. In my capacity as Scientific Director, I supervised the clinical research program, chaired the Scientific Advisory Committee of the Institutional Review Board, and was principal investigator for a number of Phase I/II studies. These studies included

innovative treatment for cancers of the head and neck, lung, breast, pancreas, and colon as well as hematological malignancies and other disorders. These new agents included antiangiogenic compounds, immunomodulators, differentiating drugs, inducers of apoptosis, and monoclonal antibodies directed against tumor-specific antigens.

I understand and respect the position and role of supportive care and complementary medicine in oncology and how they blend with conventional therapy. I conducted studies on Maitake mushroom and panax ginseng in patients with cancer. I also directed a Phase I/II randomized, open-label, single institution study of a commercially-available shark cartilage product (Cartilade®). A more detailed review of the design and results (Miller, et al, 1998) of this study will be presented in my review of the Daniel Chapter One (DCO) product known as Bio*Shark.

I have performed numerous studies in early (Phase I) and later clinical development (Phase II through Phase IV). I worked on differentiating and apoptosis-inducing agents (histone deacetylase inhibitors), monoclonal antibodies (rituximab, trastuzumab), small molecule epidermal growth factor receptor inhibitors (gefitinib), cyclin dependent kinase inhibitors (flavopiridol), and erythropoietic stimulating agents (epoetins alfa and beta). Specific tumor types included acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL), non-Hodgkin lymphoma (NHL), non-small cell lung cancer (NSCLC), mesothelioma, CRC, and cancers of the head and neck, esophagus, pancreas, breast, and skin (malignant melanoma).

Currently, I am the Oncology/Hematology Therapeutic Area Leader at PAREXEL International, one of the world's leading contract research organizations (CRO). CROs manage clinical trials for the pharmaceutical industry and are involved in the entire

process of testing and evaluating new agents through the various phases of clinical development. The ultimate goal is to make these new agents available to cancer patients and improve their survival and quality of life. As such, I am fully familiar with good clinical practice requirements, study design and conduct, regulatory requirements for each phase of clinical development, biostatistical considerations that demonstrate efficacy and safety, the role of supportive care in cancer drug development, informed consent, and regulatory guidelines for alternative and complementary treatments in patients with cancer and blood diseases. Because of potential drug-drug interactions, I am acutely aware of safety issues associated with the use of any anticancer agent and the use of concomitant drugs that might potentially increase a patient's risk of having adverse reactions (toxicity or "side effects") or decrease the efficacy of other required medications. These data are obtained in the early phases of drug development and is a major objective of Phase I/II.

I am a member of ASCO, AACR, and ASH and served on the editorial boards of the British Journal of Haematology and the American Journal of Clinical Oncology (Associate Editor, Pediatric Oncology). I have authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts. I was senior editor to 4 editions of a classic textbook in pediatric hematology/oncology, *Blood Diseases of Infancy and Childhood*

In summary, for the past 43 years (since 1966), I have been actively engaged in the design, implementation, completion, regulatory review, analysis, presentation, publication, and when appropriate, regulatory approval worldwide of many anticancer agents that were evaluated in studies designed to make these agents available to patients.

I am familiar with the pharmacology (pharmacokinetics, pharmacodynamics), mechanism(s) of action, safety, and therapeutic efficacy, including clinical benefit, of

drugs and other anticancer agents. I also understand the importance of formulation in cancer drug development. By definition, formulation is the process of adding all of the ingredients in a product, including specific concentrations of each of the active agents, excipients, stabilizers, solubilizers, flavoring, and colorizers, and determining whether the product will be in capsule, tablet, or liquid form. I am familiar with drugs and other agents as well as their formulations, doses, and dose schedules that are generally recognized by experts as safe and effective for human use in specific indications. This knowledge comes from a professional life devoted to my patients and my involvement in the process of clinical drug development.

Thus, based on my training, experience, and ongoing clinical activities, I am well qualified to offer my expert opinion in this case.

II. SCOPE OF WORK

I have been asked by the FTC to determine whether there is competent and reliable scientific evidence to substantiate the following claims:

- Bio*Shark inhibits tumor growth;
- Bio*Shark is effective in the treatment of cancer;
- 7 Herb Formula is effective in the treatment or cure of cancer;
- 7 Herb Formula inhibits tumor formation;
- GDU eliminates tumors;
- GDU is effective in the treatment of cancer;
- BioMixx is effective in the treatment of cancer; and
- BioMixx heals the destructive effects of radiation and chemotherapy.

Compensation: $250/hour.

Prior Expert Testimony: A listing for the past 4 years is in APPENDIX I.

III. MATERIALS CONSIDERED

To form my opinion, in addition to drawing upon my extensive expertise in cancer care and treatment, I have conducted literature searches as follows:

- PubMed, Google, PDQ, NCI, MSKCC, MD Anderson Cancer Center, Dana Farber Cancer Institute, Search Medica, Stanford HighWire, Clinical Trials.gov, many cancer and hematology journals (e.g. Journal of Clinical Oncology, Clinical Cancer Research, Blood, British Journal of Haematology, Supportive Care in Oncology, American Journal of Oncology, New England Journal of Medicine, etc.) (APPENDIX III)

I have also reviewed the following material provided to me by the FTC:

- Official Transcripts of DCO Healthwatch Radio Program on Accent Radio Network, July 8, 2008, and July 14, 2008
- Testimonials submitted by 30 patients who used DCO products
- Respondents' Responses to Complaint Counsel's First Set of Interrogatories
- Daniel Chapter One Product Labels (for products for which representations have been made regarding cancers or tumors)
- BioGuide, the Biomolecular Guide for Daniel Chapter One
- Literature provided by DCO:
    - Articles for Research Study of Complimentary/Alternative Proprietary Products in Support of Respondent's Claims (Appendix III)
    - Other cited articles:
        - Lane IW, Comac L. Sharks Don't Get Cancer. How Shark Cartilage Could Save Your Life. 1993.
        - Dr. Nieper's Revolution in Technology Medicine and Society, 1985

- Blumenthal M, Goldberg A, Brinckmann J, et al. Herb Medicine, Expanded Commission E Monographs,
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- Tenney L. Today's Herb Health, 3rd Ed, 1992, Woodland Books, Provo, UT.(Title/pages only)
- Miscellaneous Title/Cover pages only of The Vitamin Herb Guide, Treatment for the World's 160 Most Common Ailments, Weiner's Herb, The Guide to Herb Medicine (1990),

- Respondents' Expert Witness Disclosure
- Administrative Complaint of Federal Trade Commission
- Administrative Complaint, Exhibits A-D (re Bio*Shark, GDU, 7 Herb Formula, BioMixx)
- Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, December 2006.
- Daniel Chapter One Medical Sources for Alleged Deceptive Statements
- Relevant medical literature on efficacy and safety of components of DCO products (Bio*Shark, GDU, 7 Herb Formula, BioMixx)
- Marketing information on DCO products from www.danielchapterone.com
- Deposition Testimony, James Feijo, January 13, 2009
- Deposition Testimony, Patricia Feijo, January 14, 2009

IV. SUMMARY OF OPINIONS

Based upon my professional training and experience and my review of all of the materials cited above, it is my opinion that there is no competent and reliable scientific evidence to substantiate the claims that the products at issue treat, cure, and prevent cancer.

