FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. LANE LABS-USA, INC., a corporation, and ANDREW J. LANE, an individual, Defendant(s).	Civ. No. 99-5782 (WGB) **O P I N I O N**

APPEARANCES:

UNITED STATES DEPARTMENT OF JUSTICE
BY: Gerald C. Kell, Esq.
Office of Consumer Litigation
P.O. Box 386
Washington, D.C. 20044

OFFICE OF THE UNITED STATES ATTORNEY
BY: Michael Chagares, Esq.
Assistant United States Attorney
9700 Broad Street
Suite 700
Newark, New Jersey 07102

Counsel for Plaintiff

DEPARTMENT OF HEALTH AND HUMAN SERVICES
BY: Alex M. Azar II, Esq.

FOOD AND DRUG ADMINISTRATION
BY: Daniel E. Troy, Esq.
Eric M. Blumberg, Esq.
Paige Harrison Taylor, Esq.

Of Counsel for Plaintiff

SILLS CUMMIS EPSTEIN & GROSS, P.C.
BY: Jack Wenik, Esq.
James Hirschhorn, Esq.
One Riverfront Plaza
Newark, New Jersey 07102

ULLMAN, SHAPIRO & ULLMAN, LLP
BY: Robert Ullman, Esq.
299 Broadway
Suite 1700
New York, New York 10007

Counsel for Defendants

EMORD & ASSOCIATES, P.C.
BY: Jonathan R. Goodman, Esq.
Jonathan W. Emord, Esq.
Burke Professional Center
5282 Lyngate Court
Burke, Virginia 22015

Counsel for American Association for Health Freedom, *Amicus curiae*

BASSLER, DISTRICT JUDGE:

The central issue in this case is whether plaintiff United States of America ("the Government" or "Plaintiff") is entitled to a permanent injunction prohibiting defendants Lane Labs-USA, Inc. and Andrew J. Lane (collectively "Defendants") from marketing certain products – one made from shark cartilage, one from rice bran treated with Shiitake mushroom, and one from glycoalkaloid, which is an extract of sand brier – as treatments for cancer, skin cancer, and HIV/AIDS.

This matter comes before the Court on the Government's motion for summary judgment pursuant to Federal Rule of Civil Procedure 56. Defendants oppose the Government's motion and

cross-move to exclude portions of the Government's expert reports and testimony.[1]

The Government brought this enforcement action on behalf of the United States Food and Drug Administration ("FDA") on December 10, 1999, charging Defendants with violating the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, by improperly promoting and marketing three products — BeneFin®, SkinAnswer™ and MGN-3™ (collectively "the Products") — for the cure, mitigation or treatment of disease, thereby rendering these products misbranded and unapproved new drugs. Lane Labs contends that it has fully complied with federal law and has marketed the Products not as drugs but as dietary supplements, pursuant to the 1994 Amendments to the FDCA, the Dietary Health & Supplement Act of 1994 ("DSHEA"). The Government seeks a permanent injunction, pursuant to 21 U.S.C. § 332(a), restraining Defendants from marketing the Products as well as any other products with the same or similar ingredients. The Government also seeks an order requiring Defendants to make restitution and disgorgement to consumers who purchased the Products.

The Court exercises jurisdiction pursuant to 28 U.S.C. § 1331. Venue is proper pursuant to 28 U.S.C. § 1391(b).

For the reasons set forth below, the Government's motion for

[1] Defendants' cross-motion is addressed by the Court in a separate Memorandum Opinion and Order filed this day.

summary judgment is **granted**.

FACTUAL BACKGROUND

Both parties have submitted 56.1 Statements in compliance with Local Civil Rule 56.1. The facts below are undisputed unless otherwise noted.

I. LANE LABS AND ITS PRODUCTS

Defendant Lane Labs-USA, Inc. ("Lane Labs") is a Delaware corporation that maintains its principal place of business in Allendale, New Jersey. Lane Labs describes itself as "a prominent supplier of high quality dietary supplements." (Defs. Opp. Br. at 4.) Lane Labs has more than 40 employees and approximately $30 million in annual sales. Defendant Andrew Lane is the president of Lane Labs, as well as its director and sole shareholder.

Lane Labs sells the Products at issue in this action directly to consumers, both in and outside of New Jersey, through Lane Labs' CompassioNet division. BeneFin is a product distributed in either powder or caplet form, containing shark cartilage. MGN-3, distributed in capsule form, is a polysaccharide dietary fiber formula made from rice bran (hemicellulose B) that is produced by the hydrolysis of rice bran with the enzymatic extract of Shiitake mushroom. The main ingredient in MGN-3 is arabinoxylan. SkinAnswer is a skin cream that is applied topically and labeled as containing

glycoalkaloid, an extract of sand brier.

Lane Labs obtains the Products from overseas manufacturers. Specifically, Lane Labs purchases BeneFin and SkinAnswer from Lane-Labs Australia. Defendants purchase MGN-3 from Daiwa Pharmaceuticals ("Daiwa"), located in Japan.

B. BUSINESS RELATIONSHIP BETWEEN DRS. LANE AND GHONEUM AND LANE LABS

A. I. William Lane, Ph.D.

I. William Lane, Ph.D. ("Dr. Lane") is defendant Andrew Lane's father and has worked as a paid consultant for Lane Labs since at least 1997. Dr. Lane began studying the anti-angiogenic effects of shark cartilage in 1983.[2] Dr. Lane formed Cartilage Consultants, Inc. in 1990 to research the benefits of shark cartilage as an angiogenesis inhibitor. Dr. Lane is the sole shareholder and chairman of that corporation.

Shortly after forming Cartilage Consultants, Dr. Lane was retained as a consultant by Cartilage Technologies, a company which was in the process of developing a shark cartilage product called Cartilade. In September 1993, defendant Andrew Lane, Dr. Lane's son, also joined Cartilage Technologies. Defendants claim that Dr. Lane became disillusioned with the poor quality of shark cartilage used by Cartilage Technologies for its Cartilade

[2] Angiogenesis is the process by which new capillary blood vessels are generated and is a critical step in the growth of solid tumors. (Defs. Ex. 4.)

product. After allegedly expressing his concerns to Cartilage Technologies in 1994, Dr. Lane's consulting position was terminated and Andrew Lane was also fired.

Dr. Lane then began working with a Cartilade distributor in Australia to develop an allegedly superior method of processing shark cartilage. On August 11, 1994, Andrew Lane formed Lane Labs in order to market this new form of shark cartilage in the United States.[3] Thereafter, Dr. Lane, through Cartilage Consultants, became a paid consultant for Lane Labs. Dr. Lane's ties to the Australian manufacturer of shark cartilage products enabled the formation of a business relationship between the manufacturer and Lane Labs. That Australian distributor later became Lane Labs-Australia, which Defendants claim is an entity entirely independent of Lane Labs. Lane Labs-Australia develops and manufactures BeneFin and SkinAnswer, both of which are distributed by Lane Labs in the United States.

Dr. Lane has written a myriad of articles, books, papers and pamphlets and has participated in interviews in which he touted the positive effects of BeneFin, SkinAnswer and MGN-3. Many of these sources are available to consumers over the Internet. Specifically, Dr. Lane has promoted shark cartilage, particularly

---

[3] At his deposition, Dr. Lane testified that Andrew Lane picked the name Lane Labs for the new company after asking Dr. Lane for "permission to use the family name because [Dr. Lane's] name was well known." (Pl. Ex. E at 43.)

BeneFin, as an effective treatment for cancer. (*E.g.* Pl. Ex. 15-18, Ex. 23, Tabs B and M.) Dr. Lane has claimed glycoalkaloids, such as SkinAnswer, are safe and effective treatments for skin cancer. (*E.g.* Pl. Ex. 14 and 19.) Dr. Lane has also made assertions that MGN-3 is a safe and effective treatment for cancer and Human Immunodeficiency Virus ("HIV"). (*E.g.* Pl. Ex. 20-22, Ex. 23, Tab T.)

In addition to the many articles Dr. Lane has written on the alleged benefits of the Products, he has co-authored three books on shark cartilage as an effective treatment for cancer – Sharks Don't Get Cancer, Sharks Don't Get Cancer: How Shark Cartilage Could Save Your Life and Sharks Still Don't Get Cancer: The Continuing Story of Shark Cartilage Therapy. Dr. Lane has also produced one videotape on the same subject, *Shark Cartilage: A Promise Kept*, and one book on how glycoalkaloid cream can help treat skin cancer, The Skin Cancer Answer. (Pl. Ex. 23, Tab M.)

The Government claims that part of Dr. Lane's role as a paid consultant for Lane Labs has been to promote the Products as treatments for cancer and HIV through his position as "researcher-spokesperson." The Government further argues that the relationship between Lane Labs and Dr. Lane is so closely intertwined and financially mutually beneficial that any claims about the Products made by Dr. Lane may be attributed to Defendants.

However, Defendants contend that Dr. Lane has been compensated by Lane Labs only for his "critical" role in discovering the existence of the Products and forming business relationships with various distributors, particularly Lane Labs-Australia. Defendants assert that Dr. Lane has not been compensated to promote BeneFin, MGN-3 and SkinAnswer for the cure, mitigation or treatment of disease.

B. Mamdooh Ghoneum, Ph.D.

Mamdooh Ghoneum, Ph.D. ("Dr. Ghoneum") has also worked closely with Lane Labs. Dr. Ghoneum is an Associate Professor and Chief of Research in the Department of Otolaryngology at Charles D. Drew University. Dr. Ghoneum is one of the leading researchers of MGN-3. He has written many scientific abstracts and articles summarizing his research findings and discussing MGN-3 as a possible effective treatment for cancer, HIV and Acquired Immune Deficiency Syndrome ("AIDS").

Lane Labs has an agreement with Dr. Ghoneum such that Defendants pay Dr. Ghoneum a royalty of 9.5 percent for every kilogram of MGN-3 that Lane Labs purchases from Daiwa, the Japanese distributor. Lane Labs also agreed to pay Dr. Ghoneum an additional 8.5 percent, which is specifically earmarked for research purposes, for every kilogram of MGN-3 that Lane Labs purchases from Daiwa.

The Government asserts that Dr. Ghoneum's role in Lane Labs'

business has been that of "researcher-spokesperson." The Government contends Defendants purposefully and consistently link the Products with statements, articles and research by Dr. Ghoneum through promotional mailings, the Internet, and statements by Defendants' employees. Therefore, the Government argues that the promotional claims made by Dr. Ghoneum may also be attributed to Defendants.

Defendants paint a different picture of Dr. Ghoneum's association with Lane Labs. Similar to the purported relationship between Dr. Lane and Lane Labs, Defendants contend that Dr. Ghoneum is compensated merely for initiating and facilitating Lane Labs' relationship with Daiwa. Defendants point to Dr. Ghoneum's deposition testimony in which he testified that Lane Labs had no control over the content of his writing or research. (Pl. Ex. 29 at 76.) Defendants also highlight that much of Dr. Ghoneum's research was published prior to 1998, before he had any financial relationship with Lane Labs.

III. LANE LABS' MARKETING AND DISTRIBUTION PRACTICES

A. Promotional material disseminated to customers

Lane Labs has used many of the materials written by Dr. Lane to promote its products. For instance, Defendants have distributed materials to customers describing Dr. Lane's role in the development of BeneFin, including an article by Dr. Lane entitled "Having My Say [,] Shark Cartilage Therapy [,] A

Personal History of Its Development" (Pl. Ex. 23, Tab H at P12582 - P12586), which espouses the theory that shark cartilage could be an effective treatment for cancer.[4] Defendants often distributed the "Having My Say" article along with information about ordering BeneFin. In addition, the packaging Defendants used in distributing BeneFin and SkinAnswer has, in the past, included Dr. Lane's name and picture. Defendants allegedly ceased at least the latter practice over two (2) years ago due to concerns expressed by the FDA.