V. WHAT CONSTITUTES COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE

Based on my extensive experience in academic medicine from 1966 to 1996 and in the pharmaceutical industry from 1997 until today, it is my opinion that to constitute competent and reliable scientific evidence, a product that purports to treat, cure, or prevent cancer must have its efficacy and safety demonstrated through controlled clinical studies.

My understanding of what constitutes competent and reliable scientific evidence is consistent with the FDA's regulations that define the criteria for adequate and well-controlled clinical investigations, which are set forth at 21 C.F.R Sec. 314.126. My understanding also is coonsiteent with the guidelines set forth by FDA entitled "Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration, (October 2006)."

The proper format for any clinical trial protocol includes the following:

1) details of the **rationale** for the study relating the critical features (aims, target population, design, treatment, dosage, route of administration, duration, and primary endpoints) to the development of the investigational drug;

2) clear elucidation of **primary and secondary objectives**;

3) clear presentation of the **investigational plan,** including a) **study design**, including number of centers, type of study (e.g. open label or double-blind), randomization with or without stratification, duration of each study phase, total duration of study, treatment groups, special features, special subsets, and effects of interim analysis on power of study, if planned; b) **selection of subjects** including number, inclusion and exclusion criteria; c) **study treatments,** including dosage schedule, treatment assignment, randomization schedule, blinding/packaging/labeling, mechanisms to ensure compliance; d) documentation of **prior and concomitant illnesses and treatments;** and e) **study procedures and schedules** (for evaluation of safety and efficacy).

4) complete overview and description of specific methods of **data collection**, quality assurance, and quality control;

5) complete description of all **statistical procedures**;

6) if relevant, full reporting of results of studies of **pharmacokinetics, pharmacodynamics, quality of life, and health economics;**

7) complete and concise discussion of **overall conclusion** regarding safety and efficacy;

8) relevant **references**;

9) accompanying **Tables and Figures;**

10) selected **subject listings** of demographics, disease and treatment parameters, endpoints, safety factors, and deaths); and

11) subject narratives for serious adverse events and deaths.

Clinical drug development is a complicated, lengthy, and expensive process. Of any 5000 promising agents discovered in the laboratory and entering nonclinical testing, 5 enter Phase I and one is approved. Nonclinical studies are performed in the test tube and in animals with the aim of demonstrating potential activity and acceptable safety in animals. Once nonclinical studies have been performed, a new agent enters Phase I "first in humans" clinical trials. In oncology, previously treated cancer patients are usually enrolled in these Phase I studies. A Phase I study is designed to determine the pharmacokinetics, pharmacodynamics, maximal tolerated dose, dose limiting toxicity, safety, and recommended Phase II dose of the candidate new agent. In the next step, Phase II, the efficacy and safety of the new agent is evaluated in selected cancers and targeted patient populations. The last step is the performance of randomized, controlled Phase III clinical trials. The decision to proceed to Phase III is generally based on the justification for the dose/dose regimen, on the robustness of the efficacy data, and the assurance of an acceptable safety profile derived from the Phase II studies. A successful

Phase III study meets its predefined endpoints with statistical robustness and with an acceptable safety profile.

Determining the mechanism of action of a new agent to treat cancer is a critical aspect of cancer drug development. Anticancer agents may work by preventing cell proliferation (division), induce programmed cell death (apoptosis), inhibit growth factors or biochemical pathways that result in cell death, and important in this matter, inhibition of new blood vessel formation or angiogenesis.

Angiogenesis is an important and vital mechanism of tumor growth and metastasis. Antiangiogenic agents have an important role in the treatment of some types of cancer. During the past 9 years I have been involved in the development of a number of antiangiogenic agents, some of which are undergoing early stages of development and others are now approved to treat cancer. All of these approved antiangiogenic compounds underwent Phase I/II/III studies and have been the subject of scientific presentations and publications. These antiangiogenic agents are now being used with chemotherapy to treat a variety of solid tumors and hematologic malignancies.

Most of these antiangiogenic agents are highly purified, synthesized products, recombinant molecules, or humanized monoclonal antibodies with known mechanisms of action. They have well-characterized pharmacokinetics, pharmacodynamics, and dose/dose schedules. As targeted therapies, they have a different safety profile than conventional chemotherapy. Unlike crude raw materials, all have known targets regarding their active antiangiogenic activity.

Many of the studies cited by DCO in support of their position and provided to me by the FTC are nonclinical (in vitro or in animals). Other reported studies have evaluated

isolated compounds that are also present in certain DCO products. Some of these individual compounds showed nonspecific immunostimulatory activities or suggested cancer preventive effects. However, nonclinical studies can not replace the actual evaluation of DCO products themselves. Each DCO product or active ingredient must be subjected to the same experimental conditions to demonstrate anticancer activity. It is not possible to extrapolate from the results of a published nonclinical study of curcumin for example and state that GDU can eliminate tumors.

Complementary medicine's role is not to replace conventional anticancer therapy. Complementary medicine adds to the efficacy of standard anticancer therapy, reducing some of cancer therapy's adverse side effects (e.g. nausea and vomiting, severe neutropenia, anemia, fatigue), improving general well-being and quality of life, and permitting oncologists to administer effective doses of therapy on time. It is well known that many new targeted therapies work better when given with conventional anticancer therapy and rarely are as efficacious when given as single agents. Similarly, complementary medicine should and does not serve as an alternative to effective and safe anticancer therapy. Suggesting that it can be an effective substitute for traditional medicine would be a diservice to cancer patients. Delays in effective therapy may allow cancer cells to regrow, develop resistance to therapy, and metastasize.