Lane Labs has also used abstracts and articles authored by Dr. Ghoneum, as well as Dr. Ghoneum's name and endorsement, to market the Products. For instance, Lane Labs has distributed mailings to customers and potential customers that include articles and abstracts written by Dr. Ghoneum. One such article, entitled "One Sizeable Step for Immunology, One Giant Leap for Cancer Patients," written by Dr. Ghoneum, makes the following

---

[4] In "Having My Say," Dr. Lane's opening sentence states: "The use of shark cartilage in the complementary treatment of non-responsive solid cancer tumors has become widely used worldwide . . . ." (Pl. Ex. 23, Tab H at P12582). The article goes on to state:

> The poor results with conventional cancer therapy should suggest that any new therapy that seems promising should be investigated, especially if it is inexpensive, nontoxic and noninvasive. In these times of uncontrolled health costs, and the cancer epidemic that does not seem to be abating, all possibilities deserve attention.

(*Id.* at P12586.)

statements:

> Unlike most natural preparations, MGN-3 offers solid data collected from *human* clinical trials. This data offers compelling evidence that MGN-3 is a powerful biological response modifier that is free of toxicity or side effects. As such, it has enormous promise as an immunotherapy in the treatment of cancer and other diseases.

(Pl. Ex. 32) (emphasis in original). This article has been distributed by Lane Labs to potential customers along with information about how to order MGN-3 and other Lane Labs' products.

Lane Labs has also used the "One Sizeable Step for Immunology" article to market its products as recently as 2002. Defendants paid to place that article, as well as an article by Emmalyn McAllister entitled "MGN-3: Cure or Curiosity? The Question Persists!", as advertising supplements in various alternative heath-related publications from January through June 2002, over three years after the Government filed the Complaint in this action. (*See* Pl. Ex. 34-37.) Defendants also paid to have business reply cards inserted into the same publications. Those business reply cards bear Dr. Ghoneum's endorsement of MGN-3 and provide information on ordering MGN-3 from Lane Labs.

Defendants claim that the materials written by Dr. Ghoneum and used by Lane Labs to market MGN-3 have not touted MGN-3 as a cure or treatment for cancer or HIV. Further, Defendants assert that Lane Labs has had no control over the content of those

articles. Dr. Ghoneum testified at his deposition that he was not compensated by Lane Labs for use of the "One Sizeable Step for Immunology" article. Further, Dr. Ghoneum testified that no one from Lane Labs has made suggestions, corrections, additions or deletions to any of the abstracts or journal articles that he has published. Lane Labs contends that its use of Dr. Ghoneum's "One Sizeable Step" article, and the placement of business reply cards in various alternative health magazines, complied with federal laws concerning marketing and promotion of dietary supplements.

Lane Labs has also used Drs. Lane and Ghoneum's names and endorsements to sell the Products in other ways. For example, Lane Labs sponsored a cocktail reception on July 14, 2001, in which Dr. Ghoneum, as well as Dr. Lane, discussed the results of clinical trials involving MGN-3. (Pl. Ex. 26.)

In addition to abstracts and articles authored by Drs. Lane and Ghoneum, Lane Labs distributed other third-party promotional literature with its products. One example includes a article by Dr. David G. Williams ("Dr. Williams") entitled "A New Chapter in Healing" from the September 1998 issue of *Alternatives*, a monthly newsletter published by Dr. Williams and disseminated to potential Lane Labs customers. This article contained ordering and pricing information for Lane Labs products. In "A New Chapter in Healing," Dr. Williams promoted MGN-3 as a safe and

effective treatment for cancer, and included statements such as the following:

> Unlike most forms of cancer treatment, MGN-3 is totally non-toxic. After years of use and continued toxicity tests, there have never been any indication [*sic*] of toxicity and side effects whatsoever. Undoubtedly, this is because MGN-3's primary function is to enhance the activity of the immune system rather than to attack cancer cells directly.

(Pl. Ex. 23, Tab S at P13077) (discussing the results of various studies by Dr. Ghoneum).

The article also made claims about the ability of MGN-3 to treat HIV and AIDS: "Work with AIDS patients has been limited, although all of the patients who have taken MGN-3 reported a noticeable difference in their well-being, and all have continued to use the product. Most felt MGN-3 was instrumental in helping them stabilize their disease." (*Id.* at P13079.) In addition, Dr. Williams' article discussed SkinAnswer as a "skin cancer cream" suggesting the product is an effective treatment for skin cancer. (*Id.* at P13074.)

Lane Labs admits that it distributed the *Alternatives* newsletter containing Dr. Williams' article but contends that it did not commission the article nor did Defendants exercise any control over the article. Furthermore, the article has not been disseminated by Lane Labs in over two years.

The Government provides further examples of instances when Defendants have distributed other third-party materials to

customers and potential customers along with information about the Products, as well as ordering information. Much of this material presents the Products as potentially effective treatments for cancer and HIV and discusses Drs. Lane and Ghoneum by name. These additional materials distributed by Lane Labs have included statements such as:

> Dr. Mamdooh Ghoneum of Charles Drew University of Medicine and Science in Los Angeles, compares current cancer treatment to battling terrorists.... 'Chemotherapy, radiation or surgery are the cancer-equivalents of bombing,' he says....Even after bombing, however, some terrorists may survive, as do those cancer cells that are resistant to the usual therapies. Rather than bombing the city again, however, Dr. Ghoneum advocates sending in special forces to locate and eliminate the remaining terrorists one by one. Dr. Ghoneum's development of a natural supplement called MGN-3 is meant to arm the body's Natural Killer cells to seek and destroy dangerous invaders.

(Pl. Ex. 32) (from "Winning the War Against Cancer (,) MGN-3: Mushroom Ammunition," *Alternative Medicine*, May 1999 at 26-27).

Defendants have also distributed a Health Professional Information Kit ("the Kit") to medical doctors as recently as August 2001. At his deposition, Andrew Lane testified that one purpose behind Lane Labs' distribution of the Kit was to help generate sales for Lane Labs' products. (Pl. Ex. 2 at 101-182.) Included in the Kit were various articles by Dr. Ghoneum, including the "One Sizeable Step for Immunology Article," as well as the McAllister article, "MGN-3: Cure or Curiosity?"

Also included in the Kit was a newsletter entitled *Health &*

Healing, edited by Dr. Julian Whitaker ("Dr. Whitaker"). In his newsletter, Dr. Whitaker discusses various studies involving alternative medicines and makes recommendations regarding effective brands for consumers to purchase. In one section entitled "Solutions to Common Skin Problems," Dr. Whitaker writes:

> Any suspicious lesion should be examined by a physician to rule out melanoma, a fast-growing, potentially lethal form of skin cancer that requires immediate treatment. Basal cell and squamous cell carcinomas, however, as well as precancerous solar or actinic keratoses, are slow spreading and less likely to metastasize. Before consenting to laser, chemical or surgical removal of such lesions, I recommend that you try a product that contains glycoalkaloids....The glycoalkaloid product I recommend, SkinAnswer, is available in health food stores or by mail order from CompassioNet, 800/510-2010.

(Pl. Ex. 53, *Health & Healing* at 6.)

The Government claims that Defendants' overall marketing strategy has been to associate their products with the oral and written statements and endorsements of Drs. Lane and Ghoneum, both through materials published by Drs. Lane and Ghoneum themselves, and by third-party materials that discuss the views of Drs. Lane and Ghoneum and promote Lane Labs products for the treatment, mitigation and cure of disease. Accordingly, the Government argues that the claims made by Drs. Lane and Ghoneum, and by the third-party materials discussing Drs. Lane and Ghoneum and distributed by Lane Labs to its customers, should be considered claims made by Defendants themselves.

Defendants vociferously deny the Government's contention that the informational materials distributed by Defendants promoted the Products as treatments for cancer and HIV. Defendants assert that the Products and accompanying promotional material distributed by Defendants consisted of the type of material dietary supplement distributors are permitted to disseminate pursuant to DSHEA, 21 U.S.C. § 343-2(a), under which natural products companies are permitted to distribute third-party literature regarding their products. Furthermore, Defendants highlight that the articles and pamphlets distributed to customers often included the following disclaimer, or one like it:

> The approaches described in this brochure are not offered as cures, prescriptions, diagnosis, or means of diagnosis to different conditions. The information must be viewed as the personal experiences of the people portrayed herein. [The author and publisher] assume no responsibility in the correct or incorrect use of this information and no attempt should be made to use any of this information as a form of treatment without the approval and guidance of your doctor.

(Pl. Ex. 23, Tab B at P12504.)

Although Defendants contend that neither Dr. Lane nor Dr. Ghoneum is a paid "researcher-spokesperson" for Lane Labs, Defendants do concede that Drs. Lane and Ghoneum have in the past been compensated by Lane Labs to promote the Products and that Dr. Ghoneum receives as compensation a percentage of all Lane Labs' sales of MGN-3. In a letter to Magistrate Judge Arleo

regarding discovery issues, defense counsel wrote: "Whether Dr. Ghoneum, Dr. Lane and Cartilage Consultants have been compensated by Lane Labs for promoting Lane Labs' products is not at issue. Defendants have acknowledged making such payments. . . ." (Pl. Ex. 38 at 3, n.1.) However, Defendants strenuously argue that there is no way the statements made by Drs. Lane and Ghoneum can be interpreted as promoting the cure and treatment of cancer and HIV. Defendants further contend that statements made by third-parties cannot be attributed to Lane Labs and therefore Defendants cannot be held accountable for the claims proffered in the promotional material.

B. Lane Labs' distribution network

CompassioNet is a division of Lane Labs that markets and distributes Lane Labs' products directly to consumers in the United States. Until November 2003, Defendants sold BeneFin, MGN-3 and SkinAnswer directly to consumers over the Internet through their website compassionet.com.[5] That website included a button called "Research," which linked compassionet.com to

[5] As discussed more fully below, as of November 11, 2003, according to the Government, the compassionet.com website was still operational. However, when an FDA attorney attempted to visit the website on November 19th, after the parties had appeared before this Court for oral argument, the website was no longer available. (Taylor Decl. of 12/1/03 ¶ 3.) Instead, the website simply contained a message stating "Look for the New Compassionet.com Coming soon!" (*Id.*) As of the date of this Opinion, the compassionet.com website continues to contain only that message and appears non-operational.

another of Defendants' websites, publishedresearch.com. According to the Government, publishedresearch.com is registered to the same location as Lane Labs, and Andrew Lane is the registrant for publishedresearch.com. As of May 2002, publishedresearch.com included numerous articles and abstracts discussing shark cartilage as a possible treatment for cancer and MGN-3 as a possible treatment for cancer and HIV. Many of these articles were written by Drs. Lane and Ghoneum. A consumer who visited publishedresearch.com via the "Research" hyperlink on compassionet.com could return to the compassionet.com website simply by hitting the "Back" button on his or her web browser. Until November 2003, consumers could purchase both BeneFin and MGN-3 from the compassionet.com website.

Until at least 1999, Defendants' compassionet.com website included the following metatags:[6] "alternative cancer therapies," "non-toxic cancer therapy," "cancer treatment," "Brain Tumors," "Breast Cancer," "Cancer Patients," "Colon Cancer," "Gynecologic Cancers," "Laryngeal Cancer," "Leukemia," "Lung Cancer," "Lymphoma," "Neuroblastoma," "Ovarian Cancer," "Prostate Cancer," "Skin Cancer," "Testicular Cancer," "Thyroid Cancer," "arthritis," "osteoarthritis," "rheumatoid arthritis," "Kaposis

[6] A metatag is a code placed in a website. These codes are detected by search engines and increase the likelihood that a user searching for a particular topic will be directed to a website containing those metatags.

sarcoma," "cancer survivors," "squamous cell carcinoma," "melanoma," "Dr. Lane," "Dr. I. William Lane," "Sharks Don't Get Cancer," and "The Skin Cancer Answer."

The Government claims that Defendants have used Dr. Lane's company, Cartilage Consultants, both to promote the Products as treatments for disease and to superficially separate the sale of the Products from the sale of Dr. Lane's books. Through an undercover investigation conducted by the FDA from 1997 to 1998, the Government found that consumers who called the 1-800 number for Lane Labs' CompassionNet division were referred to Marian Murphy, then an employee of Cartilage Consultants, for information about BeneFin, MGN-3 and SkinAnswer. Ms. Murphy in turn made statements explicitly promoting the use of those products for the treatment of cancer and skin cancer. (Pl. Ex. 23, Tab A, Attach. 8 at 2-7, 11-12 & Attach. 18 at 2-3, 12-13, 16-19.)

Furthermore, FDA investigators found that if a consumer called Lane Labs' CompassioNet division to order any of the Products and asked to purchase one of Dr. Lane's books or videos, the consumer was told to call a Cartilage Consultants 1-800 number to purchase the promotional materials. Likewise, if a consumer called Cartilage Consultants' 1-800 number and asked to purchase BeneFin, MGN-3 or SkinAnswer, he or she would be referred to the 1-800 number for CompassioNet. Defendants

discontinued all of these practices, in addition to terminating Ms. Murphy, in May 2000, after this lawsuit was filed.

IV. USE OF THE PRODUCTS AND FDA INVOLVEMENT

The parties stipulate that cancer, HIV/AIDS and skin cancer are all diseases not capable of self-diagnoses or self-treatment by a layperson. The FDA has not approved any of the Products at issue in this action for the treatment, cure or mitigation of disease. Specifically, BeneFin has not be approved by the FDA for use in the cure, mitigation, treatment or prevention of any form of cancer. MGN-3 has not been approved by the FDA for use in the cure, mitigation, treatment or prevention of either cancer or HIV. Likewise, SkinAnswer has not been approved by the FDA for use in the cure, mitigation, treatment or prevention of any form of skin cancer.

There is currently no approved new drug application or abbreviated new drug application on file with the FDA for BeneFin, MGN-3 or SkinAnswer. Furthermore, there is no investigational new drug application ("IND") on file with the FDA for either MGN-3 or SkinAnswer. However, the National Cancer Institute is currently the sponsor of an IND for the study of BeneFin. The study is being conducted at the Mayo Clinic.

The Government contends there are no adequate and well-controlled studies establishing the effectiveness of BeneFin for cancer, MGN-3 for cancer or HIV, or SkinAnswer for skin cancer.

The Government further claims that the Products are not generally recognized, among qualified experts, as safe and effective treatments for the those diseases. Defendants dispute these contentions, agreeing only that the FDA has not approved the Products for these purposes. Further, Lane Labs claims that there is no evidence that BeneFin, MGN-3 and SkinAnswer are unsafe. The Government counters that without well-controlled and peer-reviewed studies, the relative safety of the Products cannot be ascertained.

Defendants assert that there is no evidence that patients forgo traditional treatments for cancer or HIV/AIDS while using BeneFin, MGN-3 or SkinAnswer. In support of this proposition, Defendants cite to, *inter alia*, a declaration from Alexander Schauss, Ph.D. ("Dr. Schauss"), the President and Director of Natural and Medicinal Products Research in the Life Sciences Division of the American Institute for Biosocial and Medical Research, Inc. ("AIBMR"), a consulting company specializing in natural products research. Dr. Schauss reviewed various studies published in the *Journal of the American Medical Association* and other publications and determined that alternative medicines were not being used in lieu of traditional treatments for HIV/AIDS and cancer. (Defs. Ex. 3, ¶¶ 17-20, 41, 45.) Dr. Shauss testified:

> After reviewing over thirty-five published papers on the use of [alternative and complementary medicine] therapies, and all of the literature reviewed by the plaintiff's experts, I was unable to find any evidence

> suggesting a risk that patients will forego conventional care for cancer or HIV in favor of dietary supplements, neutraceuticals or the like.

(*Id.* ¶ 20.)

The Government maintains that consumers can and do use the Products offered by Lane Labs in lieu of more traditional treatments for cancer and HIV. (*E.g.* Pl. Ex. 67, Miller Decl. ¶ 35) (Government expert found that "patients with cancer who have read or heard about BeneFin can and do call directly and order BeneFin for the self-treatment of cancer.").

In addition, the Government points to the hundreds of emails and letter received by Lane Labs, and produced during discovery, in which Lane Labs customers laud the medicinal benefits of the Products. The following are only excerpts from the myriad of comments sent to Lane Labs:

> I was given 17 weeks to live and no hope of a treatment that would help or cure my grade iv gioblastoma brain tumor. That was in 1995, With the use of BENEFIN shark cartilage I am still alive with hope. If I can't take benefin I will most certainly perish quickly...I might add that I never did radiation or chemo, I belief that those treatments are what kill people with my diagnosis.

(Pl. Ex. 85 at LL5088) (punctuation and spelling in original).

> I have used SkinAnswer for a small patch of skin cancer I had on my back. It is now gone. A friend of mine is now using MGN-3, instead of radiation and/or chemotherapy following surgery for colon cancer. He is doing just fine, thank you....Where would we be without these alternatives? Unlike prescription drugs, they have essentially no side effects....

(*Id.* at LL4620.)

> I think the lawsuit against Lane Labs is wrong. I was operated on Nov. 18, 1999 for colon cancer and after taking KEMO for 4 weeks I decided it was doing more harm than good, I started taking mgm-3 and Benefin from Lane Labs and when I took my last cat scan no CANCER or any sign of CANCER could be found. I am convinced the products works and that is the reason the FDA want control.

(*Id.* at LL4725) (punctuation and spelling in original).

Between June and November 1997, the FDA cautioned Lane Labs, both orally and in writing, against unlawful promotion of BeneFin and other products. Specifically, in September 1997, the FDA issued a warning letter to Defendants stating, in relevant part:

> Based on the claims made for these products and their intended uses, "BeneFin" and "SkinAnswer" are neither cosmetics nor dietary supplements. Under Section 201(g) of the Food, Drug, and Cosmetic Act (the Act) [Section 201(g)], they are drugs. They are also unapproved new drugs [Section 201(p) of the Act] and may not be legally marketed in the United States without approved New Drug Applications (§ 505). [¶] These drugs are also misbranded (§ 502(f)(1)) because the labeling fails to bear adequate directions for use....
>
> This letter is not intended to be [an] all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.[¶]...Failure to promptly correct violations may result in enforcement action initiated by the Food and Drug Administration without further notice.

(Pl. Ex. 44). The Government issued a final warning letter on September 22, 1999, warning of an impending lawsuit if Defendants did not cease their marketing activities. The Government brought suit against Defendants in December 1999.

In June 2000, Lane Labs reached a settlement and entered

into a consent decree with the Federal Trade Commission ("FTC") in a related action for false advertising. *See FTC v. Lane Labs-USA, Inc., et al.*, Civ. No. 00-3174 (D.N.J.)(WGB). The consent decree was subsequently entered by the Court on September 26, 2000 ("FTC Final Order"). On February 9, 2001, Lane Labs submitted a compliance report to the FTC without objection.

Lane Labs has also offered information about settlement negotiations that took place between the Government and Defendants in this action both before and after the Government filed its Complaint. The admissibility of these statements is discussed more fully below.

V. LANE LABS' CURRENT ACTIVITIES

In its reply brief, the Government offers new evidence regarding alleged continuing violations of the FDCA by Lane Labs. Many of these factual contentions are strenuously disputed by Defendants. On September 17, 2003, this Court granted Defendants' motion to file a sur-reply, thereby enabling Lane Labs to respond to the Government's new factual contentions. In the sur-reply filed thereafter on October 3rd, Defendants countered many of the factual contentions presented by the Government in its reply brief.

For example, the Government attached to its reply brief a declaration from Ann Stahl ("Stahl"), an investigator for the FTC. Stahl declared that she attended a Cancer Control

Convention in Universal City, California on September 2, 2002. Stahl claimed she spoke to a representative at Lane Labs' exhibit booth named "Joe" who made representations that MGN-3 is an effective treatment for cancer. The Government argues that this type of action, and continued false representations by Defendants, exhibits Lane Labs' current and ongoing statutory violations.

On sur-reply, Defendants filed a declaration from Joseph Bonneau ("Bonneau"), the inside sales director for Lane Labs. Bonneau declared that he had attended the Cancer Control Convention on September 2, 2002 with one other Lane Labs employee, Len Rubin, the former inside sales manager and current outbound sales manager for Lane Labs. Bonneau was the only individual named "Joe" representing Lane Labs at the Convention. Bonneau declared:

> I am confident I never told Ms. Stahl, or anyone else for that matter, that MGN-3 or any other Lane Labs product was an effective treatment for cancer or any other disease....Andrew Lane and other Lane Labs representatives have repeatedly emphasized to me and other Lane Labs employees that not only must we refrain from giving any inference that we are promoting any Lane Labs product for the treatment of disease, but that if anyone approaches us and starts talking about cancer or any other disease, we must immediately advise them that we are prohibited from speaking to them about Lane Labs' products in connection with the treatment of any disease.

(Bonneau Decl., Defs. Ex. 33 ¶ 7.)

One of the strongest pieces of evidence provided by the Government as to Lane Labs' continued violations is presented in

Exhibit 105, also attached to the Government's reply brief. Exhibit 105 includes printouts dated September 14, 2002 from Lane Labs' website, lanelabs.com. These web pages provide information about ordering the Products by phone, as well as links to compassionet.com. In addition, these printouts from Lane Labs' website, contain the following information: (a) a press release announcing a Phase III clinical trial of BeneFin for the treatment of cancer and quoting Andrew Lane as saying "we're confident that BeneFin will be proven effective in this trial" (Pl. Ex. 105 at 10); (b) a press release describing MGN-3 as able to "arrest tumor cell growth" based on an in vitro study conducted by Dr. Ghoneum (*Id.* at 11); (c) a press release claiming that a "new clinical study indicates that administrations of MGN3...may help reduce toxicity in patients undergoing treatment with...two common chemotherapy agents" (*Id.* at 10-11); and (d) an interview with Dr. Ghoneum discussing successful use of MGN-3 in terminal patients "to extend their lives beyond their doctors' expectations" and claiming the product "will boost natural killer cell activity to destroy any remaining abnormal cells after surgery or adjuvant treatment."[7] (*Id.* at 33-34.)

[7] The Government, citing Random House Webster's Unabridged Dictionary (2d Ed. 1998), claims that adjuvant treatment is treatment "using drugs, radiation therapy, or other means of supplemental treatment following cancer surgery...." Defendants do not dispute this definition.

In its sur-reply, Lane Labs argues that the entirety of the information presented in Plaintiff's Exhibit 105 was improperly obtained from lanelabs.com and should not have been available to the public. Defendants provide a declaration from Russell Mendola ("Mendola"), who was the webmaster for Lane Labs from October 1999 to July 2003. Mendola declared that the materials presented in Plaintiff's Exhibit 105 "were downloaded from an area of the Lane Labs' web site that was supposed to be secured and for media professionals only. The web site was designed so that a user who came to that area could not proceed any further without submitting a user name and password." (Defs. Ex. 34 ¶ 6.) Mendola declared that a breakdown in the network had occurred such that the password system had become inadvertently deactivated. Upon realizing what had happened, Menodola claims he contacted the web host provider, which immediately reset the password protections. It is unclear from Mendola's declaration who was supposed to have access to the information included in Exhibit 105. Mendola does not explain who the "media professionals" are to which his declaration refers.