Anecdotal reports of a drug's efficacy conducted outside the setting of a controlled clinical trial do not replace clinical trials that are designed to demonstrate safety and efficacy. Without confirmation of the diagnosis of cancer, predefined strict eligibility criteria, a rational and justified dosing schedule, safety monitoring, and carefully defined endpoints, anecdotal reports are not reliable and competent, lack statistical robustness, are

short on scientific quality or validity and can never substitute for a well-designed and well-conducted controlled clinical trial. Anecdotal reports represent the weakest form of evidence supporting the anticancer activity of a new agent. I am unaware that anecdotal reports provided adequate evidence to provide the basis for regulatory approval of any new anticancer agent.

As I will review, not only are there no peer-reviewed data to demonstrate a role for any DCO product in the treatment of human cancer, but also, the use of these products presents a potential harm. This is most acute if a cancer patient foregoes potentially beneficial and effective therapy and replaces that option with Bio*Shark, GDU, 7 Herb Formula, or BioMixx, alone or in combination with other DCO products. Diagnosing cancer early and treating it appropriately and effectively still offers the best chance of curing it. The use of complementary or alternative therapies exclusively as front-line (first) treatment will surely result in disease progression and death.

The risks of untested and unregulated remedies were succinctly stated by Angell and Kassirer in an editorial published in the New England Journal of Medicine in 1998:

> "It is time for the scientific community to stop giving alternative medicine a free ride. There cannot be two kinds of medicine—conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted. But assertions, speculations, and testimonials do not substitute for evidence. Alternative treatments should be subjected to scientific testing no less rigorous than that required for conventional treatments."

VI. DETAILED DISCUSSION OF FINDINGS

a. Bio*Shark

The key questions relating to Bio*Shark are:

- Does Bio*Shark inhibit tumor growth?

- Is Bio*Shark effective in the treatment of cancer?

Conclusion:

A thorough review of peer-reviewed literature and of all of the documents produced by DCO indicates that there is no competent and reliable scientific evidence that Bio*Shark inhibits tumor growth in humans or that it is effective in the treatment of cancer in humans.

Discussion

DCO cites 9 nonclinical and 1 clinical studies in support of the clinical efficacy of Bio*Shark, but Bio*Shark was not evaluated in any of them. In the absence of any nonclinical or clinical data on Bio*Shark, it appears that DCO considers any proprietary shark cartilage product as a surrogate for Bio*Shark. Such an assumption is not acceptable scientifically.

A number of reported nonclinical studies suggested that highly purified peptides isolated from shark cartilage may have antitumor activity and antiangiogenic activity. Common in all of these reports was a clear description of the experimental design that included concentration of the peptide being evaluated for its anticancer activity. The nonclinical studies of various, mostly partially purified isolates from shark cartilage suggested a number of effects including:

- Enhanced immune response and decreased tumor size in animals treated intraperitoneally (injected into the abdominal cavity).
- Inhibition of angiogenesis in rabbit cornea.
- Inhibition of endothelial cell function and decreased vascular endothelial growth factor (an important angiogenic factor) production in cancer cells.
- Inhibition of growth of lung carcinoma growth.

Three nonclinical *in vivo* studies of orally-administered crude shark cartilage have been published in the peer-reviewed literature. (PDQ, NCI, April 2008). In one study, an unidentified shark cartilage product inhibited chemically-induced angiogenesis in rats. In

a second study, shark cartilage (unknown brand) inhibited the growth of gliosarcoma in rats. In a third study, two other shark cartilage products (Sharkilage, MIA Shark Powder) did not inhibit the growth or metastasis of squamous cell carcinoma in mice. Thus, even the nonclinical efficacy data regarding orally administered shark cartilage are inconclusive.

The take home message from the nonclinical studies is that evidence of antitumor, antiangiogenic, and immunostimulatory activity in vitro or in animal models using ***highly purified peptides*** from shark cartilage administered parenterally (not by mouth) or shark cartilage powder administered orally does not translate to anticancer activity of crude shark cartilage given to human cancer patients. Specific amounts of antiangiogenic peptides were administered to animals or inserted in Petri dishes with tumor cells or endothelial cells to measure activity. Entirely unknown is the amount of functionally active antiangiogenic peptides or other anticancer compounds that are absorbed after oral administration of crude or aqueous extracts of shark cartilage in humans.

The DCO recommended dose is "2-3 800 mg capsules three times a day." The calculated daily dose is 4.8 – 7.2 g/day. Most clinical trials of crude or partially purified shark cartilage used a dose of 1 g/kg/day. Thus, even if shark cartilage were active, the dose recommended by DCO is about 10% of that given to cancer patients enrolled in clinical trials. This would imply that Bio*Shark is 10 times more potent with respect to antiangiogenic activity than other commercially available products. Comparative bioavailability/bioequivalence studies of the different commercially available products and nonclinical studies to evaluate antiangiogenic and other alleged activities of shark cartilage are needed to establish an appropriate safe and effective dose in humans. These studies have not been done.

Are there any reliable scientific data supporting a role of orally-administered shark cartilage in treating patients with cancer? NCI/PDQ in April 2008 updated the current status of the use of shark cartilage in the treatment of cancer and summarized data from 8 clinical studies that had predefined clinical endpoints (Table 1).

Table 1. Summary of Clinical Trials of Shark Cartilage

Reference^	Phase	Cancer Indication	Cartilage Product (Source)	N	Best Response	Concurrent Therapy	Level of Evidence*
Prudden et al, 1995	Case Studies	Advanced, metastatic	Catrix (bovine)	31	CR-19	Yes	3iiiDiii
Romano et Al, 1985	II	Metastatic	Catrix (bovine)	9	CR-1 (RCC)	No	3iiiDiii
Puccio, 1994	II	Metastatic renal cell	Catrix (bovine)	35	PR-3/22 evaluable	Unknown	None[f]
Falandreau, et al, 2001 Batist, et Al, 2002]	I/II	advanced, refractory solid tumors	AE-941/ Neovastat (shark)	331	↑ OS (NSCLC-Unplanned) RCC (planned)	Unknown	None[f]
Latreille et Al, 2002	I/III	IIIB/IV NSCLC	AT-941/ Neovastat (shark)	80	No DLT ↑ OS @ ↑ doses No tumor Responses	Yes or refused standard therapy	None
Miller et al, 1998	I/II	Advanced solid tumors	Cartilade (shark)	60	SD (12 wk), 10/50	No	3iiiDiii
Leitner, et Al, 1998	II	Metastatic refractory breast	Unknown (shark)	20	SD (12 wk), 2/10	No	None[f]
Leitner et al, 1998]	II	Metastatic, prostate	Unknown (shark)	12	SD (20 wk), 3/10	No	None[f]
Rosenbluth et al, 1999	II	advanced brain	BeneFin (shark)	12	SD (20 wk), 2/10	No	None[f]
Loprinzi, et al, 2005	III PC,DB	Breast, colorectal	BeneFin (shark)	42	No statistically Significant Difference	No	1i

^ Full references in APPENDIX II, Bio*Shark

*For information about Levels of Evidence analysis and an explanation of the level of evidence scores, see Levels of Evidence for Human Studies of Cancer Complementary and Alternative Medicine.