Given that much of the evidence supplied by the Government with its reply brief concerning Lane Labs' more recent alleged violations is contested by Defendants, at oral argument on November 13, 2003, this Court requested that the Government supply additional information regarding Defendants' alleged

continuing violations up to that point.[8] In response to this Court's order, the Government provided additional evidence regarding an alleged pattern of conduct by Defendants that continued until at least January 2004.

The Government has submitted extensive evidence of Defendants' continued improper marketing of the Products. After oral argument on November 13, 2003, Defendants apparently took down the compassionet.com website. (Taylor Decl. of 12/1/03 ¶ 3.) However, the Government contends that Defendants continue to make disease treatment claims for their Products through the lanelabs.com and publishedresearch.com websites, as well as through the dissemination of their CompassioNet catalog to potential customers.

For instance, as shown by the Declaration of Paige Taylor, Esq. of the FDA, as of November 11, 2003, the compassionet.com website contained an interview with Dr. Ghoneum in which he explains the benefits of MGN-3 to patients who have been exposed to adjuvant treatments. (Taylor Decl. of 12/1/03 ¶ 2, Ex. A.) In fact, this is the very interview, attached as Exhibit 105 to Plaintiff's Reply Brief, that Lane Labs had claimed was mistakenly made available through an error on its website. Not only was the Government able to access this article in November

[8] The Court acknowledges that this was a difficult task for the Government, given that fact discovery closed in this case in 2001.

2003 on the compassionet.com website, the lanelabs.com website contained the text of this very same interview with Dr. Ghoneum as late as January 6, 2004. (Taylor Am. Second Decl. of 1/8/04, Ex. A.)

In a declaration submitted in response to the Government's allegations of continuing violations, Andrew Lane declared that Lane Labs had removed the offending lines from the interview with Dr. Ghoneum highlighted in the Government's brief. (Lane Decl. of 12/18/04 ¶ 3.) However, as displayed by the January 6th Taylor Declaration submitted by the Government, the Ghoneum interview was still readily accessible to the public. Therefore, as late as January 2004, Defendants' website contained statements regarding MGN-3's effectiveness for patients who had undergone cancer treatments, statements that Andrew Lane had represented to the Court that it had removed from its websites.

That is just one of many examples provided by the Government as to Defendants' continued and systematic pattern of behavior. The Government also shows how, as of November 2003, Defendants' websites continued to associate the Products with Drs. Lane and Ghoneum and continued to link lanelabs.com to publishedresearch.com, which contains many of Drs. Lane and Ghoneum's articles and abstracts. These articles and abstracts contain various statements about cancer and HIV.

As of November 2003, Lane Labs' websites contained

four articles co-authored by Dr. Lane. (Taylor Decl. of 12/1/03, Ex. F.) One article reported alleged favorable results in "29 end stage patients with various forms of cancer" who were treated with shark cartilage. (*Id.* at 15-16.) Another article by Dr. Lane claimed that "major responses" were seen in seven out of eight terminal cancer patients in a study conducted by Dr. Lane, and that 14 of the 29 terminal patients in a trial in Cuba "are completely well and cancer-free after 34 months." (*Id.* at 30-40.)

In addition, as of November 2003, the publishedresearch.com website contained at least 11 articles authored by Dr. Ghoneum. (Taylor Decl. of 12/1/03, Ex. F.) In one of the articles, Dr. Ghoneum wrote: "In addition to very encouraging results using MGN3 in the treatment of malignancies, other research suggests a promising role for MGN3 as a therapy for HIV, Hepatitis C and other viral infections...[MGN-3] has enormous promise as an immunotherapy in the treatment of cancer and other diseases." (*Id.* at 56-59.)

Defendants do not deny the evidence presented by the Government. Rather, they contend that the information presented on their various websites does not run afoul of either the DHSEA or the FDCA.

PROCEDURAL BACKGROUND

The Government commenced this action on December 10, 1999. The Government brought its motion for summary judgment and request for statutory injunction after the parties conducted extensive discovery over a period of years.

On August 30, 2002, this Court granted a motion brought by the American Association for Health Freedom ("AAHF") for leave to file an *amicus curiae* brief in partial opposition to the Government's motion for summary judgment. Thereafter, the Government was granted leave to file an omnibus brief in reply to Defendants' opposition to the Government's motion for summary judgment and in response to the *amicus curiae* brief.

Defendants also filed a separate motion to strike six (6) exhibits offered on reply or, alternatively, for permission to file a sur-reply in further opposition to the Government's motion for summary judgment. On September 17, 2003, this Court granted Defendants' motion to file a sur-reply, but limited the content of the sur-reply to only the factual issues presented in Plaintiff's exhibits 105, 106 and 111-114, the six exhibits to which Defendants objected. The Court specifically stated it would disregard any discussion or argument by Defendants in the sur-reply beyond the scope of those exhibits.

On November 13, 2003, this Court held oral argument on the Government's motion for summary judgment and request for

injunctive and other equitable relief.

At the conclusion of oral argument, the Court ordered supplemental briefing from the parties on two important issues. First, the Court ordered briefing on the issue of the restitution and disgorgement remedies requested by the Government. Second, as mentioned above, the Court requested briefing on alleged current and continuing violations of the FDCA by Lane Labs.

The Court set dates by which the Government was to submit supplemental briefs on each of these issues as well as dates by which Defendants should file opposing briefs. On consent of the parties, and upon permission from the Court, these deadlines were extended, some until March 2004.

In April 2004, the Government moved for leave to file a reply to Defendants' supplemental brief opposing the Government's request for restitution and disgorgement. Due to the complicated and novel legal questions this case presents with respect to the restitution and disgorgement issue, on April 14, 2004, the Court granted the Government's motion for leave to file a reply brief, over the objection of Defendants.

DISCUSSION

I. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate only if there is no genuine issue as to any material fact. Fed. R. Civ. P. 56(c). The applicable substantive law determines whether or not a fact is

material. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). An issue of fact is genuine only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248 (citation omitted). In determining whether a genuine issue of material fact exists, all inferences must be drawn, and all doubts must be resolved, in favor of the non-moving party. *Coregis Ins. Co. v. Baratta & Fenerty, Ltd.*, 264 F.3d 302, 305-306 (3d Cir. 2001) (citing *Anderson*, 477 U.S. at 248).

The moving party has the initial burden of showing that no genuine issue of material fact remains. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party satisfies this requirement, the burden shifts to the nonmoving party to present evidence that there is a genuine issue for trial. *Id.* at 324.

II. REGULATORY FRAMEWORK FOR MARKETING AND DISTRIBUTING DRUGS AND DIETARY SUPPLEMENTS

The core objective of the FDCA, codified at 21 U.S.C. §§ 301-397, "is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citing 21 U.S.C. § 393(b)(2)). The FDCA grants the FDA the authority to regulate, among other items, "drugs." Section 321(g)(1) defines the statutory meaning of the term "drug."

> The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles **intended** for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) **intended** to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

21 U.S.C. § 321(g)(1) (emphasis added).

In 1994, Congress amended the FDCA by enacting DSHEA, which established a new regulatory category for dietary supplements. The DSHEA amendments to the FDCA distinguish drugs from dietary supplements. Pursuant to DSHEA, the term "dietary supplement" is defined as:

> [A] product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

21 U.S.C. § 321(ff)(1).

One purpose of DSHEA was "to narrow the reach of the FDA's preauthorization scheme out of concern over excessive regulation of dietary supplements and the suppression of truthful information." *Nutritional Health Alliance v. Shalala*, 144 F. 3d 220, 224 (2d Cir. 1998) (quotation marks and citation omitted). Prior to the enactment of DSHEA, the FDA had promulgated a

complex set of regulations requiring that certain claims made on the labels of dietary supplement first be subjected to FDA scrutiny. *See id.* at 223-224 (citing 21 C.F.R. §§ 101.13-101.14, 101.70).

DSHEA expanded the types of claims dietary supplement manufacturers are permitted to place on their products without first obtaining approval from the FDA. The type of claims allowed by DSHEA include: (1) statements asserting "a benefit related to a classical nutrient deficiency disease and disclos[ing] the prevalence of such disease in the United States"; (2) statements commonly known as "structure-function claims" that "describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans [and] characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function"; and (3) declarations of "general well-being from consumption of a nutrient or dietary ingredient." 21 U.S.C. § 343(r)(6)(A). These types of claims are permissible under DSHEA only if the manufacturer of the dietary supplement has "substantiation" that the "statement is truthful and not misleading" and if the label contains the following disclaimer in boldface type: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. §

343(r)(6)(B)-(C).

Although DSHEA permits these three types of claims without preapproval from the FDA, manufacturers are specifically prohibited from making any claim that the dietary supplement diagnoses, mitigates, treats, cures or prevents a specific disease or class of diseases. 21 U.S.C. § 343(r)(6). "If the manufacturer of a dietary supplement proposes to make [such] a statement. . .in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made." *Id.*

DSHEA also permits natural products companies to publicize the health benefits of dietary supplements without prior FDA approval. Under DSHEA's exemption for "third-party literature," manufacturers may, "in connection with the sale of a dietary supplement," provide consumers with publications such as articles, books or abstracts from scientific publications. 21 U.S.C. § 343-2. This type of material is not defined as labeling under the statute when it is used in connection with the sale of a dietary supplement to consumers and it:

(1) is not false or misleading;

(2) does not promote a particular manufacturer or brand of a dietary supplement;

(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the

> available scientific information on a dietary supplement;
>
> (4) if displayed in an establishment, is physically separate from the dietary supplements; and
>
> (5) does not have appended to it any information by sticker or any other method.

21 U.S.C. § 343-2(a). Assuming these five provisions are met, third-party literature provided to consumers regarding the health benefits of dietary supplements is permissible.

Notwithstanding DSHEA's attempt to clarify the types of claims dietary supplement manufacturers may make without FDA approval, some confusion arises when the language of § 343(r)(6) is compared to that of § 321(g)(1). Section 321(g)(1)(C) defines drugs as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." However, pursuant to § 343(r)(6)(A) of DSHEA, manufacturers of dietary supplements may make structure-function claims describing how a particular nutrient or dietary supplement is "intended to affect the structure or function in humans." From this language alone it is unclear how a dietary supplement may make a permissible structure-function claim pursuant to DSHEA without falling under FDCA's definition of a drug.

Section 321(g)(1) further explains these seemingly contradictory provisions.

> A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is

> made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

21 U.S.C. § 321(g)(1) (emphasis added).

Therefore, it does not follow that a product with a label that makes a permissible structure-function claim pursuant to § 343(r)(6)(A) is necessarily a drug under the definition in § 321(g)(1)(C). As long as the claim is "truthful and not misleading" under § 321(g)(1), and under a similar provision in § 343(r)(6)(B), manufactures of dietary supplements may make claims about how the supplement affects the structure or function of the body.

However, given that § 343(r)(6) does specifically preclude manufacturers from claiming that a product diagnoses, mitigates, treats, cures, or prevents a specific disease or class of diseases, any claim of this sort necessarily places that product under the scope of the FDCA's definition of a drug. *See* 21 U.S.C. § 321(g)(1) (presenting an alternative definition of drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease"); *see also United States v. Writers & Researchers, Inc.*, 113 F.3d 8, 11 (2d Cir. 1997) (finding a homeopathic substance is subject to FDCA requirements for drugs if it is promoted as a cure or treatment for an

existing disease, such as cancer, AIDS or other diseases); *United States v. Undetermined Quantities of Articles of Drug (Street Drug Alternatives)*, 145 F. Supp. 2d 692, 698 (D. Md. 2001).