Not included in the above review was a subsequent randomized, double-blind, placebo-controlled study of Neovastat (AE-941) in Stage 3 inoperable NSCLC treated with standard induction chemotherapy and chemoradiation therapy. AE-941 did not improve overall survival when compared with placebo. (Lu et al, 2007) The development of Neovastat in cancer has been discontinued.

In summarizing these data in 2008, NCI concluded: "Although at least a dozen clinical studies of cartilage as a treatment for cancer have been conducted since the early 1970s, relatively few results have been reported in the peer-reviewed scientific literature. At present, the use of cartilage (bovine [cow] or shark) as a treatment for cancer cannot be recommended outside the context of well-designed clinical trials."

A number of anecdotal reports of the safety and efficacy of shark cartilage (Cartilade™, BeneFin™, others) have been published in non-peer reviewed journals, presented on television, or have not conformed to good clinical practice required in Phase II or Phase III trials. These anecdotal studies do not provide any competent and reliable scientific evidence to substantiate the claims mentioned above concerning Bio*Shark. (Lane and Contreras, J Naturopath Med 1992; Menendez Lopez, JR et al, 1996; Milner, 1996). In some anecdotes, patients received conventional anticancer therapy followed by shark cartilage. However, shark cartilage was credited for the salutary effects. In summary, these anecdotal reports provide no scientifically useful, competent, valid, or reliable evidence about the efficacy or safety of shark cartilage in patients with cancer.

DCO relies on the work of Dr. I. William Lane of "Sharks Don't Get Cancer" fame. However, Dr. Lane's premise is false as careful studies at Johns Hopkins University indicate that indeed sharks do get cancer (Ostrander, et al, 2004). Ostrander et al provide details on more than 40 examples of tumors in sharks and related species.

Bio*Shark not only contains shark cartilage but also contains 50 mg of "Biomolecular Base". In addition to a number of herbal ingredients (e.g. eleuthero root, garlic, and dandelion), BioMolecular Base contains unspecified amounts of interesting elements and minerals such as barium, bismuth, gallium, silicon, silver, strontium, titanium, vanadium,

and zirconium. I have searched the literature and am unable to find reliable and competent evidence from controlled clinical trials showing any nutritional value of or daily requirement for any of these constituents in Bio*Shark (and GDU).

There are no adequate and well-controlled studies demonstrating that Bio*Shark is antiangiogenic or is effective in the treatment for cancer. There have been no specific studies of Bio*Shark evaluating its bioavailability, absorption, distribution, metabolism, excretion, pharmacokinetics, pharmacodynamics (antiangiogenic activity), or dose response. There are no good data on the amount of antiangiogenic activity/gram, milligram, microgram, or nanogram of crude shark cartilage or the shelf-life of that activity. The argument that hundreds of thousands of patients have been "treated" with shark cartilage or that the "proof lies in the pudding" does not answer the myriad of unknowns regarding shark cartilage or justify its use in cancer patients. Because the most effective dose or dose schedule has never been established, it is not possible to offer adequate directions for the use of Bio*Shark in cancer patients.

In summary, there is no competent and reliable scientific evidence that any crude shark cartilage product has any proven efficacy in treating human cancer. Furthermore, the supporting nonclinical studies of crude or partially-purified shark cartilage products are extremely limited, particularly with regard to mechanisms of action, pharmacokinetics, pharmacodynamics, establishment of the MTD and recommended Phase II/III dose, all essential components in clinical drug development.

b. 7 Herb Formula

The key questions relating to 7 Herb Formula are:

- Is 7 Herb Formula effective in the treatment or cure of cancer?
- Does 7 Herb Formula inhibit tumor formation?

Conclusion

A thorough review of peer-reviewed literature and all of the documents produced by DCO indicates that there is no reliable and competent scientific evidence that 7 Herb Formula is effective in the treatment or cure of cancer or that it inhibits tumor formation.

Discussion

7 Herb Formula contains Burdock root, sheep sorrel, slippery elm bark, Turkish rhubarb root (the 4 ingredients of another product called Essiac, which has never been evaluated in clinical trials to determine if it has any anticancer activity), cat's claw, Siberian ginseng, and watercress. Unlike the other DCO products under review in this report, the concentrations of the seven ingredients are not provided in the label. Thus, the amount of each ingredient in the DCO-recommended total daily dose of 2 to 4 ounces of 7 Herb Formula is unknown.

I will now review briefly published data about each of the components of 7 Herb Formula. Of note is that according to the label, an ounce of 7 Herb Formula contains no calories, carbohydrate, protein, or fat, and no cholesterol or sodium. The label also indicates that each ounce contains 2% of the daily value of vitamins A and C but no other vitamins, and no calcium or sodium. An analysis of the constituents of 7 Herb Formula is provided in Table 2 and suggests that the label is misleading and in error or both. If indeed 7 Herb Formula contains no carbohydrates, proteins, or fats it must be inert with respect to nutrients. My understanding is that most plants contain carbohydrates.