In sum, if this Court finds Defendants, in the process of marketing BeneFin, MGN-3 and SkinAnswer, limited their claims to permissible structure-function claims, and those claims are truthful and not misleading, this Court may consider Defendants' argument that the Products are supplements pursuant to § 343(r)(6)(A) of DHSEA. If, however, this Court finds Defendants made claims that the Products diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases, the Products must be considered drugs under the FDCA. This distinction is important because drugs are subject to much stricter FDA compliance standards than are dietary supplements. *E.g.* 21 U.S.C. § 355 (FDCA mandates that any new drug be approved by the FDA before it is marketed); 21 U.S.C. § 352(f)(1) (FDCA requires the labels of all drugs to bear "adequate directions for use").

III. DID DEFENDANTS VIOLATE THE FDCA?

The Government moves for summary judgment based on a three step argument. First, the Government contends that the Products should be considered drugs under the FDCA, because they were marketed to cure, mitigate, treat, diagnose or cure specific diseases, namely HIV/AIDS, cancer and skin cancer. Second, under the Government's theory, since the Products are not dietary

supplements under DSHEA, but are drugs under the FDCA, the Products should be classified as unapproved new drugs pursuant to 21 U.S.C. §§ 321(p) & 355(a) and misbranded drugs within the meaning of 21 U.S.C. § 352(f)(1). Finally, the Government concludes that Defendants have therefore committed three prohibited acts under 21 U.S.C. §§ 331(a), (d) & (k) of the FDCA, which prohibit the introduction of a misbranded or unapproved new drug into interstate commerce.

A. Are BeneFin, MGN-3 and SkinAnswer Drugs within the meaning of 21 U.S.C. § 321(g)(1)?

Before considering whether Defendants have violated the FDCA, this Court must first determine whether the FDCA applies to the Products as drugs, or whether DSHEA's amendments apply to the Products as dietary supplements. If this Court find Defendants limited their claims to permissible structure-function claims, the Products may be considered dietary supplements pursuant to DSHEA. If, however, this Court finds Defendants claimed the Products treat or cure any disease, the Products must be considered drugs under the FDCA.

1. Standard for determining whether a product is a drug under § 321(g)(1)(B) is objective

The Government's summary judgment motion turns on whether Defendants intended to market the Products for use in the treatment or cure of disease. *See* 21 U.S.C. § 321(g)(1)(B) (defining drugs as "articles intended for use in the diagnosis,

cure, mitigation, treatment, or prevention of disease") (emphasis added). "[C]ourts have found that because the FDCA definitions of dietary supplements and drugs are not mutually exclusive, FDA regulations may properly focus on intent." *Whitaker v. Thompson*, 239 F. Supp. 2d 23, 51-52 (D.D.C. 2003), *aff'd* 353 F.3d 947 (D.C. Cir. 2004)(citation omitted).

Defendants argue that Lane Labs' intent is a material question of fact that cannot be resolved without the benefit of an evidentiary hearing. However, the cases cited by Defendants for this proposition are inapposite in that they do not involve the FDCA and instead address the general contention that subjective intent is a question of fact for the jury.

As the Government correctly argues, the issue before this Court is not, as Defendants contend, Lane Labs' subjective intent in marketing the Products. Rather, the "intended use" referred to within the FDCA framework contemplates "the objective intent of those persons legally responsible for the labeling of drugs." 21 C.F.R. § 201.128 (emphasis added)("The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article.").

Various other courts, when considering similar FDCA enforcement actions, have upheld this objective standard. *E.g., United States v. Kasz Enterprises, Inc.*, 855 F. Supp. 534, 542 (D.R.I. 1994), *amended on other grounds*, 862 F. Supp. 717 (D.R.I.

1994) (holding "[i]t is the objective intent of the vendor, not the vendor's subjective explanations and disclaimers, which determines the intended use of a product, as gleaned not only from the vendor's statements, but from any relevant source, such as promotional material, advertising, labeling and other circumstances surrounding the distribution of the article.") (emphasis in original); *United States v. Storage Spaces Designated Nos. "8" & "49"*, 777 F.2d 1363, 1366 (9th Cir. 1985) ("[I]ntent may be derived or inferred from labeling, promotional material, advertising, or any other relevant source.") (citation omitted).

Defendants do not claim that the bulk of voluminous evidentiary materials submitted by the Government in support of its motion are inaccurate. Defendants do contest the Government's characterization of that evidence and argue that the Court should view the evidence through a particular statutory lense. Importantly, Defendants do not dispute that the labels, websites, articles and other marketing material were in fact distributed by Lane Labs.

Given that the standard for deciding whether a product is a drug under 21 U.S.C. § 321(g)(1)(B) is objective, determining Defendants' intent, as gleaned from the bulk of evidence submitted pursuant to this motion, does not itself present an issue of material fact. By relying on all the factual material

that is now before the Court, the Court may make a legal determination, pursuant to Section 321(g)(1)(B), whether Defendants intended to market the Products for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

a. BeneFin & MGN-3

Lane Labs contends it has made appropriate structure-function claims for MGN-3 and BeneFin pursuant to DSHEA, 21 U.S.C. § 343(r)(6)(A). Defendants highlight the fact that the words cancer, HIV and AIDS do not appear on either the label or packaging for MGN-3 or BeneFin. Defendants further argue that the alleged disease claims to which the Government objects were included entirely in third-party literature, which Lane Labs contends it was allowed to distribute under DSHEA, 21 U.S.C. § 343-2(a).

In the factual background section of this Opinion, this Court has outlined in some detail the marketing actions of Lane Labs over a five year period. Without rehashing the entire history of Lane Labs' marketing and distribution practices, it is clear that the claims made by Defendants with regards to the Products have gone well beyond the structure-function claims permitted by § 343(r)(6)(A).

A structure-function claim may "describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." 21 U.S.C. 343(r)(6)(A). However, Lane

Labs did not limit the contents of its promotional material to statements of that nature. In fact, many of the materials at issue in this action blatantly claimed that the given product was an effective treatment for cancer or HIV/AIDS, both of which the parties stipulate are diseases not capable of self-diagnosis or self-treatment. For example, much of the material written by Dr. Lane, including his books and the "Having My Say" article, have espoused the theory that shark cartilage is an effective treatment for cancer. Defendants have used Dr. Lane's name and picture in its packaging and have distributed his written work with the Products. In addition, Defendants have provided links to Dr. Lane's articles and interviews through its publishedresearch.com website.

Lane Labs has similarly distributed mailings to customers and potential customers that include articles by Dr. Ghoneum, such as "One Sizeable Step for Immunology, One Giant Leap for Cancer Patients," in which Dr. Ghoneum advocates that MGN-3 is a promising treatment for cancer and HIV/AIDS. Furthermore, Defendants have used Dr. Ghoneum's endorsement on advertisements for its Products, specifically MGN-3. Defendants' publishedresearch.com website also provides links to abstracts written by Dr. Ghoneum.

In addition to the materials authored by Drs. Lane and Ghoneum, Defendants have distributed third-party promotional

literature — such as the "A New Chapter in Healing" article by Dr. Williams and the *Health & Healing* newsletter edited by Dr. Whitaker – that specifically make claims about the ability of the Products to treat, cure, and mitigate diseases.

Defendants argue that these promotional materials meet the requirements of 21 U.S.C. § 343-2(a), which permits a dietary supplement distributor to use third-party literature to promote its products. This Court finds Defendants' assertions unconvincing. Section 343-2(a) of DSHEA permits the use of third-party literature only if certain provisions are met, and Lane Labs' marketing techniques met virtually none of § 343-2(a)'s mandates. For example, § 343-2(a) requires that the claims made in the promotional literature cannot be "false or misleading." The Government argues, and this Court agrees, that by claiming that the Products cure and treat cancer and HIV/AIDS, the materials in question contained misleading statements. No approved or peer-reviewed studies have been conducted providing results that confirm this contention. In fact, even Defendants admit that the Products have not been proven to effectively treat or cure cancer or HIV/AIDS.

Section 343-2(a) also mandates that permissible third-party literature may not promote a particular manufacturer or brand of a dietary supplement. This statutory provision has been repeatedly violated by Defendants. As detailed above, much of

the promotional literature distributed by Defendants push Lane Labs' products by name, even providing pricing, ordering information, and links to Lane Labs' websites.

Based on many of its past actions, Lane Labs, through its promotional material and even its own employees, promoted BeneFin and MGN-3 for the diagnosis, cure, mitigation, treatment, or prevention of diseases, namely cancer and HIV/AIDS.[9] These actions fall squarely under § 321(g)(1)(B). Accordingly, BeneFin and MGN-3 should be considered drugs under the FDCA framework. Since the Products are drugs, not dietary supplements, §§ 343-2(a) & 343(r)(6)(A) of DSHEA do not apply.

b. SkinAnswer

The Government correctly asserts that Defendants' DSHEA arguments have no applicability to this Courts' determination of whether SkinAnswer has been marketed as a drug. One requirement for a product to be considered a dietary supplement is that it must be "ingested." 21 U.S.C. § 321(ff)(2)(A)(I). Accordingly, the provisions of DSHEA do not apply to SkinAnswer, because it is not a dietary supplement, but rather it is cream that users apply topically.

[9] Lane Labs highlights the fact that many of its past marketing practices, which make up the bulk of the Government's Complaint, were discontinued over two years ago. This argument goes to the scope of relief requested by the Government, as well as the likelihood of future violations by Defendants. Those arguments will be fully discussed in the section below addressing the injunction requested by the Government.

The Government has provided ample evidence of the various ways Defendants have marketed SkinAnswer as a treatment or cure for skin cancer. For instance, the Health Professional Information Kit distributed by Defendants as late as August 2001, nearly two years after the commencement of this action, included Dr. Whitaker's *Health & Healing* newsletter. Dr. Whitaker not only made recommendations about using glycoalkaloids to treat skin cancer, but SkinAnswer was the glycoalkaloid product he specifically recommended. This is just one of many examples of Defendants' use and distribution of third-party literature to market SkinAnswer. Given that SkinAnswer does not fall under the purview of DSHEA, Defendants cannot even argue that the dissemination of these promotional materials was permissible under federal law.

Accordingly, the Government has succeeding in proving, as a matter of law, that Defendants' marketed SkinAnswer as a drug pursuant to the FDCA definition.

B. Are the Products unapproved new drugs within the meaning of 21 U.S.C. §§ 321(p) and 355(a) and/or misbranded drugs within the meaning of 21 U.S.C. § 352(f)(1)?

The Government claims BeneFin, SkinAnswer and MGN-3 are new drugs within the meaning of 21 U.S.C. §§ 321(p)[10] and 355(a)[11] and

[10] Section 321(p) defines a "new drug" as:

(1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts

are misbranded drugs within the meaning of 21 U.S.C. § 352(f)(1).[12]

Defendants concede that if BeneFin, MGN-3 and SkinAnswer are drugs within the meaning of 21 U.S.C. § 321(g)(1)(B), they are also unapproved new drugs and misbranded drugs. (Defs. Mem. in Opp. at 12) ("Lane Labs does not dispute that BeneFin, MGN-3 and SkinAnswer do not meet the regulatory criteria applicable to drugs. Nor does Lane Labs contend that any of these products are generally recognized as safe and effective as a cure or treatment for cancer, HIV/AIDS, or any other disease."). This Court has found that the Products are drugs under § 321(g)(1)(B). Since Defendants have not obtained FDA approval for the Products, nor have the Products been proven safe and effective, nor do the

---

> qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . .; or
>
> (2) Any drug . . . as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

[11] Section 355(a), which mandates approval by the FDA before a new drug can be sold, states: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with the FDA] is effective with respect to such drug."

[12] Section 352(f)(1) states that a drug is misbranded "[u]nless its labeling bears . . . adequate directions for use."