Table 2. Constituents of Components of 7 Herb Formula (from Cassileth and Lucarelli)

Constituent	Carbohydrates	Fats/cholesterol	Vitamins	Other ingredients
Burdock root	Inulin, mucilage, pectin, flavonols, polyphenols (quercetin), Phytosterols	Fatty acids, polyacetylenes, volatile oils,		Bitters, tannins
Cat's claw	Oxindole alkaloids, glycosides, polyphenols,			Tannins,

Sheep sorrel	Glycosides,		A, B complex, C, D, E, K	anthraquinones Oxalates, tannins
Siberian ginseng	Polysaccharides, glycosides, eleutherosides, glucose, maltose, sucrose,	Oleanolic acid, terpenoids, volatile oils, coniferyl aldehyde		Caffeic acid
Slippery elm bark	Mucilage, galactose, glucose, galacturonic acid,	Physterols; fatty acids (oleic, palmitic); cholesterol		Tannin, calcium Oxalate
Turkish rhubarb root	Starch	Fatty acids, volatile oils		Anthraquinones, tannins, calcium oxalate,
Watercress	Glycosides		A, C, E, nicotinamide	Nitriles, calcium, iodine, copper, manganese iron, phosphorus,

Neither nonclinical nor clinical studies of 7 Herb Formula have been reported in peer-reviewed literature. Thus, there is no evidence to support claims that 7 Herb Formula or any of its individual components are effective anticancer agents or inhibit tumor formation. Nonclinical and clinical studies of the individual components of 7 Herb Formula will now be reviewed.

Burdock root: Neither nonclinical nor clinical trials have been reported in cancer patients. In mice, burdock root stimulated macrophages (cells that phagocytose other cells, bacteria, and other debris). Other studies suggest that burdock root may induce hypoglycemia and increase carbohydrate tolerance. Other reports indicate that some Burdock root products were contaminated with belladonna alkaloids (atropine).

Cat's claw: An indole alkaloid from the tree *Uncaria tomentosa,* cat's claw appears to have immunostimulatory activity in vitro by enhancing phagocytosis and T-helper cell function, and inhibiting NF-κB and TNF-α, and increases myelopoiesis. Anti-inflammatory activity was also noted. (Sandoval et al, 2002) Cat's claw inhibits CYP3A4 and thus will increase the serum levels of a number of drugs including protease inhibitors,

non-nucleoside reverse transcriptase inhibitors (NNRTI) and cyclosporine. It increases the activity of antihypertensive agents causing hypotension, causes diarrhea, and has anticoagulant and antiplatet activity, increasing the risk of bleeding. In cancer patients with low platelet counts, this could be very dangerous. In vitro, cat's claw inhibited the growth of breast cancer cells (Riva L et al, 2001). To that extent tat cat's claw enhances DNA repair after chemotherapy, this might actually interfere with the chemotherapy by preventing programmed cell death of cancer cells.

Published results from clinical trials of cat's claw in cancer patients do not exist. Thus, there is no established or recognized role of cat's claw in treating human cancer or causing regression of tumors in cancer patients.

Sheep sorrel: Simply stated, there are no published clinical trials of sheep sorrel in cancer patients. Adverse side effects include low potassium levels in the blood. Thus, its efficacy as an anticancer agent has not been established.

Siberian ginseng: Siberian ginseng comes from the root of *Eleutherococcus senticus* and anecdotally is thought to be an enhancer of physical and intellectual performance and an immunostimulant. Most of the data supporting the mechanism of action and beneficial effects of Siberian ginseng not surprisingly came from Russia. Some of the constituents of Siberian ginseng bind to estrogen, progestin, and mineralocorticoid and glucocorticoid receptors, which might have an effect on cell proliferation. Stimulation of T-lymphocytes and natural killer cells has been reported but the mechanism of this immunostimulation is unknown. (Cassileth and Lucarelli, 2003) Randomized, controlled clinical trials in cancer patients have not been reported.

Slippery elm bark: As noted in Table 2, slippery elm bark contains carbohydrates (sugars), fatty acids, calcium, and cholesterol. Yet the label for 7 Herb Formula indicates that the content of these ingredients is 0%. Possible explanations are 1) the amount of slippery elm bark is so minimal that these ingredients are undetectable by the analytic methods used by DCO; 2) the label is wrong; or 3) what's claimed to be an active ingredient is actually inert. Specific data from an independent analysis of 7 Herb Formula and its individual components are needed to address this issue. There are no published animal or human studies that support a role for slippery elm bark as an effective anticancer agent in humans.

Turkish rhubarb root (rheum): The pharmacologically active ingredients are tannin, anthraquinones, emodin, and sennidin. At low doses of Turkish rhubarb root, tannins cause constipation; at higher doses, the metabolites of emodin and sennidin cause diarrhea. This illustrates a basic principle in drug development: Phase I studies establish the maximum tolerated dose of a new drug and identify its dose limiting toxicities. We also perform pharmacokinetic studies to learn how a drug is absorbed, distributed, metabolized, and excreted and pharmacodynamic studies to learn more about its mechanisms of action and its effect on some organ or function. Only then do we progress to evaluate the efficacy of a new agent in different types of cancer. Studies of Turkish rhubarb root in mice show antitumor effects but no studies have been performed in humans with cancer. Thus, there are no published data supporting a role of this agent in treating human cancer.

Watercress: The major active pharmacologic constituent of watercress is glucosinolates that irritate mucous membranes. This action conflicts with the purported usefulness of watercress as an agent that might reduce inflammation and mucous in the

respiratory tract. As with any pharmacologic drug, it is the dose that makes the poison. That is, low doses may be beneficial whereas higher doses may be toxic. Watercress has been used to treat urinary tract infections in children, bronchitis, and liver parasites (Hecht et al, 1995). Other studies (Hecht, 1996) indicated that glucosinolate phenethyl isothionate is released when chewing watercress leaves and inhibits the formation of a carcinogen that is present in tobacco smoke. However, there are no clinical reports to confirm the alleged beneficial effects of watercress on cancer treatment or prevention.

c. GDU

The key questions relating to GDU are:

- Does GDU eliminate tumors?
- Is GDU effective in the treatment of cancer?

Conclusion:

A thorough review of the literature and all of the documents produced by DCO, indicates that there is no competent and reliable scientific evidence that GDU is effective in the treatment or cure of cancer or that it inhibits tumor formation. An individual component of GDU, curcumin, is currently being evaluated clinically in controlled trials to determine its potential as a chemoprotective and cancer preventive agent.

Discussion:

DCO recommends that GDU is useful to eliminate and treat cancer. The product contains bromelain (quantity not stated), quercetin, a polyphenolic flavonoid with anti-inflammatory and anticancer activity, tumeric or curcumin with anticancer and cancer preventive activity, feverfew or parthenolide used primarily to treat migraine headaches, and boron. The DCO-recommended daily dose of GDU is 3-6 capsules 2-4 times per day or 6-24 capsules/day providing the following amounts of individual ingredients: tumeric 1800-7200 mg, quercitin 600-2400 mg, and feverfew 600-2400 mg. Because the amount

of bromelain and boron are not provided in the product label, the daily amount of these ingredients is unknown.

There are no controlled or uncontrolled clinical trials that have evaluated GDU in patients with cancer. I will now summarize the nonclinical and clinical studies of the ingredients of GDU in cancer patients.

Bromelain: Bromelain is a proteolytic and fibrinolytic enzyme purified from the stems of pineapple. It prevents platelet aggregation and adhesion on endothelial cells, can act as an anti-inflammatory agent, and has been proposed as an additive agent when given with conventional anticancer therapy. Proposed mechanisms of action include down-regulation of the immunosuppressive cytokine transforming growth factor-β (TGF-β) (Desser et al, 2001), modulation of immune cell function, modulation of cell adhesion, and inhibition of tumor cell growth. Bromelain is absorbed from the intestinal tract and may increase the risk of bleeding, decrease the risk of thrombosis, and increase the efficacy of certain anticancer agents (5-fluorouracil, vincristine) (Cassileth and Lucarelli, 2003). Again, bromelain is not an alternative to anticancer therapy but complements it. We do not know the amount of bromelain in GDU.

Tumeric (curcumin): Of the 5 ingredients of GDU and of all the DCO products being offered to patients for their anticancer potential, tumeric or curcumin is the single most promising agent. Curcumin is a polyphenol derived from the rhizosome and root of tumeric. A spice and coloring agent, it has had a long history in traditional Indian and Chinese medicine to treat inflammatory diseases, abdominal disorders, and other ailments, including cancer. Recent studies suggest that curcumin may have activity as a cancer preventive and therapeutic agent. In animal studies, curcumin inhibited liver cancer

induced by a chemical carcinogen (Chuang et al, 2000) and has dose-dependent cancer preventive effects in rodent models of gastrointestinal cancers extending from the oral cavity to the colon and the skin (Huang et al, 1994; Rao et al, 1995; Kawamori et al, 1999). Some proposed mechanisms of action of curcumin that may have an antitumor effect include:

- Scavenger of free radicals and antioxidant protecting DNA
- Block the local spread and metastasis of tumor cells
- Inhibit the activation of a number of growth factor receptors and intracellular signal transduction pathways important in cell proliferation, programmed cell death, and angiogenesis

However, not all of these mechanisms are beneficial. For example, curcurmin may actually inhibit the antitumor action of chemotherapeutic agents such as cyclophosphamide, doxorubicin, camptothecin, and mechlorethamine useful in treating breast cancer, colorectal cancer, and lymphomas, respectively. (Somassundaram et al, 2002). Neither the DCO BioGuide nor the GDU label warn about potential inhibitor effects of GDU on certain chemotherapeutic agents. The potent inhibition of cytochrome p450 might either increase the blood levels of certain drugs, increasing their toxicity or decrease the effective concentration of other drugs, decreasing their efficacy. Chelation of iron in cancer patients with marginal iron stores or those with anemia associated with cancer and chronic disease will have an adverse effect on these patients. (Jaio, et al, 2009) The label warns patients about the risk of bleeding because of the effect of tumeric on platelet function but provides no information about potentially adverse drug interactions.

Based upon the DCO label, daily doses of 1800-7200 mg are recommended. Each GDU capsule contains 300 mg of tumeric and the daily recommended dose is 3-6 capsules 2-4 times daily or 6-24 capsules. This dose is within the range of some of the reported activities of tumeric in the Petri dish and in animals. In Phase I clinical trials, healthy volunteers tolerated curcumin doses as high as 8 g/day with no side effects (Cheng et al, 2001). These and other studies indicated that the bioavailability of curcumin is very low in rodents and humans and that curcumin undergoes extensive metabolic inactivation in the gastrointestinal tract. (Sharma et al, 2001).

Lacking are double-blind, placebo-controlled, randomized clinical trials of curcumin in cancer patients. These studies are required to determine the safety and efficacy of curcumin to treat or prevent cancer.

Quercetin: Quercetin is a plant-derived polyphenolic flavonoid and the major source of flavonoids in our diet. It is present in apples, teas, onions, and buckwheat. Nonclinical studies suggest that quercetin has anti-inflammatory, antioxidant, and anti-allergic properties. Proposed mechanisms of action in cancer cells include down-regulation of the mutant tumor suppressor gene p53, cell cycle arrest, and inhibition of tyrosine kinase, estrogen receptor binding, heat-shock proteins, and RAS protein expression. The DCO recommended daily dose of quercetin is 600-2400 mg. No randomized clinical studies of quercetin in cancer patients have been reported. Thus the anticancer activity of quercetin is not established and claims that it is an effective and safe anticancer agent are unsupported and unwarranted at this time.

Feverfew: The active ingredient in feverfew is parthenolide. Nonclinical studies indicated that parthenolide induced apoptosis (programmed cell death) in colorectal cancer

cells (Zhang et al, 2004). Curry et al (2004) reported results from an open label, single institution, non-randomized, Phase I study of feverfew (Tanacet®) in cancer patients who were given 1 mg/d po x 28 days with dose escalations to 2, 3, 4 mg/day using a standard Fibonacci design (3+3). Twelve patients with histologically or cytologically confirmed, previously treated and refractory cancer and measurable disease were enrolled. All 11 males had prostate cancer and the single female had breast cancer. All had measurable or evaluable disease, ECOG performance status 0-2, and a life expectancy of greater than 3 mos. Response was evaluated with quantitative, predefined criteria every 8 weeks (2 cycles). Even at these low doses, a number of adverse events were recorded and included fever, nausea, diarrhea, indigestion, chills, fatigue, blurred vision The primary objective of the study was to determine the pharmacokinetics (PK) and maximum tolerated dose (MTD) of feverfew when given as a single agent. However, levels of parthenolide were undetectable in treated patients indicating that orally administered feverfew had very poor bioavailability. Not surprisingly, the MTD was not established and there were no responses to treatment. The authors concluded that more studies were needed.

The doses evaluated were at least two logs below the doses of feverfew recommended by DCO (600 mg-2400 mg/day) but were reasonable in an initial Phase I study. Considering that the relatively tiny doses administered in the Phase I study exhibited adverse effects, concern is raised about potential toxicity of higher doses of purified parthenolide. The amount of parthenolide, the active agent in feverfew, is not provided in the DCO label, nor are there any PK/PD studies of DCO's feverfew that is in GDU.