Products contain adequate labeling, the Products are unapproved new drugs and misbranded drugs under 21 U.S.C. §§ 321(p), 355(a) & 352(f)(1).

Furthermore, the parties agree that assuming the Products are unapproved new drugs and/or misbranded drugs, Lane Labs' marketing and distribution of the Products violates 21 U.S.C. §§ 331(a), (d) & (k).[13]

Given this analysis, the Court finds that Defendants have violated 21 U.S.C. § 331(a) (prohibiting the introduction of a misbranded drug into interstate commerce), § 331(k) (prohibiting the alteration or destruction of a drug label after shipment in interstate commerce resulting in the article becoming

---

[13] Section 331 prohibits:

> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> * * *
>
> (d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344 or 355 of this title.
>
> * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

misbranded), and § 331(d) (prohibiting the introduction into interstate commerce an article in violation of Section 355).

As discussed above, there is disagreement between the parties as to certain claims submitted by the Government in its Reply to the Motion for Summary Judgment. For instance, the parties disagree whether, at the September 2002 Cancer Control Convention, a Lane Labs representative made statements regarding the ability of MGN-3 to treat cancer. (*See* Bonneau Decl., Defs. Ex. 33 ¶ 7.) However, the fact that the parties dispute whether these statements were made at the 2002 convention does not preclude this Court from granting the Government's motion for summary judgment. There are enough undisputed issues of fact showing Defendants' continuous pattern of behavior such that the Court may make a judgment as a matter of law as to Defendants' violations of the FDCA. The issues of fact upon which the parties do not agree may be deemed immaterial by the Court and not considered. Therefore, summary judgment is proper at this stage.

Accordingly, the Court finds that no material issues of fact remain as to the past and current violations of the FDCA by Defendants. Accordingly, the Government's motion for summary judgment is **granted.**

IV. EQUITABLE RELIEF

The Government seeks a permanent injunction, pursuant to 21 U.S.C. § 332(a), to restrain Defendants from marketing the three Products at issue as well as any other products with the same or similar ingredients. The Government also seeks an order requiring Defendants to make restitution to consumers who purchased the Products and disgorge all profits gleaned from sale of the Products. The Government contends that the broad scope of the requested injunction is warranted not only because Defendants have been violating the FDCA for many years but also given that Defendants have deliberately organized their business in a manner that superficially separates claims they have made for their Products from the sale of their Products, in an effort to evade FDA detection and regulation.

A. The Government must show continuing and current violations of the FDCA by Lane Labs in order to obtain injunctive relief.

Although the Government succeeds in proving that the Products are drugs pursuant to the FDCA, as detailed above, the analysis does not end there. In order to obtain the injunctive relief requested, the Government must establish not only that Lane Labs violated the FDCA, but also that there is a reasonable likelihood that the purported violations will recur. *United States v. W.T. Grant, Co.*, 345 U.S. 629, 633 (1953); *United States v. Barr Labs., Inc.*, 812 F. Supp. 458, 485-486 (D.N.J.

1993). Courts have routinely held that in cases involving enforcement actions of this type, the government need not make a showing of irreparable harm and may instead provide adequate probable cause that a statute, authorizing injunctive relief, is being or has been violated. *Barr Labs*, 812 F. Supp. at 486 ("Preliminary injunctions based on violations of [the FDCA] "do not require a showing of immediate and irreparable injury.") (quoting *United States v. Spectro Foods Corp.*, 544 F.2d 1175, 1181 (3d Cir. 1976)); *W.T. Grant*, 345 U.S. at 633. Accordingly, the burden rests on the Government to demonstrate a reasonable likelihood that Lane Labs will violate the FDCA in the future.

A court should review the totality of the circumstances surrounding both the statutory violation and the violators in order to determine whether the Government can meet its burden. *United States v. Toys "R" Us, Inc.*, 754 F. Supp. 1050, 1059 (D.N.J. 1991). Even if this Court were to find that future violations by Lane Labs are likely, it does not follow that an injunction should automatically issue. *Barr Labs.*, 812 F. Supp. at 486 ("Because the language of section 332(a) is not mandatory, the Court retains discretion to grant or deny equitable relief.") Furthermore, the Court must determine whether the injunctive relief requested is needed to remedy the threatened violations. *Id.* at 486-487.

Factors courts should consider when determining whether

there is a reasonable chance of future infractions by a defendant include:

> (1) the degree of scienter involved on the part of the defendant; (2) the isolated or recurrent nature of the infraction; (3) the defendant's recognition of the wrongful nature of his conduct; (4) the sincerity of defendant's assurances against future violations; and (5) the nature of defendant's occupation. It is deemed important to consider as well the defendant's voluntary cessation of challenged practice, the genuineness of the defendant's efforts to conform to the law, the defendant's progress toward improvement and the defendant's compliance with any recommendations made by the government.

Barr Labs, 812 F. Supp. at 486 (citing *Toys "R" Us*, 754 F. Supp. at 1058-59).

Lane Labs contends that even if its past behavior violated the FDCA, Defendants allegedly ceased much of the behavior complained of by the Government years ago. Therefore, Defendants assert that an injunction at the present time would be unwarranted.

To support their argument that no continued violations have occurred or are occurring since 2001, Defendants point to the FTC Final Order entered on September 26, 2000 in *FTC v. Lane Labs-USA, Inc., et al.*, Civ. No. 00-3174 (D.N.J.)(WGB). The FTC Final Order prohibits Defendants from engaging in similar behavior to that at issue in this action. Namely, the FTC Final Order mandates that, when marketing any food, drug or dietary supplement, Defendants must not: (1) represent that BeneFin or any other shark cartilage product prevents, treats or cures

cancer, unless Defendants have evidence to substantiate those claims; (2) represent that SkinAnswer, or any other glycoalkaloid product, prevents, treats, or cures skin cancer, unless they have evidence to substantiate such claims; (3) make any unsubstantiated health-related claims about any food, drug or dietary supplement; (4) make false claims about the existence, contents or results of any tests, studies or research. (FTC Final Order.) In addition, the FTC Final Order permits the FTC to monitor Defendants' compliance with the FTC Final Order and permits the FTC to periodically require Defendants to provide the FTC with written compliance reports setting forth the manner and form in which Defendants have complied with the FTC Final Order.

Defendants make much of the fact that the FTC has made no finding that Lane Labs has violated the FTC Final Order. In fact, on February 9, 2001, Lane Labs submitted a compliance report to the FTC without objection. Defendants argue that they since they are in compliance with the FTC Final Order, they cannot be violating the FDCA in the ways in which the Government alleges here.

In response, the Government supplies a Declaration from Richard Cleland, Esq., Assistant Director in the Division of Advertising Practices at the FTC. Cleland's Declaration states that, contrary to Defendants' contentions, it is not necessarily the position of the FTC that Defendants are in full compliance

with the FTC Final Order. (Cleland Decl. of 12/22/03 ¶¶ 8-10.) In fact, claims made in Lane Labs' current promotional material "are similar to the types of efficacy claims for the prevention, treatment, and cure of cancer that were challenged in the FTC's Complaint against Lane Labs." (*Id.* ¶ 9.) Cleland states that as recently as November 21, 2003, the FTC sent a letter to Lane Labs requesting that Lane Labs produce a compliance report pursuant to the FTC Final Order.

Most notably, Cleland states that Defendants misconstrue the FTC's lack of enforcement action.

> In general, the absence of an enforcement action by the FTC is not necessarily an indication of the legality of any action or compliance with the terms of a Final Order by a former defendant to an FTC law enforcement action. For example, another government agency pursuing a law enforcement action that would provide comparable relief to what the FTC could obtain through its own independent law enforcement action may cause FTC staff to direct its resources to other matters.

(*Id.* ¶ 10.) Cleland goes on to state that the relief sought in the case at bar is similar to whatever compliance concerns the FTC might have. (*Id.* ¶ 11.)

Accordingly, given the contents of the Cleland Declaration, the Court rejects Defendants' arguments that the Government must be mistaken about any current violations of the FDCA due to the fact that the FTC has chosen not to enforce the FTC Final Order.

Defendants further contend that they have rectified any past missteps. For instance, Defendants have not used Dr. Lane's name

or picture on its packaging for over two years. Lane Labs had not distributed Dr. Williams' article "A New Chapter in Healing," in the *Alternatives* newsletter for over two years. Lane Labs no longer refers callers seeking information regarding shark cartilage or other products to Cartilage Consultants. Furthermore, Lane Labs no longer implements many of the metatags previously embedded in its websites. Defendants claim that they have cooperated with the FDA in every regard by complying with FDA inspections, permitting access to Lane Labs' facilities and supplying records and materials requested by the Government. Defendants argue that the broad reach of the requested injunction is meant to impermissibly punish Lane Labs for past violations that it has worked to rectify.[14]

However, Defendants' past pattern of activity bears upon whether Lane Labs is likely to violate the FDCA in the future. Courts have recognized the carry-over effects of marketing and

[14] Defendants further assert they have repeatedly offered to settle the instant litigation and provide the Court with specific information about Defendants' proffers during settlement. The Government asserts that information regarding settlement is inadmissable pursuant to Fed. R. Evid. 408. Defendants counter that the evidence of settlement offered does not go to the question of liability or amount of the claim and is therefore permissible under Rule 408. Without ruling on whether the settlement information bears on Defendants' liability, this Court finds the facts relating to settlement are irrelevant, at this stage in the litigation, to the question of whether there is a reasonable likelihood that Defendants' illegal behavior will continue. Therefore, the Court declines to consider the substance or content of settlement negotiations between the parties.

promotional claims in actions arising under the FDCA. *E.g., Kasz Enterprises*, 862 F. Supp. at 722 (holding "the consequences of the past promotional activities of the defendants will linger for an unknown period of time into the future . . . [and] defendants, if not appropriately enjoined, will profit from their past illegal activity"). Court have also looked to a defendant's repeated violations when issuing injunctions in other types of cases. *E.g. SEC v. Bonastia*, 614 F.2d 908, 913 (3d Cir. 1980) (holding, in a securities case, "the repetitiveness of the violations weighs heavily in favor of the imposition of an injunction."); *United States v. Oregon State Med. Soc.*, 343 U.S. 326, 333 (1952) ("When defendants are shown to have settled into a continuing practice or entered into a conspiracy violative of anti-trust laws, courts will not assume that it has been abandoned without clear proof.") (citation omitted); *SEC. v. Koracorp Indus., Inc*. 575 F.2d 692, 698 (9th Cir. 1978) (holding, in a securities case, "[a]n inference arises from illegal past conduct that future violations may occur....The fact that illegal conduct has ceased does not foreclose injunctive relief.") (citations omitted).

Additionally, although Lane Labs has admittedly ceased many of its illegal activities, Defendants continue to improperly label and promote the Products. For example, Lane Labs paid to place Dr. Ghoneum's article "One Sizeable Step for Immunology" in

alternative health magazines as recently as 2002. Also included in these magazines were business reply cards providing information about ordering MGN-3. Further, in August 2001, Defendants disseminated the Health Professional Information Kit to medical doctors, along with promotional information about the Products, including the "One Sizeable Step for Immunology" article and Dr. Whitaker's newsletter, *Health & Healing*.