GDU also contains "BioMolecular Base" that has been discussed above.

In summary, there are no randomized, controlled clinical trials of any of the individual components of GDU or of GDU itself in patients with cancer. Some studies suggest that one of its components, curcumin may actually inhibit the anticancer activity of some approved anticancer agents. Recent studies suggest that curcumin may exacerbate iron deficiency. Yet this component is the most attractive ingredient of GDU because of its possible cancer preventive and perhaps, chemotherapeutic effects. Again, more research is needed to answer these important questions.

d. BioMixx

The key questions are:

- Is BioMixx effective in the treatment of cancer?
- Does BioMixx heal the destructive effects of radiation and chemotherapy?

Conclusion

A thorough review of peer-reviewed literature and all of the documents produced by DCO indicates that there is no competent and reliable scientific evidence that BioMixx is effective in the treatment of cancer or that it heals the destructive effects of radiation and chemotherapy.

Discussion:

BioMixx contains a mixture of so-called biomolecular nutrients including goldenseal, echinacea, ginseng, gamma globulin complex, vitamins, minerals, amino acids, and enzymes. BioMixx, according to the label contains 18 amino acids and 56 other components. However, careful scrutiny of the label indicates that the quantity of the pharmacologically-active ingredients of goldenseal, the alkaloids hydrastine, berberine, canadine, and canadaline is not provided. A recommended dose of goldenseal is 250-500 mg three times a day or 750-1500 mg/day. (Cassileth and Lucarelli, 2003) The most active component of goldenseal is berberine which makes up 0.5-6% of this plant product.

Berberine and the other alkaloids in goldenseal are not mentioned as ingredients of BioMixx. Thus, the amount of berberine in the "recommended" daily dose of goldenseal would range from 4.5-90 mg/day, if goldenseal was in a given product or if pure goldenseal was taken. In vitro studies of berberine at a concentration of 50 μg/ml showed a tumoricidal effect on human and rat brain tumor cells. (Zhang RX, et al, 1990).

Clinical studies of goldenseal in cancer patients have not been reported but this argument is moot because it is uncertain if BioMixx contains either goldenseal or berberine, the presumed active anticancer agent in goldenseal. Furthermore, there are no reported studies of goldenseal in cancer patients.

BioMixx does contain echinacea (25 mg in the recommended daily dose of 151 grams or 5 scoops). The source of echinacea in BioMixx is not stated but the "recommended" daily dose of the dried root source of echinacea is 500 to 1000 mg three times a day or 1500 to 3000 mg. This represents about 2% of the recommended daily dose.

The role of ginseng (400 mg in 5 scoops of BioMixx), *Uncaria tomentosa* or cat's claw (50 mg/day), shark cartilage (916 mg/day), bromelain (122 mg), and boron (2 mg) have been discussed above in the sections on Bio*Shark, GDU, and 7 Herb Formula and will not be reviewed again.

BioMixx contains some novel ingredients that raise other questions and warrant discussion. For example, the label indicates that a day's dose of BioMixx contains ATP (153 mg), RNA (2931 mg), and DNA (1406 mg). ATP is an important high energy intermediary of intracellular metabolism but has no function as a food additive. It is uncertain what kind of "RNA" is added to Bio*Shark. Is it a viral RNA? Messenger RNA? What is the source of the DNA? Is it human? Bald eagle? Grasshoppers? Is it

nuclear or mitochondrial DNA? And what is the purported usefulness of ingesting RNA or DNA? Is this source better than eating a brook trout, a steak, or buffalo wings?

BioMixx contains 977 mg of guarana, whose major constituent is caffeine (2.5-7% or 24-68 mg). Caffeine is a recognized stimulant but does not have any anticancer activity. Another ingredient is bee pollen (365 mg). Except for its nutritive value, no salutary effect of bee pollen in cancer has been reported (Cassileth and Lucarelli, 2003). Patients allergic to bee stings should avoid taking BioMixx but there is no label warning.

This same label asserts that BioMixx is "used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments." There are absolutely no data to support this statement. To do so, DCO or a clinical research group might consider conducting a randomized, placebo-controlled clinical trial in which patients on the same chemotherapy regimen (e.g. cisplatin plus paclitaxel for stage IIIb/IV NSCLC or the same radiation therapy regimen (e.g. 5400 cGy for head and neck cancer) would be randomized to 5 scoops/day of either BioMixx or placebo. All patients would be evaluated for frequency and severity of anticipated side effects of cancer therapy (e.g. lowering of blood counts, mouth ulcerations, and neuropathy). The objective would be to enroll enough eligible patients on the study so that it is powered to reject the null hypothesis (there is no difference between placebo and BioMixx) and show that BioMixx results in a statistically significant decrease in the frequency and severity of side effects and shortens the time to recovery from adverse effects of either chemotherapy or radiation therapy. Adverse effects of cancer therapy are graded by severity and can be quantified (using the common toxicity criteria of the NCI or NCI-CTC). In evaluating toxicity,

subjective descriptors of severity are replaced by objective and quantifiable measures (e.g. number of loose stools/day, degree of anemia).

As is clear from everything written to this point, only data from well-designed, controlled, clinical trials will substantiate claims that a new therapy for cancer is safe and effective to treat, cure, or prevent this disease. Rather than conducting their own clinical trials or having some outside research organization conduct the trial, DCO has provided testimonials from patients who reportedly used their products. Testimonials do not substitute for a well-designed clinical trial.

Review of Testimonials from Users of DCO Products

DCO submitted testimonials from 30 patients with cancer and other disorders to support their claims that their products have anticancer activities. These testimonials do not constitute competent and reliable scientific evidence as to the efficacy of DCO's products.

Nearly two thirds of the testimonial cancer patients also received conventional anticancer therapy (surgery, chemotherapy, radiation therapy, immunotherapy, targeted therapy) making it impossible to assess any alleged response to or benefit from DCO products. Three patients were treated with DCO products as the only treatment for their cancer after they were diagnosed with cancer and report that they had a complete response or had no evidence of disease at the time their testimonials were submitted. Two of these patients had non-melanoma skin cancer and one had leukemia, not otherwise specified. All three received 7 Herb Formula with either Ezekiel Oil (skin cancer patients) or BioMixx (leukemia). Further nonclinical and randomized placebo-controlled clinical

trials would be required to demonstrate any clinically relevant efficacy of these DCO products in the treatment of cancer.