This pattern of marketing behavior has continued to the present. As of November 2003, lanelabs.com provided links directly to publishedresearch.com, which contained various articles by Drs. Lane and Ghoneum promoting shark cartilage and MGN-3 as effective treatments for cancer and HIV. In addition, material obtained from Defendants' websites in November 2003 has Dr. Ghoneum making the following statements: "The advantages to MGN-3 are many....It has no immutable side effects...so we know it is a very safe product. This cannot be said about most medications designed to boost the immune system. Interferon or Interleukin 2, for example, have severe side effects...." (Taylor Decl. of 12/1/03, Ex. A at 29-30 and Ex. C at 14-15.) Accordingly to the Government, Interleukin 2 is used for the treatment of metastatic renal cell carcinoma and metastatic melanoma, both forms of cancer. Pursuant to 21 C.F.R. § 101.93(g)(2), a "statement claims to diagnose, mitigate, treat, cure or prevent disease if it claims explicitly or implicitly,

that the product...belongs to a class of products that is intended to diagnose, mitigate, treat, cure or prevent disease." § 101.93(g)(2)(v). Accordingly, Dr. Ghoneum's statements, and the many similar claims throughout Defendants' websites and catalogs, make impermissible disease claims.

As recently as January 2004, a FDA attorney located an interview with Dr. Ghoneum on lanelabs.com in which he explains the benefits of MGN-3 to patients who have been exposed to adjuvant treatments, or cancer treatments. (Taylor Am. Second Decl. of 1/8/04, Ex. A.) Lane Labs claimed that they had removed this interview from their websites.

The Court finds that the supplemental information supplied by the Government is sufficient to show that Defendants continue to market the Products for the treatment, cure or mitigation of disease in violation of the FDCA. In analyzing the *Barr Labs.* factors for determining whether an injunction should issue, Defendants have failed virtually every aspect of the test. *Barr Labs*, 812 F. Supp. at 486 (citing *Toys "R" Us*, 754 F. Supp. at 1058-59). The infractions have been recurrent, Defendants appear not to recognize the wrongful nature of their conduct, and this Court has absolutely no faith in the sincerity of Defendants' assurances against future violations. *Id.* In addition, Defendants have not voluntary ceased the challenged practices, have made little effort to conform to the law, and have failed to

comply with the recommendations made by the Government. *Id.*

Defendants continue to make indefensible excuses for their behavior, claiming that the third-party literature cited by the Government conforms to the requirements of DHSEA. Defendants' assertions that any improper claims made by Drs. Lane and Ghoneum cannot be attributed to Defendants' marketing techniques are belied by Defendants' own websites. Lane Labs purposefully links website containing information about its products to articles and abstracts by Drs. Lane and Ghoneum. Likewise, the articles by Drs. Lane and Ghoneum specifically promote Lane Labs' products. Accordingly, the Court finds that Defendants continue to promote the Products as drugs under the FDCA framework, and Defendants's actions do not fall under the dietary supplement carve out provisions in DSHEA.

For the foregoing reasons, the Court concludes that the likelihood of Lane Labs continuing to violate of the FDCA is great. Therefore, the Government's motion for summary judgment is **granted** and Defendants shall be permanently enjoined from distributing and marketing the Products.

Likewise, while marketing or promoting any product containing, or purporting to contain, shark cartilage, a glycoalkaloid, arabinoxylane, or rice bran hemicellulose with Shiitake mushroom enzymes, Defendants shall be enjoined from claiming that those products are the same as, similar to, more

effective than, or intended for the same uses as BeneFin, SkinAnswer, or MGN-3. In addition, Defendants may not claim any product containing those components is safe or effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, unless and until an approved new drug application authorizing such representations for such products is in effect.

Courts often enjoin the distribution of products containing, or purported to contain, unapproved new drugs or misbranded drugs. *E.g. United States v. Syntrax Innovations, Inc.*, 149 F. Supp. 2d 880, 883-888 (E.D. Mo. 2001) (enjoining distribution of any product containing or purporting to contain tiratricol, any product bearing the word "Triax" on its labeling, and any unapproved new drug or misbranded drug); *Street Drug*, 145 F. Supp. 2d at 707 (enjoining distribution of named drugs, "or the same article designated by any other names, or any other similar article of drug").

The Court is not convinced that merely enjoining Defendants from distributing the Products will protect consumers from Defendants' impermissible drug claims. Therefore, the Court shall enjoin Defendants from making any comparison to the Products at issue here. Given Defendants' past pattern of behavior, in which Lane Labs has purposefully flouted the FDCA framework throughout the pendency of this lawsuit, this Court finds that an injunction of this scope is warranted.

B. May the Government obtain equitable relief in the form of restitution or disgorgement under the FDCA?

In addition to its request for a permanent injunction, the Government asks this Court to order Defendants to make restitution to persons who purchased the Products, directly or indirectly, from Defendants after, at the latest, September 22, 1999.[15] The Government also requests that this Court order Defendants to disgorge any profits that may remain from the sale of the Products, in the event that such profits are not exhausted by restitution payments.

Restitution and disgorgement are both equitable remedies. *See Mertens v. Hewitt Assocs.*, 508 U.S. 248, 255 (1993) (finding that injunctions and restitution are equitable remedies); *SEC v. Hughes Capital Corp.*, 917 F. Supp. 1080, 1085 (D.N.J. 1996) ("Disgorgement of illegally derived funds is a remedy within the equitable powers conferred on [the] Court..."), *aff'd*, 124 F.3d 449 (3d Cir. 1997). Restitution is a remedy that restores the *status quo* by returning to the purchaser the price of unlawfully sold goods. *See Porter v. Warner Holding Co.*, 328 U.S. 395, 402 (1946). The primary purpose of restitution is to restore

[15] On September 22, 1999, the Government notified Defendants that the Products were unapproved and misbranded drugs and stated its intention to file the current lawsuit. Although the Government had sent Lane Labs warning letters before that date, the September 22nd letter was the final warning provided to Lane Labs by the Government before the Complaint in this action was filed.

aggrieved parties to the position that existed before the illegal or wrongful transaction occurred by compensating them for loss caused by the conduct. *See Hughes*, 917 F. Supp. at 1089 (quoting *SEC v. Huffman*, 996 F.2d 800, 802 (5th Cir. 1993)).

Disgorgement is a remedy that requires a defendant to surrender all of its profits from an unlawful transaction to the government. *CFTC v. American Metals Exchange*, 991 F.2d 71, 78-79 (3d Cir. 1993). Disgorgement differs from restitution in that it seeks to force the wrongdoer to give up the amount by which he has been unjustly enriched through illegal profits and does not turn on compensating the victims. *Hughes*, 917 F. Supp. at 1085 ("Disgorgement wrests ill-gotten gains from the hands of the wrongdoer.") (quoting *Huffman*, 996 F.2d at 802).

Disgorgement and restitution are not punitive remedies. *CFTC*, 991 F.2d at 78-79 (holding that "courts have considered disgorgement to serve primarily to prevent unjust enrichment" and therefore "disgorgement may not be used punitively")(internal quotation marks and citations omitted); *United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 763 (6th Cir. 1999) ("[A]n order of restitution is not punitive where the offender has violated the law at the expense of the very consumers a restitution order seeks to make whole.").

The issue of whether the FDA may obtain restitution or disgorgement pursuant to the FDCA is a main point of contention

between the parties as well as a source of uncertainty in the law. Few courts have addressed this issue. In the face of a dearth of case law on this point, various law review articles have been written — with diametrically opposite conclusions — addressing whether or not the Government make seek this type of equitable remedy under the FDCA.[16]

Defendants argue that courts lack the authority to order restitution and disgorgement because the FDCA does not expressly provide such equitable relief. Section 302(a) of the FDCA states that federal courts "shall have jurisdiction, for cause shown to restrain violations of section 331 of this title [§ 301 of the FDCA]...." 21 U.S.C. § 332(a). Therefore, the only equitable remedy provided by the plain language of the FDCA is injunctive relief. The FDCA is silent with respect to a court's power to order equitable relief other than an injunction, including restitution or disgorgement. For this reason, Defendants argue that this Court may not grant the Government's requests for

---

[16] *Compare* Eric M. Blumberg, *Universal Management, Abbot, Wyeth, Schering-Plough, and ...: Restitution and Disgorgement Find Another Home at the Food and Drug Administration*, 58 Food & Drug L.J. 169 (2003) (concluding that the FDA may seek restitution or disgorgement under the FDCA); *with* Jeffrey N. Gibbs & John R. Felder, *Can FDA Seek Restitution or Disgorgement?*, 58 Food & Drug L.J. 129 (2003)and Erika King & Elizabeth Walsh, *The Authority of a Court to Order Disgorgement for Violations of the Good Manufacturing Practices Requirement of the Federal Food, Drug and Cosmetic Act*, 58 Food & Drug L.J. 149 (2003) (concluding that restitution and disgorgement are not remedies available under the FDCA's statutory framework).

restitution or disgorgement. Furthermore, Defendants contend that even if the Court did have the power to order monetary equitable relief, to do so would be inappropriate in this case.

Conversely, the Government, citing *United States v. Universal Management Services, Inc.*, 191 F.3d 750 (6th Cir. 1999), claims that restitution and disgorgement are not only permissible remedies under the statutory framework, they are necessary remedies in order to comply with Congress' intent in enacting the FDCA. *Universal Management* is the only current circuit opinion to address the FDA's power to grant monetary equitable relief under the FDCA. In *Universal Management*, the Sixth Circuit upheld a court's jurisdiction to order equitable relief, including restitution, when the FDA seeks an injunction pursuant to Section 332 of the FDCA. *Id.* at 760-761. As with this case, in *Universal Management*, the FDA alleged that the defendants had violated 21 U.S.C. §§ 331(a) and (k), which prohibit the interstate shipment and holding for sale of misbranded and adulterated articles. The defendants in that case distributed an unapproved electric gas grill igniter promoted to relieve pain. *Id.* at 754.

The district court granted summary judgment for the FDA, entered a preliminary injunction, and ordered the defendants to pay restitution. *United States v. Universal Mgmt. Servs., Inc.*, 999 F. Supp. 974, 981-986 (N.D. Ohio 1997). The court found that

restitution was appropriate in that case to "ensure that the public interest [was] protected by providing each person who purchased [the] adulterated product the opportunity to receive his money back." *Id.* at 980. The district court found that disgorgement was not an appropriate remedy, given the lack of previous use of that equitable remedy in prior FDA cases. *Id.*

The defendants in *Universal Management* appealed the district court's decision, which was then affirmed by the Sixth Circuit. The Sixth Circuit found that the appellants failed to "establish[] that the FDCA by 'a necessary and inescapable inference, restricts the court's jurisdiction in equity.'" 191 F.3d at 762 (quoting *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291 (1960)). The Court went on to hold:

> Nothing in the FDCA explicitly precludes a district court from ordering restitution. To find that restitution is unauthorized, this court requires Congress to make plain its desire to limit the courts inherent powers because the great principles of equity, securing complete justice, should not be yielded to light inferences or doubtful construction. Appellants have not demonstrated that the FDCA or its legislative history compels a departure from the courts inherent power to achieve equity. Therefore, we hold that nothing in the FDCA precludes a court sitting in equity from ordering restitution in appropriate cases.

Id. (internal quotation marks and citations omitted).