Summary and Conclusions

There have been no studies of the bioavailability, absorption, distribution metabolism, excretion, pharmacokinetics, pharmacodynamics, or dose response of any DCO product when used singly, in combination with other DCO products, or in combination with conventional anticancer therapy. The argument that supposedly hundreds or thousands of patients have been treated with DCO products and claim benefit does not justify their use in cancer patients. The effective and safe dose of these DCO products has never been established. Thus, it is not possible to write adequate directions for their use in cancer patients.

A thorough review of peer-reviewed literature and all of the documents produced by DCO indicates that there is no competent and reliable scientific evidence that Bio*Shark, 7 Herb Formula, GDU, and BioMixx are effective either alone or in combination with other DCO products in the treatment or cure of cancer, in inhibiting tumor formation, and in preventing the destructive effects of radiation and chemotherapy.

Cancer comprises a heterogeneous group of malignancies. Good clinical practice requires that trained, skilled, and experienced physicians diagnose and treat cancer. Cancer can not be diagnosed and treated by individuals lacking that experience. Although a number of products have been marketed to complement conventional anticancer therapy, their use should be known by physicians providing primary oncology care because of potential adverse effects of their own or adverse interactions with conventional anticancer therapy or concomitant medications used to treat other medical conditions.

It is not justifiable to suggest that the traditional and evidence-based process of finding effective treatments for cancer can be replaced by testimonials. Nor is it justifiable to claim that this process can be ignored or evaded because the cure for many patients with cancer remains elusive.

Respectfully, I conclude my report.

I reserve the right to amend, edit, and modify this report if additional substantive data or facts relating to the issues of this case and presented in this report become available.

Respectfully submitted,

Denis R. Miller, MD
January 28, 2009

APPENDIX I. PRIOR TESTIMONY

The following table lists deposition and trial testimony that I have offered during the 4 year period January 1, 2004 to December 31, 2008.

Prior Medical-Legal Testimony: January 1, 2004-December 31, 2008

Lawsuit	Nature of Suit	Court/ Jurisdiction Or site of deposition)	Date (D-depo, T-trial)	Plaintiff Defense (P or D)
Worlds v. St. Mary's Hosp	Wilms tumor	Florida	2/4/04 (D)	P
Garcia v. Holper et al	Delayed diagnosis, bone cancer	Las Vegas, NV	4/29/04 (D)	P
Coleman v. Honeywell,	Asbestos-Mesothelioma	Pittsburgh, PA	6/25/04 (D)	D
Vega v. Turkish	Delayed diagnosis, cancer	Plainfield, NJ	11/12/04 (D)	P
Newman v. CHOP	Delayed diagnosis, lymphoma	Philadelphia, PA	1/07/05 (T)	P
Sklar v. Kim	Delayed diagnosis, gastric cancer	Suffolk County,	1/14/05 (T)	P
Schlain v. Nowack	Delayed diagnosis, breast cancer	New York, NY	2/15/05 (T)	P
Hughes v. Jordan	Accidental death in breast cancer	Las Vegas, NV	5/27/05 (D)	P
Orabani v. Newman, et al	Delayed diagnosis of metastatic colon cancer	Chatham, NJ	8/12/05 (D)	P
Velasquez v. Newark Beth Israel Medical Center	Chemotherapy overdose and death in child with ALL	Newark, NJ	8/26/05 (D)	P
Miner v. Bady	Delayed diagnosis of lung cancer	Las Vegas, NV	2/10/06 (D)	P
Brown v. US	Aplastic anemia 2° to HepB vaccine	Syracuse, NY	3/30/06 (D)	P
Orabani v. Newman, et al	Delayed diagnosis of metastatic colon cancer	Toms River, NJ	7/11/06 (T)	P
Carter (Burton) v. St Francis Health System	Delayed diagnosis of lung cancer	Peoria, IL	7/24/06 (D)	P
Colicci v.	Delayed diagnosis of cancer	Syracuse, NY	9/9/06 (T)	P
Sikoryak v. Valley Hosp	Delayed diagnosis of cancer	Chatham, NJ	2/23/07 (D)	P
Anderson v. Gruber et al	Delayed diagnosis of skin cancer	Morris County, I	3/6/07 (D)	P
Caycho v. Mountainside Hospital	Delayed diagnosis of cancer	Essex County, N	3/22/07 (D)	P
Lebrun v. St. Barnabas Medical Center	Treatment of TTP in child	Essex County. N	5/3/07 (D)	D
Silander v. Howell	Treatment of TTP in adult	Jersey City, NJ	4/16/07 (D)	D
Freitas v. Honeywell et al	Causation of mesothelioma	NY,.NY	6/20/07 (D)	D
Buttitta v. Honeywell et al	Mesothelioma	Essex County, N	8/6/07 (D)	D
Doell v. Abex et al	Mesothelioma	Boston, MA	10/9/07 (D)	D
Anderson v. Gruber	Delayed diagnosis of skin cancer	Elizabeth (Union NJ	11/2/07 (T)	P
Hill v. Manning	Delayed diagnosis of lung cancer	New London, CT	4/11/08 (D)	P
Pahkomova v. Meyerfield	Delayed diagnosis of breast cancer	Chatham, NJ	5/11/08 (D)	P
Wasserstrom v. Rosenberg et al	Delayed diagnosis of parotid gland cancer	Chatham, NJ	7/7/08 (D)	P

APPENDIX II. REFERENCES SUPPORTING EXPERT MEDICAL OPINIONS OFFERED IN THIS REPORT

General

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APPENDIX III. ARTICLES FOR RESEARCH STUDY OF COMPLIMENTARY/ALTERNATIVE PROPRIETARY PRODUCTS IN SUPPORT OF RESPONDENTS CLAIMS

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Exhibit B

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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 FEIJO,	)	**Public Document**
individually, and as an officer of	)	
Daniel Chapter One	)	

[Proposed] ORDER DENYING MOTION IN LIMINE

On March 26, 2009, Complaint Counsel filed their opposition to Respondents' Motion in Limine to preclude the testimony of Complaint Counsel's proposed expert witness Dr. Denis R. Miller from any trial in this case.

IT IS HEREBY ORDERED that Respondents' Motion in Limine is DENIED.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Dated:

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 26, 2009, I have filed and served **COMPLAINT COUNSEL'S MOTION MEMORANDUM IN OPPOSITION TO RESPONDENTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF EXPERT WITNESS DR. DENIS R. MILLER** and **[Proposed] ORDER DENYING 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:

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