Given the Sixth Circuit's determination in *Universal Management*, Defendants' argument, that the Government may not seek restitution or disgorgement because the language of the FDCA does not expressly provide for that type of equitable relief, is

without merit. Defendants misapprehend the fundamental principle of inherent equitable relief. A court sitting in equity has all equitable remedies available to it, unless the statutory framework specifically deprives the court of those remedies. *Id.* at 761. The Sixth Circuit in *Universal Management* explained this principle as applied to the mandate of the FDCA: "Absent a clear command by Congress that a statute providing for equitable relief excludes certain forms of such relief, this court will presume the full scope of equitable powers may be exercised by the courts." *Id.*

This Court finds the Sixth Circuit's opinion in *Universal Management* to be well-reasoned and sound. Therefore, this Court finds that monetary equitable remedies beyond injunctive relief are available pursuant to the FDCA.[17]

Defendants proffer various other arguments in an attempt to

[17] Also instructive to this Court's determination are three consent decrees obtained by the FDA since the *Universal Management* decision. *See* Blumberg, *Universal Management, Abbot, Wyeth, Schering-Plough, and ...: Restitution and Disgorgement Find Another Home at the Food and Drug Administration*, 58 Food & Drug L.J. 169, 170-171 (2003)(citing *United States v. Abbott Labs.*, Civ. No. 99-7135 (N.D. Ill., filed Nov. 2, 1999); *United States v. Various Articles of Drug..., Wyeth-Ayerst Labs.*, Civ. No. 00-359 (E.D. Tenn., filed Oct. 4, 2000); and *United States v. Schering-Plough Corp.*, Civ. No. 02-2397 (D.N.J., filed May 20, 2002)). All three consent decrees required the defendant companies to pay disgorgement of profits derived from adulterated products sold to consumers. Although these consent decrees were by their very nature consensual, and carry no precedential weight, it is worth noting that the FDA has been successful in obtaining monetary equitable remedies pursuant to the FDCA through these consent decrees.

show why this Court should decline to grant monetary equitable relief here. All of Defendants' arguments fail.

First, Defendants attempt to distinguish *Universal Management* from this case. In its complaint in *Universal Management*, the FDA specifically requested both injunctive relief and "such other relief as the court deems just and proper, including but not limited to equitable disgorgement of profits." 999 F. Supp. at 980. Here, the Government, in addition to injunctive relief, also prays "that this Court grant such other and further relief as it deems just and proper." (Compl. at II.) Although the Government did not make a specific request for restitution or disgorgement in its Complaint, this broad language is sufficient to encompass the equitable relief the Government now requests.

Second, Defendants attempt to distinguish *Universal Management* because the unapproved device in that case, a gas grill lighter, was alleged to be "adulterated." In this case, the Government contends that the Products are simply "misbranded." Defendants' argument is meritless because a device that requires premarket approval, but is marketed without FDA approval, is deemed "adulterated" under the FDCA. 21 U.S.C. § 351(f)(1)(B); *Universal Mgmt.*, 191 F.3d at 754. Therefore, both here and in *Universal Management*, the government sought equitable monetary relief for the same conduct: the distribution of an

unapproved product that was marketed for the treatment of disease.

Third, Defendants spend a bulk of their opposition to the Government's request for restitution and disgorgement arguing that the relevant harm in this case is not economic in nature and attempt to distinguish this case from FTC actions in which the harm is allegedly economic. Defendants further argue that since the purpose of the FDCA is not, according to Defendant, to address economic harm, the Court should decline to grant restitution or disgorgement.

The Court is unconvinced by Defendants' arguments. The Government's action serves the dual purpose of protecting the safety of consumers by enjoining the sale of unproven products marketed for the treatment of serious diseases, as well as protecting consumers from the economic harm caused by their purchase of Defendants' illegal products. Restitution would compensate Defendants' victims for the money they paid for these unproven and unapproved drugs. *Universal Mgmt.*, 191 F.3d at 763 ("One of the primary goals of the FDCA is to protect consumers from economic harm.")(citing H.R. Conf. Rep. No. 74-2755, at 1 (1938)(one purpose of the FDCA is to prevent "deceit upon the purchasing public"))(other citations omitted).

Additionally, by ordering monetary equitable relief, the FDCA's purposes would be directly and materially advanced by

deterring future violations by Lane Labs and other suppliers of unapproved treatments for serious diseases by making it unprofitable to violate the FDCA. *Universal Mgmt.*, 191 F.3d at 763 (finding that an order of restitution would have a "deterrent effect", which is "consistent with the FDCA's purpose in protecting the public health").

Finally, Defendants point to the legislative intent behind the FDCA in an attempt to show that *Universal Management* went beyond the scope of what the statutory framework allowed. Defendants contend that if this Court grants disgorgement or restitution as equitable remedies in this case, that decision would be contrary to Congress' purpose behind amending the FDCA by enacting DHSEA. This argument fails because, as discussed above, due to Defendants illegal marketing techniques, the Products do not fall under the purview of DSHEA at all. Instead, the Products must be classified as drugs under the FDCA. Furthermore, the court in *Universal Management* addressed the very issue raised by Defendants and held that nothing in the legislative history of the FDCA "compels a departure from the courts inherent power to achieve equity." *Id.* at 762 (internal quotation marks and citation omitted).

Thus, for the foregoing reasons, the Government's request for monetary equitable relief is granted.

C. This Court shall enter an Order of permanent injunction and restitution against Defendants

1. Scope of the injunction

The Order following this Opinion outlines in detail the scope of the injunction hereby granted by this Court. Both Defendants and amicus curiae, the AAHF, object to the broad nature of the injunction contemplated by the proposed order submitted by the Government.

Defendants and the AAHF claim that the Government's proposed injunction impermissibly restricts speech and therefore violates the First Amendment. Commercial speech, like that at issue in this case, is protected by the First Amendment as long as it concerns a lawful activity and is not misleading. *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 564-565 (1980). The government may impose restrictions on commercial speech as long as those restrictions advance a "substantial" government interest and are no "more extensive than is necessary to serve that interest." *Id.* at 566.

A recent D.C. Circuit opinion is instructive in this regard. In *Whitaker v. Thompson*, the district court upheld the FDA's refusal to allow the defendant to market a product (saw palmetto extract) under a certain label, because the FDA determined that a claim contained on the label was a drug claim for the treatment of disease. 353 F.3d 947, 952-953 (D.C. Cir. 2004). The D.C. Circuit explained:

> Assuming that the government may condition the sale of drugs on passage through the elaborate testing that the statute requires..., the key step is the []FDCA principle that classification of a substance as a "drug" turns on the nature of the claims advanced on its behalf. That principle, in turn, rests on the idea that claims about a product by its manufacturer and vendors, including product labeling, serve as evidence of the sellers' intent that consumers will purchase and use the product for a particular purpose — and, therefore, as evidence whether the product is or is not a drug. The question is whether this use of speech to infer intent, which in turn renders an otherwise permissible act unlawful, is constitutionally valid. In fact, the First Amendment allows the evidentiary use of speech to establish the elements of a crime or to prove motive or intent. Thus it is constitutionally permissible for the FDA to use speech, in the form of labeling, to infer intent for purposes of determining that [defendant]'s proposed sale of saw palmetto extract would constitute the forbidden sale of an unapproved drug.

Id at 953 (internal quotation marks and citations omitted). Therefore, following *Whitaker*, the Government's restriction of certain labeling, as well as the dissemination of third-party literature, does not violate free speech principles.

Further, Defendants claim that the proposed injunction is overbroad in that much of the behavior the injunction would prohibit has already been curbed voluntarily by Defendants. However, if Defendants have already ceased this behavior, it should not matter if the injunction prohibits it. In this way, any alleged overbreadth on the face of the injunction should not be problematic in that it allegedly restricts behavior in which Defendants are not presently engaging.

Both the AAHF and Defendants attack paragraph 4 of the

proposed order as overbroad, because they claim it would restrict Defendants from distributing "lawful" products.[18] The Government does not dispute that, had Defendants complied with the FDCA from

[18] Paragraph 4 of the proposed order prohibits Defendants from:

> A. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, labeling, packing, processing, or distributing BeneFin, SkinAnswer, MGN-3, or any drug that is a "new drug" within the meaning of 21 U.S.C. § 321(p), unless and until:
>
> 1) an approved new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug; or
>
> 2) an investigational new drug application filed pursuant to 21 U.S.C. § 355(I) and 21 C.F.R. Part 312 is in effect for such drug and the drug is distributed and used solely for the purpose of conducting clinical investigations in strict accordance with the protocol as authorized as part of the investigational new drug application.
>
> B. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, labeling, packing, processing, or distributing any drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1).
>
> C. While the Defendants are marketing any product containing, or purporting to contain, shark cartilage, a glycoalkaloid, arabinoxylane, or rice bran hemicellulose with Shiitake mushroom enzymes, promoting, advertising, or representing in any media that shark cartilage, a glycoalkaloid, arabinoxylane, or rice bran hemicellulose with Shiitake mushroom enzymes is 1) the same as, similar to, as or more effective than, or intended for the same uses as BeneFin, SkinAnswer, or MGN-3; or 2) safe and/or effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, unless and until an approved new drug application authorizing such representations for such product(s) is in effect for such product(s).

the outset, Defendants could have marketed shark cartilage and arabinoxylane as dietary supplements and glycoalkaloid skin cream as a cosmetic. However, the Products have been classified as drugs under the FDCA as a result of the marketing practices of Defendants themselves. *See* 21 U.S.C. § 321(g)(1)(B). Defendants cannot be compared to other responsible producers of shark cartilage, arabinoxylane and glycoalkaloids, who have followed the statutory framework of the FDCA and DSHEA and therefore are permitted to market their products as dietary supplements and cosmetics.

Defendants and the AAHF claim that, if Defendants cease making disease claims for the Products, then automatically and immediately, those Products are no longer intended to be used for the treatment of cancer and HIV and therefore may be sold as dietary supplements and as a cosmetic, respectively. That position is untenable for multiple reasons. First, that scenario is no more than a hypothetical, given that Defendants continue to market the Products for the cure, treatment and mitigation of disease. Second, this is not a case where a company made improper claims for a short period of time, and those claims about the treatment of disease were not widely disseminated. Defendants have been making such claims for nearly a decade and have used a variety of marketing techniques, including direct mailing, advertising in alternative health related publications,

and advertising and promoting the Products over the Internet. The Court agrees with the Government's argument that the third-party literature used by Defendants to impermissibly promote the Products by making claims about the treatment of disease, is so intertwined with consumers' perception of the Products as to make any and all future sales of the Products problematic. *E.g. Kasz*, 862 F. Supp. at 722 (holding "the consequences of the past promotional activities of the defendants will linger for an unknown period of time into the future...[and] defendants, if not appropriately enjoined, will profit from their past illegal activity.").

Accordingly, the injunction granted by this Court shall permanently prohibit Defendants from selling and marketing the Products in any and all forms, not just if Defendants make improper claims about the treatment of disease.

2. Restitution

Furthermore, this Court agrees with the Government that, in light of the ongoing nature of Defendants' illegal activities, equitable monetary relief is also warranted. As discussed in detail above, orders of disgorgement and restitution are not punitive. *See Universal Mgmt.*, 191 F.3d at 763. In particular, restitution looks to return profits obtained illegally to consumers in order to make those consumers whole. *Id.* Defendants have, according to the Government, generated tens of

millions of dollars in sales of the Products. Those proceeds should rightfully be returned to consumers.

As in *Universal Management*, this Court is hesitant to order disgorgement of profits. *Universal Mgmt.*, 999 F. Supp. at 980 (ordering restitution to "ensure that the public interest [was] protected by providing each person who purchased [the] adulterated product the opportunity to receive his money back," but declining to order disgorgement, given the lack of use of that equitable remedy in prior FDA cases).

Therefore, the Order entered by this Court outlines in detail the scope of the permanent injunction and requires Defendants to pay restitution. A special master shall be appointed and Defendants must promptly provide to him or her all records necessary to determine the identities and addresses of those individuals who purchased BeneFin, MGN-3, and/or SkinAnswer products from September 22, 1999 to the date of the Order, as well as the dates and amounts of products ordered and price paid for such products, including any costs of shipping paid by Defendants' customers, less any refunds already paid. Defendants shall also be ordered, if necessary, to retain, at their expense, an independent contractor to effectuate the restitution payments ordered by this Court.

CONCLUSION

For the foregoing reasons, the Government's motion for summary judgment is hereby **granted**. The accompanying Order outlines in more detail the scope of the permanent injunction and restitution remedies awarded herein.

Dated: July 9th, 2004

/S/ WILLIAM G. BASSLER
UNITED STATES DISTRICT JUDGE